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(54) Title: TAVI CATHETER CAPSULE WITH INTERNAL SUPPORT

(57) Abstract: The present invention relates to a catheter system (1) for implanting a prosthetic heart valve (2), comprising: an outer shaft (10), an inner shaft (12), a prosthetic heart valve (2), a capsule (20) connected to a distal end (10a) of the outer shaft (10), wherein the capsule (20) is configured to be displaced with respect to the inner shaft (12) to release the prosthetic heart valve (2) such that the prosthetic heart valve expands from the collapsed state into an expanded state with respect to the radial direction (R), a connector (30) connected to the inner shaft (12), and a carrier (22) connected to the connector (30). According to the present invention, the catheter system (1) further comprises an elongated support member (50) extending in the axial direction (x), wherein the support member (50) is arranged in the internal space (21) of the capsule (20) and connects the connector (30) to a distal end (12a) of the inner shaft (12).

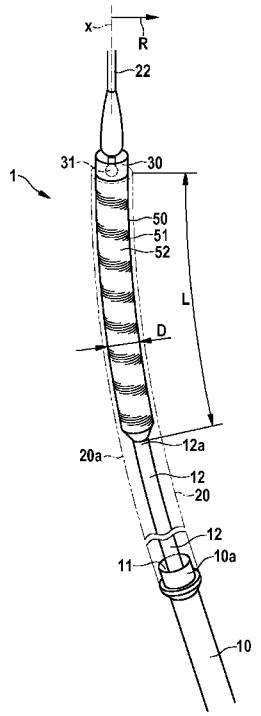


FIG. 2

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TAVI catheter capsule with internal support

The present invention relates to a catheter system for implanting a prosthetic heart valve.

Such a catheter system usually comprises a capsule for receiving the prosthesis when the latter is in a collapsed state. The capsule covers the prosthetic heart valve that is sitting on a carrier connected to an inner shaft of the catheter system while the capsule is connected to an outer shaft. Sliding of the outer shaft with respect to the inner shaft allows to displace the capsule with respect to the inner shaft/carrier to release the prosthetic heart valve. The prosthetic heart valve can be partially released and can be retracted into the capsule for the purpose of re-positioning the prosthesis so that it is situated at a proper implantation site. Reinserting the prosthesis into the capsule is commonly termed re-sheathing and is, e.g., possible by providing a connection of the prosthetic heart valve to a connector connected to the inner shaft of the catheter system.

However, particularly in the aortic arch, such a capsule can collapse or develop a kink under a bending moment and compression loads during a re-sheathing procedure, in which the prosthesis is re-inserted into the capsule so as to reposition the prosthesis with respect to the native heart valve of the patient that is to be replaced by the prosthetic heart valve. Such a kink may occur on the capsule and connector merging area due to the hardness of the connector. Disadvantageously, such a kink severely deteriorates operability of the catheter system.

US 2015/0190092 A1 discloses an electrode catheter, comprising a metal tube in which a spiral slit is formed, wherein the metal tube coupled to a shaft distal end portion constituted by a resin tube having a multi-lumen structure.

Furthermore, also EP 0 688 576 B2 discloses a catheter that comprises an inner tube that has one or more spiral slits in its distal end portion.

US 8,771,344 B2 *inter alia* describes a device for percutaneously repairing a heart valve of a patient including a self-expanding, stented prosthetic heart valve and a repsective delivery system. The delivery system includes a delivery sheath slidably receiving an inner shaft forming a coupling structure. A capsule of the delivery sheath includes a distal segment and a proximal segment. An outer diameter of the distal segment is greater than that of the proximal segment. An area moment of inertia of the distal segment can be greater than an area moment of inertia of the proximal segment. Regardless, an axial length of the distal segment is less than the axial length of the prosthesis. In a loaded state, the prosthesis engages the coupling structure and is compressively retained within the capsule. Thereby, the capsule itself is configured such that it is unlikely to kink when traversing a patient's vasculature, such as when tracking around the aortic arch, and thereby promoting recapturing of the prosthesis.

WO 2019/010303 A1 *inter alia* describes devices, systems and methods that provide improved steerability for delivering a prosthesis to a body location, for example, for delivering a replacement mitral valve to a native mitral valve location. Therein described are a number of features that can improve steerability or release of the prosthesis into the body location.

Based on the above, the problem to be solved by the present invention is to provide a catheter system that allows implantation, particularly a re-sheathing, of a prosthetic heart valve while avoiding a collapse/generation of a kink of the capsule at the same time.

Particularly, a problem to be solved by the present invention is to provide a separate structure besides the capsule itself, that is configured such that it prevents / avoids a kinking of the capsule during intervention; especially in the region of the aortic arch. Said structure is a support structure as defined by the appended claims.

This problem is solved by a catheter system having the features of claim 1. Preferred embodiments are stated in the sub claims and are described herein.

According to claim 1, a catheter system (1) for implanting an implant, comprising:

- an outer shaft (10) extending in an axial direction (x) and surrounding a lumen (11) of the outer shaft (10),
- an inner shaft (12) extending in the axial direction (x), wherein the inner shaft (12) is arranged in said lumen (11) of the outer shaft (10),
- an implant,
- a capsule (20) connected to a distal end (10a) of the outer shaft (10), wherein the capsule (10) extends in the axial direction (x) and surrounds an internal space (21) of the capsule (20), wherein the internal space (21) is configured to receive said implant when the implant is in a collapsed state with respect to a radial direction (R) extending perpendicular to said axial direction (x), wherein the capsule (20) is configured to be displaced with respect to at least the inner shaft (12) in order to release the implant such that the implant expands from the collapsed state into an expanded state with respect to the radial direction (R),
- a connector (30) connected to the inner shaft (12), wherein the connector (30) is configured to connect the implant to the inner shaft (12) when the implant is at least partially arranged in the internal space (21) of the capsule (20),
- a carrier (22) connected to the connector (30), wherein the carrier (22) extends from the connector (30) to a catheter tip (40) of the catheter system (1), wherein the implant is configured to be arranged on the carrier (22) in said collapsed state,

characterized in that

the catheter system (1) comprises an elongated support member (50) extending in the axial direction (x), wherein the support member (50) is arranged in the internal space (21) of the capsule (20) and connects the connector (30) to a distal end (12a) of the inner shaft (12), and wherein the support member (50) comprises an outer diameter (D) that is substantially equal to an inner diameter (D') of the capsule (20) with the proviso that both the support member (50) and the capsule (20) remain relatively moveable to one another at least in the axial direction (x).

With the context of the present invention and throughout the description portion and the appended claims, the term "implant" denotes a structure, object or a means implanted in something else, e.g. in a human or animal body, especially a piece of tissue, prosthetic device, e.g. a prosthetic heart valve, or other structure, object or means implanted in the human or animal body. Particularly, within the context of the present invention the term "implant" is related to a prosthetic heart valve and vice versa. Thus, in certain instances both terms implant and prosthetic heart valve may be used interchangeably with the context of the present invention.

According to the present invention, the catheter system thus *inter alia* comprises an elongated support member extending in the axial direction, wherein the support member is arranged in the internal space of the capsule to support the capsule and prevent the latter from developing a kink, wherein the support member connects the connector to a distal end of the inner shaft. Particularly, the support member is configured to contact and support an inner side of the capsule.

Thus, by using an elongated support member as disclosed herein, the invention advantageously prevents the propagation of a kink in the capsule, particularly during re-sheathing or avoids formation thereof.

In an embodiment of the present invention, the support member is configured to support an inner side of the capsule in such a way that it almost over its entire length not directly contacts an inner surface or an inner side of the capsule, but rather only closely assumes an outer diameter that is only almost equal or only substantially equal to an inner diameter of the capsule itself. This means that support member and capsule are and remain moveable relative to one another in each instance of an intervention, such as a TAVI intervention. This also means that in this embodiment there is defined a sufficient, but small space in between the outer diameter of the support member and the inner diameter of the capsule which also allows for placing one or more layer of a polymer or the like on an inside of the capsule, such as a polymer liner, but not limited thereto, and/or on an outside of the support member, such as a polymer jacket, but not limited thereto, if needed. Such polymer layer are known to the skilled person for *inter alia* reducing friction, e.g. between a support

member and a capsule of the present invention, or e.g. for a fluid sealing, e.g. between a support member and a capsule of the present invention.

With the above context, accordingly, the skilled person understands that also any polymer layer accounts for a diameter of the support member and the capsule.

Further, the skilled artisan will appreciate that with the above configuration of the support member and the capsule, both will be and remain in intimate contact but do not block or hinder each other during any movements relative to one another. Therefore, the skilled artisan readily understands that any expression such as "an equal diameter of outer diameter of the support member and inner diameter of the capsule" and the like is ever used in the sense of being "substantially equal or almost equal" with the proviso that in each instance the support member and the capsule remain moveable relatively to one another during intervention and the like.

In the meaning of the present invention, the notion "distal" refers to portions or components of the system that are remote from the user or physician that handles the catheter system while the notion "proximal" refers to those portions or components that are closer to the user/physician.

Particularly, according to an embodiment, the catheter system is configured for implantation of the prosthetic heart valve by means of transcatheter aortic valve implantation (TAVI), wherein an aortic valve of the heart of the patient is replaced by the prosthetic heart valve through the blood vessels of the patient. Particularly, the prosthetic heart valve can be implanted via a transfemoral approach (via the aortic arch).

With the context of the present invention, also the abbreviations "TAVR" and PAVR", which are commonly known to the skilled artisan, denote a transcatheter aortic valve implantation / replacement / intervention. Thereby, "TAVR" explicitly denotes a transcatheter aortic valve replacement procedure, and „PAVR" explicitly denotes a percutaneous aortic valve replacement.

According to an embodiment of the present invention, the support member is a tubular support member.

Further, according to an embodiment of the present invention, the support member comprises a circumferential (e.g. cylindrical) wall, wherein a plurality of elongated through-openings or slits is formed in the wall. Due to these openings, the tubular support member gains flexibility that allows bending of the support member which eases insertion of the capsule into the aortic arch. In a specific embodiment of the invention, the plurality of elongated through-openings or slits are arranged in a helical manner over the entire length of the support member or almost the entire length of the support member, thereby leaving out the end sections free from the openings. Arranging the plurality of elongated through-openings or slits in a helical manner in particular provides the support member with flexibility, but still yet with radial stiffness.

Further, according to an embodiment of the present invention, the support member is formed out of or comprises a metal, wherein particularly said metal is one of nitinol or stainless steel.

Further, according to an embodiment of the present invention, the support member comprises an outer diameter that is equal to an inner diameter of the capsule. This allows an efficient support of the capsule via a direct contact of the support member to the inner side of the capsule, which inner side faces the support member and prosthetic heart valve arranged on the carrier.

As detailed outlined above “equal” in the above context is to be used in the context of being “substantially equal” so that both support member and capsule remain moveable relative to one another, e.g. in axial direction (x).

In an alternative embodiment of the present invention, the support member is configured to support an inner side of the capsule in such a way that it almost over its entire length not directly contacts an inner surface or an inner side of the capsule, but rather only closely assumes an outer diameter that is only almost equal or substantially equal to an inner

diameter of the capsule itself. Thus, both components support member and capsule will be and remain in intimate contact but do not block or hinder each other during any movements relative to one another.

This means that support member and capsule are and remain moveable relative to one another in each instance of an intervention, such as a TAVI intervention. This also means that in this embodiment there is defined a sufficient, but small space in between the outer diameter of the support member and the inner diameter of the capsule which allows for placing one or more layer of a polymer or the like on an inside of the capsule, such as a polymer liner, but not limited thereto, and/or on an outside of the support member, such as a polymer jacket, but not limited thereto.

Further, according to an embodiment of the present invention, the support member comprises a length in the axial direction.

Particularly, according to an embodiment this length is in the range from 10 mm to 300 mm, preferably in the range from 50 mm to 70 mm.

This guarantees that the support member can extend along the entire aortic arch during a re-sheathing process, so that the capsule can be efficiently supported in a significantly curved vessel section.

Further, according to an embodiment of the present invention, the length of the support member is equal to a length of the carrier in the axial direction or of the prosthetic heart valve in the axial direction multiplied with a factor that is in the range from 2 to 2.5. Particularly, the length of the carrier in the axial direction corresponds to the extension of the carrier in the axial direction between the connector and a proximal end of the catheter tip.

Further, according to an embodiment of the present invention, the prosthetic heart valve comprises a self-expandable stent and a heart valve connected to the stent.

Further, according to an embodiment of the present invention, the implant, e.g. a prosthetic heart valve, comprises a self-expanding stent, such as a Nitinol stent, and an artificial heart valve structure connected to the said stent.

In an alternative embodiment of the present invention, the implant, e.g. a prosthetic heart valve, comprises an expandable stent, preferably a mechanically expandable stent, in particular a balloon-expandable stent, such as a CoCr stent, and an artificial heart valve structure connected to said stent.

In an alternative embodiment of the present invention, the implant, e.g. a prosthetic heart valve, comprises both a self-expanding stent component, such as a Nitinol stent, and an expandable stent component, preferably a mechanically expandable stent component, in particular a balloon-expandable stent component, such as a CoCr stent, and an artificial heart valve structure connected to either both stent components or the only one of them.

Further, according to an embodiment of the present invention, the stent comprises several fastening elements, wherein each fastening element is configured to engage with an associated recess or an associated protrusion of the connector to connect the stent and therewith the prosthetic heart valve to the inner shaft when the prosthetic heart valve is at least partially arranged in the internal space of the capsule.

Further, according to an embodiment of the present invention, the stent comprises several fastening elements, wherein each fastening element is configured to engage with a connecting means of the connector to connect the stent and therewith the prosthetic heart valve to the inner shaft when the prosthetic heart valve is at least partially arranged in the internal space of the capsule.

Particularly, such connecting means is a mechanical holding means. More particularly, such mechanical holding means is an expandable mechanical arm-structure.

With the context of the present invention, in an embodiment the connector comprises at least two expandable mechanical arm-structures. In an embodiment, the connector comprises at least three expandable mechanical arm-structures.

Further, according to an embodiment of the present invention, the capsule is configured to be displaced with respect to the inner shaft or carrier between a first position, in which the capsule completely covers the stent of the prosthetic heart valve when the prosthetic heart valve is arranged on the carrier in the collapsed state of the prosthetic heart valve, to an intermediary position, in which the capsule covers the fastening elements so that the prosthetic heart valve is partially expanded in the radial direction but still connected to the inner shaft via the connector.

Further, according to an embodiment of the present invention, the capsule is configured to be displaced with respect to the inner shaft or carrier from the intermediary position to a second position, in which the capsule exposes the fastening elements of the stent, so that the fastening elements disengage with the connector due to the self-expanding property of the stent and the prosthetic heart valve to assume the fully expanded state.

Furthermore, the inner shaft, support member, carrier and catheter tip can form a continuous guide wire lumen for receiving a guide wire for guiding the outer and inner shaft upon implantation of the prosthetic heart valve.

In the following, features of the present invention are described in detail with reference to the Figures which show embodiments of the catheter system according to the present invention, wherein:

Fig. 1 shows a schematic view of a catheter system according to the present invention, wherein the capsule extends in the aortic arch;

Fig. 2 shows a schematic view of the catheter system of Fig. 1 in a linear state in which the capsule and support member are not bent;

Fig. 3 shows the supporting element on the inner shaft; and

Fig. 4 shows the supporting element on the inner shaft in the capsule with the connector element and the stent.

Fig. 1 shows in conjunction with Figs. 2 and 3 a catheter system 1 for implanting a prosthetic heart valve 2. The heart valve 2 is thereby not shown, but can be exemplarily derived from Fig. 4; 60 and 61.

The catheter system 1 comprises an outer shaft 10 extending in an axial direction x and surrounding a lumen 11 of the outer shaft 10, an inner shaft 12 extending in the axial direction x, wherein the inner shaft is arranged in said lumen 11 of the outer shaft 10, and a prosthetic heart valve (2). The heart valve 2 is thereby not shown, but can be exemplarily derived from Fig. 4; 60 and 61.

The system 1 further comprises a flexible capsule 20 connected to a distal end 10a of the outer shaft 10, wherein the capsule 10 extends in the axial direction x and surrounds an internal space 21 of the capsule 20, wherein the internal space 21 is configured to receive said prosthetic heart valve 2 when the prosthetic heart valve 2 is in a collapsed state with respect to a radial direction R extending perpendicular to said axial direction x. Furthermore, the capsule 20 is configured to be displaced with respect to the inner shaft 12 along the axial direction x to release the prosthetic heart valve 2 such that the prosthetic heart valve 2 expands from the collapsed state into an expanded state with respect to the radial direction R to replace a native heart valve H at the implantation site.

The system 1 further comprises a connector 30 with an associated recess 31 connected to the inner shaft 12, wherein the connector 30 is configured to connect the prosthetic heart valve 2 to the inner shaft 12 when the prosthetic heart valve 2 is at least partially arranged in the internal space 21 of the capsule 20. Furthermore, the system 1 comprises a carrier 22 connected to the connector 30, wherein the carrier 22 extends from the connector 30 to a proximal end 40b of an (e.g. atraumatic) catheter tip 40 of the catheter system 1, wherein the prosthetic heart valve 2 is configured to be arranged on the carrier 22 in said collapsed state.

In order to avoid a collapse or the formation of a kink in the capsule 20 during a re-sheathing of a partially released prosthetic heart valve 2 during which re-sheathing the capsule 20 is bent due to being arranged in the aortic arch A (cf. Fig. 1), the system 1 comprises an elongated support member 50 extending in the axial direction x, wherein the support member is arranged in the internal space 21 of the capsule 20 and configured to support the capsule from within, wherein the support member 50 connects the connector 30 to a distal end 12a of the inner shaft 12. Thus, compared to known systems, the catheter system 1 according to the present invention comprises a prolonged capsule that is supported by an elongated, particularly tubular support member 50, that is preferably configured to extend along the whole aortic arch A as shown in Fig. 1 to limit the risk of a kink formation in the capsule during re-sheathing of the prosthesis 2.

Preferably, to provide an optimal support, the support member 50 comprises an outer diameter D that is equal (in the sense of "substantially equal"; cf. above) to an inner diameter D' of the capsule 20. In this way, the support member can contact an inner side 20a of the capsule 20 over a large area to prevent formation of kinks. According to a preferred embodiment, the length L of the support member 50 in the axial direction x is in the range from 10 mm to 300 mm, preferably in the range from 50 mm to 70 mm. Furthermore, preferably, the length L of the support member 50 is equal to a length L' of the carrier 22 in the axial direction x or of the prosthetic heart valve 2 in the axial direction x times a factor that is in the range from 2 to 2.5.

Particularly, as indicated in Fig. 3, the support member 50 comprises a circumferential (e.g. cylindrical) wall 51, wherein a plurality of elongated through-openings 52, preferably in a helical manner, is formed in the wall, particularly to provide flexibility to the wall 51/member 50.

Furthermore, as shown in Fig. 4, the prosthetic heart valve 2 comprises a self-expandable stent 60 and a heart valve connected to the stent 60. In the picture of Fig. 4, the heart valve in the stent 60 is omitted. The heart valve *per se* can be formed from a biological tissue. Particularly, the stent 60 comprises a plurality of fastening elements 61 that are each configured to engage with an associated recess 31 of the connector 30 (cf. Fig. 2) to con-

nect the stent and therewith the prosthetic heart valve 2 to the inner shaft 12 when the prosthetic heart valve 2 is at least partially arranged in the internal space 21 of the capsule 20.

Particularly, the capsule 20 is configured to be displaced with respect to the inner shaft 12 or carrier 22 between a first position, in which the capsule 20 completely covers the stent of prosthetic heart valve 2 when the prosthetic heart valve 2 is arranged on the carrier 22 in the collapsed state, to an intermediary position in which the capsule 20 covers the fastening elements engaging with the recesses so that the prosthetic heart valve 2 is partially expanded in the radial direction R but still connected to the inner shaft 12 via the fastening elements and connector 30 (not shown). This connection allows to reinsert the prosthetic heart valve 2 into the internal space 21 of the capsule 20 which is termed re-sheathing, wherein the support member 50 prevents the capsule 20 from collapsing due to a bending moment and compression loads introduced into the capsule during the re-sheathing procedure.

Once the prosthetic heart valve 2 is finally positioned, the capsule 20 is configured to be displaced from the intermediary position to a second position with regard to the carrier 22/ inner shaft 12, in which second position the capsule 20 exposes the fastening elements of the stent so that the fastening elements disengages with the recesses 31 of the connector 30 due to a self-expansion of the stent which allows the prosthetic heart valve 2 to assume its final expanded state.

In an alternative embodiment, once the prosthetic heart valve 2 is finally positioned, the capsule 20 is configured to be displaced from the intermediary position to a second position with regard to the carrier 22/ inner shaft 12, in which second position the capsule 20 exposes the fastening elements of the stent and connecting means still holding the stent so that the connecting means must be actively detached, e.g. by an actuator mechanism, from the fastening elements in order to allow for a controlled release of the prosthetic heart valve 2 at the desired site of implantation, where the prosthetic heart valve 2 is allowed to assume its final expanded state.

In view of all the foregoing disclosure, further embodiments of the invention are reflected by the following consecutively numbered embodiments:

1. A catheter system (1) for implanting a prosthetic heart valve (2), comprising:
   - an outer shaft (10) extending in an axial direction (x) and surrounding a lumen (11) of the outer shaft (10),
   - an inner shaft (12) extending in the axial direction (x), wherein the inner shaft (12) is arranged in said lumen (11) of the outer shaft (10),
   - a prosthetic heart valve (2),
   - a capsule (20) connected to a distal end (10a) of the outer shaft (10), wherein the capsule (10) extends in the axial direction (x) and surrounds an internal space (21) of the capsule (20), wherein the internal space (21) is configured to receive said prosthetic heart valve (2) when the prosthetic heart valve (2) is in a collapsed state with respect to a radial direction (R) extending perpendicular to said axial direction (x), wherein the capsule (20) is configured to be displaced with respect to the inner shaft (12) to release the prosthetic heart valve (2) such that the prosthetic heart valve (2) expands from the collapsed state into an expanded state with respect to the radial direction (R),
   - a connector (30) connected to the inner shaft (12), wherein the connector (30) is configured to connect the prosthetic heart valve (2) to the inner shaft (12) when the prosthetic heart valve (2) is at least partially arranged in the internal space (21) of the capsule (20),
   - a carrier (22) connected to the connector (30), wherein the carrier (22) extends from the connector (30) to a catheter tip (40) of the catheter system (1), wherein the prosthetic heart valve (2) is configured to be arranged on the carrier (22) in said collapsed state,

   characterized in that

   the catheter system (1) comprises an elongated support member (50) extending in the axial direction (x), wherein the support member (50) is arranged in the internal space (21) of the capsule (20) and connects the connector (30) to a distal end (12a) of the inner shaft (12).

2. The catheter system according to embodiment 1, wherein the support member (50) is a tubular support member (50).

3. The catheter system according to embodiment 1 or 2, wherein the support member (50) comprises a circumferential wall (51), wherein a plurality of elongated through-openings (52) is formed in the wall (51).

4. The catheter system according to one of the preceding embodiments, wherein the support member (50) is formed out of or comprise a metal, wherein particularly said metal is one of: xxx.

5. The catheter system according to one of the preceding embodiments, wherein the support member (50) comprises an outer diameter (D) that is equal to an inner diameter (D') of the capsule (20).

6. The catheter system according to one of the preceding embodiments, wherein the support member (50) comprises a length (L) in the axial direction (x).

7. The catheter system according to embodiment 6, wherein the length (L) is in the range from 10 mm to 300 mm, preferably in the range from 50 mm to 70 mm.

8. The catheter system according to embodiment 6 or 7, wherein the length (L) of the support member (50) is equal to a length (L') of the carrier (22) in the axial direction (x) or of the prosthetic heart valve (2) in the axial direction (x) times a factor that is in the range from 2 to 2.5.

9. The catheter system according to one of the preceding embodiments, wherein the prosthetic heart valve (2) comprises a self-expandable stent (60) and a heart valve connected to the stent (60).

10. The catheter system according to embodiment 9, wherein the stent (60) comprises a plurality of fastening elements (61), wherein each fastening element (61) is

configured to engage with an associated recess (31) of the connector (30) to connect the stent (60) and therewith the prosthetic heart valve (2) to the inner shaft (12) when the prosthetic heart valve (2) is at least partially arranged in the internal space (21) of the capsule (20).

11. The catheter system according to embodiment 10, wherein the capsule (20) is configured to be displaced between a first position in which the capsule (20) completely covers the stent (60) of prosthetic heart valve (2) when the prosthetic heart valve (2) is arranged on the carrier (22) in the collapsed state to an intermediary position in which the capsule (20) covers the fastening elements (60) so that the prosthetic heart valve (2) is partially expanded in the radial direction (R) but still connected to the inner shaft (12) via the connector (30).

12. The catheter system according to embodiment 11, wherein the capsule (20) is configured to be displaced from the intermediary position to a second position in which the capsule (20) exposes the fastening elements (61) so that fastening elements (61) disengages with the recesses (31) of the connector (31) and allow the prosthetic heart valve (2) to assume the expanded state.

Alternatively or additionally, in view of all the foregoing disclosure, the present invention comprises the following consecutively numbered embodiments:

13. A catheter system (1) for implanting an implant, comprising:
    - an outer shaft (10) extending in an axial direction (x) and surrounding a lumen (11) of the outer shaft (10),
    - an inner shaft (12) extending in the axial direction (x), wherein the inner shaft (12) is arranged in said lumen (11) of the outer shaft (10),
    - an implant,
    - a capsule (20) connected to a distal end (10a) of the outer shaft (10), wherein the capsule (10) extends in the axial direction (x) and surrounds an internal space (21) of the capsule (20), wherein the internal space (21) is configured to receive said implant when the implant is in a collapsed state with respect to a radial

direction (R) extending perpendicular to said axial direction (x), wherein the capsule (20) is configured to be displaced with respect to at least the inner shaft (12) in order to release the implant such that the implant expands from the collapsed state into an expanded state with respect to the radial direction (R),

- a connector (30) connected to the inner shaft (12), wherein the connector (30) is configured to connect the implant to the inner shaft (12) when the implant is at least partially arranged in the internal space (21) of the capsule (20),
- a carrier (22) connected to the connector (30), wherein the carrier (22) extends from the connector (30) to a catheter tip (40) of the catheter system (1), wherein the implant is configured to be arranged on the carrier (22) in said collapsed state,

characterized in that

the catheter system (1) comprises an elongated support member (50) extending in the axial direction (x), wherein the support member (50) is arranged in the internal space (21) of the capsule (20) and connects the connector (30) to a distal end (12a) of the inner shaft (12), and wherein the support member (50) comprises an outer diameter (D) that is substantially equal to an inner diameter (D') of the capsule (20) with the proviso that both the support member (50) and the capsule (20) remain relatively moveable to one another at least in the axial direction (x).

14. The catheter system according to embodiment 13, wherein the implant is a prosthetic heart valve (2).

With the context of the present invention and throughout the description portion and the appended claims, the term "implant" denotes a structure, object or a means implanted in something else, e.g. in a human or animal body, especially a piece of tissue, prosthetic device, e.g. a prosthetic heart valve, or other structure, object or means implanted in the human or animal body. Particularly, within the context of the present invention the term "implant" is related to a prosthetic heart valve and vice versa. Thus, in certain instances both terms implant and prosthetic heart valve may be used interchangeably with the context of the present invention.

15. The catheter system according to embodiment 13 or 14, wherein the support member (50) is a tubular support member (50).

16. The catheter system according to one of the embodiments 13 to 15, wherein the support member (50) comprises a circumferential wall (51), wherein a plurality of elongated through-openings (52) is formed in the wall (51).

17. The catheter system according to one of the embodiments 13 to 16, wherein the support member (50) is formed out of or comprises a metal, wherein particularly said metal is one of nitinol or stainless steel.

18. The catheter system according to one of the embodiments 13 to 17, wherein the support member (50) comprises a length (L) in the axial direction (x).

19. The catheter system according to embodiment 18, wherein the length (L) is in the range from 10 mm to 300 mm, preferably in the range from 50 mm to 70 mm.

20. The catheter system according to embodiment 18 or 19, wherein the length (L) of the support member (50) is equal to a length (L') of the carrier (22) in the axial direction (x) or of the implant in the axial direction (x) times a factor that is in the range from 2 to 2.5.

21. The catheter system according to one of the embodiments 13 to 20, wherein the implant comprises a self-expanding stent (60) and an artificial heart valve structure connected to the stent (60).

With the context of the present invention the expression "artificial heart valve structure" denotes any man-made heart valve structure that distinguishes from a native heart valve structure *per se*. For instance, such artificial heart valve structure may be made from porcine or bovine pericardium, but also made from a polymeric material or the like.

22. The catheter system according to one of the embodiments 13 to 20, wherein the implant comprises an expandable stent, preferably a mechanically expandable stent, in particular a balloon-expandable stent, and an artificial heart valve structure connected to the stent.

23. The catheter system according to embodiment 21 or 22, wherein the stent comprises a plurality of fastening elements, wherein each fastening element is configured to engage with an associated recess (31) or an associated protrusion of the connector (30) to connect the stent and therewith the implant to the inner shaft (12) when the implant is at least partially arranged in the internal space (21) of the capsule (20).

24. The catheter system according to embodiment 21 or 22, wherein the stent (60) comprises a plurality of fastening elements (61), wherein each fastening element (61) is configured to engage with an associated connecting means of the connector (30) to connect the stent (60) and therewith the implant to the inner shaft (12) when the implant is at least partially arranged in the internal space (21) of the capsule (20).

25. The catheter system according to embodiment 21 or 22, wherein the stent (60) comprises a plurality of fastening elements (61), wherein each fastening element (61) is configured to engage with an associated connecting means of the connector (30) to connect the stent (60) and therewith the implant to the inner shaft (12) when the implant is arranged fully outside of the capsule (20).

26. The catheter system according to embodiment 24 or 25, wherein the connecting means of the connector (30) is configured such that it allows for a controlled release mechanism of the implant.

27. The catheter system according to embodiment 26, wherein the connecting means is a mechanical holding means for the fastening elements (61) of the stent (60).

28. The catheter system according to embodiment 27, wherein the mechanical holding means is an expandable mechanical arm-structure that is configured for connecting

and releasing the fastening elements of the stent, particularly at least two expandable mechanical arm-structures, in particular at least three expandable mechanical arm-structures.

29. The catheter system according to any one of embodiments 23 to 28, wherein the capsule (20) is configured to be displaced between a first position in which the capsule (20) completely covers the stent (60) of the implant when the implant is arranged on the carrier (22) in the collapsed state to an intermediary position in which the capsule (20) covers the fastening elements (60) so that the implant is partially expanded in the radial direction (R) but still connected to the inner shaft (12) via the connector (30).

30. The catheter system according to embodiment 29, wherein the capsule (20) is configured to be displaced from the intermediary position to a second position in which the capsule (20) exposes the fastening elements (61) so that fastening elements (61) disengages with either the recesses (31) or the connecting means of the connector (30), the latter preferably in a controlled manner, and so to allow the prosthetic heart valve (2) to assume the expanded state.

31. The catheter system according to embodiment 29, further comprising an actuator means configured for releasing the implant in a controlled manner, and wherein the capsule (20) is configured to be displaced from the intermediary position to a second position in which the capsule (20) exposes the fastening elements (61) so that fastening elements (61) disengages with either the recesses (31) or the connecting means of the connector (30) when actuating said actuator means, and so to allow the implant to assume the expanded state in a controlled manner.

Reference List

1	catheter system
2	prosthetic heart valve
10	outer shaft
10a	distal end
11	lumen
12	inner shaft
20	flexible capsule
21	internal space
22	carrier
30	connector
31	associated recess
40	catheter tip
40b	proximal end
50	tubular support member
51	wall
52	elongated through-openings
60	stent
61	fastening element

Claims

1. A catheter system (1) for implanting an implant, comprising:
   - an outer shaft (10) extending in an axial direction (x) and surrounding a lumen (11) of the outer shaft (10),
   - an inner shaft (12) extending in the axial direction (x), wherein the inner shaft (12) is arranged in said lumen (11) of the outer shaft (10),
   - an implant,
   - a capsule (20) connected to a distal end (10a) of the outer shaft (10), wherein the capsule (10) extends in the axial direction (x) and surrounds an internal space (21) of the capsule (20), wherein the internal space (21) is configured to receive said implant when the implant is in a collapsed state with respect to a radial direction (R) extending perpendicular to said axial direction (x), wherein the capsule (20) is configured to be displaced with respect to at least the inner shaft (12) in order to release the implant such that the implant expands from the collapsed state into an expanded state with respect to the radial direction (R),
   - a connector (30) connected to the inner shaft (12), wherein the connector (30) is configured to connect the implant to the inner shaft (12) when the implant is at least partially arranged in the internal space (21) of the capsule (20),
   - a carrier (22) connected to the connector (30), wherein the carrier (22) extends from the connector (30) to a catheter tip (40) of the catheter system (1), wherein the implant is configured to be arranged on the carrier (22) in said collapsed state,

   characterized in that

   the catheter system (1) comprises an elongated support member (50) extending in the axial direction (x), wherein the support member (50) is arranged in the internal space (21) of the capsule (20) and connects the connector (30) to a distal end (12a) of the inner shaft (12), and wherein the support member (50) comprises an outer diameter (D) that is substantially equal to an inner diameter (D') of the capsule (20) with the proviso that both the support member (50) and the capsule (20) remain relatively moveable to one another at least in the axial direction (x).

2. The catheter system according to claim 1, wherein the implant is a prosthetic heart valve (2).

3. The catheter system according to claim 1 or 2, wherein the support member (50) is a tubular support member (50).

4. The catheter system according to one of the preceding claims, wherein the support member (50) comprises a circumferential wall (51), wherein a plurality of elongated through-openings (52) is formed in the wall (51).

5. The catheter system according to one of the preceding claims, wherein the support member (50) is formed out of or comprises a metal, wherein particularly said metal is one of nitinol or stainless steel.

6. The catheter system according to one of the preceding claims, wherein the support member (50) comprises a length (L) in the axial direction (x).

7. The catheter system according to claim 6, wherein the length (L) is in the range from 10 mm to 300 mm, preferably in the range from 50 mm to 70 mm.

8. The catheter system according to claim 6 or 7, wherein the length (L) of the support member (50) is equal to a length (L') of the carrier (22) in the axial direction (x) or of the implant in the axial direction (x) times a factor that is in the range from 2 to 2.5.

9. The catheter system according to one of the preceding claims, wherein the implant comprises a self-expanding stent (60) and an artificial heart valve structure connected to the stent (60).

10. The catheter system according to one of the claims 1 to 8, wherein the implant comprises an expandable stent, preferably a mechanically expandable stent, in

particular a balloon-expandable stent, and an artificial heart valve structure connected to the stent.

11. The catheter system according to claim 9 or 10, wherein the stent comprises a plurality of fastening elements, wherein each fastening element is configured to engage with an associated recess (31) or an associated protrusion of the connector (30) to connect the stent and therewith the implant to the inner shaft (12) when the implant is at least partially arranged in the internal space (21) of the capsule (20).

12. The catheter system according to claim 9 or 10, wherein the stent (60) comprises a plurality of fastening elements (61), wherein each fastening element (61) is configured to engage with an associated connecting means of the connector (30) to connect the stent (60) and therewith the implant to the inner shaft (12) when the implant is at least partially arranged in the internal space (21) of the capsule (20).

13. The catheter system according to claim 9 or 10, wherein the stent (60) comprises a plurality of fastening elements (61), wherein each fastening element (61) is configured to engage with an associated connecting means of the connector (30) to connect the stent (60) and therewith the implant to the inner shaft (12) when the implant is arranged fully outside of the capsule (20).

14. The catheter system according to claim 12 or 13, wherein the connecting means of the connector (30) is configured such that it allows for a controlled release mechanism of the implant.

15. The catheter system according to claim 14, wherein the connecting means is a mechanical holding means for the fastening elements (61) of the stent (60).

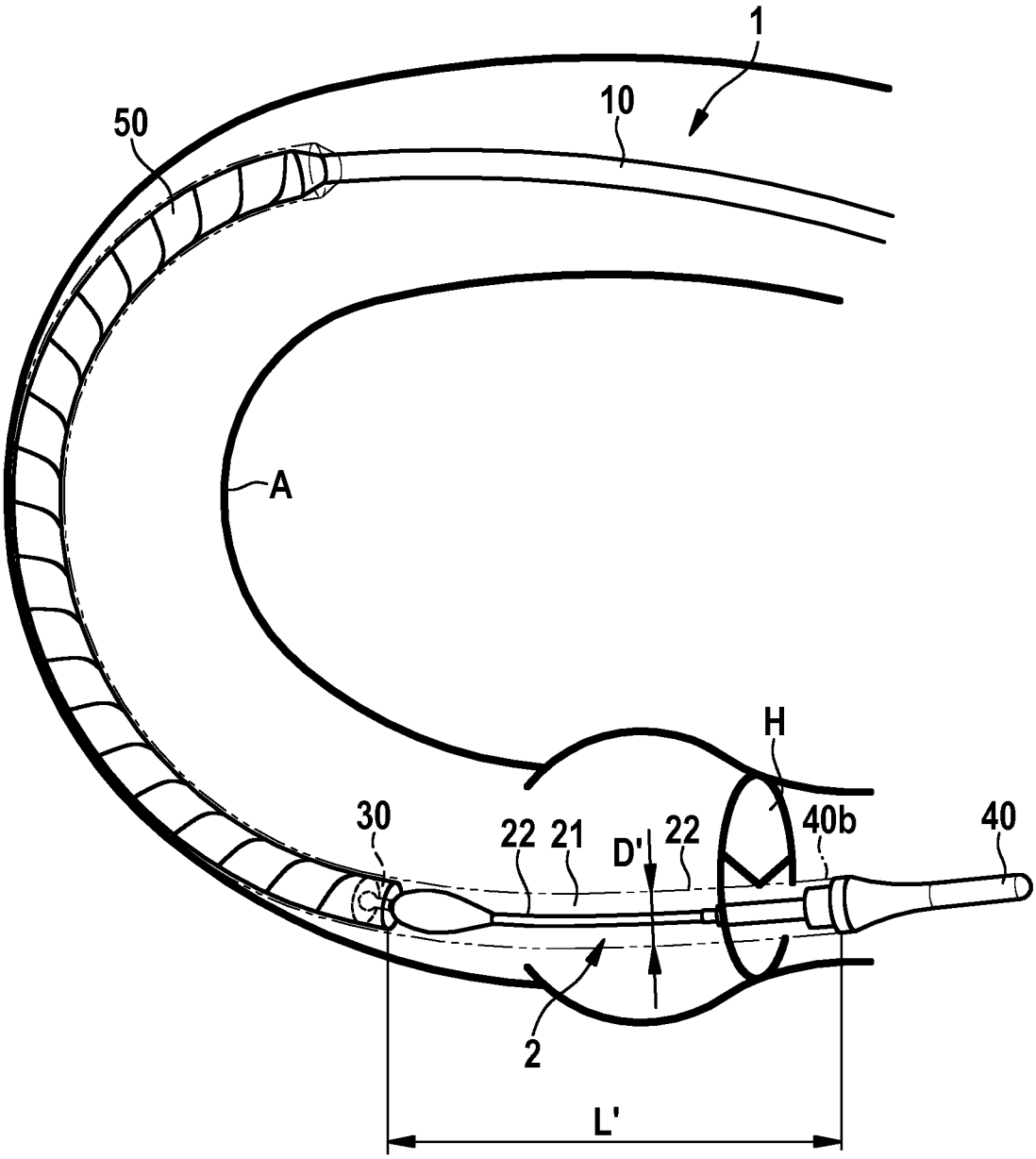


FIG. 1

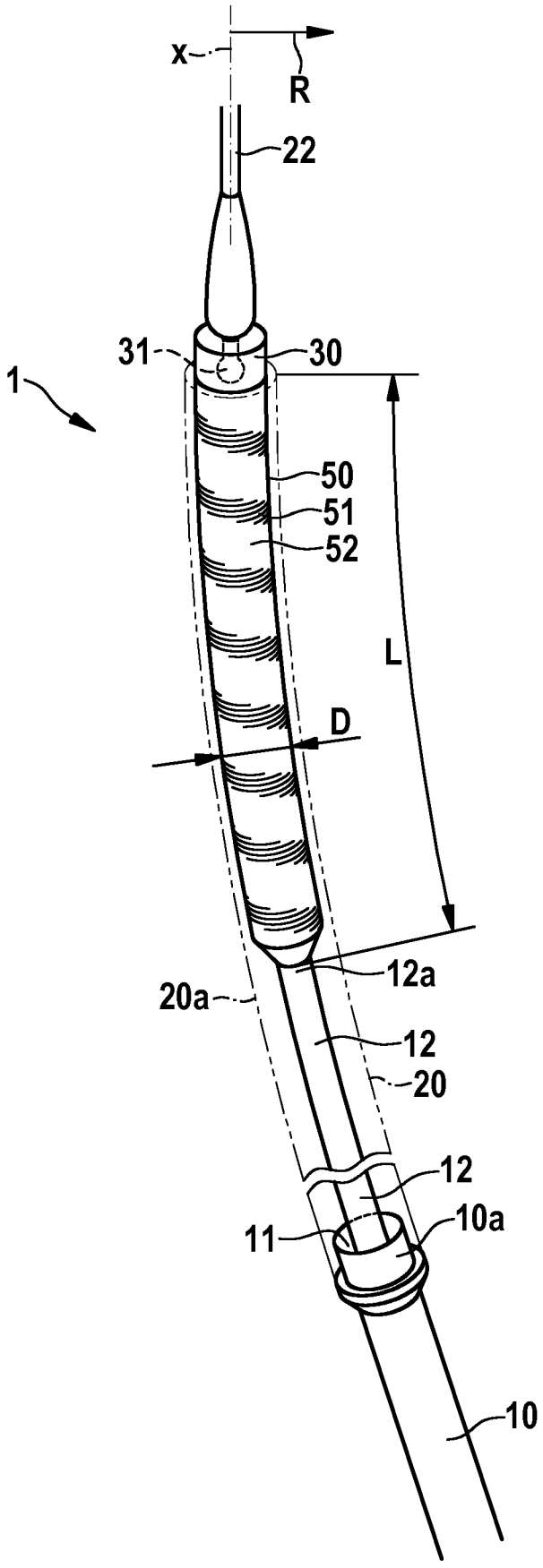


FIG. 2

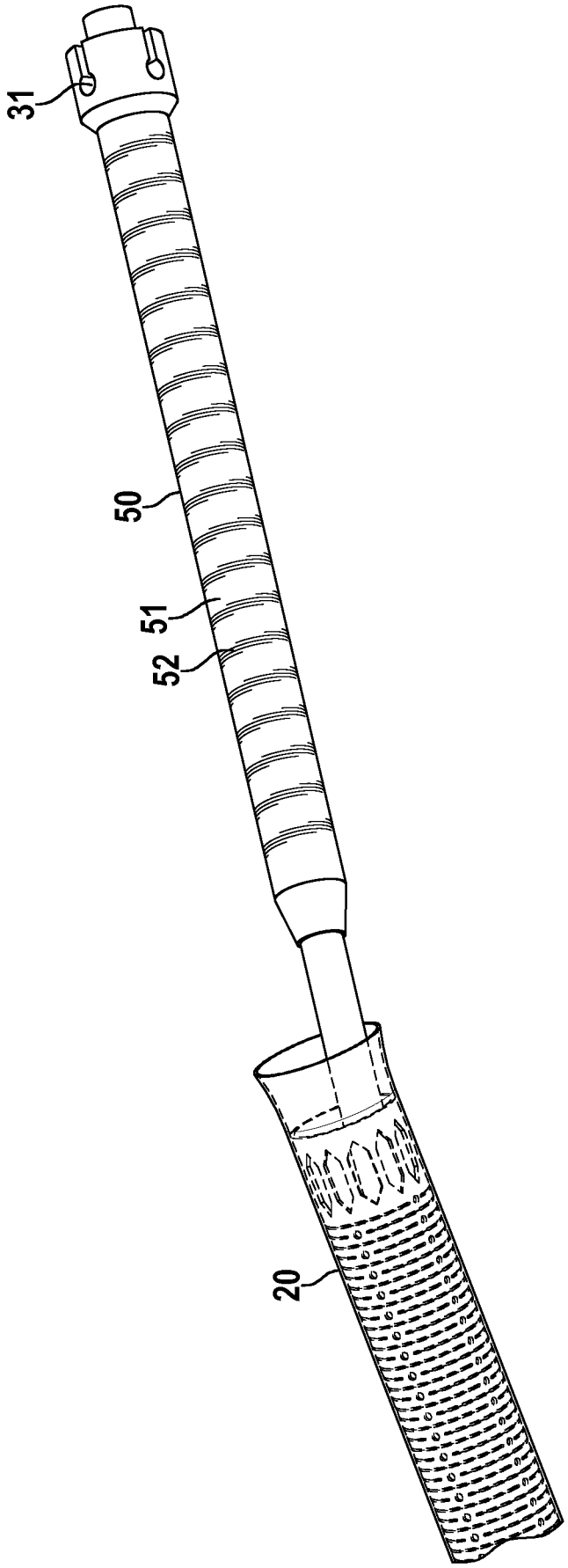


FIG. 3

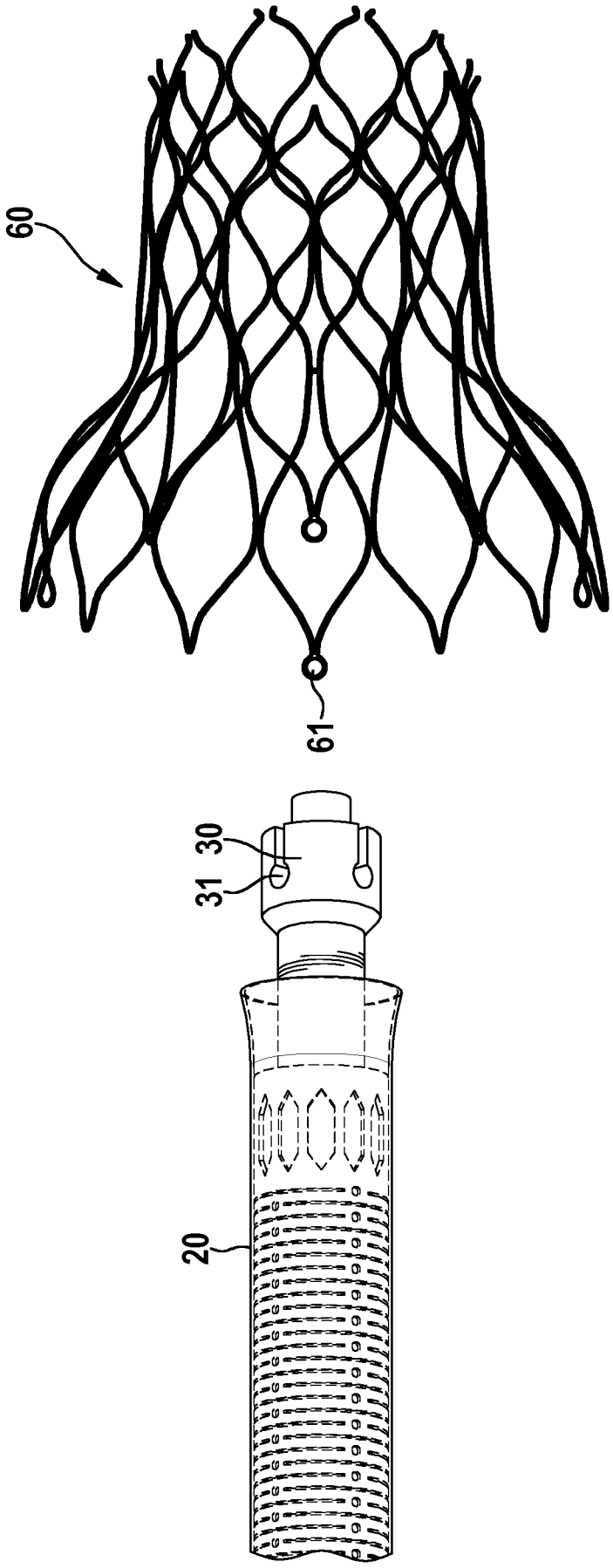


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2019/078204

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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

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.
X,P	WO 2019/010303 A1 (EDWARDS LIFESCIENCES CORP [US]) 10 January 2019 (2019-01-10) paragraph [0107] - paragraph [0126]; figures 4-6a paragraph [0137]; figures 6b, 13	1-6,9-15
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 January 2020	21/01/2020

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2019/078204

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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1

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