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(54) **Title:** CATHETER DEVICE COMPRISING SENSOR TECHNOLOGY FOR DETECTING A LEAKAGE

(57) **Abstract:** The present invention relates to a catheter device (1) for implanting a medical implant, in particular a prosthetic heart valve, particularly an aortic valve prosthesis (10), comprising: a medical implant, in particular a prosthetic heart valve, particularly an aortic valve prosthesis (10) comprising an artificial valve (12), and a connector (3) or a force-expandable holding means for holding the medical implant, particularly prosthetic heart valve, particularly the aortic valve prosthesis. According to the present invention, the catheter device (1) further comprises a heating element (S1) and a temperature sensor (S2) for detecting a leakage of the medical implant, particularly a paravalvular leakage of the prosthetic heart valve, particularly the aortic valve prosthesis (10), wherein the heating element (S1) and the temperature sensor (S2) are arranged on a distal end section (1a) of the catheter device (1).

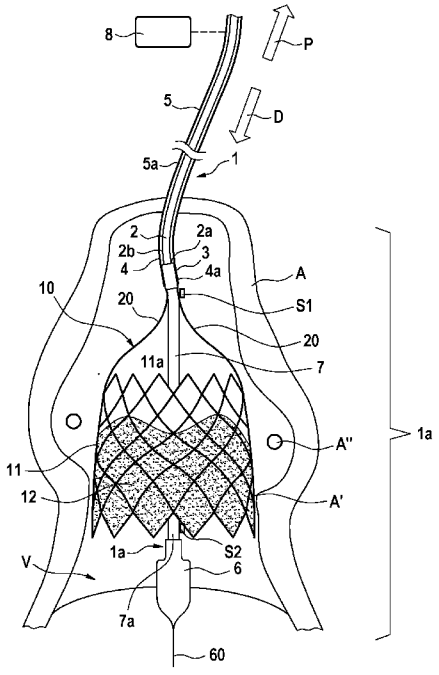

FIG. 2

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Catheter device comprising sensor technology for detecting a leakage

A leakage of a medical implant, particularly a paravalvular leakage (PVL), is one of the most important complications of medical replacement therapies, particularly of a heart valve replacement therapy such as transcatheter aortic valve implantation (TAVI) or transcatheter aortic valve replacement (TAVR), respectively, that has to be prevented or avoided. For instance, in such a TAVI / TAVR procedure a heart valve prosthesis 10 comprising a stent 11 carrying an artificial valve 12 (e.g. formed out of a biological tissue such as porcine or bovine pericardium) is implanted in the region of the annulus A' of the failed native aortic valve 13. Particularly, the implantation can be conducted via one of the following accesses: transfemoral (in the upper leg), transapical (through the wall of the heart), subclavian (beneath the collar bone), direct aortic (through a minimally invasive surgical incision into the aorta), transcarotid (through carotid artery), and transcaval (from a temporary hole in the aorta near the belly button through a vein in the upper leg).

Thus, a common therapy to treat severe aortic valve stenosis (narrowing of the aortic valve) involves implanting an artificial heart valve into the annulus of the native aortic valve. Typically, such artificial heart valves comprise a compressable and expandable frame structure such as a stent that is coupled to valve leaflets or cusps from bovine or porcine pericardium (being, e.g., dry) or a synthetic material.

As a less invasive alternative to open heart surgery, transcatheter aortic valve implantation (TAVI) or transcatheter aortic valve replacement (TAVR) or percutaneous aortic valve replacement (PAVR) has become a widely used procedure to implant a replacement heart valve in order to treat aortic valve disease; e.g. aortic stenosis. In this procedure, a catheter harboring the compressed stent with the artificial valve comprising leaflets and optionally further comprising a skirt element is advanced through the patient's arterial system via the

aorta to its final position in the native valve annulus and expanded; either by actuating a force-expandable means such as a balloon or due to its self-expanding properties such as in case of a conventional nitinol stent.

Self-expanding structures such as self-expanding stents or heart valve prostheses assume their radially expanded state automatically when released by a delivery system such as a catheter, but without having additional dilating means such as an expandable balloon or any other suitable force-expandable means. Such self-expanding structures (e.g. a self-expanding stent or a self-expanding heart valve prosthesis) are normally made of a shape-memory material such as nitinol. Nitinol is an intermetallic compound containing nickel and titanium atoms and it assumes an austenitic state at higher temperature and a martensitic state at lower temperature. For instance, a nitinol stent is typically manufactured at high temperatures, where nitinol is in the austenitic state. To load such a stent onto a catheter for delivery, the stent is typically cooled down to the martensitic state, where it can be plastically deformed, and is loaded onto an inner shaft of the catheter thereby transforming into a crimped state and hold in such a compressed state with the aid of a retention means of the catheter such as an outer shaft optionally having a distal capsule structure. The cooling reduces strain to the material and facilitates loading. At physiological temperatures in the human or animal body, the nitinol material then reassumes its original shape (i.e. a shape memory material) and displays superelastic properties which are important to provide a constant chronic outward force (COF) to a vessel or hollow organ, e.g., an aortic annulus plane of a patient's heart into which it is implanted.

For instance, during an implantation procedure of a self-expanding vascular stent, the surgeon eventually has to reposition the self-expanding structure one to, e.g., three times in order to achieve optimal placement in the vessel. To this end, the stent is recaptured in the catheter and released again for repositioning. Since the temperature in the patient body is too high to plastically deform the shape-memory material of the stent, damage is often inflicted on the stent during such recapture events, reducing the chronic outward force of the implanted stent. This may lead to complications, such as paravalvular leakage (in case of heart valve stents) or shifting (embolization) of the stent in the vessel. Accordingly, only a small number of recapture events is tolerated (typically two to maximally three recapture

events), and the stent must be removed and replaced if this number is exceeded, leading to an increased duration of the catheterization procedure and significantly raised costs.

Therefore, early adequate placement of a prosthetic heart valve is important and the generation of any leakage such as a paravalvular leakage shall be avoided as soon as possible during the intervention.

During placement of the prosthesis via TAVI / TAVR, both the location of the release and the leakage can be made visible by the administration of a contrast medium. Nevertheless, there is the risk that a prosthesis is not ideally placed, thus causing PVL to occur, i.e., regurgitation of blood B from the aorta A into the ventricle V past the prosthesis 10 as shown Fig. 1.

Known solutions to detect PVL include visual X-ray control using contrast media as well as ultrasound control. However, despite the technical solutions already available, incorrect positioning and leakage is a common problem when using TAVI / TAVR.

Based on the above, a problem to be solved by the present invention is to provide a catheter device that allows a physician to detect a leakage of a medical implant, in particular a PVL event in case of aortic valve replacement therapies, upon positioning and/or repositioning of the prosthesis at the implantation site.

Inter alia this problem is solved by a catheter device having the features of independent claim 1. Preferred embodiments are stated in the sub claims and are described herein below.

According to claim 1,
a catheter device (1) for implanting a medical implant, in particular a prosthetic heart valve, particularly an aortic valve
prosthesis (10) is disclosed, comprising:

- a medical implant, particularly a prosthetic heart valve, particularly an aortic valve prosthesis (10), comprising an artificial valve (12), and

- a connector (3) or a force-expandable holding means for holding the medical implant, particularly the prosthetic heart valve, particularly the aortic valve prosthesis (10),

characterized in that

the catheter device (1) comprises a heating element (S1) and a temperature sensor (S2) for detecting a leakage of the medical implant, particularly a paravalvular leakage of the prosthetic heart valve, particularly of the aortic valve prosthesis (10), wherein the heating element (S1) and the temperature sensor (S2) are arranged on a distal end section (1a) of the catheter device (1).

The skilled artisan readily appreciates numerous variants of a medical implant for which the cather device or the method of detecting a leakage of the medical implant can be suitable, such as stents, stent grafts, covered stents, left atrial appendage occluding devices, occluding devices in general, but also other heart valve prostheses than aortic valve prosthesis, but not limited thereto.

The prosthetic heart valve is particularly an aortic valve implant/prosthesis, i.e., the heart valve implant/prosthesis is configured to replace the native aortic valve (between the left ventricle and the aorta).

The prosthetic heart valve generally comprises a compressible and expandable frame structure, e.g., a mesh-like structure composed of interconnected struts forming openings (also termed cells) between the struts, or a wire structure, or a braided wire structure, and so to form a stent or support structure, whereby the stent or support structure is configured to provide a radially oriented (in respect of a longitudinal axis of the stent) outward force to engage native tissue and tightly anchor the heart valve in the tissue. The stent or support structure portion may be self-expanding or mechanically expandable, e.g., balloon-expandable. In particular, the stent or support structure portion may consist of nitinol (a nickel-titanium alloy displaying shape memory and superelasticity or pseudo-elasticity) in case of self-expanding systems whereas in case of a mechanically expandable system the stent or support structure may consist of a CoCr alloy such as, e.g., L605 or MP35N. Furthermore, the prosthetic heart valve comprises a plurality of cusps or valve leaflets, particularly from porcine or bovine pericardium, particularly dry porcine or bovine

pericardium, or a synthetic material, connected to the stent or support structure portion, replacing the native heart valve.

With the context of the invention, the expression "catheter device" shall be understood as any suitable medical system/delivery system that allows for the delivery and/or deployment and/or recapture and/or resheathing of any suitable kind of a medical implant, specifically a self-expanding medical implant such as a prosthetic heart valve or any suitable kind of a force-expandable medical implant, such as, e.g., balloon-expandable medical implants such as a balloon expandable prosthetic heart valve.

In certain instances, the expressions "catheter device", "delivery system" and "catheter" may be used interchangeably with the context of the invention.

Within the context of the present specification, the term "deployment" means implanting the heart valve implant, e.g., in the native valve annulus, such that the stent or support structure portion of the heart valve implant expands to anchor the heart valve in the native valve annulus. The skilled artisan hereby readily understands that a heart valve can be also placed at other suitable anatomical sites such as in the vena cava or, e.g., pulmonary veins, if indicated.

With the context of the invention, the abbreviation "TAVI" denotes transcatheter aortic valve implantation", the abbreviation "TAVR" denotes transcatheter aortic valve replacement, and the abbreviation "PAVR" denotes percutaneous aortic valve replacement.

As used herein, the term "proximal" refers to the direction towards the physician implanting the self-expanding structure or the artificial heart valve comprising a self-expanding structure or the force-expandable, e.g., balloon-expandable, prosthetic heart valve, and the term "distal" refers to the direction towards the vessel or hollow organ of the patient, e.g., an aorta.

With the context of the present invention, "a connector" may be any mechanical means suitable for (releasably) fixing / holding a self-expanding prosthetic heart valve or force-

expandable prosthetic heart valve connected to a delivery system/catheter device, e.g., to an inner shaft of a catheter. For instance, a suitable connector in accordance with the invention may be a prosthesis connector with a recess and/or a protrusion for (releasably) fixing / holding an eyelet and/or a tab, respectively, of a self-expanding prosthetic heart valve such as an aortic heart valve prosthesis.

Optionally, the connector may further comprise a connector arm and/or a connector feeler and/or a connector tether or the like for a controlled release of a self-expanding prosthetic heart valve or force-expandable prosthetic heart valve. Alternatively, a connector may be a mere connector arm or connector feeler or connector tether itself or combinations thereof without being attached to a prosthesis connector.

According to a key aspect of the invention, the catheter device comprises a heating element and a temperature sensor for detecting a leakage, in particular a PVL event, of the aortic valve prosthesis, wherein the heating element and the temperature sensor are arranged on a distal end section of the catheter device.

With the context of the invention, the expressions “paravalvular leakage”, “PVL”, and “a PVL event” may be used interchangeably and all denote a paravalvular leakage event in a singular form, i.e., at one location around a circumference of the aortic valve prosthesis, or in a plural form, i.e., on at least two locations around a circumference of the aortic valve prosthesis. Hence, there could be three, four, five, six or more paravalvular leakage events with the context of the invention.

In certain instances, however, the broader expression “leakage” may also denote any kind of leakage of a medical implant such as, e.g., in case of a prosthetic heart valve a leakage other than a paravalvular leakage, PVL, or PVL event.

In certain instances, in the framework of the present invention, the notion distal refers to a portion or component of the catheter device that is – with respect to the longitudinal axis of the catheter device – more remote from the handle or from the physician that operates the

catheter device than a corresponding proximal portion or component that is closer to the handle or physician.

In one embodiment of the invention, the aortic valve prosthesis comprises a self-expanding stent and an artificial valve carried by the stent. The stent can comprise struts that are connected to one another so that the stent forms a plurality of lateral openings delimited by the interconnected struts. The artificial valve can comprise, e.g., two or three valve leaflets. The artificial valve/valve leaflets can be made out of a biological tissue such as bovine or porcine pericardium; e.g. dry bovine or porcine pericardium. Particularly, the stent comprises at least one connecting member connected to at least one strut at a proximal end of the stent, wherein the at least one connecting member is configured to engage with the connector so that the connector holds the prosthesis through the at least one connecting member.

In one embodiment of the invention, the aortic valve prosthesis comprises a mechanically expandable stent, particularly a balloon-expandable stent, and an artificial valve carried by the stent. The stent can comprise struts that are connected to one another so that the stent forms a plurality of lateral openings delimited by the interconnected struts. The artificial valve can comprise, e.g., two or three valve leaflets. The artificial valve/valve leaflets can be made out of a biological tissue such as bovine or porcine pericardium; e.g. dry bovine or porcine pericardium. Particularly, the stent comprises at least one connecting member connected to at least one strut at a proximal end of the stent, wherein the at least one connecting member is configured to engage with the connector so that the connector holds the prosthesis through the at least one connecting member.

According to an embodiment of the catheter device, the heating element and the temperature sensor are configured such that the heating element allows to warm blood downstream the artificial valve within a physiologically acceptable temperature range, i.e., in the aorta, when the aortic valve prosthesis is positioned in the annulus of a native aortic valve to be replaced and the temperature sensor is arranged in the ventricle, so to measure a temperature of the blood residing in the ventricle. In case of a leakage, in particular a PVL event, the warmed blood in the aorta section passes alongside the prosthesis from the aorta into the ventricle

which can be measured as a corresponding temperature fluctuation and/or increase in temperature of the blood in the ventricle using the temperature sensor. Throughout the present description, warmed/heated blood with the context of the invention is to be understood as warmed/heated blood within a physiologically acceptable temperature range. In one embodiment and depending on a core temperature of a patient, the physiologically acceptable temperature range is 36 – 39°C +/- 1°C, preferably 37 – 38°C +/- 1°C.

Therefore, preferably, the heating element and the temperature sensor are sufficiently spaced apart alongside the catheter device according to an embodiment, so that the above described spatial arrangement of the heating element, the artificial valve and the temperature sensor can be achieved easily during the procedure.

Furthermore, according to an embodiment of the invention, the catheter device comprises an inner sheath, wherein the connector is connected to a distal end of the inner sheath. The inner sheath preferably comprises a lumen for receiving a guide wire along which the catheter device can be moved towards the implantation side through a vessel of the patient depending on the approach.

Furthermore, according to an embodiment, the heating element is arranged on a distal end section of the inner sheath. According to an alternative embodiment, the heating element is arranged on a distal end section of a capsule of the catheter device.

Particularly, according to an embodiment regarding a catheter device for a self-expanding aortic valve, the capsule is configured to cover the aortic valve prosthesis when the aortic valve prosthesis is held by the connector (e.g. by engagement of the at least one connecting member with the connector) and to thereby prevent release of the aortic valve prosthesis from the connector, wherein the capsule is movable in a proximal direction with respect to the aortic valve prosthesis, the inner sheath and the connector, for deploying the aortic valve prosthesis and for releasing the aortic valve prosthesis from the connector. Furthermore, the capsule is preferably movable in a distal direction for re-sheathing the aortic valve prosthesis before it is released from the connector.

According to a further embodiment, the catheter device comprises an outer sheath surrounding the inner sheath, wherein the capsule is connected to a distal end of the outer sheath. Particularly, also the outer sheath comprises a lumen, wherein the inner sheath is arranged in the lumen of the outer sheath. Furthermore, the catheter device can comprise a steering sheath for deflecting the catheter device, wherein the steering sheath can be arranged between the inner sheath and the outer sheath in the lumen of the outer sheath (i.e. the steering sheath can surround the inner sheath, wherein the steering sheath in turn is surrounded by the outer sheath).

According to an embodiment, for allowing partial deployment of the aortic valve prosthesis and optional re-sheathing of the aortic valve prosthesis, the distal end section of the capsule is configured to cover the at least one connecting member engaged with the connector so that the capsule prevents the at least one connecting member to disengage from the connector. This can be achieved by maintaining the position of the at least one connecting member with respect to the connector by means of said distal end section of the capsule such that the at least one connecting member remains engaged with the connector.

Further, according to an embodiment, the capsule is configured to be moved completely away from the at least one connecting member, so that said distal end section of the capsule no longer covers the at least one connecting member and the at least one connecting member is set free and automatically disengages from the connector so that the aortic valve prosthesis assumes the fully deployed state. Said automatic disengagement can be generated by the self-expanding property of the stent of the aortic valve prosthesis, wherein the at least one connecting member moves away from the connector and disengages the connector due to said self-expanding property once the capsule (particularly said distal end section of the capsule) no longer covers the at least one connecting member and thus no longer holds it in a fixed position with respect to the connector.

According to a further embodiment of the present invention, the catheter device comprises a catheter tip connected via a guide wire tube to the connector. The guide wire tube comprises a lumen that connects the lumen of the inner sheath and connector to a lumen of the catheter tip. Particularly, the catheter tip comprises an opening through which the guide

wire can be inserted into the continuous lumen provided by the catheter tip, guide wire tube, connector and inner sheath.

Furthermore, according to an embodiment of the invention, the temperature sensor is arranged on the catheter tip or on a distal end section of the guide wire tube.

Furthermore, according to an embodiment of the present invention, the heating element comprises a light emitting diode (LED) for generating heat for warming blood in the aorta within a physiologically acceptable temperature range, which blood when leaking alongside the prosthesis can be detected in the ventricle with the temperature sensor. Particularly, the light emitting diode is configured to emit light having a wavelength of 565 nm, for example.

Particularly, according to an embodiment, the heating element comprises an optical fiber having a distal end arranged on the distal end section of the inner sheath or on the distal end section of the capsule, wherein the light emitting diode is configured to emit light via said distal end of the optical fiber, which light is coupled into a proximal end of the optical fiber of the heating element. Particularly, a suitable optics can be provided on the distal end of the optical fiber to emit said light of the light emitting diode for warming blood in the aorta within a physiologically acceptable temperature range as defined above.

Further, according to an embodiment, the temperature sensor comprises an optical fiber (e.g. out of a polymer or a glass) having a section comprising a fiber Bragg grating. According to an embodiment, said section comprising the fiber Bragg grating is arranged on the catheter tip or on the distal end section of the guide wire tube.

According to yet another embodiment, the catheter device comprises an analyzing unit configured to analyze light reflected from the fiber Bragg grating to determine the temperature of the blood. The analyzing unit is particularly configured to be positioned outside the patient during the procedure.

According to a further embodiment, the analyzing unit is configured to detect a leakage, particularly a PVL event, of the aortic valve prosthesis through recognizing a specific

fluctuation in the temperature of the blood in the ventricle, if present, and/or a specific increase in the temperature of the blood in the ventricle, if present, and that can be attributed to a leakage, particularly to a PVL event; or by implication, the analyzing unit is configured to indicate an optimal placement of the aortic valve prosthesis, if no such fluctuation and/or increase in the temperature of the blood in the ventricle can be detected.

In the following, embodiments of the present invention as well as further features and advantages of the present invention are described with reference to the drawings, wherein:

Fig. 1 shows a schematic view of a paravalvular leakage of an implanted aortic valve prosthesis; and

Fig. 2 shows a cross-sectional view of an embodiment of a catheter device according to the present invention, wherein exemplarily a self-expanding aortic valve prosthesis is deployed in the annulus of a native valve using the catheter device positioned in the aorta; also shown are the ostia A''.

It shall be noted that the disclosed figures predominantly serve the purpose of illustrating exemplary embodiments of the invention without being bound to scales, dimensions, relations or the like. Various modifications and/or arrangements and/or implementations of the illustrated embodiments may be conceived by a skilled person with regard to his/her common general knowledge. Thus, each illustrated component/feature shall predominantly illustrate the basic arrangements, functions and interplay thereof in accordance with the invention.

Fig. 1 shows an exemplary embodiment of a schematic self-expanding aortic heart valve 10 according to the present invention. In this example, the aortic valve prosthesis 10 comprises a self-expanding stent 11 and an artificial valve 12 carried by the stent 11. The stent 11 can comprise struts 11a that are connected to one another so that the stent 11 forms a plurality of lateral openings delimited by the interconnected struts 11a (for 11a cf. Fig. 2). The artificial valve 12 can comprise three valve leaflets. The artificial valve 12/valve leaflets can

be made out of a biological tissue such as bovine or porcine pericardium; e.g. dry porcine pericardium.

Fig. 2 shows an exemplary embodiment of a schematic catheter device 1 according to the present invention in a situation of partial deployment of an exemplary self-expanding aortic heart valve 10. Preferably, the aortic valve prosthesis 10 comprises a self-expanding stent 11 and an artificial valve 12 carried by the stent 11. The artificial valve 12 can comprise three valve leaflets. The artificial valve 12/valve leaflets can be made out of a biological tissue such as bovine or porcine pericardium; e.g. dry porcine pericardium.

The catheter device 1 further comprises a connector 3 for holding the prosthesis 10, and a capsule 4 configured to cover the prosthesis 10 when the prosthesis 10 is connected to the connector 3 and to thereby prevent release of the prosthesis 10 from the connector 3, wherein the capsule 4 is movable in a proximal direction P with respect to the prosthesis 10 for deploying the prosthesis 10 and for releasing the prosthesis 10 from the connector 3, and wherein the capsule 4 is movable in a distal direction D for re-sheathing the prosthesis 10 before it is released from the connector 3.

The catheter device 1 preferably comprises an outer sheath 5 having a distal end 5a that is connected to the capsule 4. The outer sheath 5 extends along a longitudinal axis of the catheter device 1 and surrounds a lumen of the outer sheath 5. The catheter device 1 preferably further comprises an inner sheath 2 extending along the longitudinal axis, wherein the inner sheath 2 is arranged in the lumen of the outer sheath 5 and connected to the connector 3 at a distal end 2a of the inner sheath 2. The connector 3 in turn can be connected to a catheter tip 6 of the catheter device 1 via a guide wire tube 7. Particularly, the catheter tip 6 can comprise an opening formed in a distal end of the catheter tip 6, so that a guide wire 60 for guiding the catheter device 1 during implantation of the prosthesis 10 can extend in a guide wire lumen comprised by the inner sheath 2, connector 3, tube 7 and tip 6, and exit this lumen via said opening of the catheter tip 6.

In order to be able to measure if the partially deployed prosthesis 10 is properly positioned in the annulus A' of the failed native valve, the catheter device 1 comprises a heating element

S1 and a temperature sensor S2 for detecting a leakage, particularly a PVL event, of the aortic valve prosthesis 10, wherein the heating element S1 and the temperature sensor S2 are arranged on a distal end section 1a of the catheter device 1.

As shown in Fig. 2, the prosthesis 10 is nearly completely deployed, merely connecting members 20 are still engaged with the connector 3, since a distal end section 4a of the capsule still covers the connecting members 20 in the region of the connector 3 so that the connecting members 20 that are connected to struts 11a of the stent 11 cannot yet disengage with the connector. If now a PVL event can be recognized / detected using the heating element S1 and the temperature sensor S2 in accordance with the present invention, the prosthesis 10 can be re-sheathed by moving the capsule 4 in the distal direction D with respect to the prosthesis 10 and repositioned in order to prevent from or avoid any further PVL events upon final and adequate positioning of the aortic heart valve prosthesis during last deployment.

The measurement principle for detecting a PVL event of blood B as shown in Fig. 1 preferably comprises heating / warming blood downstream the positioned artificial valve 12 (i.e. heating / warming blood in the aorta within a physiologically acceptable range) using the heating element S1, which can be arranged, e.g., either on the distal end section 2b of the inner sheath 2, or – as shown in Fig. 2 – on the distal end section 4a of the capsule 4, but not limited to. In case the prosthesis 10 is not properly positioned, blood may leak alongside the prosthesis 10 from the aorta A past the annulus A' into the ventricle V, where the temperature sensor S2 is positioned in such a way that it can detect a blood temperature fluctuation and/or an increase in blood temperature due to said heating / warming of the blood in the aorta A within a physiologically acceptable temperature range. In case such fluctuation/increase in temperature is detected, an analyzing unit 8, that processes an output signal of the temperature sensor S2 can then decide that a PVL event is present based on such a detected fluctuation/temperature increase of blood in the ventricle V (but still within a physiologically acceptable range). The physician may then be informed accordingly by the analyzing unit 8 and may then re-sheath and re-position the prosthesis 10. In case no PVL event is detected, the capsule 4 can be moved further in the proximal direction P so that the connecting

members 20 disengage with the connector 3 and the prosthesis 10 is completely deployed and released from the catheter device 1.

The temperature sensor S2 can be arranged, e.g., on or close to the catheter tip 6 or on a distal end section 7a of the tube 7 as shown in Fig. 2, but not limited to.

Particularly, the heating element S1 can comprise an LED that may emit light having a wavelength in the range of 565 nm, for example. The energy source/LED may also be positioned remote from the distal end section 4a of the capsule 4 or from the distal end section 2b of the inner sheath 2, by using an optical fiber that guides the light of the LED to the desired point where blood is to be warmed within a physiologically acceptable temperature range.

Furthermore, the temperature sensor S2 can be formed by an optical fiber having a section comprising a fiber Bragg grating, wherein said section is then, e.g., arranged on the catheter tip 6 or on the distal end section 7a of the guide wire tube 7 to measure the temperature at these specific locations. The analyzing unit 8 is configured to analyze the light reflected from the fiber Bragg grating to determine the desired temperature.

The present invention *inter alia* allows for a more precise positioning of a medical implant by measuring the occurrence of a leakage of the medical implant. Advantageously, this allows reducing the amount of contrast agent used during the procedure as well as X-ray exposure of the patient. Furthermore, this method of detecting a leakage during intervention of the placement / positioning of a medical implant ensures a safe and reliable placement / positioning of the medical implant.

The present invention *inter alia* allows for a more precise positioning of a TAVI / TAVR aortic valve prosthesis by measuring the occurrence of a PVL event. Advantageously, this allows reducing the amount of contrast agent used during the procedure as well as X-ray exposure of the patient. Furthermore, this method of detecting a PVL event during TAVI / TAVR intervention ensures a safe and reliable positioning of an aortic heart valve prosthesis.

In view of all the foregoing disclosure, in another embodiment the present invention provides for a method of detecting a leakage of a medical implant.

Thus, another aspect of the invention provides a method for detecting a leakage of a medical implant in a patient undergoing a medical intervention for placement / positioning of the medical implant, wherein the method comprises the steps of providing a catheter device as defined above; warming/heating blood of the patient within a physiologically acceptable temperature range through a heating element (S1) that is positioned at a suitable location in the vicinity of the medical implant of the patient when the medical implant is placed / positioned in a site of implantation of the patient; detecting a fluctuation and/or an increase in temperature of the blood of the patient in the vicinity of the site of implantation of the medical implant through a temperature sensor (S2) that is arranged at a suitable location in the vicinity of the medical implant during intervention, whereby the presence of the fluctuation and/or the increase in temperature of the blood of the patient in the vicinity of the placed / positioned medical implant is indicative of a leakage of the medical implant in the patient.

In view of all the foregoing disclosure, in another embodiment the present invention provides for a method of detecting a PVL event.

Thus, another aspect of the invention provides a method for detecting a leakage, particularly a paravalvular leakage, of a prosthetic heart valve, particularly of an aortic valve prosthesis, in a patient undergoing a heart valve replacement, particularly an aortic heart valve replacement, wherein the method comprises the steps of providing a catheter device as defined above; warming/heating blood of the patient within a physiologically acceptable temperature range through the heating element (S1) that is positioned downstream the artificial valve (12) of the patient when the prosthetic heart valve, particularly the aortic valve prosthesis (10), is positioned in the annulus (A') of the native aortic valve (13) of the patient; detecting a fluctuation and/or an increase in temperature of the blood of the patient in the patient's ventricle through the temperature sensor (S2) that is arranged in the ventricle (V), whereby the presence of the fluctuation and/or the increase in temperature of the blood

of the patient is indicative of a leakage, particularly of a paravalvular leakage, of the prosthetic heart valve, particularly of the aortic valve prosthesis, in the patient.

By implication, an absence of the fluctuation and/or the increase in temperature of the blood of the patient is indicative of an adequate placement/deployment of the medical implant in the patient.

By implication, an absence of the fluctuation and/or the increase in temperature of the blood of the patient is indicative of an adequate placement/deployment of the prosthetic heart valve, particularly of the aortic valve prosthesis, in the patient.

In view of all the foregoing disclosure, the present invention also provides for the following consecutively numbered embodiments:

1. A catheter device (1) for implanting a prosthetic heart valve, particularly an aortic valve prosthesis (10), comprising:
   - a prosthetic heart valve, particularly an aortic valve prosthesis (10), comprising an artificial valve (12), and
   - a connector (3) or a force-expandable holding means for holding the prosthetic heart valve, particularly the aortic valve prosthesis (10),

   characterized in that

   the catheter device (1) comprises a heating element (S1) and a temperature sensor (S2) for detecting a leakage, particularly a paravalvular leakage, of the prosthetic heart valve, particularly of the aortic valve prosthesis (10), wherein the heating element (S1) and the temperature sensor (S2) are arranged on a distal end section (1a) of the catheter device (1).

In view of the above embodiment 1, and with the context of the present invention, the skilled person readily understands that this subject-matter may be suitable for detecting a leakage, particularly a paravalvular leakage, during various native heart valve interventions, particularly of an aortic valve, but also of a mitral valve; although certain modifications may be necessary to suit each specific heart valve intervention.

The expression "force-expandable holding means" denotes any holding means that is suitable to releasably fix/hold a prosthetic heart valve in position on a catheter device, e.g. in a crimped state, and that allows for an expansion of the prosthetic heart valve via any suitable mechanical means such as a balloon, a basket, or, e.g., a car jack mechanism.

In view of embodiment 1, the prosthetic heart valve being an aortic valve prosthesis is preferred and this *inter alia* applies to all the numbered embodiments 1 to 16.

2. The catheter device according to embodiment 1, **wherein** the heating element (S1) and the temperature sensor (S2) are configured such that the heating element (S1) allows to warm blood within a physiologically acceptable temperature range downstream the artificial valve (12) when the aortic valve prosthesis (10) is positioned in the annulus (A') of a native aortic valve (13), and the temperature sensor (S2) is arranged in the ventricle (V).

The term "downstream" denotes the natural flow direction of blood from the ventricle towards the aorta.

With the context of embodiment 2, it shall be noted that the blood may be warmed / heated within a physiologically acceptable temperature range, e.g., during deployment/positioning of the aortic valve prosthesis and/or upon the aortic valve prosthesis has been positioned/deployed.

3. The catheter device according to embodiment 1 or 2, **wherein** the heating element (S1) and the temperature sensor (S2) are spaced apart from one another.

4. The catheter device according to one of the preceding embodiments, **wherein** the catheter device (1) comprises an inner sheath (2), and wherein the connector (3) is connected to a distal end section (2a) of the inner sheath (2).

5. The catheter device according to one of the preceding embodiments, **wherein** the catheter device (1) further comprises a capsule (4) that is configured to cover the aortic valve prosthesis (10) when the aortic valve prosthesis (10) is held by the connector (3) and to thereby prevent a release of the aortic valve prosthesis (10) from the connector (3), wherein the capsule (4) is movable in a proximal direction (P) with respect to the aortic valve prosthesis (10) for deploying the aortic valve prosthesis (10) and for releasing the aortic valve prosthesis (10) from the connector (3), and wherein the capsule (4) is movable in a distal direction (D) for re-sheathing the aortic valve prosthesis (10) before it is released from the connector (3).

6. The catheter device according to embodiment 4 or 5, **wherein** the heating element (S1) is arranged on a distal end section (2b) of the inner sheath (2).

7. The catheter device according to embodiment 6, **wherein** the heating element (S1) is arranged on a distal end section (4a) of the capsule (4).

8. The catheter device according to embodiment 6 or 7, **wherein** the catheter device (1) comprises an outer sheath (5) surrounding the inner sheath (2), and wherein the capsule (4) is connected to a distal end (5a) of the outer sheath (5).

9. The catheter device according to one of the preceding embodiments, **wherein** the catheter device (1) further comprises a catheter tip (6) connected via a guide wire tube (7) to the connector (3).

10. The catheter device according to embodiment 9, **wherein** the temperature sensor (S2) is arranged on the catheter tip (6) and/or on a distal end section (7a) of the guide wire tube (7).

11. The catheter device according to one of the preceding embodiments, **wherein** the heating element (S1) comprises a light emitting diode (LED) for generating heat within a physiologically acceptable temperature range.

12. The catheter device according to one of the preceding embodiments, **wherein** the temperature sensor (S2) comprises an optical fiber having a section comprising a fiber Bragg grating.

13. The catheter device according to embodiments 9 and 12, **wherein** said section comprising the fiber Bragg grating is arranged on the catheter tip (6) and/or on the distal end section (7a) of the guide wire tube (7).

14. The catheter device according to embodiment 12 or 13, **wherein** the catheter device (1) further comprises an analyzing unit (8) configured to analyze light reflected from the fiber Bragg grating to determine the temperature of the blood in the ventricle (V).

15. The catheter device according to embodiment 14, **wherein** the analyzing unit (8) is configured to detect a leakage, particularly a paravalvular leakage, of the aortic valve prosthesis (10) by detecting a specific fluctuation in the temperature of the blood in the ventricle (V) and/or a specific increase in the temperature of the blood in the ventricle (V).

16. A method for detecting a leakage, particularly a paravalvular leakage, of a prosthetic heart valve, particularly of an aortic valve prosthesis, in a patient undergoing a heart valve replacement, particularly an aortic heart valve replacement, the method comprising the steps of:

(i) providing a catheter device as defined in any one of the embodiments 1 to 15;

(ii) warming / heating blood of the patient within a physiologically acceptable temperature range through the heating element (S1) that is positioned downstream the artificial valve (12) of the patient when the prosthetic heart valve, particularly the aortic valve prosthesis (10), is positioned in the annulus (A') of the native aortic valve (13) of the patient;

(iii) detecting a fluctuation and/or an increase in temperature of the blood of the patient in the patient's ventricle through the temperature sensor (S2) that is arranged in the ventricle (V), the detected fluctuation and/or increase in temperature of the blood of

the patient being indicative of a leakage, particularly of a paravalvular leakage, of the prosthetic heart valve, particularly of the aortic valve prosthesis.

17. A method for detecting a leakage of a medical implant in a patient undergoing an intervention for placement / positioning of the medical implant, the method comprising the steps of:

(i) providing a catheter device as defined in any one of the embodiments 1 to 15;

(ii) warming / heating blood of the patient within a physiologically acceptable temperature range through the heating element (S1) that is positioned at a suitable location in the vicinity of site of implantation of the medical implant in the patient;

(iii) detecting a fluctuation and/or an increase in temperature of the blood of the patient in the vicinity of the patient's site of implantation of the medical implant through the temperature sensor (S2) that is arranged at a suitable location in the vicinity of site of implantation of the medical implant, the detected fluctuation and/or increase in temperature of the blood of the patient in the vicinity of the site of implantation of the medical implant being indicative of a leakage of the medical implant.

Claims

1. A catheter device (1) for implanting a medical implant, in particular a prosthetic heart valve, particularly an aortic valve prosthesis (10), comprising:
   - a medical implant, in particular a prosthetic heart valve, particularly an aortic valve prosthesis (10), comprising an artificial valve (12), and
   - a connector (3) or a force-expandable holding means for holding the medical implant, in particular the prosthetic heart valve, particularly the aortic valve prosthesis (10),

   characterized in that

   the catheter device (1) comprises a heating element (S1) and a temperature sensor (S2) for detecting a leakage of the medical implant, particularly a paravalvular leakage of the prosthetic heart valve, particularly of the aortic valve prosthesis (10), wherein the heating element (S1) and the temperature sensor (S2) are arranged on a distal end section (1a) of the catheter device (1).

2. The catheter device according to claim 1, **wherein** the medical implant is a prosthetic heart valve, in particular an aortic valve prosthesis (10), and the heating element (S1) and the temperature sensor (S2) are configured such that the heating element (S1) allows to warm blood within a physiologically acceptable temperature range downstream the artificial valve (12) when the aortic valve prosthesis (10) is positioned in the annulus (A') of a native aortic valve (13), and the temperature sensor (S2) is arranged in the ventricle (V).

3. The catheter device according to claim 1 or 2, **wherein** the heating element (S1) and the temperature sensor (S2) are spaced apart from one another.

4. The catheter device according to one of the preceding claims, **wherein** the catheter device (1) comprises an inner sheath (2), and wherein the connector (3) is connected to a distal end section (2a) of the inner sheath (2).

5. The catheter device according to one of the preceding claims, **wherein** the medical implant is a prosthetic heart valve, in particular an aortic valve prosthesis (10), and the catheter device (1) further comprises a capsule (4) that is configured to cover the aortic valve prosthesis (10) when the aortic valve prosthesis (10) is held by the connector (3) and to thereby prevent a release of the aortic valve prosthesis (10) from the connector (3), wherein the capsule (4) is movable in a proximal direction (P) with respect to the aortic valve prosthesis (10) for deploying the aortic valve prosthesis (10) and for releasing the aortic valve prosthesis (10) from the connector (3), and wherein the capsule (4) is movable in a distal direction (D) for re-sheathing the aortic valve prosthesis (10) before it is released from the connector (3).

6. The catheter device according to claim 4 or 5, **wherein** the heating element (S1) is arranged on a distal end section (2b) of the inner sheath (2).

7. The catheter device according to claim 6, **wherein** the heating element (S1) is arranged on a distal end section (4a) of the capsule (4).

8. The catheter device according to claim 6 or 7, **wherein** the catheter device (1) comprises an outer sheath (5) surrounding the inner sheath (2), and wherein the capsule (4) is connected to a distal end (5a) of the outer sheath (5).

9. The catheter device according to one of the preceding claims, **wherein** the catheter device (1) further comprises a catheter tip (6) connected via a guide wire tube (7) to the connector (3).

10. The catheter device according to claim 9, **wherein** the temperature sensor (S2) is arranged on the catheter tip (6) and/or on a distal end section (7a) of the guide wire tube (7).

11. The catheter device according to one of the preceding claims, **wherein** the heating element (S1) comprises a light emitting diode (LED) for generating heat within a physiologically acceptable temperature range.

12. The catheter device according to one of the preceding claims, **wherein** the temperature sensor (S2) comprises an optical fiber having a section comprising a fiber Bragg grating.

13. The catheter device according to claims 9 and 12, **wherein** said section comprising the fiber Bragg grating is arranged on the catheter tip (6) and/or on the distal end section (7a) of the guide wire tube (7).

14. The catheter device according to claim 12 or 13, **wherein** the catheter device (1) further comprises an analyzing unit (8) configured to analyze light reflected from the fiber Bragg grating to determine the temperature of the blood in the ventricle (V).

15. The catheter device according to claim 14, **wherein** the analyzing unit (8) is configured to detect a leakage, particularly a paravalvular leakage, of the aortic valve prosthesis (10) by detecting a specific fluctuation in the temperature of the blood in the ventricle (V) and/or a specific increase in the temperature of the blood in the ventricle (V).

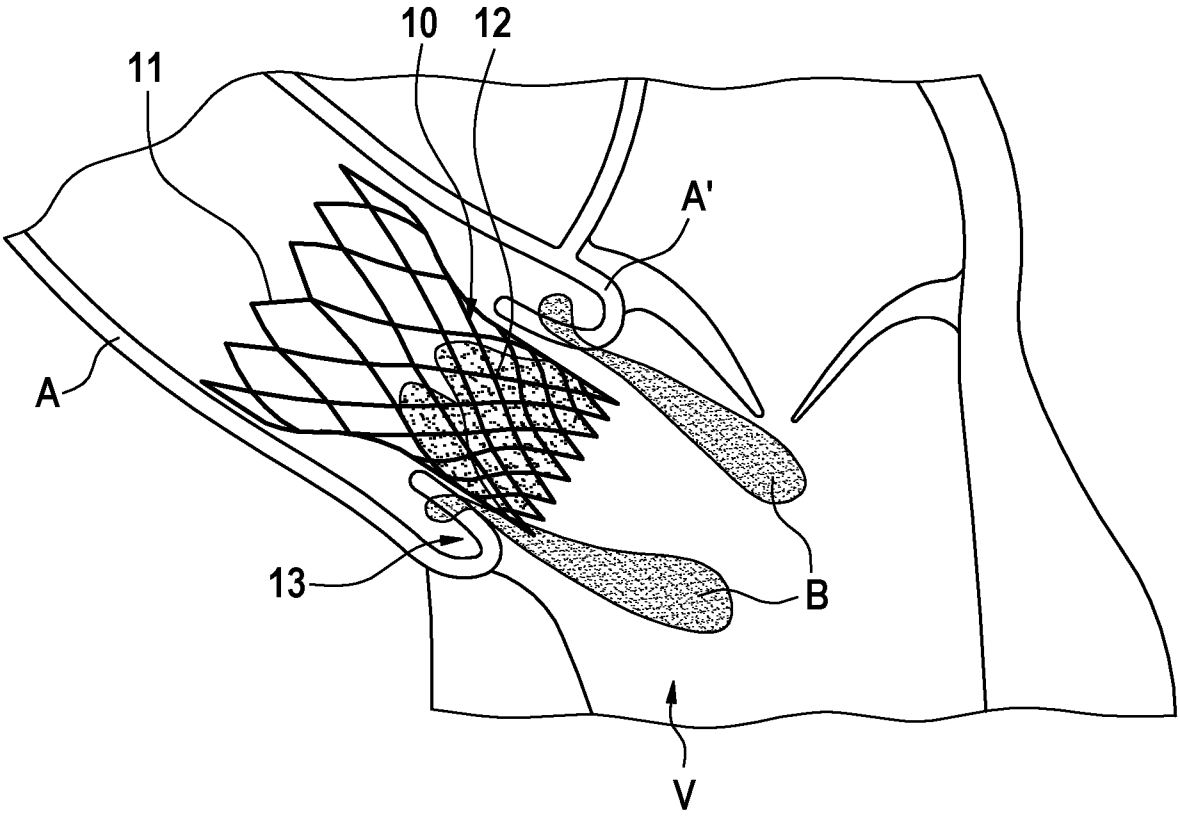

FIG. 1

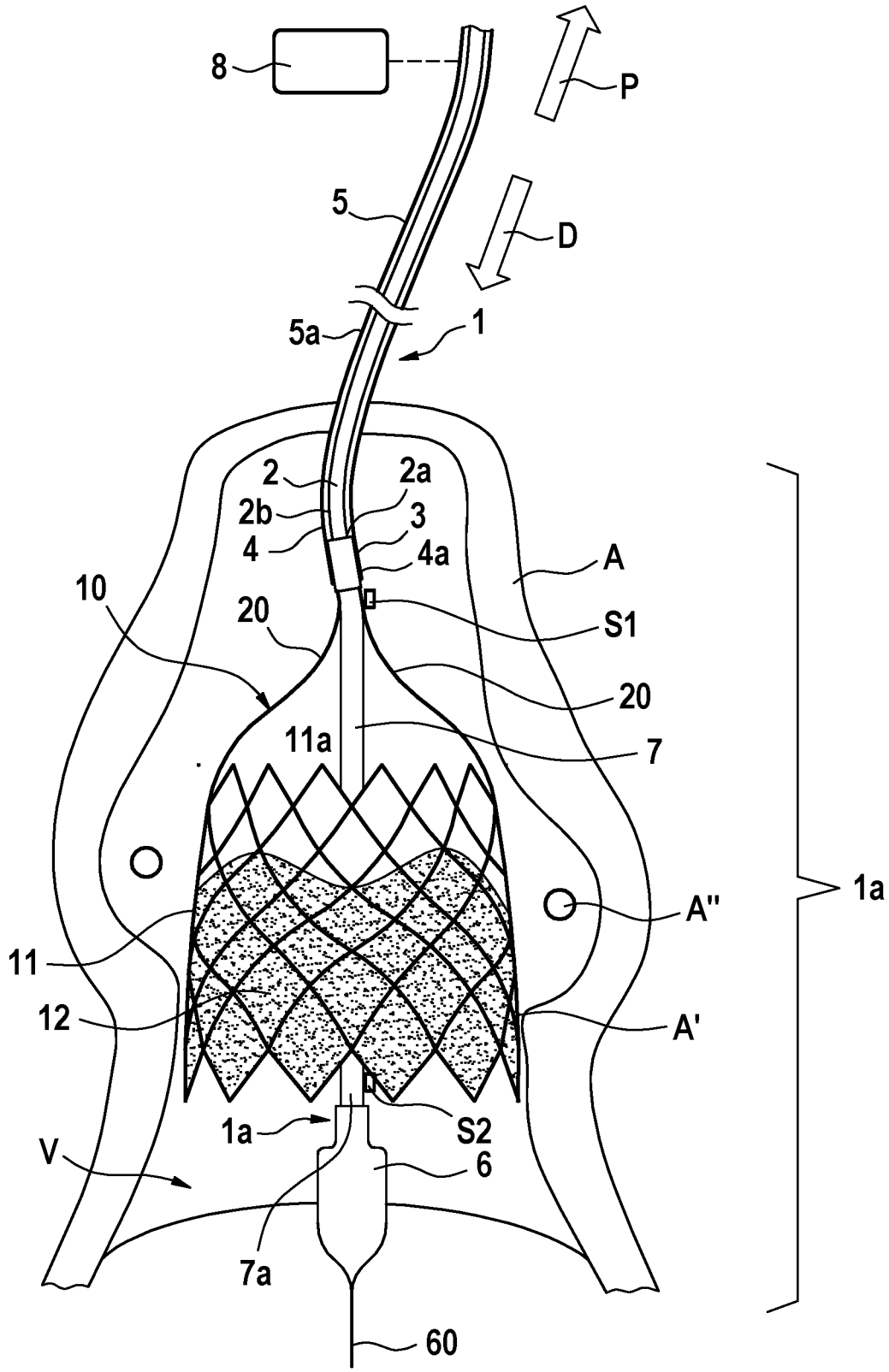

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2021/053486

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/026 A61B5/00 G01F1/68 G01P5/12 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)
A61B G01P G01F 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 Y A	US 2016/113628 A1 (SETTE MASSIMO [CH]) 28 April 2016 (2016-04-28) paragraphs [0028], [0029], [0068], [0071], [0072], [0086], [0119], [0129] - [0132]; figures 15,16,18	1,4,5, 8-10 2,3, 12-14 6,7,11, 15
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Y	US 2014/194757 A1 (T HOOFT GERT WIM [NL] ET AL) 10 July 2014 (2014-07-10) paragraphs [0015] - [0017]; claims; figures	12-14

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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 :

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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
9 April 2021	19/04/2021

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	Douskas, K

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2021/053486

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

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