Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Nordic-Baltic Regional Division
UPC_CFI_380/2023

ACT_582093/2023
CC_14323/2024
CC_14326/2024
CC_14317/2024
CC_14320/2024
CC_14325/2024
CC_14226/2024

Decision
of the Court of First Instance of the Unified Patent Court
Nordic-Baltic Regional Division
concerning European Patent 3 769 722
issued on 21 July 2025

CLAIMANT

1) **EDWARDS LIFESCIENCES CORPORATION** - One Edwards Way - 92614 - Irvine, California – US

Represented by Jens Olsson (Gulliksson), Siddharth Kusumakar, Bryce Matthewson & Adam Rimmer (Powell Gilbert), Bernhard Thum & Jonas Weickert (Thum & Partners)

DEFENDANTS

1) **MERIL LIFE SCIENCES PVT LIMITED** - Bilakhia House, Survey No. 135/139, Muktanand Marg, Chala - Gujarat 396191 - Vapi – IN

2) **MERIL GMBH** - Bornheimer Strasse 135 – 137 - D – 53119 - Bonn – DE

3) **SMIS INTERNATIONAL OÜ** - Harju maakond, Tallinn, Kesklinna linnaosa, Kaarli pst 9-1a - 10119 - Tallinn – EE

4) **SORMEDICA, UAB** - V. Kuzmos str. 28 - LT-08431 - Vilnius – LT

5) **INTERLUX, UAB** - Aviečių g. 16 - LT-08418 - Vilnius – LT

6) **VAB-LOGISTIK, UAB** - Laisvės pr. 60 - LT-05120 - Vilnius – LT

Represented by Andreas von Falck, Alexander Klicznik, Kerstin Jonen, Roman Würtenberger, Lars-Fabian Blume, Beatrice Wilden & Friederike Hermes (Hogan Lovells), Karin Westerberg & Julia Ericsson (Sandart)

PATENT AT ISSUE

EP 3 769 722

DIVISION
Nordic-Baltic Regional Division

DECIDING JUDGES – FULL PANEL

Presiding judge & judge-rapporteur	Stefan Johansson
Legally qualified judge	Kai Härmand
Legally qualified judge	Mélanie Bessaud
Technically qualified judge	Stefan Wilhelm

LANGUAGE OF THE PROCEEDINGS
English

SUBJECT MATTER OF THE PROCEEDINGS

- Infringement action – ACT_582093/2023
- Counterclaim revocation – CC_14226/2024, CC_14317/2024, CC_14320/2024, CC_14323/2024, CC_14325/2024, CC_14326/2024
- Applications to amend a patent – App_28660/2024, App_28668/2024, App_28669/2024, App_28670/2024, App_28671/2024, App_28672/2024
- Preliminary objection – App_5999/2024

DATE OF ORAL HEARING
The oral hearing was held on 16 January 2025. After the oral hearing, the Parties have submitted additional pleadings relating to parallel opposition proceedings at the European Patent Office (EPO).

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1. SUMMARY OF THE DISPUTE

1.1 Introduction

1. This case concerns alleged infringements of EP 3 769 722 B1 (hereafter referred to as EP 722, the patent in suit or the Patent). It includes counterclaims for revocation, conditional applications to amend the Patent and a preliminary objection.

2. Edwards Lifesciences Corporation (Edwards) is part of the Edwards Lifesciences group of companies, which specialises in artificial heart valves and hemodynamic monitoring.

3. Edwards has developed products for transcatheter aortic valve implantation ("TAVI"), a medical procedure that permits implantation of a prosthetic heart valve in a patient by minimally invasive techniques and without the need for open-heart surgery. Edwards' TAVI products include the SAPIEN family of transcatheter heart valves ("THVs"), as well as catheter systems for their implantation and other related accessories. Edwards is also the proprietor of a number of patents relating to TAVI, including EP 722 which has the title *Low profile delivery system for transcatheter heart valve* and relates to an apparatus for indicating flex of a distal end of a catheter.

4. Meril Life Sciences PVT Limited (hereafter referred to as Meril India) is a medical device company that operates in the THV field. Meril GmbH (hereafter referred to as Meril Germany) is a wholly owned subsidiary of Meril India and the European headquarters of the Meril Life Sciences corporate group. One of Meril's products is the "Myval System", which includes a balloon catheter delivery system (marketed as the Navigator THV delivery system and hereafter referred to as the Navigator). Until the launch of the Myval THV, SAPIEN THV was the only balloon expandable THV approved worldwide.

5. The Myval System (including the Navigator) is distributed within the European Union but cease and desist declarations and/or injunctions based on other patents restricts the distribution of inter alia the Navigator in certain member states of the European Union (EU).

6. Smis International OÜ (hereafter referred to as SMIS) is the local distributor of Meril's products in Estonia.

7. Sormedica, UAB, and Interlux, UAB, are local distributors of Meril's products in Lithuania and belong to the same corporate family, while VAB-Logistik, UAB, is a freight transport company located in Lithuania.

8. On 27 October 2023, Edwards initiated an action for infringement against Meril India, Meril Germany, SMIS, Sormedica, Interlux and VAB-Logistik (hereafter referred to as Meril et al., or the Defendants) at the Nordic-Baltic Regional Division of the Unified Patent Court (UPC), claiming that they infringed EP 722, inter alia by offering and/or placing the Navigator on the market in various participating member states of the Agreement on a Unified Patent Court (UPCA), including Estonia and Lithuania.

9. Meril et al. denied that they infringed the Patent and submitted counterclaims for revocation of EP 722, which triggered Edwards to submit conditional/auxiliary applications to amend the Patent.

10. Meril et al. also submitted a preliminary objection, which the judge-rapporteur has referred to the main proceeding. Meril et al. argue that the Nordic-Baltic Regional Division does not have competence insofar as Meril Germany is concerned.

11. The judge-rapporteur held an interim conference on 5 November 2024 and has issued an order where late filed attacks on inventive step were found inadmissible, while the conditional applications to amend the patent in suit as well as new grounds for non-infringement and arguments based on equivalence were held admissible.

12. The Panel has decided that the action for infringement and the counterclaims for revocation shall be heard together, in accordance with Article 33(3) a) UPCA. The Panel has also dismissed an application to order the Claimant to provide a security for the costs of the proceedings.

13. When this case was initiated, opposition proceedings at the European Patent Office (EPO) were still pending. After the date for UPC's oral hearing had been set to 16 January 2025, the Court was informed that the opposition division had scheduled its oral hearing for 17 January 2025. The Court was also informed about the Opposition Division's preliminary opinion.

14. On 11 December 2024, the Panel decided to proceed with the oral hearing as planned (i.e. dismissed an application to stay the proceedings) but requested the Parties to inform the Court (after the hearing) of the outcome of the opposition proceedings.

15. The oral hearing before the UPC took place on 16 January 2025 in Stockholm. After the hearing, the Parties have submitted additional pleadings. These additional submissions were admissible to the extent they were based on the request mentioned in paragraph 14 and provided information on the outcome of the parallel proceedings on EP 722 at the Opposition Division. The submission by Meril et al. dated 17 March 2025 relating to the EPO opposition proceedings against a different patent (EP 3 763 333 B1) is, however, not admissible.

1.2 The patent in suit

16. EP 722 is owned by Edwards. It is a third-generation divisional application of EP 2 291 145 (appl. no. 09743346.0). EP 2 291 145 is derived from PCT/US2009/042566, filed on 1 May 2009 and published as WO2009/137359A1 (hereafter referred to as "WO 359"), claiming priority of US 5200908 P, filed on 9 May 2008, US 8311708, filed on 23 July 2008, and US 24784608, filed on 8 October 2008. Specifically, EP 722 is a divisional application of EP 3 590 471 (appl. no. 19189544.0), which is a divisional application of EP 3 494 929 (appl. no. 18210923.1), and which in turn is a divisional application of EP 2 291 145 (appl. no. 09743346.0).

17. EP 722 was granted on 7 June 2023 and registered in the Register for unitary patent protection on 20 June 2023. Accordingly, EP 722 is a European patent with unitary effect, effective 7 June 2023.

18. It should be noted that that the description of the divisional application underlying the patent in suit (appl. no. 20194277.8) is identical with the description of the original great grandparent application (WO 359) except for that claims 1–20 in WO 359 have been added as claim-like clauses at the end of the description of the divisional application (appl. no. 20194277.8), in paragraph [0199]. The same is true of the respective specifications of the parent (EP 471) and grandparent (EP 929) applications. Therefore, when the original disclosure is discussed below, reference is only made to the great grandparent application WO 359.

19. The patent in suit has one independent claim (claim 1), which is directed to an apparatus for indicating flex of a distal end of a catheter. This claim – separated into features – reads as follows:

1	An apparatus for indicating flex of a distal end of a catheter comprising
1.1	an elongated shaft (152);
1.2	at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);
1.3	a handle portion (158) comprising
1.3.1	a flex activating member (154), activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;
1.3.2	a slide member (192) connected to the at least one pull wire (174); and
1.3.3	a flex indicating member (156);
1.4	wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and
1.5	wherein the flex activating member (154) comprises
1.5.1	a rotatable member (155, 157) which includes an internally threaded surface portion (160)
1.5.2	characterized in that the flex activating member also has an externally threaded surface portion (162)
1.5.3	wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and
1.5.4	the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156)

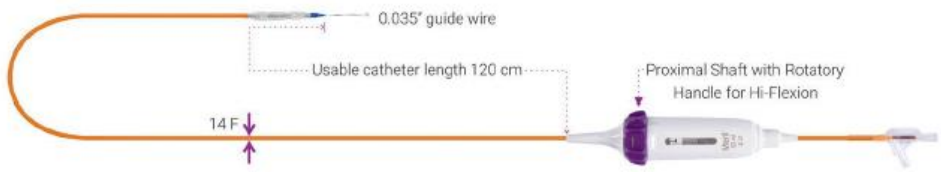
20. A notice of opposition to the Patent was filed at the EPO on 7 March 2024 by a third party and the Opposition Division found – in its decision of 3 March 2025 – that EP 722 as granted is invalid, but maintained the Patent in accordance with an auxiliary request that had been submitted in the opposition proceedings and included the following amendment to feature 1.5.2 of claim 1:

1.5.2	characterized in that the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162)

21. The decision by the Opposition Division is not yet final, and an appeal against this decision has been filed in the meantime with the EPO Boards of Appeal (BoA). Hence, the UPC will make its assessment of validity in this case based on EP 722 as granted.

1.3 The attacked embodiment (the Navigator)

22. The infringement action is directed to a catheter based THV delivery device (the Navigator) used to position a Myval THV at the site of the patient's native aortic valve, and to expand it using the balloon positioned at the distal end of the device. The image below shows the overall structure of the Navigator.



2. SUMMARY OF THE PARTIES' REQUESTS AND SUBMISSIONS

2.1 Summary of the Parties' requests

2.1.1 Infringement and the preliminary objection

Edwards

23. Edwards has requested the Court to order with immediate enforceability:

a) that the Defendants and each of them shall cease and desist from making, offering, placing on the market or using (or importing or storing for these purposes):

an apparatus for indicating flex of a distal end of a catheter comprising an elongated shaft, at least one pull wire connected to a distal end portion of the elongated shaft, a handle portion comprising a flex activating member, the flex activating member being coupled to the at least one pull wire such that adjustment of the flex activating member causes the distal end portion of the elongated shaft to flex; a slide member connected to the at least one pull wire, and a flex indicating member, wherein adjustment of the flex activating member causes the flex indicating member to move relative to the handle portion, and wherein the flex activating member comprises a rotatable member which includes an internally threaded surface portion characterised in that the flex activating member also has an externally threaded surface portion, wherein the internally threaded surface portion is configured to receive the slide member connected to the at least one pull wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member,

b) that EP 722 has been infringed by the acts of each of the Defendants in respect of the Navigator,

c) that the Defendants and each of them, at their own expense and within one week after service of the judgment to be rendered in these proceedings, shall:

- recall and / or definitively remove the products as specified in the injunction order from all channels of commerce, and

- destroy all products as specified in the injunction order and which are in the custody or control of the Defendants and each of them,

d) that the Defendants and each of them, within three weeks after service of the judgment to be rendered in these proceedings, is ordered to inform the Claimant of

- the origin and distribution channels of the infringing products,

- the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products, and

- the identity of any third person involved in the production or distribution of the infringing products,

e) that the Claimant is permitted, at each of the Defendants' expense, to display the decision and publish it in full or in part in up to five electronic or printed publications (including in industry journals) of the Claimant's choice,

f) that the Defendants and each of them publish, at their own expense, the operative part of the Court's decision on their respective websites,

g) that any failure to comply with the order to cease and desist under paragraph a) above will render the Defendants and each of them liable to pay to the Court a penalty of up to EUR 20 000 for each violation of the order, or such other amount as found appropriate by the Court,

h) that any failure to comply with the order under paragraphs c) or d) above will render the Defendants and each of them liable to pay to the Court a penalty of up to EUR 1 000 per day for the violation of the order, or such other amount as found appropriate by the Court,

i) that the Defendants and each of them are liable for all damages resulting from the patent infringement, the amount of which is to be determined in separate proceedings,

j) that the Defendants and each of them are ordered to pay to the Claimant an interim award of damages in the amount of EUR 500 000 within 14 days of the decision, and

k) that the Defendants and each of them are to bear the legal costs of these proceedings as well as all other costs incurred by the Claimant.

Meril et al.

24. Meril et al. has requested

a) that the competence of the Nordic-Baltic Regional Division is denied insofar as Defendant 2 (Meril Germany) is concerned,

b) that the action be dismissed,

c) that if the Regional Division does not dismiss the action, the decision - pursuant Article 56(1) UPCA and Rule 118.2(a) of the Rules of Procedure (RoP) - be put under the condition that the patent in suit is not held to be wholly or partially invalid by the final decision in respect of the counterclaim for revocation or a final decision of the EPO, and

d) that Claimant be ordered to bear the costs of the proceedings.

2.1.2 The counterclaim and the applications to amend the patent

Meril et al.

25. Meril et al. has requested

a) that the patent in suit (EP 3 769 722 B1) be revoked in its entirety, and

b) that Claimant be ordered to bear the costs of the proceedings.

Edwards

26. Edwards has requested

a) that the counterclaim for revocation be dismissed and EP 722 be maintained:

- as granted, or

- in the alternative, based on one of the proposed amendments of the claims of EP 722 (Auxiliary Requests 1 to 11 and 1' to 10' – see Annex 1), or

- in the further alternative, in part based on the independent validity of one or more of its dependent claims in combination with independent claim 1 as granted according to the dependencies of the claims as granted, and

b) that the Defendants be ordered to bear the costs of the proceedings, including the costs of the counterclaim.

2.2 Summary of the Parties' submissions

2.2.1 The preliminary objection

27. Meril et al. initially had three objections, namely

    a) that the jurisdiction and competence of the Court should be denied insofar as Edwards requests a decision with effect in contracting member states for which the UPCA only enters into force after this action has been initiated,

    b) that the jurisdiction and competence of the Court is denied insofar as the motions of Edwards, in particular the motions on corrective measures, right to information and compensation/damages, concern the time period prior to 1 June 2023, and

    c) that the competence of the Nordic-Baltic Regional Division is denied insofar as Meril Germany is concerned.

28. During the written procedure, Edwards clarified/confirmed that the application is based on the European patent with unitary effect (only) and that Edwards does not request any remedies (e.g. injunctive relief) in respect of countries where the UPCA only enters into force after this action was initiated (e.g. Romania).

29. During the oral hearing, Edwards withdrew its previous request for compensation based on alleged infringements committed before 7 June 2023 when the Patent was granted (i.e. based on Article 67 EPC). Edwards also confirmed that it does not seek remedies based on infringements committed before 7 June 2023.

30. Hence, what remains to be decided in the preliminary objection is whether the Nordic-Baltic Regional Division has competence insofar as Meril Germany is concerned.

31. On this question, Meril et al. allege inter alia that, for the assumption of competence, the Nordic-Baltic Regional Division cannot solely rely on the statements made by Edwards in the Statement of Claim. The Division must examine its competence in the light of all the information available to it, including the information provided by the Defendants. According to Meril et al., Edwards has not proven any acts of infringement by Meril Germany, or that Meril Germany has supported any such acts within the jurisdictional territory of the Nordic-Baltic Regional Division, or that there is a commercial relationship between Meril Germany and Defendants 3–6 (SMIS, Sormedica, Interlux and VAB Logistik).

32. Edwards argues inter alia that the Nordic-Baltic Regional Division has competence in relation to the alleged infringements by Meril Germany, because: Meril Germany is involved in an infringement – or at least threatened infringement – of EP 722 that takes place at least in Estonia and/or Lithuania by the offering and/or placing the Navigator on the market and/or by importing and/or storing the Navigator for those purposes. Meril Germany has at least induced, incited and/or persuaded the other Defendants and each of them to carry out these acts in Estonia and/or Lithuania, and/or SMIS, Sormedica, Interlux and VAB Logistik have their principal place of business in Estonia or Lithuania, and Meril India and Meril Germany have a commercial relationship with these defendants, and to each other, and the action relates to the same infringement.

33. For further details, reference is made to the grounds for the decision and to the parties' written pleadings.

2.2.2 Infringement

34. Edwards argues inter alia that Meril et al. infringe independent claim 1 as well as dependent claims 2–8 and 10–13 of EP 722, literally or by equivalence, inter alia by offering and/or placing the Navigator on the market in various participating member states of the UPCA. According to Edwards, the Patent does not only provide an exclusive right covering catheters where the elongated shaft belongs to (is part of) a guide catheter or a "guide tube" but also covers catheters such as the Navigator.

35. Meril et al. dispute that they infringe the Patent literally or by equivalence. They argue inter alia that the "elongated shaft" in features 1.1, 1.2 and 1.3.1 of claim 1 must be understood as to belong to (be part of) a guide catheter or a "guide tube", which is to be distinguished from a balloon catheter. According to Meril et al., the Navigator does not make use of this teaching, since it does not have an elongated guide tube / shaft but consists solely of a balloon catheter, which in turn consists of an inner and an outer shaft. Since independent claim 1 is not realized by the attacked embodiment "Navigator", dependent claims 2-13 are not realized either. In addition, Meril et al. argue that claim 2 as granted requires that the indicia shall depict the amount of flex using a scale, for example by means of a triangular marking system or numbers, and that the attacked embodiment the Navigator does not have scale, for example a triangular marking system or numbers.

36. Furthermore, Meril Germany is – according to the Defendants – not involved in any infringing acts within the territory of the UPCA, nor has Meril Germany supported any such acts.

37. Meril et al. also argue that the patent in suit is invalid and expected to be revoked by the EPO as well as on the basis of the counterclaim for revocation.

38. Meril et al. also object to the remedies requested.

39. For further details, reference is made to the grounds for the decision and to the parties' written pleadings.

2.2.3 Counterclaim for revocation

40. Meril et al. argue that EP 722 is invalid in its entirety, based on added subject matter, lack of inventive step and insufficiency of disclosure. The same applies to the auxiliary requests.

41. Edwards argues that EP 722 is valid. In the alternative, Edwards submit that the Patent at least is valid based on the conditional amendments according to Auxiliary Requests 1 to 11 or – if none of these are valid – Auxiliary Requests 1’ to 10’. In the further alternative, Edwards argues that EP 722 should at least be maintained based on the independent validity of its dependent claims, taking into account their respective dependencies.

42. For further details, reference is made to the grounds for the decision and to the parties' written pleadings.

3. GROUNDS FOR THE DECISION

3.1 The preliminary objection

43. The preliminary objection is admissible but shall be dismissed – i.e. the Nordic-Baltic Regional Division has competence to hear the case also against Meril Germany – for the following reasons.

44. According to Article 33.1 UPCA, actions for actual or threatened infringements of European patents shall be brought before:

    a) *the local division hosted by the Contracting Member State where the actual or threatened infringement has occurred or may occur, or the regional division in which that Contracting Member State participates; or*

    b) *the local division hosted by the Contracting Member State where the defendant or, in the case of multiple defendants, one of the defendants has its residence, or principal place of business, or in the absence of residence or principal place of business, its place of business, or the regional division in which that Contracting Member State participates. An action may be brought against multiple defendants only where the defendants have a commercial relationship and where the action relates to the same alleged infringement.*

45. This case concerns alleged infringements of EP 722 that shall, at least, have taken place in Estonia and/or Lithuania. According to Edwards, Meril Germany has participated in – or at least contributed to – these infringements. The other Defendants are Meril Germany's parent company (that inter alia is the developer and manufacturer of the Navigator as well as listed as the exporter of record in relation to shipments of the Navigator into at least Estonia and Lithuania), Meril's local distributors in Estonia (SMIS) and Lithuania (Sormedica and Interlux) and a freight transport company located in Lithuania (VAB Logistik) that is registered as importer of shipments to Lithuania.

46. The attacked embodiment (the Navigator) is thus produced by Meril Life Sciences corporate group, where Meril Germany is a subsidiary, and it has been offered for sale in inter alia Estonia and Lithuania (it has even been sold to companies in those countries). The Navigator has inter alia been offered for sale on the Meril website and in a Meril brochure. On the Meril website, Meril Germany is described as Meril's European Headquarters and the brochure specifies inter alia that Meril Germany can provide information on the availability of the Navigator in Europe.

47. These facts and evidence are sufficient for concluding that the Nordic-Baltic Regional Division has competence, based on Article 33.1(a) UPCA, in relation to Meril Germany. They are also sufficient for concluding that Nordic-Baltic Regional Division has competence based on Article 33.1(b) UPCA.

48. Hence, the preliminary objection is unfounded and shall be dismissed. The question whether Meril Germany is liable for committing, or contributing to, any infringements will be discussed below.

3.2 The patent in suit and claim construction

3.2.1 Legal standard for claim construction

49. As confirmed by the Court of Appeal in its Order on 26 February 2024 (case UPC_CoA_335/2023), the patent claim is not only the starting point, but the decisive basis for determining the protective scope of a European patent. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. This does not mean that the patent claim merely serves as a guideline and that its subject matter also extends to what, after examination of the description and drawings, appears to be the subject matter for which the patent proprietor seeks protection. The patent claim is to be interpreted from the point of view of a person skilled in the art. In applying these principles, the aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties. These principles for the interpretation of a patent claim apply equally to the assessment of the infringement and the validity of a European patent.

50. The importance of the patent claims means, inter alia, that a narrowing interpretation of the claims which deviates from the broader general understanding of the terms used therein by the person skilled in the art, can only be permitted in exceptional cases. See e.g. the Decision by Düsseldorf Local Division on 28 January 2025 (case UPC_CFI_355/2023) and the Decision by Local Division Munich on 4 April 2025 (case UPC_CFI_501/2023).

3.2.2 The person skilled in the art

51. Both parties agree that the person skilled in the art is a team. While Edwards suggests that the team be composed of a medical device engineer and an interventional cardiologist, Meril et al. suggest that also a cardiac surgeon should be included in the team.

52. The Court is of the opinion that the addition of a cardiac surgeon into the team is unnecessary, since an apparatus as claimed in EP 722 will be used in catheter-based cardiac procedures. This is something an interventional cardiologist is familiar with. Therefore, the Court agrees with Edwards that the person skilled in the art is a team composed of a medical device engineer and an interventional cardiologist. However, the Court notes that the outcome of this case would have been the same if also a cardiac surgeon had been included in the team.

3.2.3 Construction of the patent in suit

53. The description of EP 722 describes a number of different concepts, but the claimed invention relates to an apparatus for indicating flex of a distal end of a catheter.

54. The Patent includes one independent claim (claim 1) and twelve claims (claims 2-13) which are dependent on claim 1. Independent claim 1 – divided into features – reads as follows:

1	An apparatus for indicating flex of a distal end of a catheter comprising
1.1	an elongated shaft (152);

1.2	at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);
1.3	a handle portion (158) comprising
1.3.1	a flex activating member (154), activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;
1.3.2	a slide member (192) connected to the at least one pull wire (174); and
1.3.3	a flex indicating member (156);
1.4	wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and
1.5	wherein the flex activating member (154) comprises
1.5.1	a rotatable member (155, 157) which includes an internally threaded surface portion (160)
1.5.2	characterized in that the flex activating member also has an externally threaded surface portion (162)
1.5.3	wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and
1.5.4	the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156)

55. When it comes to claim construction, the Parties have only expressed different opinions on the construction of the term “elongated shaft” that is used in features 1.1, 1.2 and 1.3.1.

Meril et al.

56. Meril et al. argue that the term “elongated shaft” must be understood to belong to a guide catheter (or “guide tube”), which is to be distinguished from a balloon catheter.

57. According to Meril et al., paragraph [0115] of the patent in suit is of particular relevance for the construction of the term “elongated shaft (152)"

> [0115] The handle portion 158 is shown in greater detail in FIG. 36. As discussed above, the flex indicating device 150 (e.g., a guide catheter) includes a handle portion 158 and an elongated guide tube, or shaft, 152 extending distally therefrom. The guide tube 152 defines a lumen 175 sized to receive the shaft of the balloon catheter and allow the balloon catheter to slide longitudinally relative to the guide catheter. The distal end portion of the guide tube 152 comprises a steerable section 188, the curvature of which can be adjusted by the operator to assist in guiding the apparatus through the patient’s vasculature, and in particular, the aortic arch.

58. They also submit inter alia that this interpretation is in line with the overall objective of EP 722 and the other patents in the same patent family, which – according to them – is to provide a delivery system equipped with a prosthetic heart valve for insertion into the patient's body, the entire system having the smallest possible diameter in order to make the procedure minimally invasive and thus allow treatment of a larger patient population with improved safety. In this context, they refer to inter alia the functioning of Edwards’ own delivery system “Commander” and to paragraph [0003] in the background section and paragraph [0006] in the summary of EP 722.

[0003] An important design parameter of the THV is the diameter of the folded or crimped profile. The diameter of the crimped profile is important because it directly influences the physician's ability to advance the THV through the femoral artery or vein. More particularly, a smaller profile allows for treatment of a wider population of patients, with enhanced safety.

[0006] Traditionally, the THV is crimped directly onto a balloon of a balloon catheter and the crimped THV and balloon are navigated through the patient's vasculature to the implantation site. Because of the thickness of the balloon material, the valve cannot be crimped to its smaller possible profile. In certain exemplary devices disclosed below, the balloon is positioned either distal or proximal to the crimped THV. This allows the THV to be crimped to a smaller diameter. After the THV is advanced through narrow portions in a patient's vasculature (for example, the iliac artery which is typically the narrowest portion of the relevant vasculature), the THV is placed onto the balloon. If the THV has not yet been advanced to the treatment site when the balloon member is repositioned underneath the THV, then the THV can then be advanced further to the treatment site and the balloon can be inflated to radially expand the THV within the native heart valve.

59. Thus, EP 722 (and the other patent in the same patent family) discloses – according to Meril et al. – the so-called "off-balloon crimping" technology for this problem, which requires to use a delivery system comprising a guide catheter and a balloon catheter, the balloon catheter being arranged within the guide catheter and being longitudinally movable relative to the guide catheter. As a consequence, the term "elongated shaft" in claim 1 of EP 722 must be understood to belong to a guide catheter (or "guide tube"), which is to be distinguished from the balloon catheter.

Edwards

60. Edwards argues that the description in EP 722 discloses a number of inventions and also various embodiments of the claimed invention, including methods in which the delivery profile (i.e. diameter of the system) can be reduced. However, the claimed embodiment is – according to Edwards – disclosed in paragraphs [0008] and [0009] of EP 722 as an independent devise, namely a catheter comprising an elongated shaft.

[0008] The present invention provides an apparatus for indicating flex of a distal end of a catheter as defined in claim 1. The apparatus comprises an elongated shaft, at least one pull wire connected to a distal end portion of the elongated shaft, a handle portion comprising a flex activating member, and a flex indicating member. The flex activating member is coupled to the at least one pull wire such that adjustment of the flex activating member causes the distal end portion of the elongated shaft to flex. Adjustment of the flex activating member causes the flex indicating member to move relative to the handle portion to indicate an amount of flex of the distal end portion of the elongated shaft. The flex activating member comprises a rotatable member which includes an internally threaded surface portion and an externally threaded surface portion, wherein the internally threaded surface portion is configured to receive the slide member connected to the at least one pull wire, and the externally threaded surface portion is configured to receive the extending portion of the flex indicating member. The handle portion comprises a slot for receiving at least a portion of the flex indicating member.

[0009] In specific embodiments of the present invention, rotating the rotatable member causes the slide member to move along the internally threaded surface portion and the movement of the slide member along the internally threaded surface portion changes the amount of flex of the distal end portion of the shaft. The rotation of the rotatable member causes the flex indicating member to move longitudinally and change its position within the slot of the handle portion and the position of the flex indicating member within the slot indicates the amount of flex of the distal end portion of the shaft.

61. In this context, Edwards also refers to paragraph [030] of the originally filed patent application WO 359, which explicitly describes this apparatus as "another embodiment".

[030] In another embodiment, an apparatus for indicating flex of a distal end of a catheter is disclosed. The apparatus comprises an elongated shaft; at least one wire connected to a distal end portion of the elongated shaft; a handle portion comprising a flex activating member, the flex activating member being coupled to the at least one wire such that adjustment of the flex activating member causes the distal end portion of the shaft to flex; and a flex indicating member. Adjustment of the flex activating member causes the flex indicating member to move relative to the handle to indicate an amount of flex of the distal end portion of the shaft.

62. According to Edwards, the parts of the description that Meril et al. base their conclusion on are completely unrelated to what is claimed in claim 1 of EP 722. Reducing the crimped profile of a THV when being put in a crimped state on a delivery system is not the problem to be solved by EP 722. The technical teaching in claim 1 of EP 722 that relates to an apparatus for indicating flex of a distal end of a catheter is, according to Edwards, completely independent from a technical teaching relating to reducing the crimped profile of a THV on a delivery catheter. The disclosure in EP 722 adds an additional feature which can be used with 'off-balloon' crimping but does not need to be used with it. Edwards also refers to e.g. paragraph [0111] of EP 722, where the elongated shaft is a component of a catheter that can be (i.e. not mandatory) e.g. a guide catheter.

[0111] Flex indicating device 150 comprises a flex activating member 154, an indicator pin 156, and a handle portion 158. Flex indicating device is configured to flex a distal end of an elongated shaft 152 of a catheter (e.g., a guide catheter) by pulling on a wire (not shown) that is attached to the distal tip of the shaft 152 and which extends the length of the shaft. The pulling of the wire is achieved by rotating flex activating member 154 (e.g., a knob) that has female threads running down its length.

63. Edwards concludes that neither paragraph [0008] nor the claims of EP 722 refer to anything other than an "elongated shaft". There is no mention, explicitly or implicitly, of ballon catheters, guide catheters, or longitudinal movement between them. Nothing is said, explicitly or implicitly, about off-balloon crimping or reducing the delivery profile. Rather, the plain and simple term 'elongated shaft' is used. Hence, the skilled person has – according to Edwards – no difficulty interpreting this term and understands that it is, quite simply, an elongated shaft (of a catheter).

The Court

64. Claim 1 is directed to an apparatus for indicating flex of a distal end of a catheter. The wording of claim 1 is not limited to a specific type of catheter.

65. The technical object underlying EP 722 is elaborated on in paragraph [0109] of EP 722, which reads as follows:

[0109] Catheters, such as guide catheters, can be provided with a flexing ability so that the catheter can be steered through a patient's vasculature. However, when steering a catheter through a patient's vasculature it can be difficult to determine how much the catheter has been flexed at any given moment.

66. Flexing of a catheter allows the catheter to be navigated along the bends and curvatures of a patient's vasculature. To allow for an effective steering it needs to be known how much the catheter is flexed at a given moment.

67. From the perspective of a person skilled in the art, the objective technical object of EP 722 and the technical solution specified in the claims is independent from the construction of the catheter and applies to catheters in general. If a catheter comprises e.g. in addition to

the elongated shaft one or more inner catheters, these will also be flexed together with the (outer) elongated shaft. Catheters generally need to be steered through the vasculature of a patient, thereby moving around bends and curvatures of the vasculature. The person skilled in the art thus understands the term "catheter" generally and independent of its specific construction. The object of safely steering a catheter through the vasculature arises independently from the specific construction of a catheter.

68. EP 722 discloses various exemplary devices, embodiments and methods in the section "Summary" in paragraphs [0006] to [0042]. Paragraph [0010] discloses, as one exemplary embodiment, an apparatus comprising a main catheter, a balloon catheter and a valve carrying member. In this specific embodiment both the main catheter and the balloon catheter comprise an elongated shaft.

[0010] As one exemplary device, an apparatus for delivering a prosthetic valve through the vasculature of a patient is disclosed. The apparatus comprises a main catheter, a balloon catheter, and a valve carrying member. The main catheter comprises an elongated shaft. The balloon catheter comprises an elongated shaft and a balloon connected to a distal end portion of the shaft. The shaft of the balloon catheter is capable of moving longitudinally within the shaft of the main catheter. The valve carrying member has a mounting surface for receiving a crimped valve for insertion into the vasculature of the patient. The balloon is positioned distal or proximal to the mounting surface and the balloon is configured to be movable relative to the mounting surface, or vice versa, to position the balloon at a location extending through the crimped valve after the valve is inserted into the patient's vasculature.

69. This is reiterated in the description of other embodiments, e.g. in paragraphs [0018], [0021], [0025] and [0035]. The invention as claimed in EP 722 is referred to in paragraphs [0008] and [0009] of the general portion and in paragraphs [0109] to [0123] of the exemplary portion of EP 722. According to paragraph [0111] reproduced below, an elongated shaft is a component of a catheter. Hence, it is clear from the Patent that different types of catheters can comprise an elongated shaft. There is a variety of catheters such as e.g. guide catheters, balloon catheters and flex catheters that all can comprise elongated shafts. Hence, the term "elongated shaft" is not synonymous to the term "elongated guide shaft", which is an elongated shaft of a guide catheter.

70. It should furthermore be noted that when guide catheters are mentioned in paragraphs [0109] to [0123], they are only mentioned as examples, see e.g.:

[0109] Catheters, such as guide catheters, can be provided with a flexing ability so that the catheter can be steered through a patient's vasculature. However, when steering a catheter through a patient's vasculature it can be difficult to determine how much the catheter has been flexed at any given moment.

[0111] Flex indicating device 150 comprises a flex activating member 154, an indicator pin 156, and a handle portion 158. Flex indicating device is configured to flex a distal end of an elongated shaft 152 of a catheter (e.g., a guide catheter) by pulling on a wire (not shown) that is attached to the distal tip of the shaft 152 and which extends the length of the shaft. The pulling of the wire is achieved by rotating flex activating member 154 (e.g., a knob) that has female threads running down its length.

[0115] The handle portion 158 is shown in greater detail in FIG. 36. As discussed above, the flex indicating device 150 (e.g., a guide catheter) includes a handle portion 158 and an elongated guide tube, or shaft, 152 extending distally therefrom. The guide tube 152 defines a lumen 175 sized to receive the shaft of the balloon catheter and allow the balloon catheter to slide longitudinally relative to the guide catheter. The distal end portion of the guide tube 152 comprises a steerable section 188, the curvature of which can be adjusted by the operator to assist in guiding the apparatus through the patient's vasculature, and in particular, the aortic arch.

71. Thus, it is clear from all such passages that a guide catheter is an example of (a sub-category to) a catheter. It is clear to the person skilled in the art that the elongated shaft comprised in the apparatus for indicating flex of a distal end of a catheter as claimed can be, e.g., but is by no means mandatorily a guide shaft of a guide catheter.

72. In view of this, the claim construction provided by Meril et al. – according to which the term "elongated shaft" must be understood to belong to the guide catheter and actually needs to be understood as an "elongated guide shaft" – is not supported by EP 722 at all and thus incorrect.

73. It should also be noted that the elongated shaft of a catheter can comprise one or more (sub)shafts what is exemplified for the balloon catheter of Figs. 2A and B of EP 722 that comprise an inner (balloon) shaft 34 and an outer (balloon) shaft 26. The construction of this specific embodiment is disclosed in paragraph [0051] and Fig 2B as follows:

[0051] As can be seen in FIGS. 2A and 2B, balloon catheter 16 in the illustrated configuration further includes an inner shaft 34 (FIG. 2B) that extends from proximal portion 24 and coaxially through outer shaft 26 and balloon 28. Balloon 28 can be supported on a distal end portion of inner shaft 34 that extends outwardly from outer shaft 26 with a proximal end portion 36 of the balloon secured to the distal end of outer shaft 26 (e.g., with a suitable adhesive). The outer diameter of inner shaft 34 is sized such that an annular space is defined between the inner and outer shafts along the entire length of the outer shaft. Proximal portion 24 of the balloon catheter can be formed with a fluid passageway 38 that is fluidly connectable to a fluid source (e.g., a water source) for inflating the balloon. Fluid passageway 38 is in fluid communication with the annular space between inner shaft 34 and outer shaft 26 such that fluid from the fluid source can flow through fluid passageway 38, through the space between the shafts, and into balloon 28 to inflate the same and deploy valve 12.

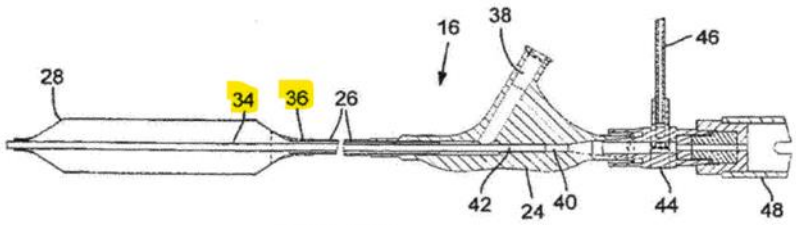


FIG. 2B

3.3 The validity of EP 722

74. Meril et al. allege that EP 722 is invalid in its entirety based on added subject matter, lack of inventive step and insufficiency of disclosure.

75. Edwards alleges that the patent as granted is valid. Edwards has also submitted – on an auxiliary basis – conditional amendments according to Auxiliary Requests 1 to 11 and – if none of these are valid – Auxiliary Requests 1' to 10'. In the further alternative, Edwards has requested that EP 722 is maintained based on the independent validity of its dependent claims, taking into account their respective dependencies.

3.3.1 Added subject matter

3.3.1.1 Legal standard for assessing added subject matter

76. According to Article 65(2) UPCA and Article 138.1(c) EPC, a European patent may be revoked on the ground that the subject matter of the patent extends beyond the contents of the application as filed or, if the patent was granted on a divisional application or on a new application under Article 61 EPC, beyond the contents of the earlier application as filed.

77. In order to determine whether there is added matter, the Court must first determine what the person skilled in the art would deduce directly and unambiguously from the whole of the application as filed, using his common general knowledge and viewed objectively and in relation to the date of filing, whereby implicitly disclosed subject matter, i.e. matter which is a clear and unambiguous consequence of what is expressly mentioned, is also considered to be part of the content of the application as filed. Where the patent is a divisional application, this requirement applies to each earlier application.

3.3.1.2 Claim 1 – feature 1.1

78. Meril et al. allege inter alia that since EP 471 and EP 929, i.e. the parent and grandparent to EP 722, both relate to a flex indicating device of a delivery system for implantation of a prosthetic heart valve (i.e. a delivery system that involves both a guide catheter and a balloon catheter), also EP 722 must relate to a flex indicating device of a delivery system for implantation of a prosthetic heart valve where the elongated shaft is a guide tube that "defines a lumen sized to receive the shaft of the balloon catheter to slide longitudinally relative to the guide catheter". In this context, they inter alia refer to paragraph [0167] of WO 359:

> *[0167] The handle portion 158 is shown in greater detail in FIG. 36. As discussed above, the flex indicating device 150 (e.g., a guide catheter) includes a handle portion 158 and an elongated guide tube, or shaft, 152 extending distally therefrom. The guide tube 152 defines a lumen 175 sized to receive the shaft of the balloon catheter and allow the balloon catheter to slide longitudinally relative to the guide catheter. The distal end portion of the guide tube 152 comprises a steerable section 188, the curvature of which can be adjusted by the operator to assist in guiding the apparatus through the patient's vasculature, and in particular, the aortic arch.*

79. According to Meril et al., the omission of the feature that the elongated shaft is a guide tube that "defines a lumen sized to receive the shaft of the balloon catheter to slide longitudinally relative to the guide catheter" represents an intermediate generalization and adds subject matter.

80. Edwards argues iter alia that EP 471 and EP 929 claim different subject matter than the patent in suit, and that these patents are based on different passages of the great grandparent application WO 359. The claims of EP 722 are, according to Edwards, based on paragraph [030] of WO 359 and additionally include specific embodiments of paragraph [031] relating to the rotatable member discussed below. Claim 1 of EP 722 relates to an apparatus for indicating flex of a distal end of a catheter and not to a flex indicating device of a delivery system for implementation of a prosthetic heart valve. Consequently, there is – according to Edwards – no added subject matter.

81. The Court agrees with Edwards on this issue. The claimed subject matter of EP 471 and EP 929 is irrelevant when assessing whether EP 722 includes added subject matter. The relevant test is, as described above, what the person skilled in the art would deduce directly and unambiguously from the original applications as filed. As already explained, the description of the original application for EP 722 is – as far as relevant here – identical to the original applications for its parent, grandparent and great grandparent. These descriptions describe a number of different inventions. The subject matter of EP 722 is – as pointed out by Edwards – primarily disclosed in paragraph [030] of WO 359, although it also includes features from paragraph [031]:

[030] In another embodiment, an apparatus for indicating flex of a distal end of a catheter is disclosed. The apparatus comprises an elongated shaft; at least one wire connected to a distal end portion of the elongated shaft; a handle portion comprising a flex activating member, the flex activating member being coupled to the at least one wire such that adjustment of the flex activating member causes the distal end portion of the shaft to flex; and a flex indicating member. Adjustment of the flex activating member causes the flex indicating member to move relative to the handle to indicate an amount of flex of the distal end portion of the shaft.

[031] In specific implementations, the flex activating member comprises a rotatable member. In other specific implementations, the handle portion comprises a slot for receiving at least a portion of the flex indicating member. In other specific implementations, the rotatable member includes an internally threaded surface portion and an externally threaded surface portion. The internally threaded surface portion is configured to receiving a slide member connected to the at least one wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member. In other specific implementations, rotating the rotatable member causes the slide member to move along the internally threaded surface portion and the movement of the slide member along the internally threaded surface portion changes the amount of flex of the distal end portion of the shaft. The rotation of the rotatable member causes the flex indicating member to move longitudinally and change its position within the slot of the handle portion and the position of the flex indicating member within the slot indicates the amount of flex of the distal end portion of the shaft.

82. This disclosure is not limited to a flex indicating device of a delivery system for implantation of a prosthetic heart valve where the elongated shaft is a guide tube that "defines a lumen sized to receive the shaft of the balloon catheter to slide longitudinally relative to the guide catheter". Hence, there is no added subject matter in this respect.

3.3.1.3 Claim 1 – feature 1.3

83. Meril et al. allege that omission of the feature that "the handle portion comprises a slot for receiving at least a portion of the flex indicating member" adds subject matter. According to Meril, paragraphs [030] and [031] of WO 359 need to be understood as one embodiment, where paragraph [030] and the first four sentences of paragraph [031] particularly describe the arrangement of the components of the apparatus while the last two sentences explain the functional relationship of the components.

[030] In another embodiment, an apparatus for indicating flex of a distal end of a catheter is disclosed. The apparatus comprises an elongated shaft; at least one wire connected to a distal end portion of the elongated shaft; a handle portion comprising a flex activating member, the flex activating member being coupled to the at least one wire such that adjustment of the flex activating member causes the distal end portion of the shaft to flex; and a flex indicating member. Adjustment of the flex activating member causes the flex indicating member to move relative to the handle to indicate an amount of flex of the distal end portion of the shaft.

[031] In specific implementations, the flex activating member comprises a rotatable member. In other specific implementations, the handle portion comprises a slot for receiving at least a portion of the flex

indicating member. In other specific implementations, the rotatable member includes an internally threaded surface portion and an externally threaded surface portion. The internally threaded surface portion is configured to receiving a slide member connected to the at least one wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member. In other specific implementations, rotating the rotatable member causes the slide member to move along the internally threaded surface portion and the movement of the slide member along the internally threaded surface portion changes the amount of flex of the distal end portion of the shaft. The rotation of the rotatable member causes the flex indicating member to move longitudinally and change its position within the slot of the handle portion and the position of the flex indicating member within the slot indicates the amount of flex of the distal end portion of the shaft.

84. According to Meril et al., the skilled person directly and unambiguously derives from this disclosure that the relative movement of the flex indicating member to the handle disclosed in the last sentence of paragraph [030] corresponds to the longitudinal movement of the flex indicating member within the slot of the handle portion explained in paragraph [031] and specified in feature 1.4 of claim 1. The "specific implementations" to which paragraph [031] refers, and on which claim 1 as granted is particularly based, are further explained in paragraphs [0162] to [0175] and Figures 31 to 38B. Thus, according to them, the original disclosure directly and unambiguously teaches the skilled person that the handle portion 158 comprises a longitudinal slot. This longitudinal slot represents an essential feature of the apparatus according to claim 1. Moreover, the indicator pin as originally disclosed comprises a portion that extends upwards into the longitudinal slot. According to Meril et al., the omission of these features adds subject matter. Meril et al. also point out that dependant claim 5 refers to "the slot (164)", even though this claim only depends on independent claim 1 (and not on dependent claim 4, which specifies that the handle portion comprises a slot), and argue that this confirms that the longitudinal slot represents an essential feature of the apparatus according to claim 1.

85. Edwards argues that paragraph [031] discloses that “in some other specific embodiments” the flex activating member of paragraph [030] may comprise, for example, a slot. Therefore, the slot would not represent a mandatory feature. Edwards also submits that feature 1.5.4 requires that “the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156)”, and that from a technical perspective, a slot is not the only way of receiving an extending portion of the flex indicating member (i.e. the slot is not inextricably linked to the flex indicating member).

86. The Court agrees with Edwards that when studying the application as a whole, in particular paragraphs [030] and [031], the person skilled in the art would understand that there may be a slot, but there must not be a slot. Hence, there is no added subject matter in this respect.

3.3.1.4 Claim 1 – feature 1.3.1

87. Meril et al. allege that feature 1.3.1 is inadmissibly broadened because the feature of “at least one pull wire” represents an intermediate generalization. Feature 1.3.1 of claim 1 as issued specifies “at least one pull wire” whereas the general part of WO 359, in particular paragraph [030], only mentions “at least one wire”. The term “pull wire” is only disclosed in paragraphs [171] and [172] and relates to exemplary embodiments. In these examples, where the flex indicating device is used in connection with a guide catheter (see paragraph [161]), the term “pull wire” is only disclosed in conjunction with the adjustment knob 155 and the steerable connection 188. The adjustment knob 155 and the steerable section 188

are connected by the pull wire 174 to produce movement of the steerable section 188 upon rotation of the adjustment knob 155. According to Meril et al. it is therefore apparent from paragraphs [0171] and [0172] that the purpose and function of the pull wire 174 is to connect the adjustment knob 155 to the steerable section 188, i.e. that the pull wire is inextricably linked to other features, such as the adjustment knob 155 and the steerable section 188. If claim 1 is not limited to a guide catheter and since it is not limited to a resilient steerable section, there is – according to Meril et al. – an intermediate generalization.

[0161] In another embodiment, a flex indicating device can be used in connection with a guide catheter that is capable of flexing at its distal end. […]

[0171] One or more pull wires 174 connect the adjustment knob 155 to the steerable section 188 to produce movement of the steerable section upon rotation of the adjustment knob. In certain embodiments, the proximal end portion of the pull wire 174 can extend into and can be secured to a retaining pin 180, such as by crimping the pin 180 to the pull wire. The pin 180 is disposed in a slot in the slide nut 192. The pull wire 174 extends from pin 180, through a slot in the slide nut, a slot 200 in the sleeve 190, and into and through a pull wire lumen in the shaft 152. The distal end portion of the pull wire 174 is secured to the distal end portion of the steerable section 188.

[0172] The pin 180, which retains the proximal end of the pull wire 174, is captured in the slot in the slide nut 192. Hence, when the adjustment knob 155 is rotated to move the slide nut 192 in the proximal direction, the pull wire 174 also is moved in the proximal direction. The pull wire pulls the distal end of the steerable section 188 back toward the handle portion, thereby bending the steerable section and reducing its radius of curvature. The friction between the adjustment knob 155 and the slide nut 192 is sufficient to hold the pull wire taut, thus preserving the shape of the bend in the steerable section if the operator releases the adjustment knob 155. When the adjustment knob 155 is rotated in the opposite direction to move the slide nut 192 in the distal direction, tension in the pull wire is released. The resiliency of the steerable section 188 causes the steerable to return its normal, non deflected shape as tension on the pull wire is decreased. Because the pull wire 174 is not fixed to the slide nut 192, movement of the slide nut in the distal direction does not push on the end of the pull wire, causing it to buckle. Instead, the pin 180 is allowed to float within the slot of the slide nut 192 when the knob 155 is adjusted to reduce tension in the pull wire, preventing buckling of the pull wire.

88. Edwards refers to the general disclosure of paragraph [30] and argues that this paragraph discloses that at least one wire is used as a transmission means between the flex activating member and the distal end portion of the shaft.

89. Edwards refers to the general disclosure of paragraph [30] and argues that this paragraph discloses that at least one wire is used as a transmission means between the flex activating member and the distal end portion of the shaft.

[30] In another embodiment, an apparatus for indicating flex of a distal end of a catheter is disclosed. The apparatus comprises an elongated shaft; at least one wire connected to a distal end portion of the elongated shaft; a handle portion comprising a flex activating member, the flex activating member being coupled to the at least one wire such that adjustment of the flex activating member causes the distal end portion of the shaft to flex; and a flex indicating member. Adjustment of the flex activating member causes the flex indicating member to move relative to the handle to indicate an amount of flex of the distal end portion of the shaft.

90. Edwards further argues that this wire appears to be a pull wire, in view of the disclosure as a whole and that, according to the last sentence of paragraph [171], the pull wire is connected to the distal end portion – which term is considered as synonymous with the term “steerable section” – of the elongated shaft in accordance with what is disclosed in paragraph [030]. Edwards also submits that it is clear to the person skilled in the art that

an adjustment knob is just a specific embodiment of a flex activating member and that there is no inextricable link between the adjustment knob as such and the pull wire. Therefore, Edwards submits that all essential features are disclosed; the pull wire, its coupling to the flex activating member and the corresponding functional features (the coupling being such that manual adjustment of the flex activating member causes the distal end portion of the elongated shaft to flex). Hence, feature 1.3.1. does not include added subject matter.

91. The Court agrees with Edwards on this point too, for the reasons just mentioned. Accordingly, there is no added subject matter in this respect. This conclusion is in line with the decision by the Opposition Division.

3.3.1.5 Claim 1 – feature 1.4

92. Meril et al. allege that feature 1.4 is inadmissibly broadened because the feature "to indicate an amount of flex of the distal end portion of the shaft" was omitted. According to Meril et al. the omitted feature is comprised in paragraph [30] of WO 359 that forms the basis for claim 1 and must therefore not be omitted:

> *[30] In another embodiment, an apparatus for indicating flex of a distal end of a catheter is disclosed. The apparatus comprises an elongated shaft; at least one wire connected to a distal end portion of the elongated shaft; a handle portion comprising a flex activating member, the flex activating member being coupled to the at least one wire such that adjustment of the flex activating member causes the distal end portion of the shaft to flex; and a flex indicating member. Adjustment of the flex activating member causes the flex indicating member to move relative to the handle <u>to indicate an amount of flex of the distal end portion of the shaft.</u>*

93. Edwards argues that this objection disregards the technical content/teaching of claim 1 as a whole. Claim 1 as granted already specifies that the purpose of the apparatus claimed is to indicate (an amount of) flex of a distal end of a catheter, and that the adjustment of a flex activating member causes the flex indicating member to move relative to the handle portion.

1.	*An apparatus for indicating flex of a distal end of a catheter comprising*
2.	*[…]*
1.3.1	*a flex activating member (154), activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;*
1.3.2	*a slide member (192) connected to the at least one pull wire (174); and*
1.3.3	*a flex indicating member (156);*
1.4	*wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), […]*

94. The Court agrees with Edwards that claim 1 includes the functionality that "[a]djustment of the flex activating member causes the flex indicating member to move relative to the handle to indicate an amount of flex of the distal end portion of the shaft". Accordingly, there is no added subject matter in this respect. This conclusion is in line with the decision by the Opposition Division.

3.3.1.6 Claim 1 – feature 1.5.2

95. Meril et al. allege that feature 1.5.2 in claim 1 ("characterized in that the flex activating member also has an externally threaded surface portion (162)") represents an inadmissible generalization. In this context, Meril et al. refer to paragraph [031] of WO 359, which reads as follows (emphasis added):

> *[031] In specific implementations, the flex activating member comprises a rotatable member. In other specific implementations, the handle portion comprises a slot for receiving at least a portion of the flex indicating member. In other specific implementations, the rotatable member includes an internally threaded surface portion and an externally threaded surface portion. The internally threaded surface portion is configured to receiving a slide member connected to the at least one wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member. […]*

96. According to Meril et al., this original disclosure teaches that it is the rotatable member (a sub-ordinate feature of the flex activating member) that comprises the externally threaded surface portion. There is, according to Meril et al., no disclosure of a generalised flex activating member comprising an externally threaded surface portion, where it is not specifically the rotatable member that comprises the externally threaded surface portion.

97. Edwards submits that the above passage also discloses that the flex activating member comprises a rotatable member so that the externally threaded surface would necessarily be a component of the flex activating member, as well. Therefore, a flex indicating member with an externally threaded surface portion would – according to Edwards – lack novelty over the disclosure of WO 359; it can be directly and unambiguously derived from the content of WO 359. Edwards also refers to paragraph [0165] of WO 359:

> *[0165] The shaft 157 also includes an externally threaded surface portion 162. As shown in FIG. 37, an extending portion 166 of indicator pin 156 mates with the externally threaded surface portion 162 of flex activating member 154. The shaft 157 extends into the handle portion 158 and the indicator pin 156 is trapped between the externally threaded surface portion 162 and the handle portion 158, with a portion of the indicator pin 156 extending upward into a longitudinal slot 164 of the handle. As the knob 155 rotated to increase the flex of the distal end of the shaft of catheter 152, indicator pin 156 tracks the external threaded portion 162 of the flex activating member and moves in the proximal direction inside of slot 164. The greater the amount of rotation of the flex activating member 154, the further indicator pin 156 moves towards the proximal end of handle 158. Conversely, rotating the knob 155 in the opposite direction decreases the flex of the distal end of the shaft of the catheter and causes corresponding movement of the indicator pin 156 toward the distal end of the handle.*

98. The Court notes that the disclosure of [031] of WO 359 is in line with the specific embodiment disclosed in [0161] to [0175] and Figs. 31-38B of WO359. It can be taken from there that the shaft 157 is integrally connected to the rotatable knob 155 and comprises both an internally and an externally threaded surface; see, e.g., [0164] and Fig. 32 of WO 359:

> *[0164] Referring to FIG. 32, flex activating member 154 comprises an adjustment knob 155 and a shaft 157 extending from the knob. The shaft 157 has an internally threaded surface portion 160 that mates with a slide nut that has male threads. The proximal end of the wire is attached to the slide nut via a crimp pin and a counter bored hole or slot. As the flex activating member 154 is rotated, the slide nut translates along the internally threaded surface portion 160 towards the proximal end of the flex indicating device 150, thereby causing the distal end of the catheter 152 to flex. As the amount of the*

rotation of the flex activating member 154 increases, the slide nut moves further toward the proximal end of the flex indicating device 150 and the amount of flex of the distal end of catheter 152 increases.

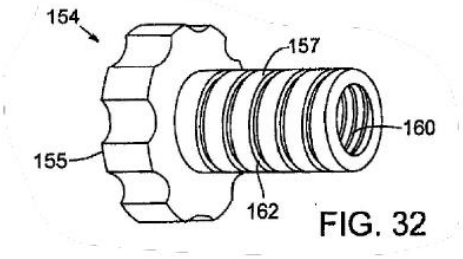


FIG. 32

99. Paragraph [0165] does not lead to a different conclusion. It explicitly refers to Fig. 37 which clearly shows that the external threaded surface is part of the shaft that is integrally connected to the rotatable knob:

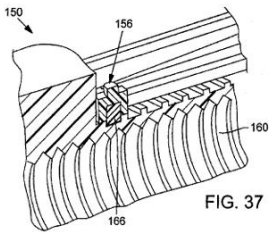


FIG. 37

100. Granted claim 1 has a wider scope since it does not require that the externally threaded surface is part of the rotatable member or the shaft. The externally threaded surface could also be part of another portion of the flex activating member.

1.5	wherein the flex activating member (154) comprises
1.5.1	a rotatable member (155, 157) which includes an internally threaded surface portion (160)
1.5.2	characterized in that the flex activating member also has an externally threaded surface portion

101. The skilled person would not directly and unambiguously derive such alternative embodiments from the application as filed, using the common general knowledge at the date of filing. Therefore, claim 1 as granted contains subject matter which extends beyond the content of the application as filed. This conclusion is in line with the decision by the Opposition Division.

3.3.1.7 Dependent claim 2

102. Dependent claim 2 reads as follows:

"The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers".

103. Meril et al. allege, by reference to paragraph [0166] of WO 359, that the indicia specified in claim 2 are only disclosed with other features of the flex indicating device which are mentioned in paragraphs [0162] to [0165], and omitting these other features – e.g. a slot – represents an unallowable intermediate generalization.

[0166] Referring to FIGS. 35A and 35B, the flex indicating device 150 desirably includes indicia 168 that indicate the amount of flex of the distal end of catheter 152. Indicia 168 can identify the amount of flex

in any of a variety of manners. For example, FIG. 35 shows indicia 168 depicting the amount of flex using a triangular marking system while FIG. 36 shows indicia 168 depicting the amount of flex using numbers.

104. Edwards argues that Meril's objection is inadmissible because it is insufficiently substantiated and that there, in any case, is no inextricable link and hence no unallowable intermediate generalization.

105. The Court is not convinced that there is an inextricable link between the indicia specified in claim 2 and the slot, or with any other unspecified features in paragraphs [0162] to [0165]. Hence, Meril et al. has in any case failed to prove the existence of an unallowable intermediate generalization. The Court notes that the Opposition Division came to the same conclusion.

3.3.1.8 Dependent claim 3

106. Dependent claim 3 reads as follows:

"The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members".

107. Meril et al. allege that the original application does not disclose that the flex activating member and the flex indicating member are separate members. Therefore, claim 3 is not clearly and unambiguously disclosed in WO 359, neither explicitly nor implicitly.

108. Edwards argues that it is apparent from paragraphs [030] and [031] of WO 359 that adjustment of the flex activating member causes the flex indicating member to move relative to the handle portion:

[30] In another embodiment, an apparatus for indicating flex of a distal end of a catheter is disclosed. The apparatus comprises an elongated shaft; at least one wire connected to a distal end portion of the elongated shaft; a handle portion comprising a flex activating member, the flex activating member being coupled to the at least one wire such that adjustment of the flex activating member causes the distal end portion of the shaft to flex; and a flex indicating member. Adjustment of the flex activating member causes the flex indicating member to move relative to the handle to indicate an amount of flex of the distal end portion of the shaft.

[31] In specific implementations, the flex activating member comprises a rotatable member. In other specific implementations, the handle portion comprises a slot for receiving at least a portion of the flex indicating member. In other specific implementations, the rotatable member includes an internally threaded surface portion and an externally threaded surface portion. The internally threaded surface portion is configured to receiving a slide member connected to the at least one wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member. In other specific implementations, rotating the rotatable member causes the slide member to move along the internally threaded surface portion and the movement of the slide member along the internally threaded surface portion changes the amount of flex of the distal end portion of the shaft. The rotation of the rotatable member causes the flex indicating member to move longitudinally and change its position within the slot of the handle portion and the position of the flex indicating member within the slot indicates the amount of flex of the distal end portion of the shaft.

109. From this, the person skilled in the art would – according to Edwards – understand the flex activating member and flex indicating member necessarily are separate members. It would otherwise be nonsensical to refer to the one member causing movement of the other member.

110. Edwards has also provided the following marked and annotated version of Fig. 36:

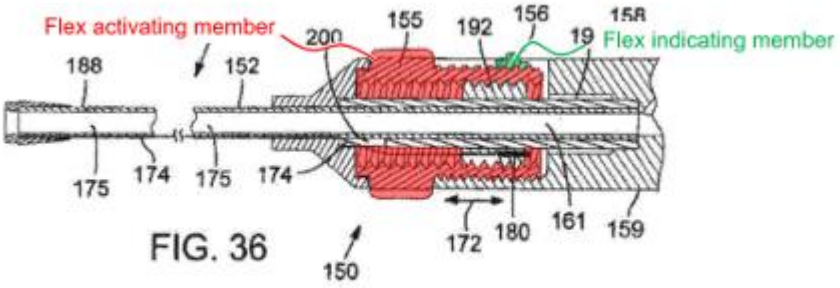


Figure 3: FIG. 36 of EP 722 (colour and annotations added)

111. The Court agrees with Edwards that paragraphs [030] and [031] of WO 359 clearly and unambiguously disclose to the skilled person that the flex activating member and the flex indicating member are separate members. This follows, in particular, from the fact that adjustment of a member (the flex activating member) causes another member (the flex indicating member) to move relative to the handle. Thus, there is no added matter in this respect. This conclusion is in line with the decision of the Opposition Division, that notes that also claim 1 as such requires the two members to be separate.

3.3.1.9 Dependent claim 4

112. Dependent claim 4 reads as follows:

> *"The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot".*

113. Meril et al. argue that the skilled person would take from paragraph [0031] in combination with paragraph [0165] and Figs. 31, 33, 35A-B and 37 of WO 359 that the slot needs to be longitudinal, i.e. that the longitudinal shape is not just preferred as specified in claim 4. Meril et al. also submit that paragraph [0165] discloses further features inseparable of the longitudinal shape of the slot that would not be specified in claim 4, such as the indicator pin (156), the adjustment knob (155), the shaft (157) and the slide nut (192). Therefore, dependent Claim 4 contains – according to Meril et al. – added subject matter.

114. Edwards argues that the general feature of a slot is disclosed in paragraph [031] of WO 359. According to paragraph [0165] of WO 359, the slot can be longitudinal in shape. According to Edwards, this means that longitudinal slot represents a specific embodiment of the general disclosure of [031], but it does not mean that the longitudinal slot must include the specific features of the specific embodiment mentioned in paragraph [0165].

115. The Court agrees with Edwards on this point. Paragraph [031] of WO 359 explicitly discloses that in a specific embodiment the handle portion comprises a slot for receiving at least a portion of the flex indicating member. According to paragraph [165] of WO 359, the slot can be longitudinal in a specific embodiment. However, Meril et al. have not demonstrated that the specific shape of the slot is inextricably linked to any of the other features of the flex indicating device disclosed in paragraph [165] of WO 359. Therefore,

the Court finds that there is no unallowably added subject matter in claim 4. This conclusion is in line with the decision of the Opposition Division.

3.3.1.10 Dependent Claim 5

116. Dependent Claim 5 reads as follows:

> *"The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152)".*

117. Meril et al. argue inter alia that claim 5 adds subject matter for the following reasons. Paragraph [031] of WO 359 discloses that "the handle portion comprises a slot for receiving at least a portion of the flex indicating member". Claim 5 is dependent only on claim 1, but the feature of a "slot" is introduced in dependent claim 4. Since the parent application, in particular paragraph [031], provides no justification for the generalising isolation of the feature of the "slot" (in isolation from "the handle portion comprising [the] slot" and the "slot" being "for receiving at least a portion of the flex indicating member", as specified in claim 4), claim 5 amounts to an intermediate generalisation of paragraph [031].

118. Edwards argues that it would be clear to the person skilled in the art that the slot of claim 5 is a slot as defined in claim 4, so that there would be no added matter. Also, this issue would be at most a clarity objection that is not a ground for revocation.

119. The Court notes that claim 5 specifies that the rotation of the rotatable member "...causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion...". This means that claim 5 as such includes the features that the handle portion comprises a slot and that the slot is longitudinal and receives a portion of the flex indication member, i.e. the relevant features from dependent claim 4. For this reason, claim 5 does not comprise an intermediate generalization. This conclusion is in line with the decision by the Opposition Division.

3.3.1.11 Dependent claim 6

120. Dependent claim 6 reads as follows:

> *"The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62)".*

121. Meril et al. allege that paragraph [0168] of WO 359, which is the basis for dependent claim 6, does not disclose that the internal passage of the side arm fluidly communicates with the central lumen "at the main body (159) of the handle portion (158)". They also argue that claim 6 omits the other features of the flex indicating device 150

disclosed in paragraphs [0162] through [0175]. Therefore, claim 6 adds subject matter, according to Meril et al.

[0168] The handle portion 158 includes a main body, or housing, 159 formed with a central lumen 161 that receives the proximal end portion of the guide tube 152. The handle portion 158 can include a side arm 62 (as shown in FIG. 1) defining an internal passage which fluidly communicates with the lumen 161. A stopcock can be mounted on the upper end of side arm 62.

122. Edwards argues that the allegedly missing feature is implicitly disclosed in [0168] of WO 359. The meaning of paragraph [0168] is, according to Edwards, that there is a main body with a lumen, and that the side arm is connected to said lumen. Since the lumen is formed in the main body, it is necessarily the case that the connection between the side arm and the lumen is at the main body. Therefore, there is – according to Edwards – disclosure for the features of claim 6. With regard to the second objection, Edwards notes that Meril et al. have not substantiated that any features mentioned in paragraphs [0162] to [0175] of WO 359 are inextricably linked to the features of claim 6. The mere presence of further features in an original description does not establish that not referring to these features is an inadmissible intermediate generalisation.

123. The Court agrees with Edwards on this point. Hence, Meril et al. have – for the reasons described by Edwards – failed to show that claim 6 adds subject matter. This conclusion is in line with the decision by the Opposition Division.

3.3.1.12 Dependent claim 7

124. Dependent claim 7 reads as follows:

The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

125. Meril et al. allege that paragraph [0169] of WO 359 does not disclose that the "slide member (192)" is "disposed on and slidable relative to the inner sleeve (190)", and that claim 7 therefore adds subject matter.

126. The "threaded slide nut 192", mentioned in e.g. paragraph [0169], is – according to Meril et al. – not synonymous to the term "slide member" disclosed, for example, in paragraph [031]. Meril et al. also argues inter alia that the "threaded side nut 192" mentioned in paragraph [0169] of WO 359 would be inextricably linked to the features of a "sleeve 190" and "external threads that mate with internal threads of the adjustment knob". According to Meril et al., no specific implementation according to paragraph [0031] of WO 359 discloses a handle portion (158) including an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

[0169] The handle portion 158 can be operatively connected to the steerable section and functions as an adjustment to permit operator adjustment of the curvature of the steerable section via manual adjustment of the handle portion. In the illustrated embodiment, for example, the handle portion 158 includes an inner sleeve 190 that surrounds a portion of the guide tube 152 inside the handle body 159. A threaded slide nut 192 is disposed on and slidable relative to the sleeve 190. The slide nut 192 is formed with external threads that mate with internal threads of an adjustment knob 155. Sleeve 190 also has

an external threaded portion that mates with an extension member of a flex indicating member 156. Flex indicating member 156 is shown in more detail in FIG. 37.

[031] In specific implementations, the flex activating member comprises a rotatable member. In other specific implementations, the handle portion comprises a slot for receiving at least a portion of the flex indicating member. In other specific implementations, the rotatable member includes an internally threaded surface portion and an externally threaded surface portion. The internally threaded surface portion is configured to receiving a slide member connected to the at least one wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member. In other specific implementations, rotating the rotatable member causes the slide member to move along the internally threaded surface portion and the movement of the slide member along the internally threaded surface portion changes the amount of flex of the distal end portion of the shaft. The rotation of the rotatable member causes the flex indicating member to move longitudinally and change its position within the slot of the handle portion and the position of the flex indicating member within the slot indicates the amount of flex of the distal end portion of the shaft.

127. Edwards argues that it is clear for the person skilled in the art that the slide nut 192 of the exemplary embodiment in e.g. paragraph [0169] is a slide member in the sense of original paragraph [031]. Therefore, the literal disclosure that a "slide nut 192 is disposed on and slidable relative to the sleeve 190" in paragraph [0169], in combination with the general disclosure of a slide member in original paragraph [031], directly and unambiguously discloses to the person skilled in the art the features of claim 7 of EP 722.

128. The Court finds that while paragraph [031] of WO 359 discloses that the internally threaded surface portion of the handle causes the slide member to move along such threaded surface, it does not disclose that the slide member has an externally mating threaded surface effecting such movement. It is furthermore apparent from the passage of paragraph [0169] underlined above, that the slide nut and its external threads are in inextricable interaction with the sleeve and the mating internal threads of the adjustment knob 155. Thus, there is an inextricable link between the side nut/slide member, the "sleeve 190" and the "external threads that mate with internal threads of the adjustment knob". Omitting these other features in the claim represents an unallowable intermediate generalisation.

129. Hence, claim 7 adds subject matter.

3.3.1.13 Dependent claim 8

130. Dependent claim 8 reads as follows:

The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

131. Meril et al. argue that although paragraph [169] of WO 359 discloses that the "slide nut 192" is formed with external threads, it does not disclose that the "slide member (192)" is formed with external threads. According to Meril et al., the threaded slide nut of [0169] would be different from the slide member of [031]. Therefore, claim 8 adds subject matter.

132. Edwards argues that it is clear for the person skilled in the art that the slide nut 192 of the exemplary embodiment is a slide member in the sense of original paragraph [031]. Therefore, the literal disclosure that "[t]he slide nut 192 is formed with external threads" in original paragraph [0169] – in combination with the general disclosure of a slide member

in original paragraph [031] – directly and unambiguously discloses to the person skilled in the art the features of claim 8 of EP 722.

133. The Court finds that paragraph [169] of WO 359 explicitly discloses that "the slide nut 192 is formed with external threads that mate with internal threads of an adjustment knob 155". Since claim 8 requires that the slide member (192) has the same construction and function as the slide nut in paragraph [169], no technical difference can be seen between these two elements.

134. Hence, claim 8 does not add subject matter.

3.3.1.14 Dependent claim 9

135. Dependent claim 9 reads as follows:

> *The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).*

136. Meril et al. argue that paragraph [0169] of WO 359 presents the features of claims 7–9 as being inextricably linked and that both alternatives of claim 9 (dependence on 7 or 8) therefore are inadmissibly generalized. In particular, Meril et al. argue that paragraph [0169] of WO 359 discloses that the "the handle portion 158 includes an inner sleeve 190 that surrounds a portion of the guide tube 152 inside the handle body 159 [...] sleeve 190 also has an external threaded portion that mates with an extension member of a flex indicating member 156." According to Meril et al., the use of the term "also" in paragraph [0169] clearly links the features of the inner sleeve 190 specified in claim 9 to the preceding features of the inner sleeve 190 in this paragraph, which are generally specified in claim 7. Consequently, also when dependent on claim 8 (which is dependent only on claim 1), claim 9 amounts – according to Meril et al. – to an impermissible intermediate generalisation since the claim combination omits claim 7.

> *[0169] The handle portion 158 can be operatively connected to the steerable section and functions as an adjustment to permit operator adjustment of the curvature of the steerable section via manual adjustment of the handle portion. In the illustrated embodiment, for example, the handle portion 158 includes an inner sleeve 190 that surrounds a portion of the guide tube 152 inside the handle body 159. A threaded slide nut 192 is disposed on and slidable relative to the sleeve 190. The slide nut 192 is formed with external threads that mate with internal threads of an adjustment knob 155. Sleeve 190 also has an external threaded portion that mates with an extension member of a flex indicating member 156. Flex indicating member 156 is shown in more detail in FIG. 37.*

137. Edwards argues that claim 9 does not add subject matter. The alleged problem where claim 9 is dependent only on claim 8 does not exist, since claim 9 explicitly refers to "the inner sleeve". According to Edwards, there may at the most be an unclarity associated with this reference, but this is not a ground for revocation. In view of EP 722 as a whole, the person skilled in the art would, according to Edwards, immediately understand that the inner sleeve referred to in claim 9 is an inner sleeve as defined in claim 7, since this is the only preceding claim which refers to an inner sleeve. Hence, the resulting subject matter has – according to Edwards – direct and unambiguous disclosure in the original application documents.

138. The Court has already, when discussing claim 7, concluded that in paragraph [0169] of WO 359 there is an inextricable link between the side nut/slide member, the "sleeve

190" and the "external threads that mate with internal threads of the adjustment knob". Claim 7 was found inadmissibly broadened because all these features were not included. This problem applies also to the combination of claims 1, 7 and 9, i.e. there is added subject matter.

139. Regarding claim 9 being dependent on claim 8, the Court has already found that claim 8 as such does not add subject matter. The Court also notes that paragraph [0169] of WO 359 discloses a sleeve and that the "[s]leeve 190 also has an external threaded portion that mates with an extension member of a flex indicating member 156", i.e. the feature recited in claim 9. However, in paragraph [0169] of WO 359, this feature is inextricably linked with the features specifying the position of the sleeve in the handle portion. The Court does not agree with Edwards that the expression "the inner sleeve" in claim 9 would lead the skilled person to the conclusion that all features of claim 7 are included also in the combination of claim 1, 8 and 9. Isolating the feature of an external threaded surface of the sleeve from its arrangement in the handle, i.e. the features of claim 7, represents an intermediate generalisation.

140. Hence, claim 9 adds subject matter in both alternative dependencies.

3.3.1.15 Dependent claim 10

141. Dependent claim 10 reads as follows:

> *The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).*

142. Meril et al. argue that claim 10 does not have direct and unambiguous basis in the original application documents. In particular, paragraph [0170] of WO 359 states that the "slide nut 192 can be formed with two slots formed on the inner surface of the nut and extending the length thereof", while claim 10 specifies that two slots are formed on an inner surface of the slide member. Thus, paragraph [0170] does not disclose that the "slide member (192)" has "two slots formed on an inner surface". In this context, Meril et al. also refers inter alia to the EPO Opposition Division's opinion in the proceedings against the parent application (EP 929) that the features of dependent claims 11 and 12 (claims 10 and 11 of the patent in suit) are inextricably linked in paragraph [0170] of WO 359. Meril et al. also points out that claim 10 relates back to one of claims 7 to 9 and argue that since claims 7 to 9 are inadmissibly extended also claim 10 adds subject matter.

143. Edwards argues that it is clear to the person skilled in the art that the slide nut 192 of the exemplary embodiment is a slide member in the sense of [031] of WO359. Therefore, literal disclosure of a side nut with two slots on an inner surface of the nut in [0170], in combination with the general disclosure of a slide member in original paragraph [031], directly and unambiguously discloses to the person skilled in the art the features of claim 10 of EP 722. The reference to the parallel proceeding concerning EP 929 is, according to Edwards, irrelevant.

> *[031] In specific implementations, the flex activating member comprises a rotatable member. In other specific implementations, the handle portion comprises a slot for receiving at least a portion of the flex indicating member. In other specific implementations, the rotatable member includes an internally*

threaded surface portion and an externally threaded surface portion. The internally threaded surface portion is configured to receiving a slide member connected to the at least one wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member. In other specific implementations, rotating the rotatable member causes the slide member to move along the internally threaded surface portion and the movement of the slide member along the internally threaded surface portion changes the amount of flex of the distal end portion of the shaft. The rotation of the rotatable member causes the flex indicating member to move longitudinally and change its position within the slot of the handle portion and the position of the flex indicating member within the slot indicates the amount of flex of the distal end portion of the shaft.

[0170] Slide nut 192 can be formed with two slots formed on the inner surface of the nut and extending the length thereof. Sleeve 190 can be formed with longitudinally extending slots that are aligned with the slots of the slide nut 192 when the slide nut is placed on the sleeve. Disposed in each slot is a respective elongated nut guide, which can be in the form of an elongated rod or pin. The nut guides extend radially into respective slots in the slide nut 192 to prevent rotation of the slide nut 192 relative to the sleeve 190. By virtue of this arrangement, rotation of the adjustment knob 155 (either clockwise or counterclockwise) causes the slide nut 192 to move longitudinally relative to the sleeve 190 in the directions indicated by double-headed arrow 172.

144. The Court has already found that claims 7 and 9 are inadmissibly broadened, since in paragraph [0169] of WO 359 there is an inextricable link between the side nut/slide member, the "sleeve 190" and the "external threads that mate with internal threads of the adjustment knob" – and that all these features have not been included. This problem applies also to claim 10, when depending on claim 7 or 9.

145. Furthermore, claim 10 specifies that the slide member and the inner sleeve each exhibit two slots that are aligned with each other while claim 11 specifies that an elongated guide such as an elongated rod or pin extend into each slot of the side member so that a rotation of the side member relative to the inner sleeve is prevented. Thus, claims 10 and 11 separate the inextricable feature of the location of the slots in the slide member and the inner sleeve, respectively, from the rods/pins preventing rotation. However, in paragraph [0170] of WO 359, there is – as pointed out by Meril et al. – an inextricable link between these features. In case the slide member and the inner sleeve exhibit coexisting slots the presence of rods/pins that extend into the slot of the slide member is required in order to prevent a rotation of the slide member relative to the inner sleeve. By virtue of these inextricably linked features the slide member moves longitudinally relative to the sleeve. Based on this, claim 10 also represents an intermediate generalization on its own and adds subject matter.

146. Hence, claim 10 includes added subject matter.

3.3.1.16 Dependent claim 11

147. Dependent claim 11 reads as follows:

The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

148. Meril et al. argue that neither paragraph [031] nor paragraph [0170] of WO 359 discloses that an "elongated guide" extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

According to paragraph [0170] it is "nut guides" that extend radially into the slots of the "slide nut 192", which – according to them – is not the same. Meril et al. also argues that claim 11 is inadmissibly extended because claim 11 relates back to claim 10, which in turn relates back to one of claims 7 to 9 and thereby includes the inadmissible extension of claims 7, 8 and 9.

[031] In specific implementations, the flex activating member comprises a rotatable member. In other specific implementations, the handle portion comprises a slot for receiving at least a portion of the flex indicating member. In other specific implementations, the rotatable member includes an internally threaded surface portion and an externally threaded surface portion. The internally threaded surface portion is configured to receiving a slide member connected to the at least one wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member. In other specific implementations, rotating the rotatable member causes the slide member to move along the internally threaded surface portion and the movement of the slide member along the internally threaded surface portion changes the amount of flex of the distal end portion of the shaft. The rotation of the rotatable member causes the flex indicating member to move longitudinally and change its position within the slot of the handle portion and the position of the flex indicating member within the slot indicates the amount of flex of the distal end portion of the shaft.

[0170] Slide nut 192 can be formed with two slots formed on the inner surface of the nut and extending the length thereof. Sleeve 190 can be formed with longitudinally extending slots that are aligned with the slots of the slide nut 192 when the slide nut is placed on the sleeve. Disposed in each slot is a respective elongated nut guide, which can be in the form of an elongated rod or pin. The nut guides extend radially into respective slots in the slide nut 192 to prevent rotation of the slide nut 192 relative to the sleeve 190. By virtue of this arrangement, rotation of the adjustment knob 155 (either clockwise or counterclockwise) causes the slide nut 192 to move longitudinally relative to the sleeve 190 in the directions indicated by double-headed arrow 172.

149. Edwards argues that using the term "elongated guide" instead of "elongated nut guide" is a mere linguistic issue that does not represent a generalized teaching. According to Edwards, the structural and functional features of the elongated guide are exactly the same as of the elongated nut guide described in paragraph [0170] of WO 359. The guide mentioned in paragraph [0170] is – according to Edwards – referred to as "nut guide" only because the slide member is a slide nut in the embodiment discussed in paragraph [0170].

150. The Court finds that since claim 11 requires that the elongated guides have the same construction and function as the elongated nut guides in paragraph [0170], there is no technical difference between these two elements. However, the Court has already found that claim 10 is inadmissibly broadened to the extent it is dependent on claim 7 or 9, since there in paragraph [0169] of WO 359 is an inextricable link between the side nut/slide member, the "sleeve 190" and the "external threads that mate with internal threads of the adjustment knob" – and that all these features have not been included. This problem applies also to claim 11, which refers back to claim 10.

151. Hence, claim 11 includes added subject matter.

3.3.1.17 Dependent claim 12

152. Dependent claim 12 reads as follows:

The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

153. Meril et al. argue that paragraph [0171] of WO 359 discloses that the pin 180 is disposed in a slot in "the slide nut 192", not the "slide member (192)". Changing the terms does – according to them – represent an unallowable broadening. Meril et al. also argue that paragraph [0171] discloses several additional features that are omitted from claim 12 and that the referral back to "one of claims 7–11" represents an inadmissible broadening at least to the extent the claims referred to are inadmissibly broadened. Hence, claim 12 extends – according to Meril et al. – beyond the content of the original application.

154. Edwards argues that it is clear for the person skilled in the art that the slide nut 192 of the exemplary embodiment is a slide member in the sense of original paragraph [031]. Therefore, the literal disclosure that "[t]he pin 180 is disposed in a slot in the slide nut 192" in original paragraph [0171] in combination with the general disclosure of a slide member in original paragraph [031] directly and unambiguously discloses to the person skilled in the art the features of claim 12 of EP 722. The mere presence of further features in an original description does not mean that their omission causes an added matter problem. An inextricable link or any other reason why the alleged "omission" should cause an added matter problem is – according to Edwards – not substantiated by the Defendants.

155. The Court has already concluded that claim 1 as issued provides means for actuating the pull wire by adjustment of the flex activating member causing the distal end portion of the elongated shaft to flex. Hence, no essential technical information has been omitted from claim 1 of EP 722, and the pull wire is not inextricably linked to the adjustment knob described in [0163] to [0165] and [0171] to [0172]. This means that claim 1 can be combined with the disclosure of [0171] as originally disclosed.

156. However, the Court has already found that claims 7, 9, 10 and 11 includes added subject matter, since in paragraph [0169] of WO 359 there is an inextricable link between the side nut/slide member, the "sleeve 190" and the "external threads that mate with internal threads of the adjustment knob" – and that all these features have not been included. This problem applies also to claim 12, which refers back to these claims.

157. Hence, claim 12 includes added subject matter.

3.3.1.18 Dependent claim 13

158. Dependent claim 13 reads as follows:

> *The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.*

159. Meril et al. argue that since all preceding claims are inadmissible extended, also claim 13 – which refers back to "one of the preceding claims" – is inadmissibly extended.

160. Edwards notes that there is no substantiated added matter attack against claim 13 as such. The general attack is according to Edwards not substantiated and should therefore be disregarded.

161. The Court agrees that to the extent the preceding claims are inadmissibly extended, so is dependent claim 13, by its reference to these claims. However, claim 13 as such does not add subject matter.

3.3.2 Sufficiency of disclosure

3.3.2.1 Legal standard for assessing sufficiency of disclosure

162. According to Article 65 (2) UPCA and Article 138.1 (b) EPC, the Court may revoke a European patent, either entirely or partly, if the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

163. This assessment shall be based on the application as a whole, including examples, and taking into account the common general knowledge of the skilled person.

3.3.2.2 Claim 1

164. Meril et al. allege inter alia that claim 1 is not sufficiently disclosed since it does not specify the presence of a longitudinal slot into which a portion of the flex indicating member extends upwards, even though the presence of a slot is an essential element because the mechanical interaction between the flex indicating member and the slot would be essential for moving the flex indicating member relative to the handle portion (feature 1.4 of claim 1). More specifically, the interaction between the longitudinal slot and the flex indicating member would – according to Meril et al. – be the only means disclosed in the patent to prevent a rotational movement of the flex indicating member and to allow for a longitudinal movement of the flex indicating member relative to the handle portion. They also argue that although Edwards seems to assume that the "knob 155" can be a "rotatable member", there is no example of an embodiment in which "the knob 155" has an externally threaded surface portion configured to receive an extending portion of the flex indicating member. Thus, the skilled person cannot – according to Meril et al. – perform claim 1 over the entire breadth of the claim.

165. Edwards argues inter alia that the alleged omission of an essential feature in claim 1 gives, at the most, rise to a clarity objection that is not a reason for revocation. Edwards adds that the claimed invention is disclosed sufficiently clear and complete in the patent specification as a whole, specifically in the context of Figs. 31 to 38B. Edwards refers to paragraph [0008] of EP 722, where a flex activating member comprising a rotatable member which includes an externally threaded surface portion is discussed, and concludes that the patent contains one workable example to carry out the invention and that Meril et al. has failed to demonstrate that the invention cannot be carried out.

166. The Court agrees with Edwards that the alleged omission of an essential feature from the independent claim is a clarity issue and that EP 722 clearly discloses one way to carry out the invention. This is sufficient, since Meril et al. have not demonstrated that the invention cannot be carried out. Hence, the invention according to claim 1 is sufficiently disclosed. This conclusion is in line with the decision by the Opposition Division.

3.3.2.3 Dependent claims 2–13

167. Meril et al. allege that since claims 2 to 13 all depend on independent claim 1 and none of the dependent claims specify a longitudinal slot or the extending portion of the

flex indicating member as mandatory, the subject matter of these claims is also not sufficiently disclosed over the whole area claimed. Meril et al. also argue that dependent claim 9 is not sufficiently disclosed by the patent in suit and that the same applies mutatis mutandis to dependent claims 10 to 13 when dependent on claim 9.

168. The Court has already found that the patent discloses the invention according to claim 1 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Hence, this objection to dependent claims 2 to 13 is unfounded.

169. The second attack on sufficient disclosure relates to claim 9, which reads as follows:

The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).

170. Dependant claims 10 to 13 have been cited above, and they all refer back to this claim 9.

171. According to Meril e al., claim 9 is in conflict with the teaching of the Patent, e.g. in paragraph [0113], that an extending portion of the flex indicating member mates with the externally threaded surface portion of the flex activating member. The purpose of the inner sleeve is that the threaded slide nut is disposed on and slidable relative to the sleeve, i.e. that it provides a slidable movement of the slide nut. In particular, in Figure 36 the sleeve 190 does not even comprise an externally threaded portion, nor does Figure 36 or any other part of the patent in suit mention that the sleeve 190 is capable of rotation. Thus, the patent in suit does not provide any guidance to the skilled person on how to provide an inner sleeve on which the slide nut is slidable disposed, i.e. the sleeve is positioned inside the slide nut, and at the same time comprises an external threaded portion that mates with an extension member of the flex indicating member that is positioned outside the slide nut.

[0113] The shaft 157 also includes an externally threaded surface portion 162. As shown in FIG. 37, an extending portion 166 of indicator pin 156 mates with the externally threaded surface portion 162 of flex activating member 154. The shaft 157 extends into the handle portion 158 and the indicator pin 156 is trapped between the externally threaded surface portion 162 and the handle portion 158, with a portion of the indicator pin 156 extending upward into a longitudinal slot 164 of the handle. As the knob 155 rotated to increase the flex of the distal end of the shaft of catheter 152, indicator pin 156 tracks the external threaded portion 162 of the flex activating member and moves in the proximal direction inside of slot 164. The greater the amount of rotation of the flex activating member 154, the further indicator pin 156 moves towards the proximal end of handle 158. Conversely, rotating the knob 155 in the opposite direction decreases the flex of the distal end of the shaft of the catheter and causes corresponding movement of the indicator pin 156 toward the distal end of the handle.

172. Edwards argues that the person skilled in the art considering claim 9 would immediately recognise that it contains an obvious error, and the correction would be immediately apparent to them. In particular, the person skilled in the art would understand from the disclosure as a whole that the extension member of the flex indicating member mates with the external threads of the flex activating member. Accordingly, the person skilled in the art would immediately understand that reference to an "inner sleeve (190) in dependent claim 9" should be to a "flex activating member (154)".

173. Meril et al. have disputed that the person skilled in the art would immediately understand that the reference to an "inner sleeve (190) in dependent claim 9" is an obvious error and that it should be to a "flex activating member (154)".

174. The Court of Appeal has, when dealing with an application for provisional measures, clarified that "a linguistic error, a spelling mistake or any other inaccuracy in a patent claim can only be corrected by way of interpretation of the patent claim if the existence of an error and the precise way to correct it are sufficiently certain to the average skilled person on the basis of the patent claim, taking into account the description and the drawings and using common general knowledge" (Order on 14 December 2024, UPC_CoA_402/2024).

175. In this case, the Court notes that Edwards has not explained in any detail why the person skilled in the art would immediately understand that reference to an "inner sleeve (190) in dependent claim 9" should be to a "flex activating member (154)". In addition, the Court notes that "the disclosure as a whole" – to which Edwards refers – also contains literal support for the claim 9 as granted. Paragraph [0117] reads as follows:

[0117] The handle portion 158 can be operatively connected to the steerable section and functions as an adjustment to permit operator adjustment of the curvature of the steerable section via manual adjustment of the handle portion. In the illustrated embodiment, for example, the handle portion 158 includes an inner sleeve 190 that surrounds a portion of the guide tube 152 inside the handle body 159. A threaded slide nut 192 is disposed on and slidable relative to the sleeve 190. The slide nut 192 is formed with external threads that mate with internal threads of an adjustment knob 155. Sleeve 190 also has an external threaded portion that mates with an extension member of a flex indicating member 156. Flex indicating member 156 is shown in more detail in FIG. 37.

176. For these reasons, Edwards has failed to convince the Court that the person skilled in the art would conclude that the reference to an "inner sleeve (190)" in dependent claim 9 is an error and that the reference should be to a "flex activating member (154)". Hence, the examination of whether the invention according to claim 9 is sufficiently disclosed shall be done under the assumption that this is not an error.

177. Edwards has not argued that the skilled person would understand how to provide an inner sleeve on which the slide nut is slidable disposed and at the same time comprises an external threaded portion that mates with an extension member of the flex indicating member that is positioned outside the slide nut. It can also be taken from Fig. 36 that the sleeve (marked in yellow) is considerably spaced apart from the indicator pin (marked in green). Hence, it is not clear to the person skilled in the art how Fig. 36 of EP 722 need to be modified to meet the requirements of claim 9.

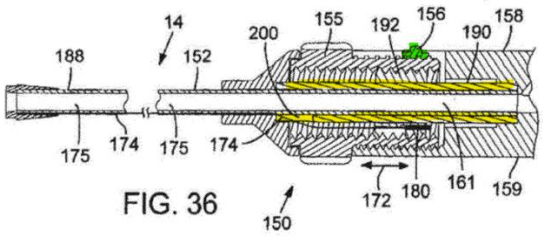


FIG. 36

178. For these reasons, the Court concludes that that dependent claim 9 is not sufficiently disclosed by the patent in suit and that the same applies mutatis mutandis to dependent claims 10 to 13 when depending on claim 9.

3.3.3 Inventive step

3.3.3.1 Legal standard for assessing inventive step

179. According to Article 65 (2) UPCA and Article 138.1 (a) EPC, the Court may revoke a European patent, either entirely or partly, if the subject matter of the patent is not patentable under Articles 52 to 57 EPC.

180. Article 52.1 EPC stipulates inter alia that a European patent may only be granted for an invention that involves an inventive step and Article 56 EPC specifies that an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

181. For assessing whether an invention shall be considered obvious, having regard to the state of the art, in a structured form, the EPO has developed a test that normally is referred to as the problem-solution approach (PSA). This test is regularly used by the EPO, including the BoA, and by most national courts in the participating member states. However, there is no legal obligation to apply the PSA. Some national Courts use a different test but normally come to the same result.

182. So far, the UPC has explicitly referred to and applied the PSA in some cases, but in other cases the Court has applied a test that is very similar if not identical to the test for inventive step applied by the German Federal Court of Justice.

183. In this case, the parties have used the PSA as the basis when they have discussed inventive step and the Court sees no reason to make its assessment based on a different test. Hence, the PSA will be applied.

3.3.3.2 The attacks based on Marchand as a starting point

184. Marchand is a US patent application (no. US 2008.0065O11 A1) with the title "Integrated heart valve delivery system". It was published on 13 March 2008 and represents a suitable starting point for the skilled person.

185. Meril et al. argue that EP 722 lacks inventive step based on the following combinations

- Marchand in combination with the CGK
- Marchand in combination with Hammersmark
- Marchand in combination with Shturman
- Marchand in combination with Lashinski
- Marchand in combination with Phan
- Marchand in combination with Levine
- Marchand in combination with the (the prior use of) the CoreValve delivery system

Distinguishing features and the objective technical problem

186. Marchand is structurally closest to the apparatus for indicating flex of a distal end of a catheter claimed in the patent-in-suit EP 722. Fig. 3B of Marchand shows a cross-

section of the guide catheter of Marchand and is reproduced below, next to Fig. 36 of EP 722 which shows a cross section of a handle portion of a flex indicating device in EP 722.

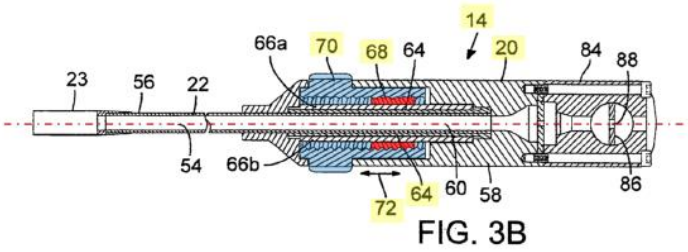


Figure 4: FIG. 3B of Marchand (colour and annotations added)

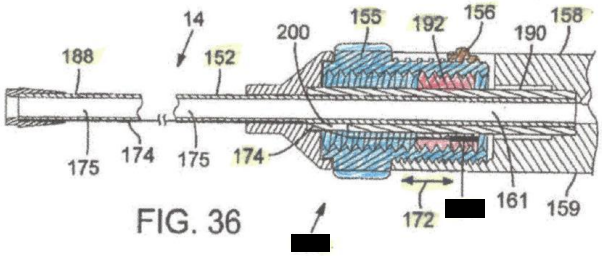


Figure 36 in EP 722 B1)

187. Both devices comprise a handle portion (20_Fig.3B Marchand/158_Fig. 36 EP 722) with an adjustment knob (70_Fig. 3B Marchand/155_Fig. 36 EP 722). The adjustment knob is rotatable about a rotation axis (dashed dotted line in Fig.3B_Marchand) that extends parallel to a longitudinal axis of the guide catheter (14_Fig.3B Marchand/150_Fig. 36 EP 722).

188. The adjustment knob 70/155 is formed with internal threads that mate with external threads of a slide nut which here is highlighted in red (68_Fig.3B Marchand/192_Fig. 36 EP 722). Turning the adjustment knob 70/155 around its rotation axis causes the slide nut 68/192 to move longitudinally relative to a sleeve (64_Fig.3B Marchand/150_Fig. 36 EP 722), as indicated by the double-headed arrow (72_Fig.3B Marchand/190_Fig. 36 EP 722).

189. In Fig. 36 of EP 722 a pull wire 174 is connected to a pin 180 in the slide nut 192; this is not shown in Fig. 3B of Marchand but it is disclosed in [0072] of Marchand that a pull wire is connected to the slide nut 68 and to a distal end portion of a steerable section of the guide catheter 14. Due to this arrangement, the longitudinal movement of the slide nut 68/192 is transferred via the pull wire to the steerable section (56_Fig.3B Marchand/188_Fig. 36 EP 722), whose flex can accordingly be adjusted by rotating the adjustment knob 70 around the rotation axis.

190. What Marchand fails to disclose is

- the presence of a flex indicating member
- the presence of a flex indicating member (156) that moves relative to the handle portion (158) when a flex activating member (154) is adjusted adjustment,
- the presence of a flex activating member that has an externally threaded surface portion, and

- the presence of an externally threaded surface portion (162) that is configured to receive an extending portion (166) of the flex indicating member (156).

191. This means that features 1.3.3, 1.4, 1.5.2 and 1.5.4 are missing, as illustrated by the following feature analysis for Marchand vs. Claim 1 of EP 722:

Feature #	Claim 1 of EP 722 as issued	Marchand
1	An apparatus for indicating flex of a distal end of a catheter comprising	+
1.1	an elongated shaft (152);	+
1.2	at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);	+
1.3	a handle portion (158) comprising	+
1.3.1	a flex activating member (154), activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;	+
1.3.2	a slide member (192) connected to the at least one pull wire (174); and	+
1.3.3	a flex indicating member (156);	-
1.4	wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and	-
1.5	wherein the flex activating member (154) comprises	+
1.5.1	a rotatable member (155, 157) which includes an internally threaded surface portion (160)	+
1.5.2	characterized in that the flex activating member also has an externally threaded surface portion	-
1.5.3	wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and	+
1.5.4	the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156)	-

192. Meril et al. argue, with reference to a paragraph in a decision by UK High Court of Justice (HL-CC 8), that the adjustment knob 70 of Marchand gives some indication of flex. They also submit that the "flex indicating member" in EP 722 only provides information on the current amount of rotation of the adjustment knob, not of the actual flex at the distal end, and that Edwards has failed to show that features 1.3.3. and 1.4 would have a technical effect not already provided by Marchand. Therefore, the objective technical problem underlying EP 722 in view of Marchand is – according to Meril et al. – the provision of an alternative structure to indicate flex, or to provide (alternative) means to determine the amount of rotation of the rotatable member.

193. The decision by UK High Court of Justice, which deals with the question whether Meril's delivery system Navigator infringes EP 3,494,929 (i.e. EP 722's parent), includes the following paragraph:

"However this knob does give some tactile indication of the flex. That is because turning the knob in the same direction will ultimately reach a stop, so that the operator will feel that the knob cannot be turned any further. One stop indicates that the guide catheter is straight and the other stop represents the fully flexed state. That is a simple tactile indication of the amount of flex (all or nothing) and so the knob itself

as it turns relative to the handle portion, seems to me to fall within feature I. But there are no visual indicia in the example just given (which corresponds to the common general knowledge of Retroflex). Feature J is not satisfied by the tactile feedback provided by the knob".

194. Edwards argues, on the other hand, that Meril et al. bear the burden of proof for the absence of a technical effect. According to Edwards, distinguishing features 1.3.3, 1.4, 1.5.2, and 1.5.4 assure that the flex indicating member reliably moves in a controlled and well-defined manner when the flex activating member (= the adjustment knob 155) is actuated. Due to the engagement between the externally threaded surface portion and the flex indicator, actuation of the flex activating member is translated into movement of the flex indicator which directly corresponds to the actuation. The technical effect resulting from the features missing in Marchand is therefore to indicate the adjusted flex in a mechanically reliable and accurate manner. Paragraphs [030] and [031] of WO 359 clearly and unambiguously disclose to the skilled person that the flex activating member and the flex indicating member are separate members. It is irrelevant whether or not it may theoretically be possible to inspect the adjustment knob 70 of Marchand in order to conclude whether there is flex in the steerable section of the guide catheter. The Defendants' suggestion to focus on the amount of rotation of the rotatable member, is inter alia based on hindsight. Thus, the objective problem underlying EP 722 in view of Marchand is – according to Edwards – to provide apparatus which allows indicating the adjusted flex in a mechanically reliable and accurate manner.

195. The Court notes that the adjustment knob of Marchand is the flex activating member. The argumentation submitted by Meril et al. assume that the person skilled in the art would consider it to be simultaneously a member for indicating flex at the distal end of a catheter. The Court considers this conclusion to be driven by hindsight. Furthermore, while it in theory might be possible to draw certain conclusions based on the fact that an adjustment knob in Marchand has reached a stop, paragraphs [030] and [031] of WO 359 clearly and unambiguously disclose to the skilled person that the flex activating member and the flex indicating member are separate members where the adjustment of a member (the flex activating member) causes another member (the flex indicating member) to move relative to the handle.

196. The effect of the differences between Marchand and the invention, in terms of technical features, is thus that the patent provides means to indicate the adjusted flex at the distal end of a catheter (in a mechanically reliable and safe fashion). The alternatives suggested by Meril et al., i.e. to focus on the amount of rotation of the rotatable member/knob when formulating the problem, is driven by hindsight and contain pointers to the solution used in the invention. The objective technical problem must be formulated in such a way that it does not contain such pointers or partially anticipate the solution. Hence, the objective technical problem relative to Marchand is to provide an apparatus which allows the indication of the adjusted flex at the distal end in a reliable and safe fashion.

The inventive step attack based on Marchand in combination with Hammersmark

197. Hammersmark is a patent application directed to "a turn limiter for a catheter with a twistable tip". It discloses in Figs. 2 and 3 an apparatus for rotating a torque element 25 (=pull wire) of a torque catheter.

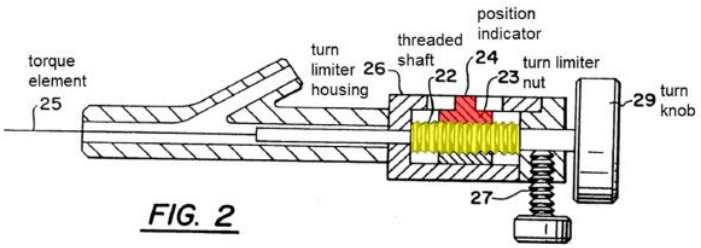


FIG. 2

198. The turn knob 29 is connected to a threaded shaft 22 that mates with the internal threads of a turn limiter nut 23 so that the turn limiter nut 23 and the position indicator 24 move along the threaded shaft 22 when the turn knob is rotated. In the description, it is stated (p. 7, lines 19–21) that "[t]he position indicator gives the operator a visual indication of the amount of torque applied to the torque element 25."

199. Meril et al. argue inter alia that Hammersmark teaches that "the flex indicating member has an externally threaded surface portion that is configured to receive an extending portion of the flex indicating member", so that Hammersmark would disclose features 1.5.2 and 1.5.4. They also refer to Clarke (US 5,114,403), which is a patent mentioned in the background section of Hammersmark.[1] Clark discloses a swivel housing 490 in Figs. 8 and 9 and comprises an internally threaded surface portion 500 and an externally threaded surface portion 610.

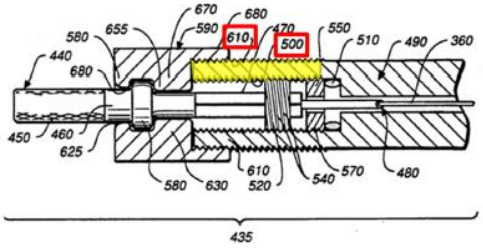


FIG._8

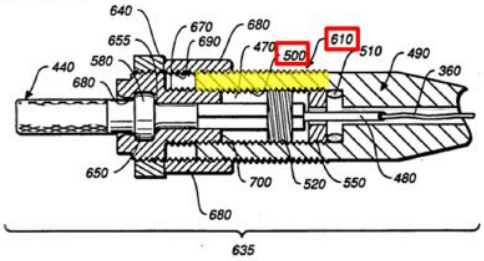
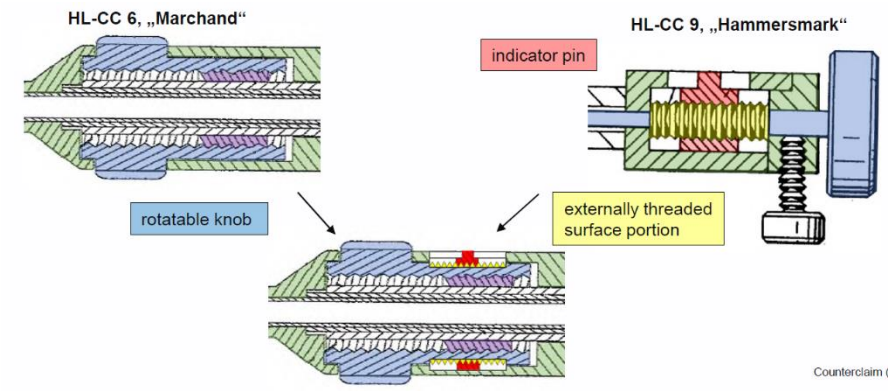


FIG._9

200. It could, according to Meril et. al., be taken from Clarke that cylindrical components having both an internally threaded surface portion and an externally threaded surface portion were common means of handle portions. Hence, the person skilled in the art would – according to Meril et al. – have modified the handle portion of Marchand in view of the teaching of Hammersmark and inevitably arrived at the subject matter of claim 1.

[1] Page 3, lines 8–14: "Another turning means is suggested by Clark et al., U.S. Patent No. 5,114,403. The Clark torque mechanism has many parts and does not have a friction means for preventing the handle from returning to its original position when turned and then released by an operator."



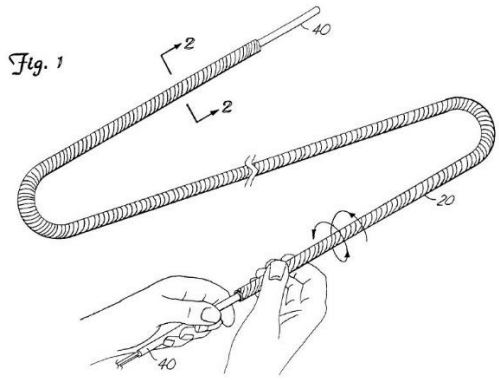
201. Edwards argues inter alia that Hammersmark relates to a twistable tip catheter aimed at controlling the beam emanating from the optical fibres to ablate obstructions, i.e. to a different field, and that it does not disclose means for indicating distal flex, but rather a torque limiter with indicating means, since the rotational movement of the turn mob is applied to the shaft and not transferred into a translational movement. Therefore, the person skilled in the art would – according to Edwards – not have considered a combination of Marchand with Hammersmark in the first place. The constructions of Marchand and Hammersmark would also be completely different, and their combination would not trigger the person skilled in the art to add a second threaded surface and a second element which moves longitudinally with respect to the handle portion of Marchand. A combination would instead have led away from the claimed subject matter e.g. by replacing the internally threaded surface and slide nut received therein with an externally threaded surface portion and a position indicator. In terms of Clarke, Edwards submits that a swivel house would be a concept completely different from an apparatus for indicating flex of a distal end of a catheter. The mere presence of externally threaded surface portions on a handle portion would not provide any motivation to combine Marchand, Hammersmark and Clarke. This would – according to Edwards – anyway be a combination of three references and rather support the presence of an inventive step.

202. The Court agrees with Edwards that the constructions of Marchand and Hammersmark are completely different and that it is hard to see why the person skilled in the art would combine them. Nor is it obvious that such a combination would lead to the invention according to claim 1. In particular, it would not be obvious how to maintain features 1.5.1 and 1.5.3 when these two documents are combined. Hence, the Court concludes that the invention involves an inventive step in view of a combination of Marchand with Hammersmark. This conclusion is in line with the decision by the Opposition Division.

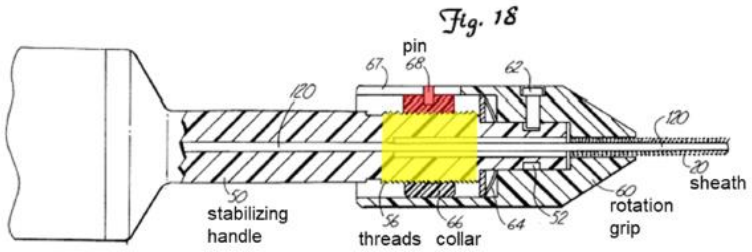
The inventive step attack based on Marchand in combination with Shturman

203. Shturman is a US patent that relates to a rotatable intravascular apparatus having a flexible, elongated medical device and a mechanism for controlling the rotational orientation of the distal end of the medical device. According to the description, the apparatus of the invention is usable, for example, in connection with a wide variety of devices, including, for example, catheters, including guiding catheters, and may also be successfully utilized to temporarily (when needed) increase the rotational control of the distal end of guide wires or guiding catheters.

204. Fig. 1 of Shturman is a perspective view of a rotatable medical apparatus of the invention.



205. Fig. 18 of Shturman discloses a handle portion 50 and a rotation grip portion 60 of a rotatable medical apparatus that has a torquing sheath 20.



206. Similarly to what was discussed with respect to Hammersmark above, Shturman discloses a device that imparts a rotational movement to the torque sheath. The device has a handle that comprises an externally threaded surface portion that mates with an internally threaded portion of a collar 66. The collar bears a pin 68 whose longitudinal location in a slot 67 provides an indication of the rotational torque applied to the sheath.

207. Meril et al. argue inter alia that Shturman anticipates the alleged distinguishing features of claim 1 of the patent in suit and that the person skilled in the art was motivated to implement the features of Shturman into the apparatus of Marchand and, thus, would arrive at the subject matter of claim 1 without any inventive skills.

208. Edwards argues inter alia that Shturman does not relate to flexing a catheter, and that it does not disclose a flex indicating member or any flex indicating mechanism or even a flex activating member. According to Edwards, Shturman is at least as remote from the teaching of Marchand as Hammersmark, and the same arguments apply. The person skilled in the art would not have combined the documents, and even if he/she would have done so, the combination would not have suggested adding an externally threaded surface portion to the adjustment knob 70 of Marchand based on the teaching of Shturman. Instead, a combination of the two documents would – according to Edwards – have led further away from a flex activating member with two different threaded surface portions.

209. The Court finds that the comments made above with respect to Hammersmark apply to Shturman mutatis mutandis. The constructions of Marchand and Shturman are completely different, and it is hard to see why the person skilled in the art would combine them. Nor is it obvious that such a combination would lead to the invention according to claim 1. In particular, it would not be obvious how to maintain features 1.5.1 and 1.5.3 of claim 1 when these two documents are combined. Hence, the Court concludes that the

invention involves an inventive step in view of a combination of Marchand with Shturman. This conclusion is in line with the decision by the Opposition Division.

The inventive step attack based on Marchand in combination with Lashinsky

210. Lashinski is a patent application directed to a turn-limiting proximal adaptor for steerable catheter systems. It discloses a proximal adaptor for steerable catheter systems that comprises a stationary central element 19 and a turn-limiter section 9 comprising a rotator 10.

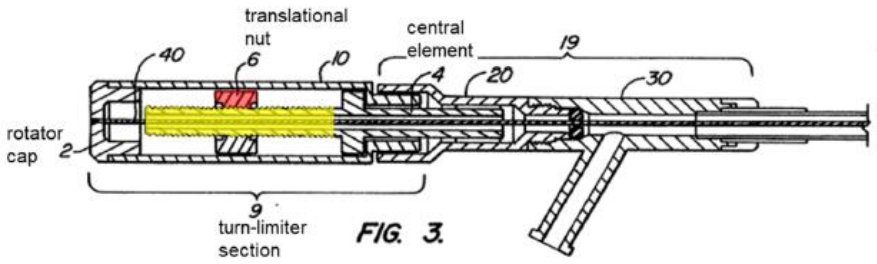


FIG. 3.

211. The rotational force applied to the rotator 10 transfers directly to the translational nut 6 which has an internally threaded surface mating the externally threaded surface of the rotator (see Lashinsky, p. 9, line 32 to p.10, line 2). As with Hammersmark and Shturman, the rotational (rather than the flexing) force applied to the rotator "….is transferred to the guide wire 40 through the rotator cap 2 causing the guide wire 40 to rotate with the rotator" (p. 10, lines 3 and 4 of Lashinsky).

212. It is disclosed on p.11, lines 13 seq. of Lashinsky that in the preferred embodiment "the rotator 10 is made of a translucent material, and the translational nut 6 is made of a particularly "eye-catching" coloured material, such as flourescent plastic, which in combination allows the user to view the travel of the translational nut 6 along the longitudinal axis of the threaded central element 4 as the turn-limiting section 9 is rotated".

213. Meril et al. allege inter alia that Lashinsky provides motivation to the person skilled in the art to implement the externally threaded surface of the rotator 10 mating with the corresponding internal surface of the translational nut 6 into Marchand. According to them, this would lead the person skilled in the art to the subject matter of claim 1 without any inventive skills.

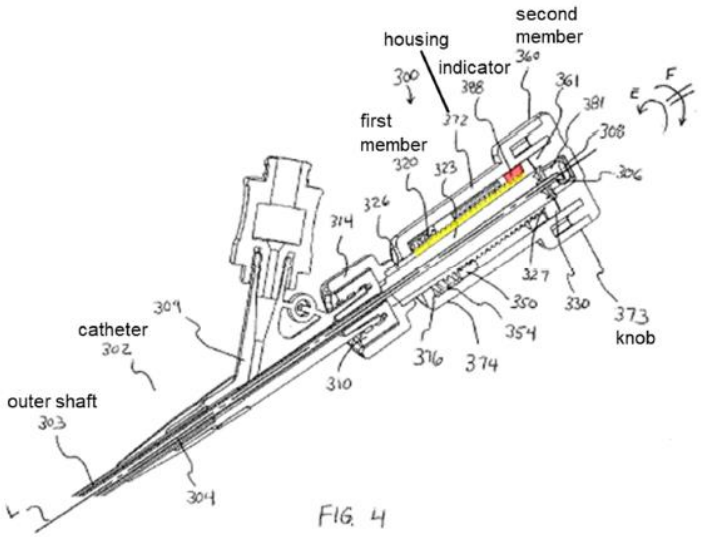
214. Edwards points out inter alia that the externally threaded surface forms part of the threaded central element 4 rather than of the rotator 10 so that Lashinsky does not disclose an actuation member with an externally threaded surface. Edwards also states that Lashinsky discloses a translational nut 6 as a turn limiter but not a flex indicating member (feature 1.3.3).

215. The Court agrees with Edwards that the construction of Lashinshky is far away from the construction disclosed in Marchand, and it is certainly not straight forward for the person skilled in the art to implement the solution of Lashinshky in Marchand and thereby arriving at the invention according to claim 1 with, inter alia, its inner threaded portions for pull wire actuations and its outer threaded portions for flex indicator movement. Hence, the Court concludes that the invention involves an inventive step also in view of a

combination of Marchand with Lashinshky. This conclusion is in line with the decision by the Opposition Division.

The inventive step attack based on Marchand in combination with Phan

216. Phan is a patent application that refers to an apparatus (and methods) for use of expandable members in surgical applications. It is configured so that at least a portion of the expandable member can be twisted about a longitudinal axis of the catheter assembly (see claim 2 of Phan). Expandable members are used in various minimally-invasive medical procedures e.g. for repairing bone defects, displacing tissue and/or compressing tissue (paragraphs [0004] and [0005] of Phan).



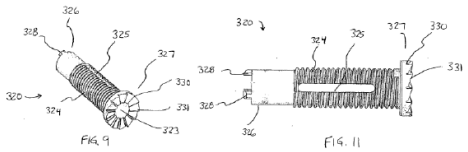
217. Phan discloses an actuator 300 comprising a first member 320 and a second member 360. Similar to the central threaded element 19 of Lashinsky the first member 320 cannot move relative to the catheter assembly 302 (see, e.g., paragraphs [0103] and [0121] of Phan). The proximal end portion 327 of the first member comprises a ratchet wheel 330 removably engageable with the pawl portion 361 of the second member 360 so that the second member 360 can rotate around the first member 320.

218. The first member has an externally threaded portion 324 that receives the indicator pin 388 via mating threads 390. It is disclosed in paragraph [0119] of Phan that "… the housing portion 372 of the second member 360 is constructed from a transparent material ….thereby allowing a user to visually determine how far the indicator has travelled".

219. The first member 320 comprises a ratchet wheel on that the second member 360 can ride via its pawl portion 361.

220. Meril et al. argue inter alia that Phan is within a related technical field since it relates to an apparatus comprising a catheter assembly and an expandable member for repairing bone defects or replacing/compressing tissue (paragraph [0004] of Phan). According to them, Phan discloses the distinguishing features of claim 1 and the person skilled in the art would be motivated to implement the features of Phan into the apparatus of Marchand and, thus, arrive at the subject matter of claim 1. In this context, Meril et al. submit inter alia that the first member 320 would be a flex activating member having an externally

threaded surface in mating connection with the corresponding threaded surface of an indicator 388. They also submit that the first member 320 of the apparatus comprising a ratchet wheel 330 is highly similar to the rotating knob of the patent-in-suit:



Figures 9 and 11 of HL-CC 12

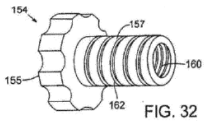


Figure 32 of the patent in suit

221. Edwards points out that the construction of the apparatus of Phan is completely different from the apparatus for indicating flex of a distal end of a catheter claimed in EP 722. The object of Phan is to twist an expandable material by rotating the second member 360 around the first member 320. The stylet 304 that is connected to and rotates with the second member 360 around the first member 320 can be connected to an expandable material which can then be twisted. That is – according to Edwards – completely different from the flex indicating mechanism of the apparatus of the patent in suit. Edwards also submits inter alia that the first member is stationary and hence not an actuating member. Phan thus does not disclose an externally threaded surface portion of an actuating member. Therefore, the comparison between the actuating means of Fig. 32 of EP 722 with the ratchet wheel portion 327 of the first member 320 is completely beside the point.

222. The Court finds that Phan discloses a relative complex system with a construction that is far away from the apparatus for indicating flex of a distal end of a catheter claimed in EP 722. In fact, the disclosure of Phan is similar to that of Lashinski and what already has been said about Lashinski applies mutatis mutandis to Phan. Hence, the Court concludes that the invention involves an inventive step also in view of a combination of Marchand with Phan. This conclusion is in line with the decision by the Opposition Division.

Inventive step attack based on Marchand in combination with Levine

223. Levine is a patent application directed to a steerable balloon catheter. It discloses in Fig. 9 a catheter with a flexing mechanism. An annotated version of Fig. 9 provided by Meril et al. is disclosed below:

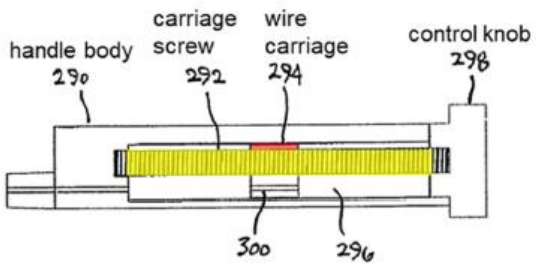


Fig. 9

224. The handle body 290 comprises a carriage screw (coloured in yellow) that may be attached proximally to a control knob 298 which may be rotated to advance either proximally or distally the wire carriage 294 (partly coloured in red) and the push/pull wire 300, i.e. the wire carriage 294 and the push/pull wire are advanced longitudinally (see paragraph [0064] of Levine). The carriage screw thus is a flex actuating member.

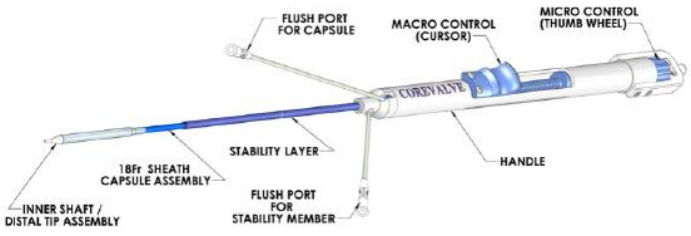
225. Meril et al. argue inter alia that Levine discloses the distinguishing features of claim 1 and that the person skilled in the art would be motivated to implement the features of Levine into the apparatus of Marchand and, thus, arrive at the claimed invention. In view of Levine, it would – according to them – have been plainly obvious inter alia to impart an externally threaded surface portion to the flex actuating member of Marchand and equates the wire carriage with a flex indicating member.

226. Edwards submits inter alia that there is no motivation at all to provide Marchand with an externally threaded surface portion. Marchand would disclose a completely different construction of the flexing apparatus, and that imparting the actuating member with an externally threaded portion would represent the wisdom of hindsight. Edwards also submits that Levine would not disclose a flex indicating means.

227. The Court agrees with Edwards that the constructions of Levine and Marchand are completely different and there is not a sufficient basis for concluding that the person skilled in the art would be encouraged to combine them and thereby arriving with at apparatus in accordance with claim 1. It is e.g. unclear how Marchand could be modified in view of Levine while maintaining the internally threaded surface portion of the actuating member and its mating connecting to the slide member 192. Hence, the Court concludes that the invention involves an inventive step also in view of a combination of Marchand with Lashinshky. This conclusion is in line with the decision by the Opposition Division.

Inventive step attack based on Marchand in combination with the prior use of the CoreValve delivery system

228. The CoreValve system comprises a self-expandable aortic valve made from Nitinol and a 18F delivery catheter system. The handle portion of the delivery system is shown in Fig. 2 of a post-published FDA regulatory document as follows:



229. According to #51 of the decision of the UK High Court of Justice referred to above the CoreValve system was prior art

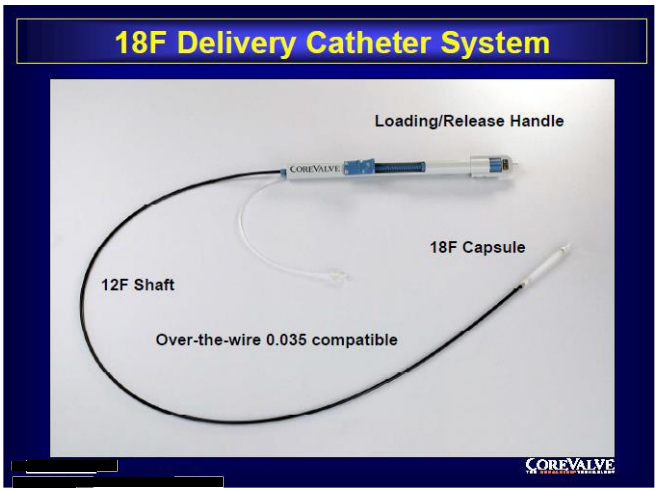
51. Meril referred to a page from a CoreValve manual for details of the CoreValve delivery device at the relevant time. The device had a handle which included a slider labelledin the manual as "Macro Control (Cursor)" and a thumbwheel labelled "Micro Control (Thumb wheel)". The CoreValve implant is self-expanding. It is delivered in practice by placing it into the right position and then carefully withdrawing a sheath around the outside of the implant, allowing the cage material to spring outwards into shape inside the aorta. The sheath is controlled by a threaded rod in the handle and both the slider and the thumb wheel engage that

same thread. The slider allows the operator to make large movements of the screw by riding on the thread while the thumb wheel allows fine control. As the slider rides on the thread it slides down the length of the handle. The result is that the position of the slider gives an indication of the degree to which the sheath has been pulled back at the distal end and so, says Meril, that is why it is called "cursor". I accept this CoreValve device and its mode of operation was common general knowledge. If it matters, I am not convinced the term "cursor" for the macro control slider was itself common general knowledge.

230. Meril et al. argue inter alia that when the thumb wheel is rotated the macro control (cursor) travels longitudinally in the slot of the handle. The cursor thus acts as an indicator that provides a visual and tactile response to the surgeon. They also allege that the person skilled in the art would be motivated to include the externally threaded surface portion and the mating cursor of the handle portion of the CoreValve delivery system to the handle portion of Marchand and, thereby, have arrived at the subject matter of claim 1 of the patent in suit.

231. Edwards agrees that the person skilled in the art would be aware of the CoreValve delivery system, since at the priority date it was one of only two transcatheter prosthetic heart valves approved (the other being Edwards' balloon-expandable prosthetic heart valve). According to Edwards, the person skilled in the art would additionally be aware that the valve was delivered with a 'sheath' covering the valve, and that the valve was expanded by longitudinally moving the valve relative to the sheath such that the valve was 'released' from the sheath. However, while the functioning of the CoreValve device is not clearly apparent from the documents submitted by Meril et. al, it is – according to Edwards – at least clear from the text on page 3 of the FDA regulatory document submitted by Meril et al. that "[t]he handle features macro and micro adjustment control of the retractable capsule sheath". Accordingly, the two controls are both associated with controlling the retraction state of a capsule sheath at the distal end of the catheter, which has nothing to do with, and no relevance to, controlling flex or flex indication. Nor does CoreValve provide any motivation to add an externally threaded surface portion to an activating member that already has an internally threaded surface portion. Hence, the person skilled in the art would – according to Edwards – not have any motivation to combine Marchand with CoreValve and even if he/she did so, he/she would not have arrived at the claimed subject matter of claim 1.

232. The Court notes that public prior use of the CoreValve delivery system was discussed in the parallel opposition proceedings before the Opposition Division of the EPO, based on documents that also have been submitted in these proceedings (a presentation on the CoreValve delivery system, an FDA regulatory document and the decision by the UK High Court of Justice that already has been mentioned). The Opposition Division concluded inter alia that the FDA regulatory document was post-published on 17 January 2014, that the decision by the UK High Court of Justice could not be evaluated because the underlying evidence was not on file, and that it was not proven that presentation was pre-published. However, since the public availability of the presentation on the CoreValve delivery system had not been explicitly disputed by the patentee, the Opposition Division considered it as pre-published prior art but concluded that it was irrelevant because it just disclosed a perspective view of the handle on slide #5 (reproduced below) without giving any further details.



233. In these proceedings, Edwards has not explicitly disputed that these documents describe the CoreValve delivery system at priority date. Instead, Edwards has provided substantive arguments on the three documents treating them as one collective piece of prior art. Therefore, this Court will assess whether Marchand in combination with the content of these three documents would lead the person skilled in the art to the invention.

234. As already mentioned, the decision by the UK High Court of Justice provides the following description of the CoreValve and its delivery system:

> *51. Meril referred to a page from a CoreValve manual for details of the CoreValve delivery device at the relevant time. The device had a handle which included a slider labelledin the manual as "Macro Control (Cursor)" and a thumbwheel labelled "Micro Control (Thumb wheel)". The CoreValve implant is self-expanding. It is delivered in practice by placing it into the right position and then carefully withdrawing a sheath around the outside of the implant, allowing the cage material to spring outwards into shape inside the aorta. The sheath is controlled by a threaded rod in the handle and both the slider and the thumb wheel engage that same thread. The slider allows the operator to make large movements of the screw by riding on the thread while the thumb wheel allows fine control. As the slider rides on the thread it slides down the length of the handle. The result is that the position of the slider gives an indication of the degree to which the sheath has been pulled back at the distal end and so, says Meril, that is why it is called "cursor". I accept this CoreValve device and its mode of operation was common general knowledge. If it matters, I am not convinced the term "cursor" for the macro control slider was itself common general knowledge.*

235. This is in line with the disclosure on p. 3 of the FDA regulatory document which also provides a perspective view of the CoreValve delivery device:

V.2. Delivery Catheter System with AccuTrak Stability Layer (AccuTrak DCS)

The DCS (Figure 2) is used to deploy the TAV. The TAV is loaded within the capsule which features an atraumatic, radiopaque tip and protective sheath. The AccuTrak stability layer is fixed at the handle and extends down the outside of the catheter shaft to provide a barrier between the catheter and vessel walls. The handle features macro and micro adjustment control of the retractable capsule sheath. There are two models of the DCS: model DCS-C4-18FR-23 for the 23 mm TAV only and model DCS-C4-18FR for the 26, 29, and 31 mm TAVs.

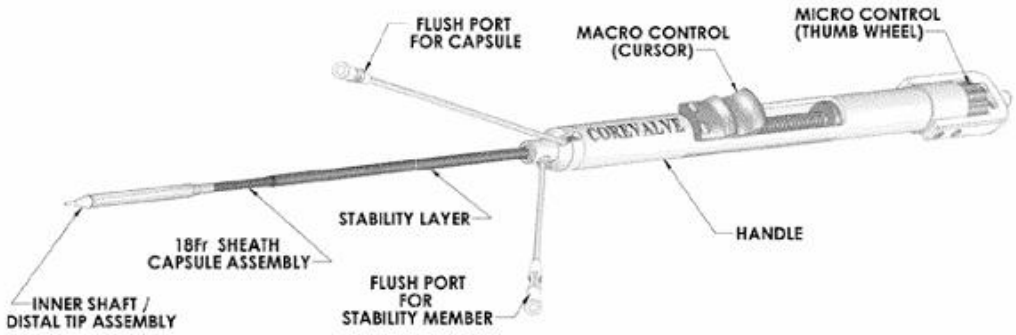
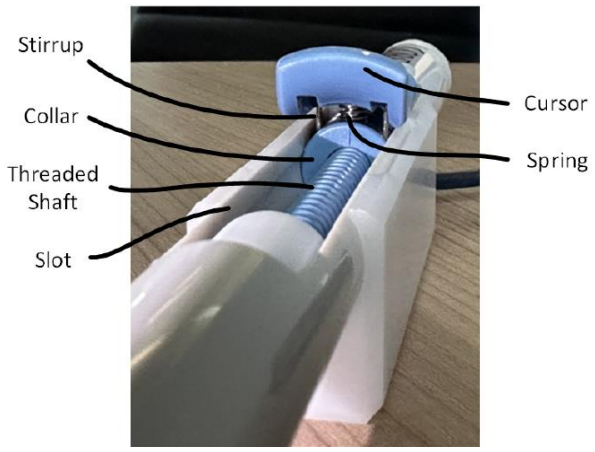


Figure 2: CoreValve Delivery Catheter System

236. Meril et al. has also submitted the following photograph, that is alleged to have been taken from a delivery device having model number C1073-25001, on page 62 of its counterclaim for revocation.



237. However, neither this picture not the picture in the presentation mentioned above adds anything to the disclosure of the FDA regulatory document and the decision by the UK High Court of Justice. Meril et al. have also not explained the circumstance of the prior public disclosure (if any) of the delivery with model number C1073-25001, i.e. if this still is the same piece of prior art.

238. It can only be taken from the FDA regulatory document and the decision by the UK High Court of Justice that the handle of the CoreValve delivery system allows for a macro and micro adjustment of the retractable capsule sheath of the CoreValve implant. Neither one of the two references discloses flexing of the tip of the shaft of the catheter, let alone the object of providing a safe and reliable indication of flex.

239. Hence, the combination of Marchand with the alleged public prior use of the CoreValve delivery system does not render claim 1 of EP 722 obvious.

The inventive step attack based on Marchand in combination with CGK

240. Meril et al. argue inter alia that the subject matter of claim 1 lacks inventive step in view of Marchand and the common general knowledge of a handle portion comprising a rotatable member with an externally threaded surface portion which is configured to receive an extending portion of an indicating member to determine the amount of rotation of the rotatable member. Hence, the person skilled in the art – e.g. the interventional cardiologist – who wanted to know how much the adjustment member has been rotated clockwise (increasing flex) or counterclockwise (decreasing flex) to improve navigation of the catheter, had – according to Meril et al. – a clear motivation to add the missing features and would arrive at the subject of claim 1. He could just add known features from e.g. Hammersmark, Shturman, Lashinsky, Phan, Levine or the CoreValve delivery system. Meril et al. also argue that the person skilled in the art was familiar with Retroflex I and II and its inner mechanism (Retroflex I and II are products based on Marchand).

241. Edwards disputes that the common general knowledge included handle portions comprising a rotatable member with an externally threaded surface portion which is configured to receive an extending portion of an indicating member to determine the amount of rotation of the rotatable member. Edwards also disputes that the mechanisms disclosed in Hammersmark, Shturman, Lashinski, Phan and Levine belonged to the common general knowledge. Furthermore, Edwards disputes that the specific designs and inner mechanisms of RetroFlex I, RetroFlex II and the CoreValve delivery system belonged to the common general knowledge but agrees that the person skilled in the art was generally aware of their existence. Edwards adds that most of these disclosures does not relate to flex indication, but to rotation. Even if a teaching regarding an amount of rotation existed, there would – according to Edwards – be no motivation for the person skilled in the art to consider it when attempting to provide an apparatus which allows indicating the adjusted flex in a mechanically reliable and accurate manner. Adding an additional mechanism (an externally threaded surface portion) to an existing device adds complexity, and the person skilled in the art would not consider such a modification without a clear motivation to do so. This is – according to Edwards – even more so when considering that an additional threaded surface portion would have to be added to an element which already has an internally threaded surface portion. Hence, Marchand in combination with the common general knowledge would not make the person skilled in the art arrive at the invention according to claim 1.

242. The Court agrees with Edwards that patent documents normally are considered as not belonging to the common general knowledge. Hence, it would have been for Meril et al. to prove that this was the case.

243. With regard Retroflex, it should be noted that during the written procedure, Meril et al. tried to broaden its inventive step attack by relying not only on Marchand but in addition and/or alternatively to Marchand on the RetroFlex products as a starting point.

244. While the use of the RetroFlex products as a separate and additional starting point was not admitted into the proceedings by the judge-rapporteur, Meril et al. was allowed to further elaborate on its allegation that the RetroFlex products and its constructional details were part of the common general knowledge. Meril et al. had already, in the counterclaim for revocation, alleged that apparatuses for flexing a distal end of a catheter were part of the common general knowledge and – somewhat in passing – referred to the decision by the UK High Court of Justice mentioned above that briefly also refers to "Retroflex".

245. This UK decision states, for example, in paragraphs 244 and 245 that Marchand discloses the Retroflex products and their construction:

> *Marchand*
> *244. Part of Marchand describes what was the then common general knowledge Retroflex system. For example, figure 1 looks like this:*

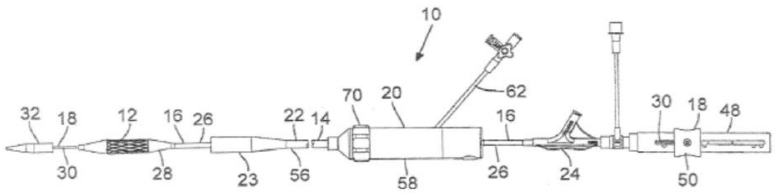


FIG. 1

> *245. That is Retroflex. Note also its similarity to figure 1 of the 929 patent. The user imparts flex on the distal portion by turning the knob. As I have construed the claim, this does provide an indication of the amount of flex but does not provide indicia because the tactile feedback provided by the limits on turning the knob is not visual.*

246. This was further elaborated on in the expert opinion by Dr. [redacted] who states inter alia as follows:

> *25. Features of the RetroFlex II device are embodied in United States Patent Application no. 2008/0065011 Al ("Marchand"), published 13 March 2008 (HL-CC 6, attached as Exhibit RS1). Figures 3A and 3B in Marchand, together with the description of those figures in paragraphs [0069] to [0073], describe the same handle as that of the RetroFlex II.*

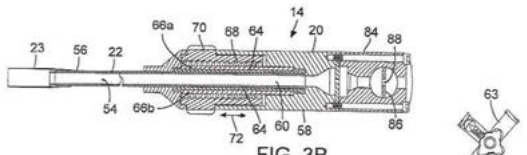


FIG. 3B

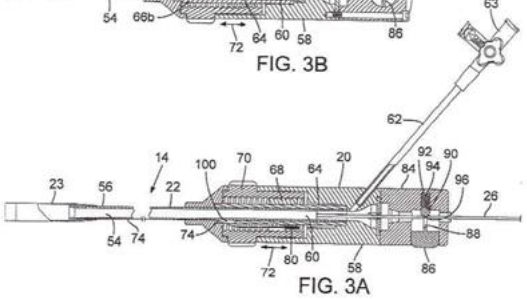


FIG. 3A

Figures 3A and 3B of RS1

247. A photograph of the Retroflex catheter is shown in Eltchaninoff et al., Transcatheter aortic valve implantation: technical aspects, results and indications", published January 2008, as follows:

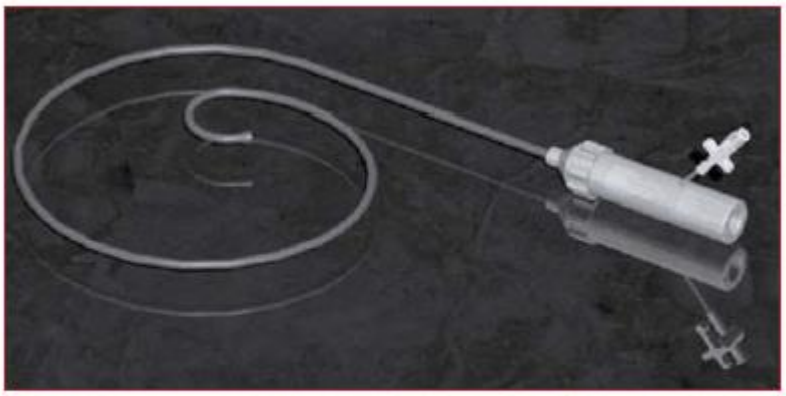


Figure 2. The Retro-Flex catheter. Its distal end can be deflected to help advancing the delivery system within the tortuous arterial access and to centralize the guide wire at the time of native valve crossing.

248. In view of this, the Court concludes that the evidence that has been submitted in relation to Retroflex do not add anything over the disclosure of Marchand. Furthermore, the Court has already concluded that the invention involves an inventive step in view of a combination of Marchand with each of Hammersmark, Shturman, Lashinsky, Phan, Levine or the CoreValve delivery system. There is no concrete evidence suggesting that the common general knowledge involved something more or something else that would have led the person skilled in the art to modify the apparatus in Marchand and arrive at claim 1 as granted.

249. Hence, the Court concludes that the invention involves an inventive step also in view of a combination of Marchand with the common general knowledge. This conclusion is in line with the decision by the Opposition Division.

3.3.3.3 The attacks based on Bowden as a starting point

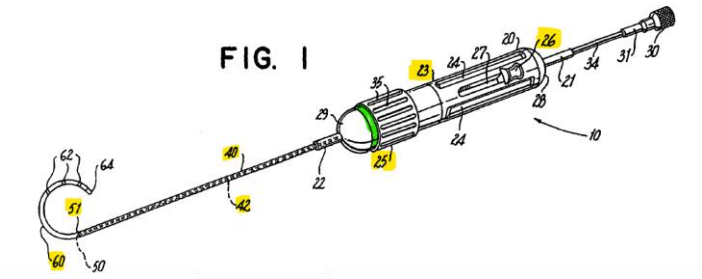
250. Bowden is a European Patent (EP 0 787 019 B1) with the title “Steerable catheter”. It was published on 11 February 2004 and represents a suitable starting point for the skilled person.

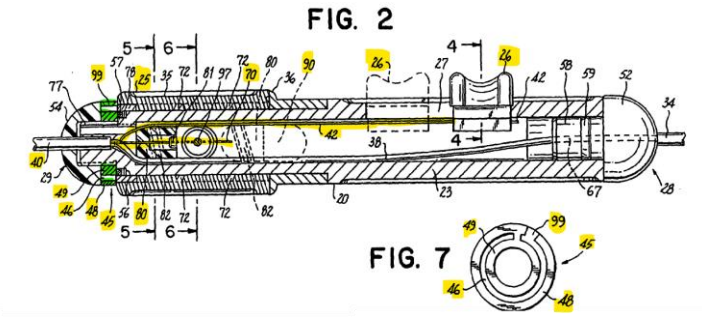
251. Meril et al. argue that EP 722 lacks inventive step based on the following combinations

- Bowden in combination with the CGK
- Bowden in combination with Hammersmark
- Bowden in combination with Shturman
- Bowden in combination with Lashinski
- Bowden in combination with Phan
- Bowden in combination with Levine
- Bowden in combination with the CoreValve delivery system

Distinguishing features and the objective technical problem

252. Bowden relates to a deflectable tip steerable catheter 10. The catheter comprises a steerable tip 60, a thumbwheel 25, a slide actuator 26 and an indicator ring 45 marked in green in Figs. 1 and 2 below.





253. The slide actuator 26 can be moved longitudinally to change the position of the distal end 51 of the adjustment wire 42 within the catheter main shaft 40.

254. It can be seen from Fig. 2 that a two-part slide block 80,90 is mounted in a longitudinal slot within the interior of control handle tubular housing 23. The deflection pull wire 70 passes through the slide blocks 80 and 90; the distal part of the slide block 80 freely rides on the pull wire 70 whereas the proximal part of the slide block 90 is releasably secured to the pull wire 70.

255. The deflection mechanism is disclosed in [0051] of Bowden as follows:

> *[0051] The distal part 80 of the slideblock includes helically angled, laterally disposed external threads or wings 82,84. When mounted within the tubular housing 23 of the handle 20, the wings 82,84 engage and travel within the internal helical thread 72 of the cylindrical thumbwheel 25. Accordingly, upon rotation of the thumbwheel 25 in a first direction, the distal portion 80 of the slideblock is forced to travel proximally, thus pushing the proximal portion 90 of the slideblock in a proximal direction. This places tension on pullwire 70 and causes deflection of the tip portion 60 of the catheter. The mechanical advantage achieved by this rotation-to-axial translation provides a passive resistance or passive lock of sufficient frictional force so as to prevent the tip deflection angle from changing without further manipulation of the thumbwheel 25 by the user.*

256. The degree of deflection is shown by an interaction of a flat tab that is provided by the thumbwheel 25 and mates with the annular groove 46 of the indicator ring 45 that is illustrated in Fig. 7 (reproduced from Edwards' defence to the CC).

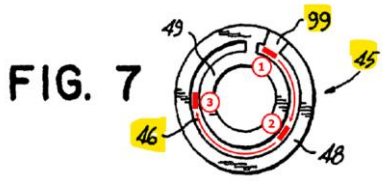


Figure 12: FIG. 7 of Bowden (colour and annotations added)

257. Meril et al. argue inter alia that Bowden discloses almost all features of claim 1 in EP 722 (except does not explicitly disclose that the flex activating member of the apparatus has an externally threaded surface portion which is configured to receive an extending portion of the flex indicating member, i.e. features 1.5.2, and 1.5.4). Regarding feature 1.4 (*"wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and"*), Meril et al. refer to paragraph [0047] of Bowden:

> *[0047] A tip deflection indicator ring 45 is supported by the threaded distal end portion 77 of the tubular housing 23, and rests against the sealing O-ring 57 and the distal-most annular face of the cylindrical thumbwheel 25. The indicator ring 45 comprises an inner, annular ring 49 supported by and connected to an outer annular ring 48, the rings 49,48 being separated by an annular space 46. A distally protruding flat tab (not shown) is preferably provided on the distal-most annular face of the thumbwheel 25 and slidably mates into the annular groove 46. By virtue of the construction of the indicator ring 45, as illustrated in Figure 7, the annular groove or slot 46 ensures that the thumbwheel 25 can travel only approximately one full revolution about the handle axis, due to the interference between the thumbwheel flat tab (not shown) and the connecting support structure attaching the inner annular ring 49 to the outer ring 48 of indicator ring 45. The outer annular ring 48 is further provided with a through hole 99 as seen in Figs. 2 and 7 so that the protruding flat tab (not shown) may be visually observed when the thumbwheel 25 is rotated to a particular position. That position is selected to be the fully relaxed or undeflected position of the distal tip portion 60 of the electrode catheter 10. In this way, the user can be assured, for example, during retraction of the electrode catheter 10 through the vascular approach, that the distal tip is in its undeflected state. Without an indicator, such assurance is not always possible even under direct fluoroscopic inspection.*

258. According to Edwards, at least features 1.4, 1.5.2, and 1.5.4 of claim 1 are not known from Bowden. Regarding feature 1.4, Edwards argues inter alia that the flat tab in Bowden is a part of the thumbwheel 25. Hence, the movement of the thumbwheel does not cause a movement of the flat tab; instead, there is only a single movement, namely that of the thumbwheel as a whole. Thus, the flex indicating ring only indicates the movement of the thumbwheel similar to what is disclosed in Marchand. In any case, Bowden fails – according to Edwards – to disclose a flex activating member with both an internally threaded surface portion and an externally threaded surface portion, and it further fails to disclose a flex indicating member which is received in an externally threaded surface portion. In particular, the flat tab is not received in any threaded surface portion.

259. Edwards has also, with reference to paragraph [0047] of Bowden, pointed out that the indicator in Bowden only shows whether the distal portion of the catheter is fully flexed or not, and illustrated this by indicating three positions of the flat tab in the groove of the indicator ring (1, 2 and 3 in Fig. 7 above). In position 1 the steerable tip 60 is in the fully undeflected (or relaxed) state; this state can be verified since the flat tab can be viewed from the outside through hole 99. When the thumbwheel is rotated, the tab is moved to (arbitrarily chosen) positions 2 or 3, which are characterized by an increasing amount of tension within the pull wire 70, the flat tab cannot be viewed from the outside through hole 99.

260. The Court finds that the flat tab is a part of the flex activating member/thumbwheel 25 and not a separate member or part of the indicator ring 45. Instead, it is the indicator ring 45 that may be seen as a flex indicating member. The flex indicating member/indicator ring 45 is in a fixed position and not caused to move relative to the handle portion when the flex activating member/thumbwheel 25 is caused to move. Hence, Bowden fails to disclose (at least) that the flex activating member causes the flex indicating member to move relative to the handle portion, and an externally threaded surface of the flex activating member that is configured to receive an extending portion 166 of the flex indicating member (i.e. features 1.4, 1.5.2 and 1.5.4).

261. Therefore, the following table summarizes the feature analysis for Bowden relative to Claim 1 of EP 722:

Feature #	Claim 1 of EP 722 as Issued	Bowden
1	An apparatus for indicating flex of a distal end of a catheter comprising	+
1.1	an elongated shaft (152);	+
1.2	at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);	+
1.3	a handle portion (158) comprising	+
1.3.1	a flex activating member (154), activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;	+
1.3.2	a slide member (192) connected to the at least one pull wire (174); and	+
1.3.3	a flex indicating member (156);	+
1.4	wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and	-
1.5	wherein the flex activating member (154) comprises	+
1.5.1	a rotatable member (155, 157) which includes an internally threaded surface portion (160)	+
1.5.2	characterized in that the flex activating member also has an externally threaded surface portion	-
1.5.3	wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and	+
1.5.4	the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156)	-

262. Meril et al. argue, similar to what was argued in respect of Marchand, that Bowden at least gives some indication of flex by providing an “all or nothing” indicator. When the thumbwheel 25 is not rotated there is no flex applied to the steerable tip; this corresponds to the position 99 in the flex indicating ring 45. The maximum flex is reached when the thumbwheel 25 is rotation by one full revolution. Thus, the objective technical problem is – according to Meril et al. – to provide an alternative flex indicating mechanism, or to provide (alternative) means to determine the amount of rotation of the rotatable member.

263. Edwards refers to its comments regarding Marchand, inter alia that the missing features assure that the flex indicating member reliably moves in a controlled and well-

defined manner when the flex activating member is actuated, and concludes that the technical effect resulting from the features missing in Bowden is to indicate the adjusted flex in a mechanically reliable and accurate manner.

264. The Court finds that the question at hand is similar to what already has been discussed in relation to Marchand. Bowden provides an indication of whether the distal portion of the catheter is fully flexed or not, but it does not indicate any difference between a very small flex and full flex. The distinguishing features provides an indication of to what extent the distal portion of the catheter is flexed. This means that the technical effect is (at least) that the distinguishing features in the Patent provides improved means to indicate the adjusted flex at the distal end of a catheter in a mechanically reliable and safe fashion. Hence, the objective technical problem – which shall be formulated in such a way that it does not contain pointers to the solution or partially anticipate the solution – relative to Bowden is to provide an apparatus which allows an improved indication of the adjusted flex at the distal end in a reliable and safe fashion.

Assessment of the different attacks based on Bowden

265. As already mentioned, Meril et al. argue that EP 722 lacks inventive step based on the following combinations

- Bowden in combination with the CGK
- Bowden in combination with Hammersmark
- Bowden in combination with Shturman
- Bowden in combination with Lashinski
- Bowden in combination with Phan
- Bowden in combination with Levine
- Bowden in combination with the CoreValve delivery system

266. However, Meril et al. do not elaborate on this specifically. Instead, they refer to the discussion on the combination of Marchand with these references that would be applicable mutatis mutandis.

267. Also, Edwards refers to what has been said about Marchand, in particular that the entire cited prior art is silent regarding a flex activating member with two threaded surface portions, and this feature is further not known from the common general knowledge. Hence, the person skilled in the art would therefore not have added these features to Bowden. Edwards adds that it is the key teaching of Bowden to provide the binary information to the user whether or not the catheter is fully relaxed or flexed (to some unknown degree). This is a safety function, associated with the problem that retracting a flexed catheter can severely harm the patient. Bowden provides this binary information. There would be no motivation for the skilled person to replace this binary indicator, which serves an important safety function, with any mechanism that uses a gradual indicator.

268. The Court finds that the invention involves an inventive step in view of Bowden in combination with the common general knowledge, Hammersmark, Shturman, Lashinski, Phan, Levine and/or the CoreValve delivery system. The arguments already mentioned in relation to Marchand applies mutatis mutandis in relation to Bowden.

3.3.4 Conclusion on validity

269. It follows from chapter 4.4.1 that the patent as granted includes added subject matter in independent claim 1 as well as in dependent claims 7, 9 and 10. In addition, dependent claims 11, 12 and 13 include added subject matter to the extent they depend on the claims just mentioned. The Court has also found that there is a lack of sufficient disclosure in relation to dependent Claim 9 (and claims 10–13, when dependent on claim 9), i.e. that they cannot be carried out. For these reasons (only) the patent as granted is invalid.

270. Edwards has submitted 22 conditional auxiliary requests to amend the patent (Annex 1). During the written, interim and oral procedure, Edwards made it perfectly clear that the condition for auxiliary request 1 is that the main request is not allowable, the condition for auxiliary request 2 is that auxiliary request 1 is not allowable, the condition for auxiliary request 3 is that auxiliary request 2 is not allowable, and so forth. Edwards further argued that the condition for auxiliary request 1' is that auxiliary request 11 is not allowable, the condition auxiliary request 2' is that auxiliary request 1' is not allowable, the condition for auxiliary request 3' is that auxiliary request 2' is not allowable, and so forth. Thus, the order in which the requests were made were summarized as follows: main request -> auxiliary requests 1 to 11 -> auxiliary requests 1' to 10'. When Meril et al. argued that the number of auxiliary requests were not reasonable, Edwards also explained that auxiliary request 11 and 1' to 10' had been submitted in order to streamline the proceedings and to simplify the Court's work in case there would be an issue in one of the dependent claims.

271. It was against this background that the judge-rapporteur on 10 December 2024 found that the number of auxiliary requests was reasonable and dismissed a request from Meril et al. to declare them inadmissible.

272. After the oral hearing in these proceedings, the Opposition Division of the EPO issued its decision on the patent in suit and found that it was invalid as granted, but upheld the patent in accordance with an auxiliary request that had been submitted in the opposition proceedings (Annex 2) but not in proceedings at the UPC, not even after the Opposition Division had issued its preliminary opinion. However, when Edwards informed the Court about the outcome of the opposition proceedings, i.e. after the UPC's oral hearing, Edwards argued – with reference to Article 65(3) UPCA – that if the Court agreed with the Opposition Division on substance it could uphold the patent with the same claims as accepted by the Opposition Division, by starting from auxiliary request 1 (in Annex 1) and delete dependent claims 7, 10 and 11 (instead of moving on to auxiliary request 2).

273. Meril et al. argue that the auxiliary requests are not patentable, inter alia for reasons mentioned above. They also argue that the Court should deal with the auxiliary requests in the order presented by Edwards during the written, interim and oral phase of these proceedings and not start creating new sets of claims based on Article 65(3) UPCA, as Edwards has suggested after the oral hearing.

274. The Court notes that Article 65(3) UPCA stipulates, without prejudice to Article 138(3) of the EPC, that if the grounds for revocation affect the patent only in part, the patent shall be limited by a corresponding amendment of the claims and revoked in part. This means inter alia that if a patent contains two independent claims and the defendant

only argue that one of them is invalid, the patent shall in principle (at least) be upheld to the extent of the other independent claim, at least if this does not require a redrafting of the claims. It can be discussed whether and to what extent the same principle could and/or should be applied in relation to dependent claims, but there is no need for the Court to take a position on that question in this case.

275. As already concluded by the Central Division in Paris, in case UPC_CFI_309/2023, Article 65(3) UPCA applies to limitations of the patent as granted but not to applications to amend the patent (ORD_598482/2023, ACT_571669/2023). Furthermore, in this case Edwards has during the written and interim procedures and during the oral hearing made it perfectly clear how the Court shall proceed if there is an issue in one of the dependent claims (cf. Article 76.1 UPCA). Hence, the Court will deal with the auxiliary requests in the order argued by Edwards during the written, interim and oral phase and ignore the suggestion submitted by Edwards only after the oral hearing (when the Opposition Division had confirmed its previously published preliminary opinion).

276. Auxiliary requests 1–10 focus on different amendments to claim 1 and they all include inter alia dependent claim 7, which has been found to include added subject matter. Auxiliary request 11 consists of claim 1 as granted, which also has been found to include added subject matter. Thus, the first auxiliary request that might be valid is auxiliary request 1', which contains the following amendment to feature 1.5.2 of granted claim 1 (and all dependent claims deleted):

1.5 wherein the flex activating member (154) comprises
1.5.1 a rotatable member (155, 157) which includes an internally threaded surface portion (160)
1.5.2 characterized in that the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162)

277. Meril et al. argue that auxiliary request 1' is inadmissibly extended, insufficiently disclosed and lacks both clarity and inventive step.

278. The Court has already concluded that claim 1 as granted adds subject matter only because it does not require that the externally threaded surface is part of the rotatable member or the shaft. This inconsistency is solved by auxiliary request 1'. Hence, claim 1 of auxiliary request 1' does not add subject matter. For reasons explained above concerning claim 1 as granted, auxiliary request 1' is sufficiently disclosed and involves an inventive step. The alleged lack of clarity is based on clerical error in one of Edwards' pleadings, where the terms "flex indicating member" and "flex activating member" where inadvertently confused in one instance, and clearly unsubstantiated.

279. Hence, EP 722 shall be maintained in accordance with auxiliary request 1'. Auxiliary request 1' comprises only one claim as reproduced below:

1	An apparatus for indicating flex of a distal end of a catheter comprising
1.1	an elongated shaft (152);
1.2	at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);
1.3	a handle portion (158) comprising

1.3.1	a flex activating member (154), activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;
1.3.2	a slide member (192) connected to the at least one pull wire (174); and
1.3.3	a flex indicating member (156);
1.4	wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and
1.5	wherein the flex activating member (154) comprises
1.5.1	a rotatable member (155, 157) which includes an internally threaded surface portion (160)
1.5.2	characterized in that the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162)
1.5.3	wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and
1.5.4	the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156)

3.4 Infringement

3.4.1 Literal infringement of Claim 1 as amended

280. Based on their claim construction (chapter 3.2.3), Meril et al. argue that the attacked embodiment does not reproduce features 1.1, 1.2 and 1.3.1 because the Navigator does not have a guide catheter. Rather, it consists solely of a single balloon catheter, which in turn consists of an inner and an outer shaft, and where the valve is crimped directly onto the balloon. According to Meril et al., the outer shaft of the attacked embodiment cannot be regarded as an elongated (guide) tube / shaft within the meaning of the patent in suit. It is not slidable relative to a balloon catheter. Rather, the outer shaft of the Navigator forms an integral part of the balloon catheter and cannot be moved relative to the remaining arrangement. The attacked embodiment is – according to Meril et al. – designed according to the prior art described as disadvantageous in the patent in suit (cf. paragraph [0003] of EP 722), i.e. the THV "Myval" is crimped directly onto the balloon of the single balloon catheter prior to insertion into the vascular system and remains there until deployment at the implantation site.

281. Meril et al. add that the two shafts of the attacked embodiment serve the sole function of the balloon catheter. Through the space between the outer (red highlighting in Figure 20 below) shaft and the inner shaft (green highlighting in Figure 20 below) of the Navigator, the balloon inflation fluid is directed into the balloon (cf. pink waves in the Figure 20 below).

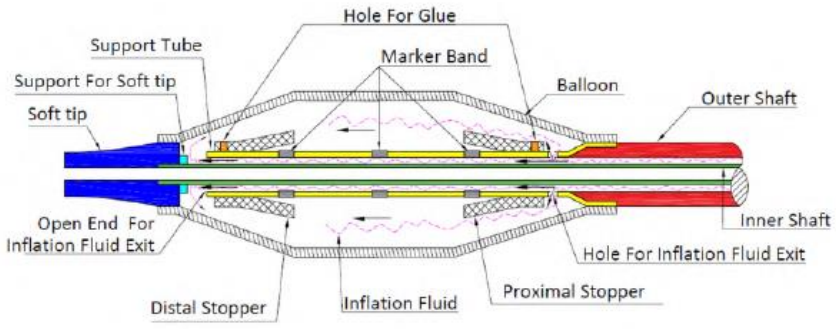


Figure 20

282. Edwards refers to its claim construction (chapter 3.2.3) and argue inter alia that although the Navigator system comprises of a single catheter with two shafts, namely an outer and an inner shaft, the distal end of the outer shaft is in direct communication with the device's balloon, and the proximal end of the outer shaft passes through the device handle and joins the Y-connecter.

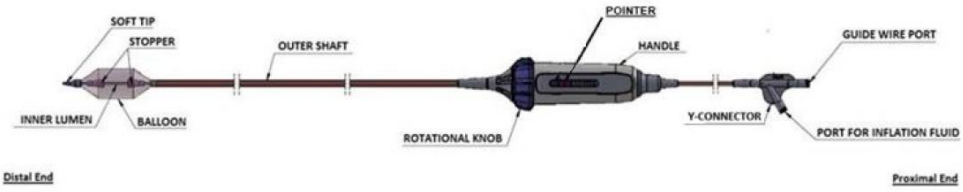


Figure 34

283. Edwards also refers to Meril et al.'s Fig. 20 above and submit that the annular space between the outer and inner shafts provides a conduit for the flow of inflation fluid to inflate the balloon. The outer shaft is made of two sections that are integrally connected to each other: a section with no flexing capability and the steering section. The steering section can be bent in a controlled manner, e.g. in order to navigate the shape of the aortic arch. The steering section is shown in Fig. 34 above. The distal section comprising the THV is not flexible. The steering section is made from a material which is relatively more flexible than the rest of the outer shaft. The steering section is flexed by turning a rotational knob on the handle. The flexing action is achieved through a pull wire mechanism. Hence, the

Navigator system does – according to Edwards – reproduce features 1.1, 1.2 and 1.3.1 and has an "elongated shaft" in the sense of the patent in suit. Edwards adds that this would be the case even if one would adopt the Defendants' assertion that the "elongated shaft" should belong to a guide catheter, since the skilled person would understand that in the context of EP 722 a guide catheter is a catheter used to guide an implantable device (such as a THV) to the site of implantation.

284. The Court finds that the Navigator system infringes claim 1 of Auxiliary Request 1' of EP 722 for the following reasons. The analysis provided below is based on the Amended Product and Process Description (PPD) filed by Edwards together with its statement of claim. The PDD was signed by [redacted] Sr. Vice President, Meril Life Sciences Pvt.Ltd.

285. Reference is made to the following paragraphs in the PPD:

> 34. As outlined above, the Navigator delivery system comprises a single catheter with two shafts: an outer shaft and an inner shaft, which passes coaxially through the outer shaft. The distal end of the the outer shaft is in direct communication with the device's balloon, and the proximal end of the outer shaft passes through the device handle and joins the Y-connecter at the inflation fluid port. A labelled diagram of the full Navigator system is set out at Figure 33 below.

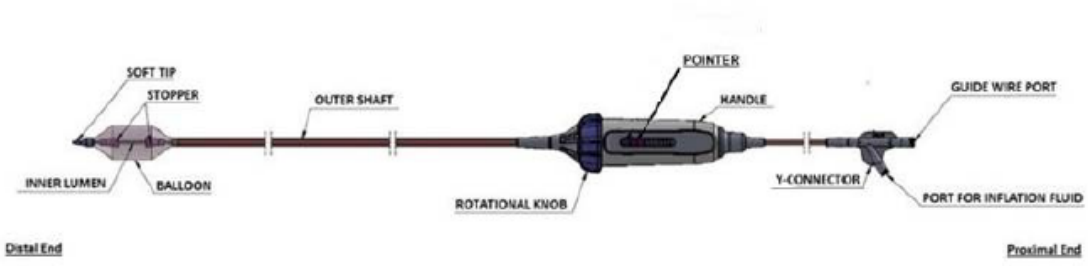


Figure 33

> 35. As is apparent from Figure 32, the annular space between the outer and inner shafts provides a conduit for the flow of inflation fluid to inflate the balloon.
>
> 36. The outer shaft is made of two sections that are integrally connected to each other: a section with no flexing capability and the steering section. The steering section can be

bent in a controlled manner, e.g. in order to navigate the shape of the aortic arch. The location of the steering section is shown in Figure 34 below.

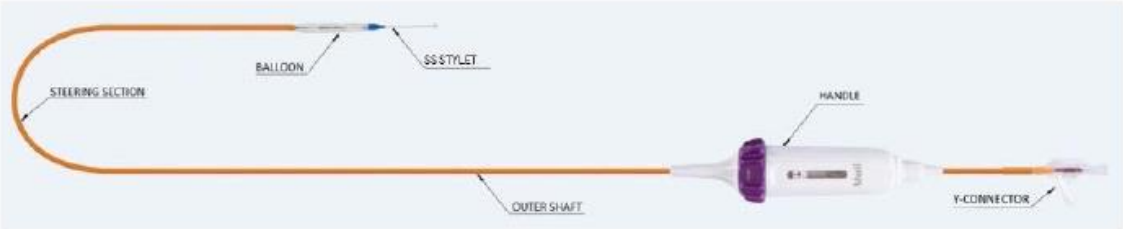


Figure 34

37. The steering section is made from a material which is relatively more flexible than the rest of the outer shaft. The steering section is flexed by turning a rotational knob on the handle. The flexing action is achieved through a pull wire mechanism, as described below. The distal end of the pull wire is attached to a metal ring located at the distal end of the steering section of the outer shaft. This is shown in Figure 35 below.

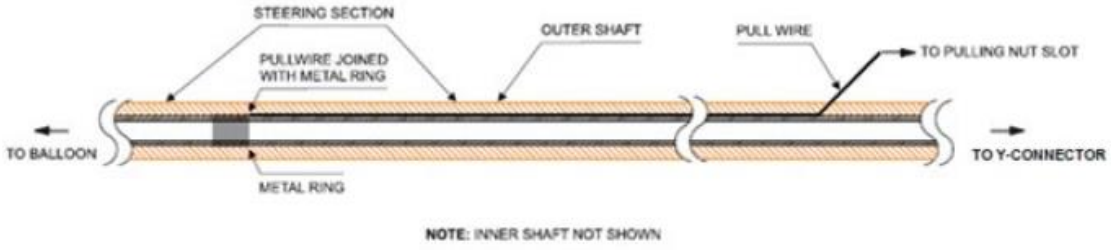


Figure 35

39. The handle portion of the Navigator device comprises a number of components, as shown at Figure 37 below.

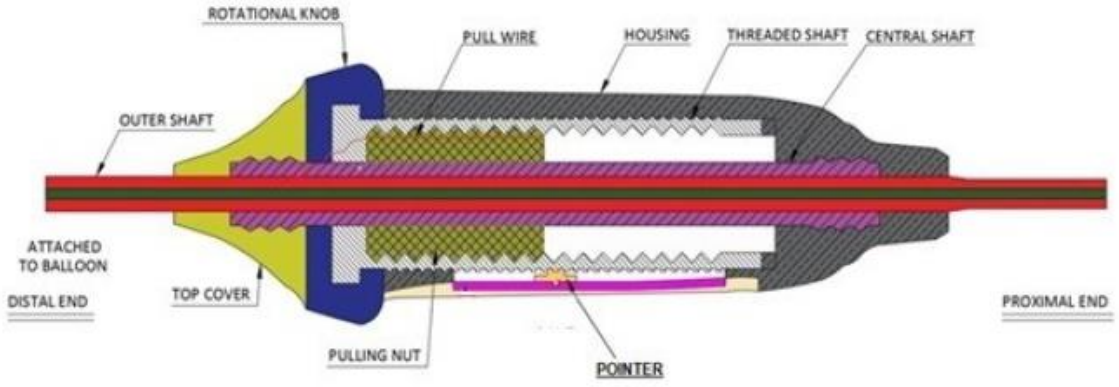


Figure 37

286. The Court has, in its claim construction, already concluded that feature 1 of claim 1 must be understood to cover not only an apparatus for indicating flex of a distal end of a guide catheters, or constructions that involve both a guidecatheter and a balloon catheter (e.g. the so-called "off-balloon crimping" technology), but also e.g. balloon catheters that do not comprise a guide catheter. Feature 1 of claim 1 rather refers to catheters in general.

287. The Navigator system comprises a balloon catheter that is a specific embodiment of a catheter referred to in feature 1. The Navigator system further comprises an elongated (balloon catheter) shaft that is comprised of an outer and an inner elongated shaft (feature 1.1).

288. The apparatus further comprises a handle portion (Fig. 33) that comprises a flex activating member that comprises a rotational knob (Fig. 37). A pull wire (shown in red in Fig. 37) is proximally coupled to the activating member and distally to the end portion of the elongated shaft (see Figs. 34 and 35) such that the adjustment of the flex activating member causes the distal end portion of the elongated shaft to flex. It is stated in paragraph 37 that “the steering section is flexed by turning a rotational knob on the handle. The flexing action is achieved through a pull wire mechanism as described below.” Thus features 1.2., 1.23 and 1.3.1 are fulfilled, as well.

289. Meril et al. have not contested that the other features of claim 1 are infringed. Hence, there is literal infringement of EP 722 as amended.

3.4.2 Infringing acts and liability

290. Edwards alleges

a) that Meril Germany and Meril India, and each of them, has infringed EP 722 by offering the Navigator and / or placing it on the market and / or importing and / or storing the Navigator for those purposes in various participating member states of the UPCA, including in Estonia and Lithuania, without the consent of Edwards,

b) that SMIS has infringed EP 722 by offering the Navigator and / or placing it on the market and / or importing and / or storing the Navigator for those purposes in Estonia without the consent of Edwards,

c) that Sormedica, Interlux and VAB Logistik has infringed EP 722 by offering the Navigator and / or placing it on the market and / or importing and / or storing it for those purposes in Lithuania without the consent of Edwards,

d) that Meril India, Meril Germany and SMIS have acted pursuant to a common design and induced, incited and / or persuaded each other to carry out the acts complained of within Estonia,

e) that Meril India, Meril Germany, SMIS Sormedica, Interlux and VAB Logistik have acted pursuant to a common design and induced, incited and / or persuaded each other to carry out the acts complained of within Lithuania, and

f) that Meril India and Meril Germany, in respect of various other participating member states of the UPCA excluding Estonia and Lithuania, have acted pursuant to a common design and induced, incited and / or persuaded the other to carry out the acts complained of within those jurisdictions.

291. Meril Germany disputes that it has committed any acts of infringement or by any means or actions supported acts concerning sales of the Navigator in the UPCA territory since the patent was granted. The other Defendants do not dispute that they have committed the alleged acts.

292. The allegations against Meril Germany are inter alia based on the following.

a) Meril Germany is a wholly owned subsidiary of Meril India, i.e. to the company that inter alia is 1) the developer of the Navigator, 2) the manufacturer of the Navigator, 3) the holder of the trademark "Navigator", 3) the holder of the copyright in the Meril Website, and 4) listed as the exporter of record in relation to shipments of the Navigator into at least Estonia and Lithuania.

b) Navigating to the "Contact Us" page from the Meril Website, where the Navigator is offered for sale in the participating member states of the UPCA (at least in most of them, since the brochure contained the information that it was not available in some of the participating member states) and selecting "International Addresses" provides the name and contact details for Meril GmbH. On this webpage, Meril GmbH is described as "Meril European Headquarters".

c) On the Meril Website, there was at least until 5 July 2023 also a link to a brochure (the Myval Brochure) where inter alia the Navigator was offered for sale in the participating member states of the UPCA (at least in most of them, since the brochure contained the information that the Navigator was not available in some of the participating member states). Page 28 of this brochure is headed "Myval THV System and Components – Ordering Information". Further down on the same page, under the heading "Check availability of Myval THV in your country", there is a map over Meril's global presence. For the European Union, the name and contact details of Meril Germany are provided.

d) As of at least 1 September 2023, a new Myval Brochure (the "New Myval Brochure") was available to view and download via a link on the Meril Website. Also, this brochure contained an offer to sale inter alia the Navigator in the participating member states of the UPCA (at least in most of them, since the brochure contained the information that the Navigator was not available in some of the participating member states). Page 1 of the New Myval Brochure is headed "Myval THV System and Components – Ordering Information". Further down on the same page, under the heading "Check availability of Myval THV in your country", there is a map over Meril's global presence. For the European Union, the name and contact details of Meril Germany are provided.

e) Meril is in fact distributing the Navigator to the participating member states of the UPCA, at least to Estonia and Lithuania.

293. Meril Germany disputes that the information on the websites and in the brochures constitutes an offering for sale. Meril Germany also argues inter alia that even if this information would be an offer, Edwards has not shown that it is directed to any participating member states of the UPCA or that Meril Germany has committed, induced, incited and / or persuaded the other to carry out any infringing acts.

294. The Court notes that the information described above is available on the Meril's website, i.e. on the website for the Meril Life Sciences corporate group which includes Meril Germany (Meril Germany does not have its own website). On the website and in the brochures, the Myval THV System and its components – including the Navigator – is described together with information on who to contact if you wish to buy the products. The only company to contact in the member states of the European Union is Meril Germany that also is described as "Meril European Headquarters". The website and the brochures also contain the information that the Navigator is not available for sale in a limited number of specified countries. From this, the user will understand that the Navigator is offered for sale in the participating member states of the UPCA that are not explicitly excluded and that interested customers are invited to contact Meril Germany. Hence, it is clear that the offer on the website and in the brochures originates from inter alia Meril Germany.

295. Since Meril India and Meril Germany have acted in a close and interdependent commercial relationship, based on their structure as members of a group of companies, they have a joint liability for their infringing acts in the participating member states of the UPCA (cf. e.g. the Decision by Local Division Munich on 4 April 2025 in case UPC_CFI_501/2023).

296. Since SMIS is the local distributor of Meril's products in Estonia while Sormedica and Interlux are the local distributors of Meril's products in Lithuania and VAB Logistik is involved in the importation to Lithuania, there are sufficient grounds for holding also them jointly and severely liable for the infringements in Estonia respectively Lithuania.

3.5 Remedies

3.5.1 Injunction

297. Where a decision is taken finding an infringement of a patent, the Court may, according to Article 63 UPCA, grant an injunction against the infringer aimed at prohibiting the continuation of the infringement. Where appropriate, non-compliance with the injunction shall be subject to a recurring penalty payment payable to the Court.

298. Edwards has requested that the Defendants, and each of them, are ordered to cease and desist from making, offering, placing on the market or using (or importing or storing for these purposes) an apparatus as described in claim 1. According to Edwards, the grant of an injunction is the general rule and only in exceptional cases may the prohibition order be denied despite patent infringement having been established. Any failure to comply with the injunction should – according to Edwards – render the Defendants and each of them liable to pay to the Court a penalty of up to EUR 20 000 for each violation of the order, or such other amount as found appropriate by the Court.

299. Meril et al. have disputed this request and argued inter alia that the Court should exercise its discretion under Article 63(1) UPCA and refrain from issuing an injunction, since an injunction would be disproportionate. An injunction would, in their opinion, cause a considerable, disproportionate hardship for third parties because of overriding public health interests. The public interest is, according to Meril et al., the functioning and proper care of patients with severe heart disease (aortic valve stenosis) and this requires the availability of the THV Myval. The Navigator is – according to Meril et al. – necessary for the implantation of the THV Myval, or at least superiour/safer than alternative delivery systems.

300. According to Meril et al., the Court should at least exclude (from an injunction) the Navigator in intermediate sizes (i.e. 21.5mmx30mm, 24.5mmx30mm, 27.5mmx30mm, 27.5mmx35mm) and in XL-sizes (i.e. 30.5mmx35mm and 32mmx35mm), since Edwards' "Sapien 3" and the "Sapien 3 Ultra" are not available for those sizes. Only the "Myval"-THV-system (and the "Myval Octacor"-THV-system, which, however, is not available in all European countries) offers the variety of sizes that is desired by the medical community (and required). Only the "Myval"-THV- system offers patients with large anuli beyond 30mm the possibility of a TAVI-procedure whereas neither the Claimant's products nor available self-expanding transcatheter heart valve prostheses satisfy this need.

301. In the alternative, an order of an injunction should – according to Meril et al. – be refrained from in return for a payment in lieu that is reasonable under the circumstances of the case and that takes into account the economic value of a hypothetical license.

302. In the utmost alternative, the Court should – according to Meril et al. – grant the Defendants' a grace period allowing them to offer, distribute, use or possess for this purpose those Navigator delivery systems which are in the direct or indirect possession or ownership of Defendants within the UPC-territory. In particular, the Defendants should be allowed to distribute those "Myval"-THVs and Navigator delivery systems that have already been ordered. If an injunction is issued and made subject to n penalty payment, the amount should be lower.

303. Edwards has replied that even if the Court would be allowed to refrain from issuing an injunction based on proportionality, any balancing of interest would favour Edwards. According to Edwards, Meril et al. have not substantiated a public interest in the availability of the infringing embodiments (i.e. the Navigator), let alone a public interest amounting to a very exceptional circumstance. At the outset, Meril has an alternative delivery system which does not make use of the protected flex indicator. Furthermore, the existence of intermediate sizes is not necessary for everyday comprehensive patient care and in those very rare cases where a Myval XL THV may be medically necessary, Edwards consents to its use – including the use of the Navigator – on a case-by-case basis. Accordingly, even in countries where the Myval THV is not available (either due to court injunctions or due to voluntary cease and desist declarations by Meril), a Myval XL THV can be implanted if medically necessary. There is an online portal set up for this purpose (the Medical Request Portal, or MRP for short). Since the implementation of the regime described above, Meril has launched a new THV device, the "Octacor". The Octacor THV comes in XL sizes and is now being used to treat patients with extra-large annuli (instead of the Myval XL THV). Consequently, the intermediate sizes and the XL sizes of the Myval THV should – according to Edwards – not be excluded from an injunction.

304. Regarding Meril et al.'s alternative requests, Edwards argues inter alia that ordering a compensation payment and granting a grace period are not appropriate in the present case either, as it does not meet the criteria for engaging the public interest. As the only other provider of balloon expandable valves on the market, Meril should not be able to increase its market share at the direct cost of the Claimant by using the Claimant's patented technology.

305. The Court finds that since Article 63(1) UPCA explicitly states that the Court "may" issue an injunction, it is clear that the Court has a possibility to refrain from issuing an injunction in certain situations. This means that the Court is expected to consider counterarguments presented by the Defendants, which may include arguments based on proportionality. At the same time, it is clear that the main function of a patent is to give the proprietor a right to prevent others from using the invention during the term of protection, see e.g. Article 25(a) UPCA. The possibility to apply for and be granted a compulsory license, if there is the public interest calling for it, should also be taken into account. Hence, when the Court finds that a patent has been infringed, a request for an injunction should normally be granted.

306. In this case, Meril et al. have argued that there is an overriding public interest that would make an injunction in this case disproportionate, but their argumentation primarily focuses on the public's need for Meril's valve prosthesis and not on the delivery device that is the subject of these proceedings, i.e. the Navigator. In fact, it is undisputed that Meril already has undertaken – or been ordered – to refrain from distributing the Navigator in member states covered by the request in this case. It is also undisputed that Meril has an alternative delivery device that may be used. For these reasons alone, the Court finds there is no reason to refrain from issuing an injunction in this case (not even in return for a payment in lieu), or to exclude certain sizes or grant a grace period. Given the circumstances of the case, it is clear that Edwards' request for an injunction is justified and should be granted.

307. The obligation to comply with the injunction shall be made subject of a recurrent penalty payment of up to EUR 10 000 for each violation. The placing on the market of each individual infringing product should be considered as a separate violation.

3.5.2 Declaration of infringement

308. According to Article 64.2(a) UPCA, the Court may declare that the Patent has been infringed by the Defendants' use of the attacked embodiment. Edwards is entitled to such a declaration in this case. Hence, Edwards request for such a declaration shall be granted.

3.5.3 Corrective measures

309. According to Article 64 UPCA, the Court may order that appropriate corrective measures be taken with regard to products found to be infringing a patent, e.g. recalling the products from the channels of commerce, definitively removal of the products from the channels of commerce and the destruction of the infringing products. The Court shall order that those measures be carried out at the expense of the infringer, unless particular reasons are invoked for not doing so, and the order may – according to Article 82.4 UPCA – be subject to an obligation to pay a recurring penalty payment to the Court. In considering a request for corrective measures, the Court shall according to Article 64.4 UPCA take into

account the need for proportionality between the seriousness of the infringement and the remedies to be ordered, the willingness of the infringer to convert the materials into a non-infringing state, as well as the interests of third parties.

310. Edwards has requested that the Defendants and each of them, are ordered at their own expense, within one week after service of the judgment to be rendered in these proceedings to:

a) recall and / or definitively remove the products as specified in the injunction order from all channels of commerce,

b) destroy all products as specified in the injunction order and which are in the custody or control of the Defendants and each of them, and

c) that any failure to comply with the order under a) or b) will render the Defendants and each of them liable to pay to the Court a penalty of up to EUR 1 000 per day for the violation of the order, or such other amount as found appropriate by the Court.

311. Meril et al. have disputed these requests and argue that they would be disproportionate considering the "seriousness" of the infringement and in light of prevailing public health interests (see above). According to Meril et al., any order on recall and/or definitive removal and/or destruction of the products as specified in the injunction shall at least be dismissed insofar as they are based on acts that occurred before 7 June 2023. Furthermore, they argue that Meril Germany does not possess, control or have custody over the attacked embodiment. Therefore, the request must at least be dismissed in respect of Meril Germany. In any case, the time for carrying out these activities must be extended. They will need one month to carry out these acts.

312. The Court finds that is not disproportionate to recall and definite remove the infringing products from the channels of commerce. Nor is it disproportionate to order the destruction of the infringing goods Meril et al. have in their possession in the member states where the Patent has unitary effect. The arguments presented above concerning the injunction applies mutatis mutandis here.

313. During the oral hearing, Edwards clarified that the remedies requested are not based on infringements that have taken place before 7 June 2023, when the Patent was granted. Hence, it is clear that the order shall be limited to products that have been placed on the market in the relevant member states since 7 June 2023, when the Patent was granted.

314. During the oral hearing, Edwards also accepted that the Defendants are given two weeks – instead of one week – to comply with the requested order on corrective measures. According to the Court, two weeks must be sufficient for carrying out the recall set out in this decision and for the destruction of products that already are in the possession of the Defendants in the member states where the Patent has unitary effect. However, it would be impossible for the Defendants to destroy products that have been recalled, but not yet returned, within these two weeks. For the recalled products, the time limit for destruction should therefore be two weeks from the date when recalled goods came in the custody or under control of the Defendants.

315. In the case at hand a periodic fine of EUR 1,000 for each day of delay seems to be reasonable.

3.5.4 Right to information

316. According to Article 67 UPCA and Rule 191 RoP, the Court may inter alia order an infringer to inform the applicant of:

a) the origin and distribution channels of the infringing products or processes;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products; and

c) the identity of any third person involved in the production or distribution of the infringing products or in the use of the infringing process.

317. An order to communicate information may, according to Article 82.4 UPCA, be subject to an obligation to pay a recurring penalty payment to the Court.

318. Edwards has requested that the Defendants and each of them, within three weeks after service of the decision to be rendered in these proceedings, is ordered to inform the Claimant of

a) the origin and distribution channels of the infringing products,

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products, and

c) the identity of any third person involved in the production or distribution of the infringing products,

and that any failure to comply with the order shall render the Defendants and each of them liable to pay to the Court a penalty of up to EUR 1 000 per day for the violation of the order.

319. During the oral hearing, Edwards made the limitation that the request for information only relates to infringements committed after the Patent was granted. Edwards also accepted the Defendants' suggestion that they should be given six weeks, after service of the decision, to comply with the order for information.

320. The Court finds that the request for information is justified and should be granted with respect to products that have been subject to an infringing act by a Defendant since 7 June 2023, when the Patent was granted. The parties have agreed that the time limit for complying with the order on information shall be set to six weeks after service of the decision rendered in this case, which shall be accepted by the Court.

321. In the case at hand a periodic fine of EUR 1 000 for each day of delay seems to be reasonable.

3.5.5 Publication

322. According to Article 80 UPCA, the Court may order appropriate measures for the dissemination of information concerning the Court's decision, including displaying the decision and publishing it in full or in part in public media.

323. Edwards has requested

a) that it is permitted, at each of the Defendants' expense, to display the decision and publish it in full or in part in up to five electronic or printed publications (including in industry journals) of Edwards' choice, and

b) that the Defendants and each of them are ordered to publish, at their own expense, the operative part of the Court's decision on their respective websites.

324. Meril et al. argue that these requests shall be dismissed. According to them, Edwards has not shown a legitimate interest in a publication. Any balancing decision must therefore come out in favour of Defendants. Furthermore, there is no need for a far-reaching announcement of a decision or of its operative part to eliminate a patent infringement. Those who have a business relationship with the Defendants would already be sufficiently informed by a recall. The attacked embodiment is a "special need-product" which is not purchased by the general public. Rather, it is directed only to limited specialist circles (doctors and hospitals) from the outset. They also argue that the request for publication on the Defendants' websites is unfounded in relation to Meril Germany, SMIS and Vab-Logistik, since these companies do not maintain a website.

325. The Court finds that Edwards has not shown sufficient reasons for ordering the publication of the decision on the Defendants' websites, or to give Edwards the right to publish the decision in publications at the Defendants' expense. Hence, these requests shall be dismissed.

3.5.6 Damages

326. According to Article 68 UPCA, the Court shall, at the request of the injured party, order the infringer who knowingly, or with reasonable grounds to know, engaged in a patent infringing activity, to pay the injured party damages appropriate to the harm actually suffered by that party as a result of the infringement. The amount of the damages or the compensation may, according to Rule 118 RoP, be stated in the order or determined in separate proceedings [Rules 125-144].

327. Since the Defendants have acted culpably, Edwards is entitled to damages. Edwards has requested that the Court at this stage only take a decision in principle, i.e. that the determination of the amount of damages shall be dealt with in a separate proceeding. This request shall be granted.

328. However, according to the wording of Edwards' request, the Court is requested to declare that "the Defendants and each of them are liable for all damages resulting from the patent infringement". At the same time, Edwards has only argued – and the Court has accepted – that while Meril India and Meril Germany are liable for all infringements in the contracting member states where the Patent has unitary effect, the liability for SMIS is

limited to infringements in Estonia and the liability for Sormedica, Interlux and VAB Logistik is limited to infringements in Lithuania. This should be reflected in the decision.

329. Since Edwards has withdrawn its previous request for compensation for infringements prior grant of the Patent (Article 67 of the EPC), it should be made clear that the obligation to reimburse damages only applies to infringements that have occurred since 7 June 2023, when the Patent was granted.

3.5.7 Interim award of damages

330. According to Rule 119 RoP, the Court may order an interim award of damages to the successful party in the decision on the merits, subject to any conditions that the Court may order. Such award shall at least cover the expected costs of the procedure for the award of damages and compensation on the part of the successful party.

331. Edwards has requested that the Defendants and each of them are ordered to pay Edwards, within 14 days of the decision, an interim award of damages in the amount of EUR 500 000. Edwards has explained that the request is inter alia based on that the Court fee for the separate proceeding on the amount of damages will be EUR 23 000 (since the value is EUR 3 000 000) and that the actual costs for representatives will exceed EUR 400 000.

332. Meril et al. argue that this claim is unsubstantiated and that any interim award of damages should be lower.

333. The Court finds that Edwards is entiteled to an interim award of damages and that the proposed sum is reasonable, given the circumstances of the case and the estimated costs for a separate proceeding on the amount of damages. Hence, the request shall be granted.

3.5.8 Legal costs

334. According to Article 69 UPCA, reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity requires otherwise, up to a ceiling set in accordance with the Rules of Procedure. Where a party succeeds only in part or in exceptional circumstances, the Court may order that costs be apportioned equitably or that the parties bear their own costs. A party should bear any unnecessary costs it has caused the Court or another party.

335. According to Rule 118.5 RoP, the Court shall – in the decision on the merits – decide in principle on the obligation to bear legal costs in accordance with Article 69 UPCA. This cost decision may, according to Rule 150 RoP et al., be the subject of separate proceedings following a decision on the merits and, if applicable, a decision for the determination of damages.

336. In this case, Edwards is the successful party in the action on infringement and largely also in the counterclaim on revocation, although independent claim 1 was slightly amended and the dependent claims were deleted.

337. Edwards has requested that the Court orders that the Defendants and each of them are to bear the legal costs of these proceedings as well as all other costs incurred by the Claimant. Hence, Meril et al. should be obliged to reimburse Edwards for all (100 %) its reasonable and proportionate legal costs and other expenses in the infringement action and for most (75 %) of the costs in the counterclaim for revocation.

338. The fact that Edwards, during the proceeding, has chosen to withdraw its request for remedies (in particular compensation) to the extent they were based on alleged infringements committed before 7 June 2023, when the Patent was granted, and has confirmed/clarified that it does not seek remedies in respect of countries that were not parties to the UPCA when the action was initiated, should not affect Edwards right to reimbursement of costs (cf. the preliminary objection, but also e.g. the order of the Court of Appeal on 2 June 2025 in case UPC_CoA_156/2025).

3.5.9 Enforceability

339. It follows from Article 82.1 UPCA and Rule 354.1 RoP that, subject to Rule 118.8 and 352 RoP, decisions and orders of the Court shall be directly enforceable from their date of service in each contracting member state.

340. Edwards has requested that the Court attaches to its decision an order for its immediate enforceability.

341. Meril et al. have requested that the decision be put under the condition that the Patent is not held to be wholly or partially invalid by the final decision upon the counterclaim for revocation or by a final decision of the EPO or under any other term or condition.

342. The Court finds that there is no legal basis for making the Court's decision subject to the condition that the Court of Appeal agrees with this panel's decision on the validity of the Patent. Nor are there, in view of the assessment made on the basis of the counterclaim, sufficient reasons for making the decision subject to the condition that the Patent is not held to be wholly or partially invalid by the EPO Boards of Appeal (cf. Article 56.1 UPCA and Rule 118.2(a) RoP).

343. The Defendants' have not requested that the decision is made subject to the rendering of a security and the Court cannot see any reason for such a condition.

344. This means that no security must be lodged beforehand and the decision is not made subject to conditions under Rule 118.2(a) RoP. However, Rule 118.8 RoP must be complied with.

4. DECISION

345. For all these reasons:

I) The Court dismisses the preliminary objection.

II) The Court decides to uphold EP 3 769 722 as amended by auxiliary request 1' in Annex 1.

III) The Court orders the Defendants and each of them to cease and desist from making, offering, placing on the market or using, or importing or storing for these purposes:

an apparatus for indicating flex of a distal end of a catheter comprising an elongated shaft, at least one pull wire connected to a distal end portion of the elongated shaft, a handle portion comprising a flex activating member, the flex activating member being coupled to the at least one pull wire such that adjustment of the flex activating member causes the distal end portion of the elongated shaft to flex; a slide member connected to the at least one pull wire, and a flex indicating member, wherein adjustment of the flex activating member causes the flex indicating member to move relative to the handle portion, and wherein the flex activating member comprises a rotatable member which includes an internally threaded surface portion characterised in that the rotatable member of the flex activating member also has an externally threaded surface portion, wherein the internally threaded surface portion is configured to receive the slide member connected to the at least one pull wire, and the externally threaded surface portion is configured to receive an extending portion of the flex indicating member,

within the territory where EP 3 769 722 has unitary effect (hereafter the Territory).

IV) The Court orders the Defendants and each of them to comply with the order in paragraph III), subject to a recurrent penalty payment of up to EUR 10 000 for each violation of the order. The placing on the market of each individual infringing product will be considered as a separate violation.

V) The Court declares that EP 3 769 722 has been infringed by each of the Defendants in the Territory in respect of the Navigator.

VI) The Court orders the Defendants and each of them, at their own expense and under threat of a recurring penalty payment of up to EUR 1 000 for each day of delay, to take the following actions with regard to the products described in paragraph III) that have been placed on the market in the Territory since 7 June 2023:

a) within two weeks after service of this decision , to recall the products, with reference to the legally established patent-infringing nature of the products, and with the binding commitment to take back the products and to bear any fees as well as necessary packaging and transport costs and customs and storage costs associated with the return, and

b) to destroy the recalled products that are taken back, within two weeks from the date when the recalled goods came in the custody or under control of the Defendants.

VII) The Court orders the Defendants and each of them, at their own expense and within two weeks after service of this decision , under threat of a recurring penalty payment of up to EUR 1 000 for each day of delay, to destroy all products described in paragraph III) that are in the custody or control of the Defendants in the Territory.

VIII) The Court orders the Defendants and each of them to provide Edwards, within six weeks after service of this decision and under threat of a recurring penalty payment of up to EUR 1 000 for each day of delay, with information about the acts described in paragraph III) since 7 June 2023, by specifying:

a) the origin and distribution channels of the infringing products,

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products, and

c) the identity of any third person involved in the production or distribution of the infringing products.

IX) The Court dismisses the request for publication of the decision at the expense of the Defendants, and the request that the Defendants shall be ordered to publish the decision on their websites.

X) The Court declares

a) that Meril India, Meril Germany and SMIS are jointly and severally obliged to compensate Edwards for the damage that Edwards has suffered and will suffer as a result of the acts described in paragraph b) above committed since 7 June 2023 in Estonia,

b) that Meril India, Meril Germany, Sormedica, Interlux and VAB Logistik are jointly and severally obliged to compensate Edwards for the damage that Edwards has suffered and will suffer as a result of the acts described in paragraph b) above, committed since 7 June 2023 in Lithuania, and

c) that Meril India and Meril Germany are jointly and severally obliged to compensate Edwards for the damage that Edwards has suffered and will suffer as a result of the acts described in paragraph b) above, committed since 7 June 2023 in other contracting member states where the Patent has unitary effect.

XI) The Court orders the Defendants and each of them to pay EUR 500 000 as provisional damages to Edwards within 14 days of service of this decision.

XII) The Court orders the Defendants and each of them to bear the reasonable and proportionate legal costs and other expenses incurred by Edwards in the infringement proceedings, and to bear 75 percent of the reasonable and proportionate legal costs and other expenses incurred by Edwards in the

proceedings on the counterclaim for revocation, in accordance with Article 69 UPCA.

XIII) The Court declares that this decision is immediately and directly enforceable from the date of service in each contracting member state.

XIV) The Court dismisses all other requests.

Issued and read in open Court, in Stockholm, on 21 July 2025.

Stefan Johansson Presiding judge and judge-rapporteur	Stefan Erik Johansson Digitally signed by Stefan Erik Johansson Date: 2025.07.10 16:25:18 +02'00'
Kai Härmand Legally qualified judge	Kai Härmand Digitally signed by Kai Härmand Date: 2025.07.10 14:34:05 +02'00'
Mélanie Bessaud Legally qualified judge	Mélanie, Jeanne, Lison Bessaud Digitally signed by Mélanie, Jeanne, Lison Bessaud Date: 2025.07.09 23:17:45 +02'00'
Stefan Wilhelm Technically qualified judge	Stefan Maria Wilhelm Digitally signed by Stefan Maria Wilhelm Date: 2025.07.10 10:15:25 +02'00'
For the Deputy-Registrar Johanna Mikkola Jäghammar Clerk	JOHANNA ANNIKKI CHRISTINA MIKKOLA JAGHAMMAR Digitally signed by JOHANNA ANNIKKI CHRISTINA MIKKOLA JAGHAMMAR Date: 2025.07.10 16:32:54 +02'00'

INFORMATION ABOUT APPEAL

An appeal against the present Decision may be lodged at the Court of Appeal, by any party which has been unsuccessful, in whole or in part, in its submissions, within two months of the date of its notification (Art. 73(1) UPCA, R. 220.1(a), 224.1(a) RoP).

INFORMATION ABOUT ENFORCEMENT

Art. 82 UPCA, Art. Art. 37(2) UPCS, R. 118.8, 158.2, 354, 355.4 RoP. An authentic copy of the enforceable decision will be issued by the Deputy-Registrar upon request of the enforcing party, R. 69 RegR.

Annex 1

Claims according to Auxiliary Request 1

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.

5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the

internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~9. The apparatus of one of claims 7 to ~~9~~8, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~10. The apparatus of claim ~~10~~9, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~11. The apparatus of one of claims 7 to ~~11~~10, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~12. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 2

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.

5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the

internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~9. The apparatus of one of claims 7 to ~~9~~8, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~10. The apparatus of claim ~~10~~9, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~11. The apparatus of one of claims 7 to ~~11~~10, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~12. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 3

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152), wherein the distal end portion comprises a steerable section;

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160), wherein the rotatable member is an adjustment knob **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.

5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the

internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~9. The apparatus of one of claims 7 to ~~9~~8, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~10. The apparatus of claim ~~10~~9, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~11. The apparatus of one of claims 7 to ~~11~~10, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~12. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 4

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156), wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156).

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

4. The apparatus of one of claims 1 to 3, ~~wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably~~ wherein the slot (164) is a longitudinal slot.

5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded

surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~9. The apparatus of one of claims 7 to ~~9~~8, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~10. The apparatus of claim ~~10~~9, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192)

relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~11. The apparatus of one of claims 7 to ~~11~~10, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~12. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 5

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), wherein the slot (164) is a longitudinal slot.

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5~~4. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

~~6~~5. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

~~7~~6. The apparatus of claim ~~6~~ 5 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

~~8~~7. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~8. The apparatus of one of claims ~~7~~ 6 to ~~9~~7, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~9. The apparatus of claim ~~10~~8, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~10. The apparatus of one of claims ~~7~~ 6 to ~~11~~9, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~11. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 6

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.

5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the

internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~9. The apparatus of one of claims 7 to ~~9~~8, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~10. The apparatus of claim ~~10~~9, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~11. The apparatus of one of claims 7 to ~~11~~10, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~12. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 7

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156).

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

4. The apparatus of one of claims 1 to 3, ~~wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably~~ wherein the slot (164) is a longitudinal slot.

5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~9. The apparatus of one of claims 7 to ~~9~~8, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~10. The apparatus of claim ~~10~~9, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~11. The apparatus of one of claims 7 to ~~11~~10, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~12. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 8

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), wherein the slot (164) is a longitudinal slot.

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5~~4. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

~~6~~5. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

~~7~~6. The apparatus of claim ~~6~~ 5 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

~~8~~7. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~8. The apparatus of one of claims ~~7~~ 6 to ~~9~~7, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~9. The apparatus of claim ~~10~~8, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~10. The apparatus of one of claims ~~7~~ 6 to ~~11~~9, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~11. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 9

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152), wherein the distal end portion comprises a steerable section;

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160), wherein the rotatable member is an adjustment knob **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156).

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

4. The apparatus of one of claims 1 to 3, ~~wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably~~ wherein the slot (164) is a longitudinal slot.

5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~9. The apparatus of one of claims 7 to ~~9~~8, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~10. The apparatus of claim ~~10~~9, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~11. The apparatus of one of claims 7 to ~~11~~10, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~12. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 10

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152), wherein the distal end portion comprises a steerable section;

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160), wherein the rotatable member is an adjustment knob **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), wherein the slot (164) is a longitudinal slot.

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5~~4. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

~~6~~5. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

~~7~~6. The apparatus of claim ~~6~~ 5 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

~~8~~7. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10~~8. The apparatus of one of claims ~~7~~ 6 to ~~9~~7, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

~~11~~9. The apparatus of claim ~~10~~8, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12~~10. The apparatus of one of claims ~~7~~ 6 to ~~11~~9, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

~~13~~11. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.

Claims according to Auxiliary Request 11

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end~~

portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).

10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 1'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end~~

portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).

10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 2'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the~~

~~internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).~~

~~6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).~~

~~7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).~~

~~8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).~~

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).~~

~~11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 3'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152), wherein the distal end portion comprises a steerable section;

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160), wherein the rotatable member is an adjustment knob **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the~~

~~internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).~~

~~6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).~~

~~7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).~~

~~8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).~~

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).~~

~~11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 4'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156), wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156).

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded~~

surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).

8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).

10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).

11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192)

~~relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 5'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156), wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), wherein the slot (164) is a longitudinal slot.

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).~~

~~6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).~~

~~7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).~~

~~8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).~~

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).~~

~~11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 6'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the~~

~~internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).~~

~~6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).~~

~~7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).~~

~~8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).~~

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).~~

~~11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 7'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156).

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).~~

~~6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).~~

~~7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).~~

~~8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).~~

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).~~

~~11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 8'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), wherein the slot (164) is a longitudinal slot.

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).~~

~~6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).~~

~~7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).~~

~~8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).~~

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).~~

~~11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 9'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152), wherein the distal end portion comprises a steerable section;

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160), wherein the rotatable member is an adjustment knob **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156).

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).~~

~~6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).~~

~~7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).~~

~~8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).~~

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).~~

~~11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Claims according to Auxiliary Request 10'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152), wherein the distal end portion comprises a steerable section;

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and

a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158) to indicate an amount of flex of the distal end portion (188) of the elongated shaft (152), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160), wherein the rotatable member is an adjustment knob **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156),

wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), wherein the slot (164) is a longitudinal slot.

~~2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.~~

~~3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.~~

~~4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.~~

~~5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).~~

~~6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).~~

~~7. The apparatus of claim 6 when dependent on claim 1, wherein the handle portion (158) includes an inner sleeve (190) surrounding a portion of the elongated shaft (152) inside the main body (159), the slide member (192) being disposed on and slidable relative to the inner sleeve (190).~~

~~8. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).~~

~~9. The apparatus of claim 7 or 8, wherein the inner sleeve (190) has an external threaded portion that mates with an extension member (166) of the flex indicating member (156).~~

~~10. The apparatus of one of claims 7 to 9, wherein the slide member (192) has two slots formed on an inner surface of the slide member (192) and extending the length thereof, and wherein the inner sleeve (190) is formed with longitudinally extending slots that are aligned with the slots of the slide member (192) when the slide member (192) is placed on the inner sleeve (190).~~

~~11. The apparatus of claim 10, wherein an elongated guide extends radially into each slot in the slide member (192) to prevent rotation of the slide member (192) relative to the inner sleeve (190), wherein the elongated guides are preferably in the form of an elongated rod or pin.~~

~~12. The apparatus of one of claims 7 to 11, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).~~

~~13. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.~~

Annex 2

Claims according to Auxiliary Request 1'

1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);

at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);

a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;

a slide member (192) connected to the at least one pull wire (174); and a flex indicating member (156);

wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and

wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160) **characterised in that** the rotatable member (155, 157) of the flex activating member also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156).

2. The apparatus of claim 1, wherein indicia (168) indicating the amount of flex of the distal end portion of the elongated shaft (152) are provided at the handle portion (158), preferably wherein the indicia (168) depict the amount of flex using a triangular marking system or numbers.

3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members.

4. The apparatus of one of claims 1 to 3, wherein the handle portion (158) comprises a slot (164) for receiving at least a portion of the flex indicating member (156), preferably wherein the slot (164) is a longitudinal slot.

5. The apparatus of claim 1, wherein rotating the rotatable member (155, 157) is configured to cause the slide member (192) to move along the internally threaded

surface portion (160) and the movement of the slide member (192) along the internally threaded surface portion (160) changes the amount of flex of the distal end portion of the elongated shaft (152), wherein the rotation of the rotatable member (155, 157) causes the flex indicating member (156) to move longitudinally and change its position within the slot (164) of the handle portion (158) and the position of the flex indicating member (156) within the slot (164) indicates the amount of flex of the distal end portion of the elongated shaft (152).

6. The apparatus of one of the preceding claims, wherein the handle portion (158) includes a main body (159) formed with a central lumen (161) that receives a proximal end portion of the elongated shaft (152), preferably wherein the handle portion (158) includes a side arm (62) defining an internal passage which fluidly communicates with the central lumen (161) at the main body (159) of the handle portion (158), more preferably wherein a stopcock is mounted on the upper end of side arm (62).

7. The apparatus of claim 1, wherein the slide member (192) is formed with external threads that mate with the internally threaded surface portion (160) of the rotatable member (155, 157).

8. The apparatus of claim 7, wherein a proximal end portion of the pull wire (174) extends into and is secured to a retaining pin (180), wherein the retaining pin (180) is disposed in a slot in the slide member (192).

9. The apparatus of one of the preceding claims, wherein the apparatus for indicating flex is a flex catheter for implantation of a prosthetic heart valve.