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(54) Title: CATHETER DEVICE COMPRISING AN IMPLANT CAPSULE ATTACHED TO THE OUTER SHAFT BY MEANS OF TABS

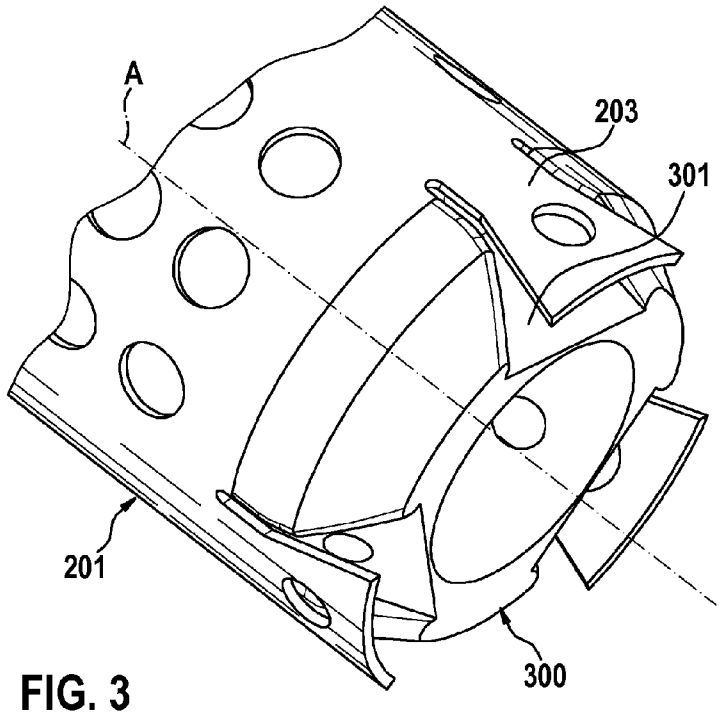

FIG. 3

(57) Abstract: The invention relates to a catheter device (100) for transporting an implant to a target location in a body lumen and also for releasing the implant at the target location, comprising: an outer shaft (5) for transporting the implant to the target location, and an implant capsule (200) for receiving the implant, wherein the implant capsule (200) has a tubular capsule core (201), which surrounds the implant prior to the release. In accordance with the invention, the capsule core (201), at a proximal end (201a) of the capsule core, has a plurality of tabs (203) for fixing the capsule core (201) to the outer shaft (5), which tabs protrude from a tubular portion (202) of the capsule core (201) along an axial direction (A) of the capsule core (201).

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Catheter device comprising an implant capsule attached to the outer shaft by means of tabs

The invention relates to a catheter device according to claim 1.

Catheter devices of this type are used to transport an implant, for example in the form of a stent or a (for example bioprosthetic) heart valve to a target location in a body lumen of a human or possibly animal patient. Such a catheter device has an inner shaft for supporting said implant, an outer shaft for transporting the implant to the target location, wherein the outer shaft surrounds the inner shaft in cross-section. Furthermore, an implant capsule for receiving the implant is provided on the outer shaft, wherein the implant capsule has a tubular capsule core, which surrounds the implant prior to the release. The implant can be moved out from the implant capsule by displacing the inner shaft relative to the outer shaft and can be released and implanted at the target location. Furthermore, an outermost stabilisation shaft for stabilising the outer shaft can be provided, wherein the outer shaft is arranged displaceably in a lumen of the stabilisation shaft surrounded by the stabilisation shaft.

The implant capsule generally has a capsule core, which for example forms a supporting structure of the implant capsule and is to be suitably fixed to the outer shaft.

For this purpose, solutions are known in which a connection means (connector) in the form of a plastics injection-moulded part is secured to the outer shaft, to which the implant capsule or prosthesis capsule is glued. Solutions are also known in which the implant capsule has a metal core and the end thereof has finger-like extensions, which are then encapsulated in a plastics connector.

These connections based on adhesive bonding, injection moulding, etc. are often very rigid and have a large overall length, which leads to an inhomogeneous bending form of the catheter. In addition, the catheter in this transition region has an unfavourable jump in stiffness.

On this basis, the object of the present invention is to further improve a catheter device of the type described in the introduction in respect of the aforementioned problems.

This object is achieved by a catheter device having the features of claim 1.

Advantageous embodiments of the invention are specified in the dependent claims and will be described hereinafter.

In accordance with the invention the subject of claim 1 provides that the capsule core, at one end of the capsule core, has a plurality of tabs for fixing the capsule core to the outer shaft, which tabs protrude from a tubular portion of the capsule core along an axial direction of the capsule core.

This allows a connection of the capsule core to the outer shaft via said tabs, which advantageously provides a sufficient mechanical stability and enables a comparatively short overall length, with which the proportion of the rigid portion can be kept advantageously short.

In the sense of the present invention, "distal" means that a corresponding distal component, a distal portion, or a distal end is distanced further from a handle or an operator (doctor) of the catheter device in the axial direction of the outer shaft, along which the longitudinal axis of the outer shaft extends, than a proximal component, a proximal portion, or a proximal end.

The catheter device can also comprise an inner shaft mounted displaceably in the outer shaft for supporting the implant, wherein the implant can be guided out from the implant capsule by displacing the outer shaft relative to the inner shaft.

The invention is suitable in particular for a catheter system where the implant is released by a displacement of the outer shaft relative to the inner shaft, in particular where the release is implemented by retracting the outer shaft. In the preferred variant the capsule core then has, at a proximal end of the capsule core, a plurality of tabs for fixing the capsule core to the outer shaft, wherein the tabs protrude from a tubular portion of the capsule core along an axial direction of the capsule core.

The implant capsule can also have an outer covering or material layer arranged on the capsule core, which covering or material layer preferably consists of an elastic or viscoelastic polymer. Here, polymers such as polyurethane or thermoplastic polymers such as thermoplastic copolyamides, for example known under the trade name PEBAX, can be considered as material.

Furthermore, the implant capsule can comprise an inner covering or material layer surrounded by the capsule core and fixed thereto, which covering or material layer surrounds the actual implant and preferably consists of a plastic having reduced coefficients of friction. In particular, PTFE (also known under the trade name Teflon) or ePTFE or a plastics composite comprising proportions of PTFE or ePTFE is suitable here.

However, it is also conceivable to use a monolayer implant capsule, which in this case would consist just of the capsule core, which is then referred to as a capsule sleeve. In an embodiment of this type a composite material formed of carbon fibres and a plastic is advantageous, wherein the carbon fibres are integrated in the plastic.

In accordance with a preferred embodiment of the invention, it is also provided that the tabs each have two sides extended along the axial direction, which sides face away from one another in a peripheral direction of the tubular portion, wherein the two sides extend away from one another along the axial direction starting from said tubular portion, such that each tab (starting from said tubular portion) becomes wider accordingly. The tabs are therefore also referred to as dovetails. In this embodiment it is important that the two sides, starting from the tubular portion, extend substantially away from one another. However,

the tabs can have small interruptions or indentations, without impairing the function of this embodiment. The widening is decisive for a good transfer of force.

It is also provided in accordance with one embodiment of the invention that a connection means preferably running around the outer shaft is fixed, in particular welded in place, on a distal end portion of the outer shaft, via which connection means the tabs are connected to the outer shaft, more specifically preferably by screwing the tabs to the connection means Screwing is the preferred and simplest securing method. It also additionally offers the mechanical advantage that the prestress of the tabs can be determined precisely in combination with the connection means. In the case that the connection means are milled out accordingly, the lateral flanks of the tabs can be introduced without play into the milled-out area. The tab is tensioned by means of the screwed connection and the flanks lie without play on the corresponding counterpieces of the recess. In principle, however, other methods for securing the tabs, such as gluing or welding, are equally conceivable, but in this case the generation of the prestress and the play-free insertion of the tabs into a possible milled-out area in the connection means is more complex.

The connection means, which in the present case is also referred to as a connector, is particularly preferably formed as an annular body, which surrounds the outer shaft in cross-section. In an embodiment of the invention where the catheter is inserted via an antegrade route, the connector surrounds the inner shaft in cross-section.

In accordance with a preferred embodiment of the invention, it is also provided that each tab fixed to the connection means also engages in an associated recess in the connection means, wherein these recesses are formed on a peripheral outer side of the connection means. In accordance with one embodiment of the invention it is provided that each tab fixed to the connection means preferably engages in an interlocking manner in its associated recess in the connection means.

In accordance with a preferred embodiment of the invention it is also provided that said outer side, at a proximal end of the connection means, comprises a peripheral conical portion, such that the connection means, at the proximal end of the connection means, has a

peripheral chamfer on the outer side, wherein those recesses for receiving the tabs are formed in the conical portion of the outer side.

In accordance with a preferred embodiment of the invention it is also provided that each recess has two flanks facing towards one another, which start from a base of the corresponding recess, wherein the recesses taper in the axial direction of the outer shaft towards the tubular portion of the capsule core, such that both flanks extend towards one another accordingly.

In accordance with a preferred embodiment of the invention it is also provided that each tab, in a state not fixed to the connection means, has a curvature in the peripheral direction of the tubular portion. This curvature can correspond to the curvature of the tubular portion in the peripheral direction thereof.

In accordance with a preferred embodiment of the invention it is also provided that each tab fixed to the connection means has a smaller curvature in the peripheral direction than in the state not fixed to the connection means, wherein the corresponding tab fixed to the connection means presses with each of its sides against an associated flank of the recess in which the tab is engaged.

In other words, each tab when fixed, in particular screwed in place, in the corresponding recess is pressed flat, thus producing the contact between the outer sides of the corresponding tab and the flanks of the associated recess.

In accordance with a preferred embodiment of the invention it is also provided that said smaller curvature does not disappear. In other words, the tabs are fixed or screwed in place in the recesses such that they are not completely pressed flat, but instead a certain residual curvature remains.

In accordance with a preferred embodiment of the invention it is also provided that the tubular portion bears against a peripheral step of the connection means via edge portions extending between adjacent tabs, wherein in accordance with a preferred embodiment of the invention it is provided that said edge portions are drawn against the step by the tabs

fixed to the connection means. This can be ensured by the extension of the outer sides of the tabs away from one another and also the corresponding shape of the flanks, whereby the tabs are made to draw the tubular portion of the capsule core fixed thereto against the step during the fixing process

In accordance with a preferred embodiment of the invention it is also provided that the tabs fixed to the connection means are curved, starting from the tubular portion, towards the base of their respective associated recesses in the connection means.

In accordance with a preferred embodiment of the invention it is also provided that the tabs are fixed to the connection element by means of screws, wherein each screw engages through a through-opening in the corresponding tab and is screwed by means of its external thread to an internal thread of an associated opening in the base of the corresponding recess.

In accordance with a preferred embodiment of the invention it is also provided that the capsule core and/or the connection means are/is manufactured from a metal, in particular from a steel. In addition to stainless steel, chromium-nickel steel and also cobalt-chromium mixtures or alloys can also be used advantageously as materials in this embodiment of the invention. Nickel-titanium alloys (nitinol) or composite materials with carbon fibres are also expedient in specific embodiments.

In accordance with a preferred embodiment of the invention it is also provided that the tubular portion of the capsule core has a plurality of parallel slots running along the peripheral direction and also in particular through-openings arranged between adjacent slots. The through-openings are formed here automatically as holes created by melting in specific embodiments of the invention where the slots are produced by means of laser cutting in a capsule core made of metal. What are key for this embodiment, however, are the slots running in the peripheral direction. The rigidity of the capsule core can be varied by the width and frequency of the slots. Here, the rigidity of the capsule core can be varied by the width and frequency of the slots. Here, the rigidity of the capsule core is preferably increased gradually towards the transition to the connection means or connector so as to en-

sure that the tensile and compressive stresses occurring as a result of bending load are continuously introduced into said connection means or connector.

Further features and advantages of the invention will be explained in the description of drawings of exemplary embodiments of the invention, with reference to said drawings, in which:

Fig. 1 shows a detail of a catheter device according to the invention,

Fig. 2 shows a perspective view of a detail of a capsule core before being fixed to the connection means (connector);

Fig. 3 shows a further perspective view of a detail of a capsule core before being fixed to the connection means (connector);

Fig. 4 shows a perspective view of a detail of a capsule core fixed to the connection means; and

Fig. 5 shows an illustration of the forces occurring during the fixing process.

Figure 1 in conjunction with Figures 2 to 4 shows a catheter device 100 for transporting an implant I (not shown) to a target location of a body lumen of a patient. The device 100 here has an elongate inner shaft (not shown) for supporting the implant I, wherein the implant I can be fixed to a distal end of the inner shaft. The distal end of the inner shaft is opposite its proximal end, which for example can be fixed to a handle of the catheter device, by means of which the inner shaft and the outer shaft 5 are moved. The outer shaft 5 serves here to transport the implant to the selected target location in the body lumen of the patient. Here, the outer shaft 5 surrounds the inner shaft, such that this can be guided in the outer shaft 5 and is movable relative to the outer shaft 5 so as to move the implant, for example in the known manner, out from an implant capsule 200 fixed on the outer shaft 5, such that the implant can unfold at the target location or can be unfolded there. In this embodiment

the outer shaft 5 also has a core made of a cut metal tube (also referred to as a Hypotube), which is sheathed by a polymer (not illustrated).

The implant capsule 200 has a capsule core 201 made of a metal, for example made of a steel tube, which is cut such that it has, at its proximal end 201a, continuing tabs 203, which for example form a trapezoidal end. Each tab 203 or each dovetail 203 thus has outer sides 203a and 203b facing away from one another, which extend away from one another starting from a tubular portion 202 of the capsule core 201. The capsule core 201 can also be surrounded outwardly by an outer covering or material layer 207 (also referred to as an outer jacket), wherein an inner covering or material layer 206 can be provided on the inner side of the capsule core and is also referred to as an inner liner.

The steel tube or the tubular portion 202 has a cut pattern, which for example has parallel slots 204 running in a peripheral direction U and through-openings 205 arranged between the slots 204. The cut pattern is formed here such that the rigidity of the capsule core 201 increases gradually at the transition to a connector 300, to which the tabs 203 are fixed.

It is thus ensured that the tensile and compressive stresses occurring as a result of a bending load are introduced continuously into the connector 300.

The annular connector or connection means 300 preferably manufactured from a metal preferably has an outer side 300a with a conical portion 300c. Preferably three dovetail-shaped or trapezoidal recesses 301 are formed on this conical surface 300c of the cone and taper towards the distal end of the catheter device 100. The congruently shaped counterpieces in the form of the tabs 203, which are disposed on the capsule and are preferably formed integrally with a proximal end 201a of the capsule core 201, are drawn into these pockets 301, in each case by means of a screw 400. Here, each screw 400 engages through a through-opening 208 in the associated tab 203 and is screwed into an opening 303 provided on the base 301c of the corresponding recess 301. Since these counterpieces 203 are curved in the peripheral direction U, they are pressed flat when screwed down. As a result, the outer sides 203a, 203b of the tabs are pressed against the accordingly extending flanks or walls 301a, 301b of the recesses 301. Here, a prestressed interlocking connection is pro-

duced, which in particular is free from play. The connector 300 additionally has a peripheral step or ring 302, which serves as a stop, wherein the edge portions 201b of the tubular portion 202 of the capsule core 201 extending between the tabs 203 are drawn against said stop.

The forces occurring as the tabs 203 are fixed at the connection means/connector 300 are indicated in Figure 5.

By pressing down the curved tab (for example dovetail) 203, this is straightened in the radial direction or peripheral direction U and presses with F_f against the flanks 301a, 301b of the connector 300.

The resultant force F_{res} consequently draws the capsule core 201 by means of its edge portions 202b against the step or stop shoulder 302 at the connector 300. The capsule core 201 presses thereagainst by the reaction forces F_{react}.

The geometry of the tabs and their respective counterpieces in the connector 300 (recesses 301) are selected such that the curve in the assembled state is always retained to a small extent; it can thus be guaranteed that the component parts are braced against one another and that the contact faces thus rest on one another.

The capsule 200 is connected by means of its load-bearing element, i.e. the capsule core 201 laser-cut from a metal tube for example, to the outer shaft in the above-described way, and thus in an interlocking and play-free manner. In accordance with one embodiment, the distal connector 300 is manufactured from a steel, wherein it is preferably welded onto the outer shaft on the catheter side. The high load-bearing capability of the steel at the connector 300 and in the capsule 200 allows a short design, which significantly reduces the rigid proportion of the catheter end. With the play-free connection to the connector 300 and an additional welding of the outer plastic coverings, it is additionally ensured that the tightness in the transition is ensured. Alternatively, an O-ring can also be used to produce the tightness (not illustrated). A further advantage of this design is that the manufacturing process does not include any injection moulding or gluing. This makes it possible for the

capsule 200 to be produced using simple shrinking tubes and hot air fans by means of a melting method, or for the outer jacket 207 to be applied and for the inner liner 206 to be fixed to the core 201 via holes (for example 205) in the capsule core 201, said holes having been produced by melting.

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Patent claims

1. A catheter device (100) for transporting an implant (I) to a target location in a body lumen and also for releasing the implant at the target location, comprising:
   - an outer shaft (5) for transporting the implant to the target location,
   - an implant capsule (200) for receiving the implant, wherein the implant capsule (200) has a tubular capsule core (201), which surrounds the implant prior to the release,

   characterised in that

   the capsule core (201), at one end (201a) of the capsule core, has a plurality of tabs (203) for fixing the capsule core (201) to the outer shaft (5), which tabs protrude from a tubular portion (202) of the capsule core (201) along an axial direction (A) of the capsule core (201).

2. The catheter device according to claim 1, **characterised in that** the tabs (203) each have two sides (203a, 203b) extended along the axial direction, wherein the two sides (203a, 203b) extend away from one another along the axial direction (A) starting from said tubular portion (202), such that each tab (203) becomes wider accordingly.

3. The catheter device according to claim 1 or 2, **characterised in that** a connection means (300) is fixed to a distal end portion (5a) of the outer shaft (5), via which connection means (300) the tabs (203) are connected, preferably screwed, to the outer shaft (5).

4. The catheter device according to claim 3, **characterised in that** each tab (203) fixed to the connection means (300) engages in an associated recess (301) in the connection means (300), wherein these recesses (301) are formed on a peripheral outer side (300a) of the connection means (300).

5. The catheter device according to claim 4, **characterised in that** the outer side (300a), at a proximal end (300b) of the connection means (300), has a conical portion (300c), wherein the recesses (301) are formed in the conical portion (300c) of the outer side (300a).

6. The catheter device according to claim 4 or 5, **characterised in that** each recess (301) has two flanks (301a, 301b) facing towards one another, which start from a base (301c) of the corresponding recess (301), wherein the recesses (301) taper along the axial direction (A) of the outer shaft (5) towards the tubular portion (202) of the capsule core (201), such that both flanks (301a, 301b) extend towards one another accordingly.

7. The catheter device according to any one of claims 3 to 6, **characterised in that** each tab (203), in a state not fixed to the connection means (300), has a curvature in the peripheral direction (U) of the tubular portion (202).

8. The catheter device according to claims 2, 6 and 7, **characterised in that** each tab (203) fixed to the connection means (300) has a smaller curvature in the peripheral direction (U) than in the state not fixed to the connection means (300), wherein the corresponding tab (203) fixed to the connection means (300) presses with each of its sides (203a, 203b) against an associated flank (301a, 301b) and also the base (301c) of the recess in which the tab (203) is engaged.

9. The catheter device according to claim 8, **characterised in that** said smaller curvature does not disappear.

10. The catheter device according to any one of claims 3 to 9, **characterised in that** the tubular portion (202) bears against a peripheral step (302) of the connection means via edge portions (202b) extending between adjacent tabs (203).

11. The catheter device according to claim 10, **characterised in that** said edge portions (202b) are drawn against the step (302) by the tabs (203) fixed to the connection means (300).

12. The catheter device according to claim 4 or any one of claims 5 to 11 insofar as dependent on claim 4, **characterised in that** the tabs (203) fixed to the connection means (300) are curved starting from the tubular portion (202) towards the base (301c) of their respective associated recesses (301) in the connection means (300).

13. The catheter device according to any one of claims 3 to 12, **characterised in that** the tabs (203) are fixed to the connection element (300) by means of screws (400).

14. The catheter device according to any one of the preceding claims, **characterised in that** the capsule core (201) and/or the connection means (300) are fabricated from a metal, in particular from a steel.

15. The catheter device according to any one of the preceding claims, **characterised in that** the tubular portion (202) of the capsule core (201) has a plurality of parallel slots (204) running along the peripheral direction and also in particular through-openings (205) arranged between adjacent slots (204).

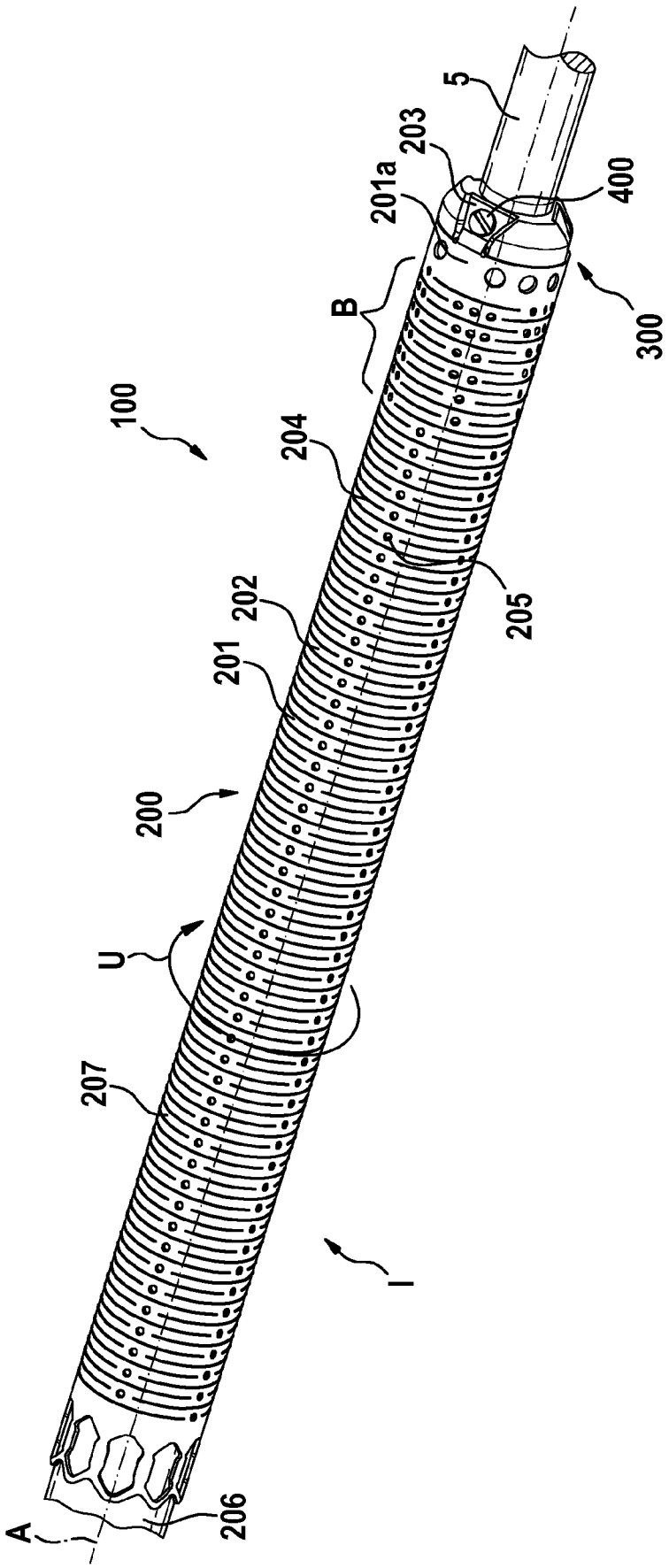

FIG. 1

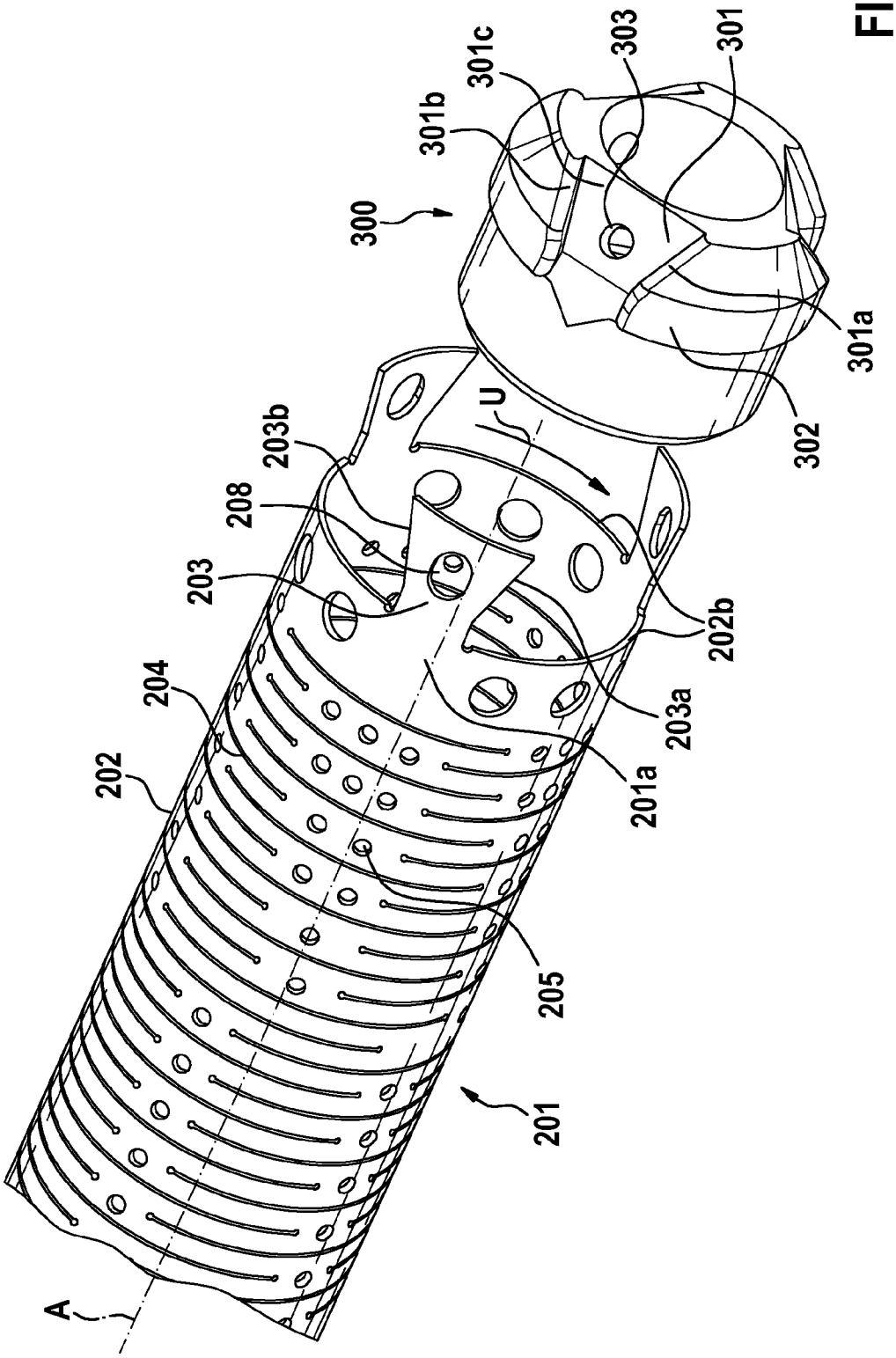
300
301
301a
301b
301c
302
303
201
201a
202
202b
203
203a
203b
204
205
208
A
U

FIG. 2

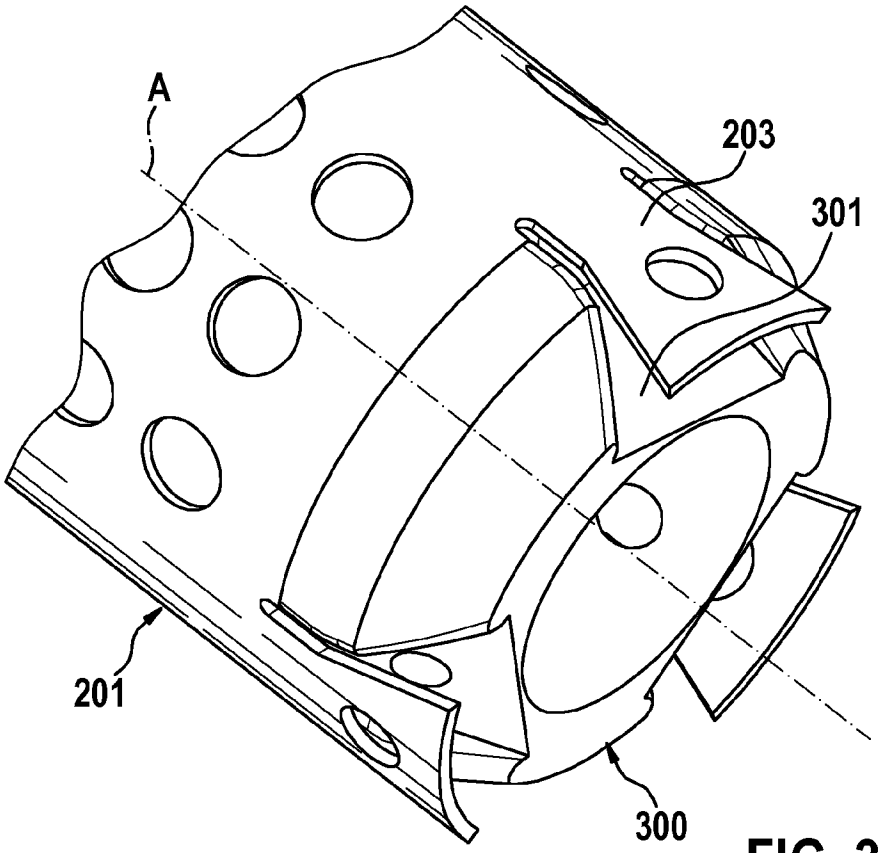

FIG. 3

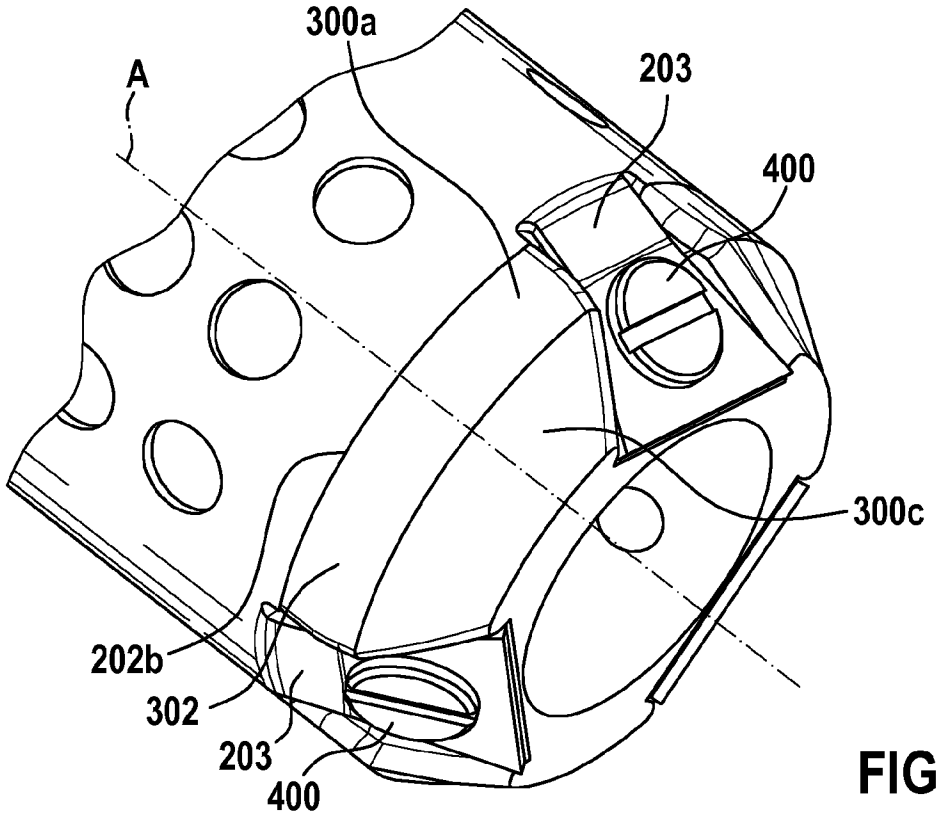

FIG. 4

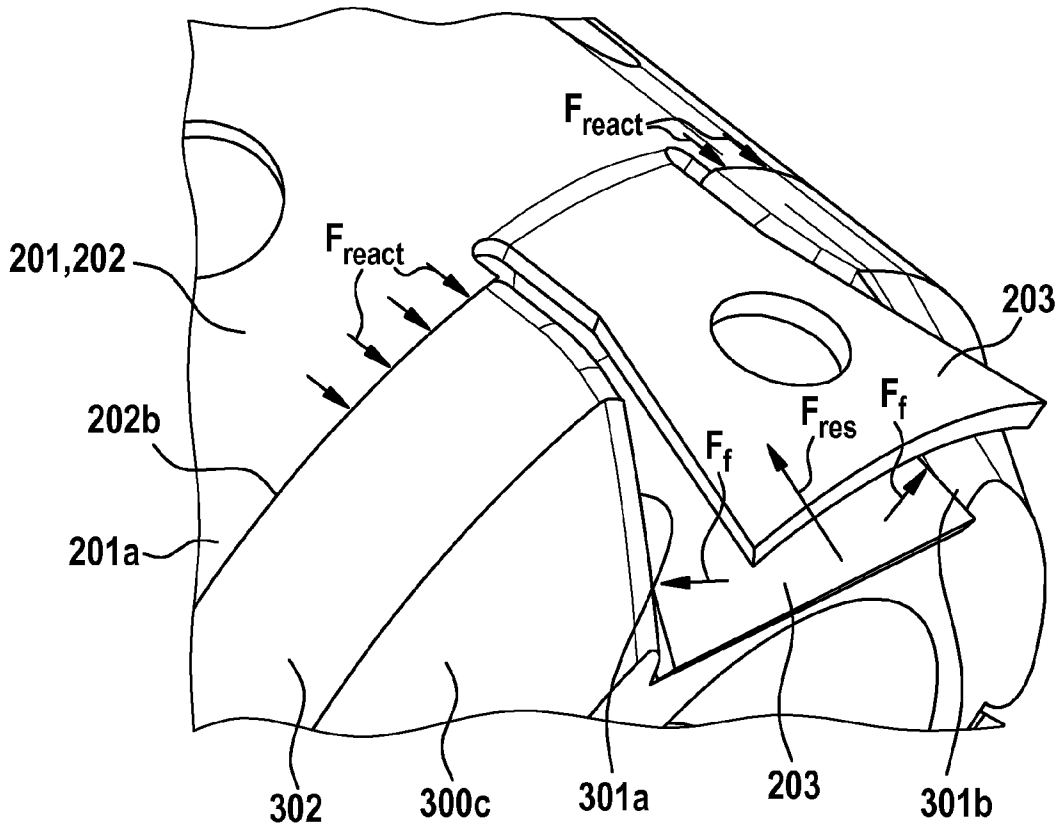
F react
F react
201,202
203
202b
F f
F res
F f
201a
302
300c
301a
203
301b

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/057503

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/966 A61M25/00 A61F2/24
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2013/066883 A1 (MERIT MEDICAL SYSTEMS INC [US]) 10 May 2013 (2013-05-10) paragraphs [0061], [0062], [0067]; figure 4D	1-15
A	US 2006/074477 A1 (BERTHIAUME WILLIAM A [US] ET AL) 6 April 2006 (2006-04-06) paragraph [0059]; figure 2	1-15
A	WO 93/01768 A1 (STEVENS JOHN H [US]) 4 February 1993 (1993-02-04) page 10, line 22 - line 36; figures 1,2	1-15
A	US 2014/324164 A1 (GROSS YOSSI [IL] ET AL) 30 October 2014 (2014-10-30) paragraphs [0204] - [0215]; figures 9B-9E	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
7 April 2017	18/04/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Geuer, Melanie

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/057503

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