(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2013 (27.12.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/189620 A1

(51) International Patent Classification:
A61B 17/00 (2006.01) *A61B 17/34* (2006.01)

(21) International Application Number:
PCT/EP2013/057427

(22) International Filing Date:
10 April 2013 (10.04.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12172583.2 19 June 2012 (19.06.2012) EP

(71) Applicant: **JENAVALVE TECHNOLOGY INC.** [US/US]; c/o Regus Business Centre, Wilmington Downtown, 1000 N. West Street, Suite 1200, Wilmington, Delaware 19801 (US).

(72) Inventor: **TÖLLNER, Thomas**; Pannierstrasse 31, 12047 Berlin (DE).

(74) Agent: **TRINKS, Ole**; Meissner, Bolte & Partner GbR, P.O. Box 102605, 86016 Augsburg (DE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *with amended claims and statement (Art. 19(1))*

(54) Title: APPARATUS FOR PROVIDING ACCESS TO A VISCUS, SYSTEM FOR PERFORMING DIRECT CARDIAC CATHETERIZATION AND METHOD FOR MINIMALLY-INVASIVE SURGERY

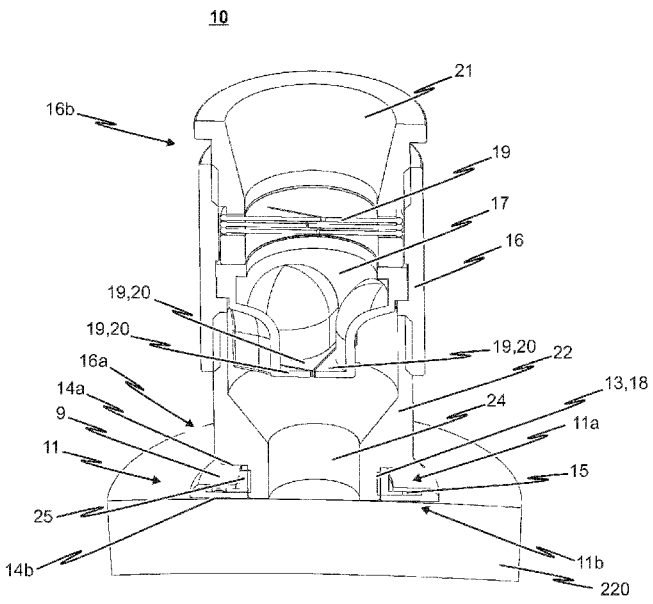

Fig. 5

(57) Abstract: The present disclosure relates to an apparatus (10) for providing access to a viscus (220) of a patient required for delivering therapeutic devices into the viscus (220) for structural repair procedures. The apparatus (10) comprises a base member (11) having a first surface (11a) and an opposite second surface (11b) and a channel (12) extending there through, the base member (11) being configured to be manually fixed to the outer wall of the viscus (220). The apparatus (10) further comprises a tubular member (16) defining a lumen (17), the tubular member (16) having a first end (16a) and an opposite second end (16b) and being configured to be coupled with its first end (16a) to the first surface (11a) of the base member (11) such that the lumen (17) and the channel (12) communicate with each other thereby defining a passage (18) through which an elongate medical instrument (30, 30') is movable in the direction of the viscus wall.

WO 2013/189620 A1

"Apparatus for providing access to a viscus, system for performing direct cardiac catheterization and method for minimally-invasive surgery"

Description

The present disclosure relates generally to surgical procedures, and more specifically to devices and methods for minimally-invasive surgery, such as minimally invasive cardiac surgery. In more detail, some embodiments of the disclosure relate to access and closure technologies pertinent to wound or defect closure, such as closures required following transapical or transventrical cardiac diagnostic and interventional procedures.

Heart valve surgery is used to repair or replace diseased heart valves. Medical technology has long since endeavored to correct valvular defects such as, for example, aortic valve insufficiencies or aortic valve stenosis, without requiring open heart surgery by means of minimally invasive methods. During the last decades minimally invasive forms of treatment have been developed and improved. They are in particular characterized in that a catheter delivery system is employed in order to advance to the site inside the body where, e.g. implantation of a prosthetic device is required. Since by employing a catheter delivery system only small incisions are necessary resulting in a faster patient recovery with less pain and bodily trauma. Furthermore, in particular, in the case of performing a minimal invasive heart surgery the patient need not be placed on cardiopulmonary bypass for the duration of the surgery allowing the procedure to be performed under local

anesthesia. This, in turn, reduces the medical costs and the overall disruption to the life of the patient.

A medical delivery system includes, for example, a medical system with which a stent system can be advanced in minimally invasive fashion to the site of implantation in the patient's heart, for example to treat an aortic valve stenosis and/or aortic valve insufficiency. Minimally invasive includes, for example, a heart-lung machine is not needed when performing the procedure on the anaesthetized patient such that the medical procedure can not only be performed at reasonable cost, but there is also less physical and psychological strain on the patient.

Aortic valve stenosis and/or aortic valve insufficiency generally refer to, for example, a congenital or acquired dysfunction of one or more cardiac valves. Such valvular disorders can affect any of the four cardiac valves, whereby the valves in the left ventricle or left chamber aortic and mitral valve are typically more affected than those on the right side of the heart pulmonary and tricuspid valve. The dysfunction can be a constriction stenosis, an incompetence insufficiency or a combination of the two combined vitium.

A catheter delivery systemgenerally includes, for example, a system that can be inserted into a body cavity, duct or vessel. A catheter delivery system thereby allows access by surgical instruments. The process of inserting a catheter delivery system is catheterisation. In most uses, a catheter delivery system is a thin, flexible tube: a "soft" catheter system; in some uses, it is a larger, solid tube: a "hard" catheter system.

A medical delivery system usually may comprise a catheter delivery system by means of which a stent, as needed with a prosthetic heart valve affixed thereto in a folded state, can be introduced into the patient's body in its folded state. For example, the medical delivery system can exhibit a catheter tip having at least one manipulatable receiving area at a proximal end section of the catheter delivery system; i.e. closest to the heart.

It is moreover conceivable for the medical delivery system to exhibit a handle at the proximal end section of the catheter delivery system; i.e. at the end section of the catheter delivery system farthest from the heart and the catheter tip, with which the at least one receiving area of the catheter tip can be appropriately manipulated such that the expandable stent accommodated in the catheter tip, as

needed with a prosthetic heart valve affixed thereto, can be incrementally released from the catheter tip according to a predefined or predefinable sequence of events.

Generally, there are two minimally invasive approaches known for implanting a prosthetic heart valve. The first approach is the so-called transarterial or transfemoral approach in which a medical instrument, for example a catheter tip with an expandable heart valve prosthesis housed therein, is advanced to the implantation site via the aorta of a patient.

A transarterial or transfemoral retrograde valve delivery procedure for valve replacement is typically limited by the size of the delivery system and is generally not recommended for patients with an existing peripheral vascular disease.

The second approach is the so-called transapical or transventrical approach, wherein access to the heart is provided through the apical area of the heart or through a ventricle of the heart in order to introduce for example an expandable stent system.

Generally, the apical area or apex of the heart corresponds to the blunt rounded inferior extremity of the heart formed by the left and right ventricles. A transapical or transventrical retrograde valve delivery procedure is the most direct, shortest, antegrade and controllable access for transcatheter aortic valve replacement (TAVR).

Transapical or transventrical transcatheter valve implantation techniques typically involve an incision, for example, a thoracotomy, in order to gain access to the heart. After reaching the implantation site with the transapical or transventrical approach, a stent with a prosthetic heart valve affixed thereto can then be positioned and unfolded. After unfolding, the prosthetic heart valve can be anchored in the desired position in the heart, for example with the aid of anchoring hooks.

A heart valve prosthesis of this type may include, for example, a self-expanding or balloon-expanding anchoring support (also termed "heart valve stent" or "stent"), to which the actual prosthetic heart valve is fastened, preferably in the inflow area of the stent.

With a minimally invasive transapical or transventrical approach, a direct access to the heart through the heart wall, e.g. the apex of the heart, may be provided in a less complicated way compared with a transarterial or transfemoral approach. In particular, a minimally invasive transapical or transventrical approach is not as limited with respect to constraints which are present in the transfemoral approach. While access to the heart through the femoral vessels in the transfemoral approach is limited to the diameter of the vessel approximately 8 mm, access to the heart through the apical area is significantly larger approximately 25 mm.

Additionally, compared to the transfemoral approach, with the transapical or transventrical approach the distance from the initial point of introduction to the implantation site is shorter. This allows a better controllability during the surgery as well as easier placement and positioning of the prosthetic device.

Thus, transapical or transventrical access to the heart often permits greater flexibility with respect to the types of devices and surgical methods that may be performed in the heart. Furthermore, the unique anatomical structure of the apical area permits the introduction of various surgical devices and tools into the heart without significant disruption of the natural mechanical and electrical heart function, enabling surgery without cardiopulmonary bypass of the patient by means of a heart-lung machine.

Although a transapical or transventrical approach permits the introduction of various surgical devices and tools into the heart without significant disruption of the natural mechanical and electrical heart function, this approach also presents certain clinical challenges to the surgical team. With this approach, for example, the surgeon creates transcutaneous access to the region around the apex of the heart with a surgical thoracotomy, followed by direct access to the left ventricle using a needle or other device aimed to access the left ventricle around the left ventricular apex, which may be followed by one or more dilating instruments to create a temporary access port to the left ventricle.

A transapical or transventrical implantation approach, however, also poses problems, in particular associated with respect to the fact that the apical access passage used for the introduction of instruments during surgery needs to be sealed in order prevent significant blood loss and outflow of blood from the ventricle while the heart is pumping. A successful closure of a transapical or transventrical wound on a beating heart of a patient is obviously of high criticality to such a

procedure, as is the minimization of loss of blood. Conventional transapical or transventrical closure techniques typically involve the placement of small sutures to create a purse-string type effect to close the wound as the instrumentation is withdrawn, and it may be very difficult to repeatably create acceptable closures using these techniques without a larger thoracotomy or improved instrumentation.

Apart from the problem of sealing, there is also the fundamental problem that the tissue at the apex is quite sensitive and can easily be damaged and is prone to rupture. In conjunction hereto, often likewise regarded as problematic is that the change and manipulation of surgical instruments introduced through the passage of the apex often leads to enhanced stress to the apical area increasing the risk of tissue damage. This is especially due to the fact that during a manipulation of a medical instrument introduced through the passage in the apex relative motions between the instruments and the wall of the heart occur. In case of beating heart surgery, these relative motions are even further pronounced since the wall of the heart is moving while the heart is pumping. Therefore, the risk of severe tissue damage to the surrounding tissue of the passage in the apex is increased.

One of the key challenges to transapical or transventrical intervention, however, remains transapical or transventrical wound closure. Indeed, it is believed that transapical or transventrical access may provide enhanced stability and control during procedures such as aortic valve replacement, due to the fact that the operator may have a relatively direct mechanical connection with the pertinent instrumentation, relative to the connection that he may have using, for example, an antegrade or retrograde vascular approach with more compliant catheter type tools.

Accordingly, it is an object of the disclosure to successfully address at least some of the challenges of transapical or transventrical access and closure.

Further, it would be desirable to have a system for simplifying and standardizing a technique for opening and closing the beating heart during cardiac surgery. Moreover, there is a need for a wound or access closure technology that is applicable not only to transapical or transventrical access port closure, but also other closure demands pertinent to other surgical interventions of the human body wherein wounds or ports are created, such as in gastrointestinal or gynecological surgery.

On the basis of the problems outlined above, the present disclosure relates to an access device for cardiac stent delivery as well as to a method for fixing the same to the apex of the heart with which the problems are overcome.

An aspect of some embodiments of the disclosure relates to an apparatus for providing access to a viscus of a patient required for delivering therapeutic devices into the viscus for structural repair procedures. In some embodiments disclosed herein, the apparatus comprises a flange-like base member having a first surface and an opposite second surface, and also having a channel extending through the base member. The flange-like base member is configured to be manually fixed to the outer wall of a viscus required for delivering therapeutic devices into the viscus. In accordance with some embodiments of the present disclosure, the apparatus also comprises a tubular member defining a lumen. In some embodiments, the tubular member has a first end and an opposite second end, and is configured to be coupled with its first end to the first surface of the flange-like base member such that the lumen and the channel communicate with each other such as to define a passage into which an elongate medical instrument can be inserted and moved in the direction of the viscus wall.

An aspect of some embodiments of the present disclosure relates to systems for performing direct cardiac catheterization, in particular transapical or transventrical catheterization. In preferred embodiments of the disclosure, the system for performing direct cardiac catheterization comprises an apparatus for providing access having a flange-like base member and also having a tubular member. The flange-like base member is preferably configured to be manually fixed to the outer wall of a ventricle of a patient's heart, in particular to the outer wall of a ventricle at the apex of the heart. A passage formed by a lumen defined by the tubular member and the channel of the flange-like base member may serve as a guidance for a medical puncture device, in particular puncture needle, stylet or trocar, adapted for puncturing the wall of the heart.

Some embodiments of the system for performing direct cardiac catheterization preferably further comprises a surgical closured apparatus for closing the area of the heart wall punctured by a medical puncture device.

According to some embodiments of the present disclosure, the flange-like base member of the apparatus for providing access comprises a first coupling arrangement, whereas the tubular member of the apparatus for providing access

comprises a second coupling arrangement. The second coupling arrangement is complementary to the first coupling arrangement for allowing a releasable coupling between the base member and the tubular member. The first and second coupling arrangements are, for example, configured to form a thread connection, a clip connection, a magnetic connection or a bayonet lock. Of course, other embodiments for the first and second coupling arrangements are also conceivable.

According to some embodiments of the present disclosure, the tubular member of the apparatus for providing access is provided with a sealing arrangement for preventing leakage of fluid, in particular blood, through the second end of the tubular member when the tubular member is coupled with its first end to the first surface of the base member. The sealing arrangement may comprise a mechanical seal arranged in the interior of the lumen defined by the tubular member. The mechanical seal is configured to allow passing an elongate medical instrument there through.

Preferably, the mechanical seal is self-adjustable to the outer diameter of an elongate medical instrument, when the elongate medical instrument passes through the interior of the lumen and the mechanical seal arranged in the interior of the lumen. In this regard, it is conceivable for example, that the mechanical seal comprises a plurality of sealing lips which are movably connected to the inner wall of the lumen, and which are pre-tensioned such as to close the lumen when an elongate medical instrument is not inserted into the lumen. The sealing lips are then self-adjustable to the outer diameter of an elongate medical instrument when the elongate medical instrument is inserted into the lumen of the tubular member.

In accordance with some embodiments of the present disclosure, the mechanical seal may comprise at least one sealing lip, in particular sprung sealing lip, arranged inside the tubular member for preventing leakage of fluid, in particular blood, through the second end of the tubular member when the tubular member is fixed with its first end to the first surface of the base member. Also, it is conceivable that the sealing arrangement may comprise at least one circular seal or O-ring arranged inside the tubular member.

In some embodiments of the present disclosure, the flange-like base member of the apparatus for providing access is provided with a sealing arrangement for preventing leakage of fluid, in particular blood, through a coupling between the first end of the tubular member and the first surface of the base member. The sealing

arrangement of the base member may, for example, comprise a mechanical seal, in particular gasket, washer or circular seal or O-ring.

In more detail, the sealing arrangement of the base member preferably comprises a mechanical seal which fills the space between the matting surfaces defined by the first end of the tubular member on the one hand and the first surface of the base member on the other hand. In this regard, leakage from or into the joint tubular member and base member is prevented. Preferably, the sealing arrangement of the base member is adapted to fill irregularities of the matting surfaces. According to some embodiments disclosed herein, the sealing arrangement is made from a material that is at least to some degree yielding such that it is able to deform thereby ensuring that the space between the first end of the tubular member and the first surface of the base member, including any slight irregularities, is tidily filled.

In some embodiments of the disclosed apparatus for providing access, the flange-like base member is provided with a sealing arrangement for preventing leakage of fluid, in particular blood, between the second surface of the flange-like base member and the outer wall of the viscus when the flange-like base member is fixed to the outer wall of the viscus. The sealing arrangement may comprise, for example, a mechanical seal which is preferably made from a material that is to some degree yielding such that it is able to deform and thereby able to tidily fill the space between the second surface of the base member and the outer wall of the viscus, including any slight irregularities.

With respect of the coupling between the first end of the tubular member and the first surface of the base member, it is preferred in some embodiments of the apparatus for providing access that the base member comprising a flange-like base plate and a port fixed to the base plate, wherein the port is configured to form a releasable connection with the first end of the tubular member for coupling the tubular member to the base member. Preferably, the flange-like base plate of the base member is circular or approximately circular, wherein the port which defines the releasable connection with the first end of the tubular member is arranged at the center of the base plate. Preferably, the port is arranged on the second surface of the base member and surrounds at least partly the opening of the channel which extends through the base member.

According to some embodiments of the present disclosure, the base member comprises a base plate and a port fixed to the flange-like base plate, wherein the port is configured to form a releasable connection with the tubular member for coupling the tubular member to the base member. Preferably, the flange-like base plate and the port are made of a biocompatible material. For example, the flange-like base plate may be made of a rigid material, in particular metal, for example titanium, or a rigid plastic material.

In order to allow that the base member of the inventive apparatus can be manually fixed to the outer wall of the viscus, according to some embodiments of the present disclosure, the flange-like base plate of the base member is provided with an arrangement for fixing the base member to the outer wall of the viscus. For example, the fixing arrangement may comprise at least one and preferably a plurality of holes and/or eyelets for receiving a thin wire or thread required for suturing the base member to the outer wall of the viscus. The holes and/or eyelets are preferably uniformly distributed around an outer circumference of the flange-like base plate.

According to some implementations of the apparatus for providing access, the base member comprises a flange-like base plate which is made of a polymer material, in particular a flexible polymer material. Preferably, the flange-like base plate is at least partly reinforced such as to allow suturing the base member to the outer wall of the viscus. In this regard, it is conceivable that fibres are integrated into the polymer material for reinforcement.

In accordance with some preferred embodiments of the present disclosure, the first surface of the base member, i.e., the surface of the base member which is in contact with the outer wall of the viscus when the base member is fixed to the outer wall of the viscus, is at least partly formed such as to be adapted to the anatomy of the outer wall of the viscus. In some embodiments, for example, it is preferred that the first surface of the base member is at least partly curved.

In order to simplify an insertion of an elongate medical instrument into the interior of the tubular member, i.e. the lumen defined by the tubular member, in some embodiments of the present disclosure, a first funnel-shaped element is provided at the second end of the tubular member.

In addition to or alternatively to a first funnel-shaped element provided at the second end of the tubular member, a second funnel-shaped element may be provided at the first end of the tubular member, wherein the second funnel-shaped element is configured such as to simplify an insertion of an elongate medical instrument into the channel of the base member when the tubular member is coupled with the base member. The first funnel-shaped element and/or the second funnel-shaped element are/is preferably integrally formed with the tubular member. As an alternative, the first funnel-shaped element and/or the second funnel-shaped element may be separate elements / a separate element connected with the respective ends of the tubular member.

In accordance with some embodiments of the apparatus for providing access, the base member is at least partly formed of a biologically degradable material. particularly preferred implementation of this embodiment provides for the biologically degradable material to comprise a polymer composite which exhibits a hydrolytically degradable polymer, in particular poly-hydroxycarboxylic acids or the corresponding copolymers. Hydrolytic degradation has the advantage that a rate at which degradation occurs is independent of the side of implantation since water is present throughout the body of the patient.

Making use of enzymatically degradable polymers, however, is also conceivable in other embodiments. Conceivable in particular is that the biologically degradable material comprises a polymer composite which exhibits a biodegradable thermoplastic amorphous polyurethane-copolyester polymer network.

Likewise conceivable for the chemical composition to the polymer composite for the base member is that the polymer composite exhibit a biodegradable elastic polymer network, obtained from cross-linking of oligomer diols with diisocyanate.

In accordance with embodiments of the present disclosure, the channel provided in the base member has an inner diameter defining the maximum achievable diameter of an access hole which can be realized by an elongate medical instrument inserted into the passage defined by the lumen of the tubular member and the channel provided in the base member. Preferably, the elongate medical instrument, which is insertable into the passage defined by the lumen of the tubular member and the channel provided in the base member, is selected from the group consisting of: a catheter, a cannula, a dilator, a needle, a guidewire, an elongate probe, and a medical puncture device, in particular puncture needle, stylet or trocar.

A further aspect of the present disclosure relates is directed to an apparatus for providing transapical or transventrical access to the heart of a patient required for delivering therapeutic devices to the heart for structural heart repair procedures. The base member of the apparatus for providing transapical or transventrical access is configured to be manually fixed to the outer wall of a ventricle at the apex of the heart.

Another aspect of the present disclosure relates to a system for performing direct cardiac catheterization, in particular transapical or transventrical catheterization. The system comprises an apparatus for providing access of the kind as previously described, i.e. an apparatus which comprises a preferably flange-like base member having a first surface and an opposite second surface, and also having a channel extending therethrough. The apparatus further comprises a tubular member defining a lumen. The tubular member has a first end and an opposite second end and is configured to be coupled with its first end to the first surface of the base member such that the lumen and the channel communicate with each thereby defining a passage into which an elongate medical instrument is insertable. According to some embodiments disclosed herein, the base member of the apparatus for providing access is configured to be manually fixed to the outer wall of a ventricle of the heart, in particular to the outer wall of a ventricle at the apex of the heart, wherein the passage formed by the lumen of the tubular member of the apparatus and the channel of the base member of the apparatus serves as a guidance for a medical puncture device, in particular puncture needle, stylet or trocar, i.e. a medical device which is adapted for puncturing the wall of the heart.

In accordance with some embodiments of the present disclosure, the system for performing direct cardiac catheterization further comprises a surgical closure apparatus for closing the area of the heart wall punctured by the medical puncture device.

According to some embodiments of the system for performing direct cardiac catheterization, the surgical closure apparatus comprises an expandable or self-expandable occlusion device which is introducible into the ventricle of the heart in a minimally invasive fashion via the passage formed by the lumen of the tubular member and the channel of the base member, and via the puncture of the heart wall performed by the medical puncture device.

Preferably, the occlusion device is introducible into the ventricle of the heart by using a corresponding catheter delivery system. For this reason, it is preferred that the occlusion device of the surgical closure apparatus exhibits a collapsed shape as the occlusion device is being inserted into the ventricle of the heart by using a catheter delivery system, and an expanded shape as the occlusion device is in its implanted state.

In accordance with some embodiments disclosed herein, the occlusion device comprises a retention area which exhibits a flattened umbrella-shaped contouring in an expanded state of the occlusion device. In some embodiments of the surgical closure apparatus, the retention area of the occlusion device consists of a braiding of thin wires or threads given a suitable form by means of a moulding and heat treatment procedure.

Preferably, the braiding consists of nitinol or of another shape-memory material or material having memory effect. Such other material could conceivably be, for example, copper-zinc aluminum alloys, gold-cadmium alloys or even ferrous alloys such as, for example, iron-manganese-silicon alloys, or also plastics, all which are characterized by their extremely high memory capacity.

In some embodiments of the present disclosure, it is particularly provided for the braiding of the retention area of the occlusion device to be formed from a shape-memory polymer based on, for example, polyanhydride matrixes or on polyhydroxycarboxylic acids. These are synthetic, biodegradable materials which have a thermally-introduced shape-memory effect.

Yet also conceivable would be other shape-memory polymers such as, for example, block copolymers as described for example in the special edition of *Applied Chemistry* 2002, 114, pages 2138 to 2162, by A. Lendlein and S. Kelch.

Another advantageous implementation or development of the previously-cited embodiments of the occlusion device provides for the polymer composite to comprise a linear, phase-segregated multiblock copolymer network which can exhibit at least two different phases, whereby the first phase is a hard segment-forming phase in which a plurality of hard segment-forming blocks are formed in the polymer which serve the physical cross-linking of the polymer structure and define and stabilize the permanent shape to the braiding, and whereby the second phase is a switching segment-forming phase, in which a plurality of switching

segment-forming blocks are formed in the polymer which serve to fix the temporary shape of the braiding, whereby the transition temperature from the switching segment-forming phase to the hard segment-forming phase is the switching temperature, and whereby conventional methods such as injection moulding or extrusion processes can be used to set the profile form to the braiding above the transition temperature of the hard segment-forming phase.

With respect to the chemical composition of the polymer composite of which the braiding of the occlusion device may be comprised, a preferred implementation of the occlusion device having a braiding consisting of a shape memory polymer composite can provide for the polymer composite to have thermoplastic polyurethane elastomers of a multiblock structure, whereby the hard segment-forming phase is formed by conversion of diisocyanates, in particular methylene-bis(4-phenylisocyanate) or hexamethylene diisocyanate, with diols, in particular 1,4-butanediol, and whereby the switching segment-forming phase yields from oligomeric polyether/poly-esterdiols, in particular based on OH-terminated poly(tetrahydrofuran), poly(.epsilon.-caprolactone), poly(ethylene adipate), poly(ethylene glyocol) or poly(propylenglycol).

In an alternative yet advantageous implementation, it is conceivable for the phase-segregated diblock copolymers of the polymer composite to exhibit an amorphous A-block and a semi-crystallized B-block, whereby the glass transition of the amorphous A-block constitutes the hard segment-forming phase, and whereby the melting temperature of the semi-crystalline B-block serves as the switching temperature for the thermal shape memory effect.

It is advantageously provided in the latter preferred implementation with respect to the polymer composite for this compound to have polystyrol as the amorphous A-block and poly(1,4-butadiene) as the semi-crystalline B-block.

In consequence thereof, the linear phase-segregated multiblock copolymers constitute an important group of shape memory polymers. These polymers have two separate phases, whereby the one phase with the higher transition temperature serves the physical cross-linking and for defining the permanent shape. Conventional processes for profile shaping such as injection moulding or extrusion can be used above this melting temperature. As indicated above, the second phase is then molecular switching and serves to fix the temporary shape,

whereby the transition temperature of the switching phase can be a melting or a glass transition temperature.

Included among the shape memory polymers which function in accordance with this operating principle based on linear block copolymers are thermoplastic polyurethane elastomers having a multiblock structure.

Alternatively to the embodiment in which the polymer composite, of which the braiding of the occlusion device may be composed, exhibits a phase-segregated diblock copolymer, it is provided for the polymer composite to exhibit a phase-segregated triblock copolymer having a semi-crystalline central B-block and two amorphous terminal A-blocks whereby the A-blocks constitute the hard segment and the B-block establishes the switching temperature.

It would be conceivable here for the polymer composite to have semi-crystalline poly-(tetrahydrofuran) as the central B-block and amorphous poly(2-methyloxazolin) as the terminal A-blocks.

Pursuant thereto, other shape memory polymers based on linear block copolymers and which function according to the above-described operating principle are the claimed phase-segregated diblock or triblock copolymers, which would include, for example, AB-block copolymers of 34 wt. % polystyrol (PS) as the amorphous A-block and 66 wt. % poly(1,4-butadiene) (PB) as the semi-crystallized B-block.

Likewise proven to be advantageous is for the polymer composite to exhibit a covalent cross-linked polymer network formed by polymerization, polycondensation and/or polyaddition of difunctional monomers or macromers with additive of tri or higher functional cross-linking, whereby given an appropriate selection of the monomers, their functionality and ratio of cross-linkers, the chemical, thermal and mechanical properties of the polymer network as formed can be specifically and selectively set. This thus enables the precise and advance establishing of the properties for the occlusion device at the transition from the first preliminary definable profile shape to the second preliminary definable profile shape, and in particular, the precise and advance establishing of the course of events upon expansion of the occlusion device.

A particularly preferred implementation of the latter embodiment provides for the polymer composite to be a covalent polymer network which constitutes a cross-

linker by cross-linking copolymerization of stearylacrylate and methacrylic acid with N,N'-methylenebisacrylamide, whereby the shape memory effect of the polymer composite is based on crystallizing stearyl-side chains.

It is likewise feasible for the polymer composite to exhibit a covalent cross-linked polymer network which is formed by subsequent cross-linking of linear or branched polymers.

Additionally conceivable here would be, for example, activating the cross-linking by ionizing radiation or by thermal fission of radical-forming groups.

Hence, a large group of shape-memory polymers constitute the covalent cross-linked polymer networks as previously indicated at the outset. Based on their structure, two different strategies for synthesis are advantageously followed:

A first synthesis variant for covalent shape-memory polymer networks is given by polymerization, polycondensation or polyaddition of difunctional monomers or macromers with additive of tri or higher functional cross-linking. Given the appropriate selection of the monomers, their functionality and the ratio of cross-linkers, the chemical, thermal and mechanical properties of the polymer network as formed can be specifically and selectively set.

A second synthesis variant for covalent shape-memory polymer networks is given by the subsequent cross-linking of linear or branched polymers. Cross-linking density is hereby heavily dependent on the reaction conditions selected. Here, the crosslinking is usually activated by ionizing radiation or by thermal fission of radical-forming groups. For example, polyethylene films receive heat-shrinking properties from irradiating polyethylene with gamma-radiation or cross-linked polyethylene-polyvinylacetate copolymers obtain shape memory effect by homogenous addition of the dicumylperoxide radical initiator.

Of particular interest with respect to the use of occlusion devices are implant materials which are synthetically biodegradable. Degradable materials, respectively polymers, have bonds which are fissionable under physiological conditions. Degradableness is the term used if a material decomposes from loss of mechanical properties due to or within a biological system. An implant's external form and dimensions may in fact remain intact during the decomposition. What is meant with respect to degradation time, provided no additional quantifying data is given,

is the time it takes for the complete loss of mechanical properties. Biostable materials refer to materials which remain stable within biological systems and which degrade at least only partially over the long term.

The present disclosure provides for the medical occlusion devices of the type specified at the outset and in accordance with the previously-cited preferred embodiments to comprise a braiding which is synthesized from a polymer composite comprising at least one bio-degradable material.

A particularly preferred implementation of the latter embodiment provides for the polymer composite to exhibit a hydrolytically degradable polymer, in particular poly(hydroxy carboxylic acids) or the corresponding copolymers. Hydrolytic degradation has the advantage that the rate at which degradation occurs is independent of the site of implantation since water is present throughout the system.

However, making use of enzymatically degradable polymers is also conceivable in another embodiment. Feasible in particular is that the polymer composite exhibit a biodegradable thermoplastic amorphous polyurethane-copolyester polymer network.

Likewise requisite for the chemical composition to the polymer composite for the inventive medical occlusion device is that the polymer composite exhibit a biodegradable elastic polymer network, obtained from crosslinking of oligomer diols with diisocyanate.

For the braiding from which the occlusion device may be configured, the disclosure claims both hydrolytically as well as enzymatically degradable polymer composites for the degradable polymers. As stated above, hydrolytic degradation has the advantage that the rate at which degradation occurs is independent of implant location. In contrast, local enzyme concentrations vary greatly. Given biodegradable polymers or materials, degradation can thus occur through pure hydrolysis, enzymatically-induced reactions or through a combination thereof.

Typical hydrolyzable chemical bonds for the polymer composites of the occlusion device are amide, ester or acetal bonds. Two mechanisms can be noted with respect to the actual degradation. With surface degradation, the hydrolysis of chemical bonds transpires exclusively at the surface. Because of the hydrophobic

character, polymer degradation is faster than the water diffusion within the material. This mechanism is seen especially with poly(anhydrides) and poly(orthoesters).

In particular to the poly(hydroxy carboxylic acids) such as poly(lactic acid) or poly(glycol acid), polymer degradation transpires throughout the entire volume. The step which determines the rate here is the hydrolytic fission of the bonds since water diffusion in the somewhat hydrophilic polymer matrix occurs at a relatively fast rate.

Decisive for the use of biodegradable polymers is that, on the one hand, they degrade at a controlled or variable speed and, on the other, that the products of decomposition are non-toxic.

The concept of polymer material resorption includes, for example, the substance or mass degrading through to the complete removal of a material from the body by way of the natural metabolism. In the case of homogenous implants (occlusion devices) of only one degradable polymer, resorption begins as of that point in time of the complete loss of the mechanical properties. Specification of the resorption time covers the period starting from implantation and running through to the complete elimination of the implant.

Among some of the most important biodegradable synthetic classes of polymers from which the braiding of the occlusion device according to embodiments of the disclosure is advantageously synthesized are, for example,:

- polyesters such as poly(lactic acid) PLA, poly(glycol acid) PGA, poly(3-hydroxybutyric acid) PBA, poly(4-hydroxyvalerate acid) PVA or poly(-caprolactone) PCL or the respective copolymers;
- polyanhydrides synthesized from dicarboxylic acids such as, for example, glutar PAG, amber PAB or sebacic acid PAS; or
- poly(amino acids) or polyamides such as, for example, poly(serine ester) PSE or poly(aspartic acid) PAA.

In summary, it can be stated that shape memory properties play a significant role with respect to implants, particularly in terms of minimally invasive medicine. Degradable implants having shape memory properties are particularly effective in this regard.

For example, this type of degradable implant can be introduced into the body in compressed (temporary) form through a small incision and once in place, then assume the memory shape relevant to its application after being warmed by the body temperature. The implant will then degrade after a given interval of time, thereby doing away with the need for a second operation to remove it.

In one possible embodiment of the occlusion device, biodegradable thermoplastic amorphous polyurethane copolyester polymer networks having shape memory properties are used as the material for the occlusion device. First, suitable biodegradable star-shaped copolyester polyols are synthesized here based on commercially available dilactide DL (cyclic lactic acid dimer), diglyocolide DG (cyclic glycol acid dimer) and trimethylolpropane TP (functionality F=3) or pentaerythrit PE (F=4) with glass transition temperatures between 36°C and 59°C, which are then cross-linked with commercial trimethylhexa-methylene diisocyanate TMDI in forming a biodegradable polyurethane network.

Particularly preferred is for the occlusion device to exhibit at least one fabric insert arranged at the retention area of the occlusion device. This fabric insert serves to close any remaining gaps in the retention area of the occlusion device after the device has been inserted into the body of a patient. The fabric insert is, for example, stretched over the retention area of the occlusion device in such a manner that it can cover the retention area like a close. The fabric insert can, for example, be made of Dacron®. Of course, other materials and other positioning to the fabric insert in or on the occlusion device are also conceivable here.

According to some embodiments of the surgical closure apparatus utilized in the system for performing direct cardiac catheterization, the surgical closure apparatus comprises an expandable or self-expandable occlusion device comprising a retention area, wherein the retention area consists of a foldable support frame and a flexible membrane fixed to the foldable support frame. The foldable support frame may be composed of nitinol or of another shape-memory material or material having memory effect. The foldable support frame may be composed in particular of nitinol or of a shape-memory polymer of the kind as already described in connection with the braiding of the retention area. The flexible membrane fixed to the foldable support frame is preferably composed of silicone, polyurethane or a polymer containing material.

In accordance with some embodiments of the system for performing direct cardiac catheterization, the surgical closure apparatus comprises an occlusion device comprising a fixing arrangement for fixing a retention area of the occlusion device to the base member of the apparatus for providing access. In this regard, the area of the heart wall punctured by a medical puncture device may be closed after performing cardiac catheterization.

Preferably, the fixing arrangement of the occlusion device comprises a tie element fixed to the retention area of the occlusion device, wherein the tie element is configured to extend at least partly into the puncture of the heart wall when the occlusion device is in its implanted state. The fixing arrangement may comprise, for example, a locking element configured to be coupled to the tie element such that the retention area of the occlusion device and the locking element are positioned on the two sides of the puncture to be occluded in the heart wall. Preferably, the locking element comprises a heat portion having a diameter larger than the diameter of the channel extending through the base member of the apparatus for providing access.

More preferably, the locking element is provided with a tie element fixed to the heat portion, wherein said tie element is connectable to the tie element fixed to the retention area of the occlusion device. The tie element fixed to the retention area of the occlusion device and the tie element fixed to the heat portion of the locking element are preferably provided with a threaded area configured to be engageable with each other.

In some embodiments of the surgical closure device utilized with the inventive system for providing direct cardiac catheterization, the tie element fixed to the retention area of the occlusion device is configured to be connectable with the tip of a stylet, catheter or cannula for implanting the occlusion device and positioning the retention area.

In accordance with some embodiments of the surgical closure device utilized in the system for performing direct cardiac catheterization, the occlusion device comprises a fixing arrangement having a locking element, wherein the locking element is provided with at least one port for supplying a filling material in the volume between the two sides of the puncture to be occluded in the heart wall.

There is further provided, in accordance with some aspects of the present disclosure, a method for minimally-invasive surgery, in particular minimally-invasive cardiac surgery, the method comprising the steps of:

- providing an apparatus for providing access of the kind as previously described;
- fixing the base member of the apparatus to the outer wall of a viscus to be treated;
- connecting the tubular member of the apparatus with the base member such that the lumen of the tubular member and the channel provided in the base member communicate with each other in form a passage; and
- puncturing the viscus wall at an area accessible by a medical puncture device, in particular puncture needle, stylet or trocar, when the medical puncture device passes through the passage formed by the lumen of the tubular member and the channel provided in the base member.

Preferably, the method further comprises the step of:

- passing a catheter into the viscus through the puncture in the viscus wall performed by the medical puncture device for performing a structural repair procedures inside the viscus.

In accordance with some embodiments of the method, an additional step of closing the area of the viscus wall punctured by the medical puncture device by using a surgical closure apparatus is provided.

The following will make reference to the drawings and providing a more precise detailing of preferred embodiments of the disclosure.

Fig. 1: illustrates aspects of the human heart anatomy;

Fig. 2a: illustrates schematically a retrograde implementation procedure of a heart valve stent;

Fig. 2b: illustrates schematically an antegrade implantation procedure of a heart valve stent;

Fig. 3a: illustrates an exemplary embodiment of a flange-like base member of an apparatus for providing access to a viscus of a patient;

Fig. 3b: illustrates an exemplary embodiment of a coverage for the base member in accordance with Fig. 3a;

Fig. 3c: illustrates the exemplary embodiment of a base member in accordance with Fig. 3a and the exemplary embodiment of a coverage in accordance with Fig. 3b in an assembled condition;

Fig. 4a: illustrates the exemplary embodiment of a base member in accordance with Fig. 3a, wherein the base member is fixed to the outer wall of a viscus;

Fig. 4b: illustrates the exemplary embodiment of a base member in accordance with Fig. 4a with assembled coverage;

Fig. 4c: illustrates the exemplary embodiment of a base member with assembled coverage in accordance with Fig. 4a in a side-sectional elevation;

Fig. 5: illustrates an exemplary embodiment of an apparatus for providing access to a viscus of a patient in a side-sectional elevation, said apparatus comprising a base member assembled with a coverage in accordance with Fig. 4b and a tubular member coupled to the base member;

Fig. 6: illustrates the exemplary embodiment of an apparatus for providing access to a viscus of a patient in accordance with Fig. 5 in a side-sectional elevation, wherein an elongate medical instrument is received within a passage defined by the base member and the tubular member coupled to the base member;

Fig. 7: illustrates the exemplary embodiment of an apparatus for providing access to a viscus of a patient in accordance with Fig. 6 in a side-sectional elevation after removing the elongate medical instrument from the passage defined by the base member and the tubular member of the apparatus;

Fig. 8: illustrates the exemplary embodiment of an apparatus for providing access to a viscus of a patient in accordance with Fig. 7 in a side-sectional elevation, wherein a tip of a catheter delivery system is received within the passage defined by the base member and the tubular member, and wherein an exemplary embodiment of a surgical closure apparatus in a collapsed state is accommodated in the catheter tip of the catheter delivery system;

Fig. 9: illustrates the exemplary embodiment of an apparatus for providing access to a viscus in accordance with Fig. 8 in a side-sectional elevation, wherein an occlusion device of the exemplary embodiment of the surgical closure apparatus is at least partly released from the tip of the catheter delivery system;

Fig. 10: illustrates the exemplary embodiment of an apparatus for providing access to a viscus of a patient in accordance with Fig. 9 in a side-sectional elevation after disconnecting and removing the tubular member from the base member fixed to the outer wall of the viscus;

Figs. 11a to c: illustrate an exemplary embodiment of a medical closure system comprising a base member in accordance with Fig. 4c fixed to the outer wall of a viscus and further comprising an exemplary embodiment of a medical closure apparatus connected with the base member for closing an area of the viscus previously punctured by a medical puncture device;

Fig. 12: illustrates the exemplary embodiment of the medical closure system in accordance with Figs. 11a to 11c in an assembled but explanted state;

Fig. 13: illustrates a retention are of an occlusion device which is part of the surgical closure apparatus utilized in the medical closure system in accordance with Figs. 11a to 11c; and

Fig. 14: illustrates an exemplary embodiment of a locking element which is part of an occlusion device utilized in the surgical closure apparatus in accordance with Figs. 11a to 11c.

Both the right and left halves of the human heart consist of a ventricle and an atrium. These cavities are separated by the septum of the heart, divided into the atrial septum (*septum interatriale*) and the ventricular septum (*septum interventriculare*).

Blood can only flow in one direction through the chambers of the heart due to the cardiac valves situated between the atria and ventricles and in the arteries connected to the ventricles which function like mechanical valves. The superior and inferior vena cava (*vena cava superior et inferior*) flow into the right atrium. They supply the oxygen-depleted (venous) blood from the systemic circulation to the heart. The tricuspid valve which, like a mechanical valve, prevents a reverse flow of blood into the atrium upon ventricular contraction (systole) is situated between the right atrium and the right ventricle. It comprises three segments which are affixed like flaps to the ventricular musculature by ligaments (hence also called the "flap valve"). The two pulmonary arteries depart the right ventricle of the heart via a common trunk (*truncus pulmonalis*). There is also a valve between the ventricle and the pulmonary trunk, the so-called pulmonary valve. This type of valve is also called a semi-lunar valve due to its shape. The pulmonary arteries supply the oxygen-depleted blood to the pulmonary circulation.

Oxygen-rich (arterial) blood then usually flows through four pulmonary veins from the pulmonary circulation to the left atrium. From there, it reaches the left ventricle through a further flap valve, the mitral valve. The outflow is carried by the aorta which, like the pulmonary artery, has a semi-lunar valve (aortic valve).

During a heart cycle, the atria are filled first while the ventricles concurrently disgorge the blood into the arteries. When the ventricular musculature relaxes, the flap valves open due to the drop in pressure in the ventricle and the blood flows in from the atria (*auricular systole*). This is supported by a contraction of the atria. Ventricular contraction follows: the ventricular musculature contracts, the pressure rises, the flap valves close and the blood can now only flow into the arteries through the now-opened semi-lunar valves. A reverse blood flow from the arteries during the relaxation phase (diastole) is prevented by the closing of the semi-lunar valves such that the direction of flow is determined solely by the valves.

The four cardiac valves work like mechanical valves in the heart and prevent a reverse flow of blood in the wrong direction. Each half of the heart has a flap valve

(atrioventricular valve) and a semi-lunar valve. The atrioventricular valves are situated between the atrium and the ventricle and are called the bicuspid/mitral valve and the tricuspid valve. The semi-lunar valves are situated between the ventricle and the vascular outflow and are called the pulmonary valve and the aortic valve respectively.

A valve defect, i.e. a dysfunction of a cardiac valve's function, can affect any of the four cardiac valves, although the valves on the left side of the heart (aortic and mitral valves) are affected considerably more frequently than those on the right side of the heart (pulmonary and tricuspid valves). Dysfunction can encompass constriction (stenosis), insufficiency or a combination of the two (combined vitium).

In medicine, the term "aortic valve insufficiency", or "aortic insufficiency" for short, generally refers to the defective closing of the heart's aortic valve and the diastolic reverse flow of blood from the aorta into the left ventricle as a result. Depending on the severity of the aortic insufficiency and the extent of resistance to aortic depletion, the volume of reverse flow can be up to two thirds of the left ventricle's ejection volume (normal cardiac output: 40 to 70 ml). This results in characteristically high blood pressure amplitude. This regurgitated blood flow increases the diastolic filling of the left chamber and leads to a volume overload of this section of the heart, a consequence of which is eccentric hypertrophy.

Aortic valve stenosis is a valvular heart disease caused by the incomplete opening of the aortic valve. When the aortic valve becomes stenotic, it causes a pressure gradient between the left ventricle and the aorta. The more constricted the valve, the higher the gradient between the left ventricle and the aorta. For instance, with a mild aortic valve stenosis, the gradient may be 20 mmHg. This means that, at peak systole, while the left ventricle may generate a pressure of 140 mmHg, the pressure that is transmitted to the aorta will only be 120 mmHg.

In individuals with aortic valve stenosis, the left ventricle has to generate an increased pressure in order to overcome the increased afterload caused by the stenotic aortic valve and eject blood out of the left ventricle. The more severe the aortic stenosis, the higher the gradient is between the left ventricular systolic pressures and the aortic systolic pressures. Due to the increased pressures generated by the left ventricle, the myocardium (muscle) of the left ventricle undergoes hypertrophy (increase in muscle mass).

Angina in the setting of aortic valve stenosis is secondary to the left ventricular hypertrophy that is caused by the constant production of increased pressure to overcome the pressure gradient caused by the aortic valve stenosis. While the myocardium (i.e. heart muscle) of the left ventricle gets thicker, the arteries that supply the muscle do not get significantly longer or bigger, so the muscle may become ischemic (i.e. doesn't receive an adequate blood supply). The ischemia may first be evident during exercise, when the heart muscle requires increased blood supply to compensate for the increased workload. The individual may complain of exertional angina. At this stage, a stress test with imaging may be suggestive of ischemia.

Mitral valve insufficiency (also called "mitral insufficiency") is a frequent cardiac valve defect in human medicine and also in at least some animal species. It involves a closing defect or "leakage" of the heart's mitral valve which leads to reverse blood flow from the left ventricle into the left atrium during the ejection phase (systole).

The mitral valve functions like a mechanical valve between the left atrium and the left ventricle of the heart. It opens during the filling phase of the ventricle (diastole) and thus enables the inflow of blood from the atrium. At the beginning of the ejection phase (systole), the sudden increase in pressure in the ventricle leads to the closing of the valve and thus to a "sealing" of the atrium. In so doing, a pressure of only about 8 mmHg prevails in the atrium, while at the same time the systolic pressure of about 120 mmHg in the ventricle forces the blood along its usual path into the main artery (aorta).

In cases of severe mitral insufficiency, however, the regurgitation opening is larger than 40 mm^2 and the regurgitation volume greater than 60 ml, which can lead to serious and at times life-threatening changes.

In the acute stage, with a normal size to the left ventricle and the left atrium, there is a considerable increase of the pressure in the atrium and thus also in the pulmonary veins. This can be up to 100 mmHg which, given a normal condition to the pulmonary vessels, leads to immediate pulmonary oedema. The then predominantly reverse blood flow can result in insufficient outflow into the aorta and thus decreased blood flow to all the organs.

To treat a severe narrowed cardiac valve or cardiac valve insufficiency, it is necessary for a valvular prosthesis (hereinafter also referred as "heart valve prosthesis") to perform the valve function of the narrowed, diseased or diseased cardiac valve. Essential in this respect is that the valvular prosthesis is securely positioned and anchored in the implantation site in the heart; i.e. in the plane of the (diseased) cardiac valve to be replaced, so that the valvular prosthesis is not displaced or shifted despite the, at times considerable, forces acting on it. An effective seal during systole is also important.

Over the past few years, minimally invasive interventional procedures for the treatment of a severe narrowed cardiac valve or cardiac valve insufficiency have become an established therapeutic alternative to "conventional" open surgical procedures. Certain procedures, however, involve placement of relatively large devices into targeted locations within tissue structures. Procedures such as aortic valve replacement conventionally have been addressed with open surgical procedures which are highly invasive. More recently, such procedures have been attempted using natural lumen excess and catheter delivery systems.

Referring to the human heart anatomy illustrated in Fig. 1, such natural lumen access and delivery systems typically are configured, for example, to reach the aortic valve location 212 inside of the heart 202 from an antegrade approach, i.e. performed in the normal direction of blood flow. An antegrade approach generally requires navigating instrumentation through the right ventricle 222, the left atrium, and the left ventricle 220 of the beating heart 202, by way of the mitral valve 210.

A retrograde approach, i.e. an access performed backward or against the usual direction of blood flow, is an alternative to reach the aortic valve location 212 inside of the heart 202. A retrograde approach generally requires navigating instrumentation along the aortic arch, from the descending aorta 204 to the ascending aorta 206 and adjacent the aortic valve 212.

A transarterial access to the heart 202 of a patient as an example for a retrograde approach is schematically shown in Fig. 2a. In the illustration in accordance with Fig. 2a, a heart valve stent 100 is advanced with the aid of a medical catheter delivery system (only schematically shown) via the femoral artery to the aortic valve 212.

In some cases, a retrograde approach cannot be used in patients who have small or tortuous femoral or iliac vessels or severe peripheral vascular disease such as persons with previous aortobifemoral grafting. Rather, for such patients, an antegrade approach, for example transapical approach, is preferred, whereby the surgeon creates a transcutaneous access to the region around the apex 224 of the beating heart 202 with a surgical thoracotomy, followed by direct access to the left ventricle 220 using a needle or other puncture device aimed to access the left ventricle 220 around the left ventricular apex 224.

Aspects of an antegrade (transapical) access procedure are illustrated in Fig. 2b, wherein the pericardium is opened by using a needle device for puncturing the muscular heart wall to gain access of the left ventricle 220 around the location of the left ventricular apex 224. A guidewire 180 may be advanced toward and through the aortic valve 212 to assist with diagnostic and interventional aspects of the procedure. After treatment of the heart 202, the apex 224 is closed, for example, by using a purse-string suture technique. A purse-string suture is a continuous suture placed in a circle about a round wound or punctures which needs to be closed. The opening is closed by tightly drawing the ends of the suture together.

However, frequently some negative accompaniments occur with the conventional transapical or transventrical access procedure. These are, for example, unwanted bleedings during procedure and breakage of the tissue around the location of the left ventricular apex 224 while final closing the suture which could lead to death of the patient.

With the foregoing as background, the present disclosure provides a system to simplify and standardize the technique for opening and closing the beating heart during a cardiac surgery. The inventive system makes a transapical or transventrical access and closure procedure required for delivering therapeutic devices to the heart more routine for all surgeons.

The improved heart surgery system disclosed herein comprises a sealed port system to be mounted on the outer wall of the heart at the location of the left ventricular apex prior to puncture the left ventricle. The port system is adapted and designed for allowing the puncture of the left ventricle by using, for example, the well-known Seldinger Method.

Moreover, the port system is adapted and designed for allowing a transapical insertion of medical devices into the interior of the left ventricle, for example an insertion of balloon- catheters and delivery systems for heart valve prostheses.

According to some embodiments disclosed herein, the port system comprises a base member having a first surface and an opposite second surface, and further having a channel extending through the base member, said base member being preferably a flange-like member and configured to be manually fixed to the outer wall of a viscus, for example, at the left-ventrical apex of the heart of a patient. The port system disclosed herein preferably further comprises a tubular member defining a lumen, the tubular member having a first end and an opposite second end and being configured to be coupled with its first end to the first surface of the base member such that the lumen of the tubular member and the channel of the base member communicate with each other thereby defining a passage through which an elongate medical instrument is moveable in the direction of the viscus wall.

Hence, the port system is configured to provide a platform securely attached to the viscus, for example, the beating heart. Surgeons can then deliver therapeutic devices, such as a heart valve prosthesis or left ventricular assist devices, into the beating heart without loss of blood or exposure to air.

Once a therapeutic device has been delivered and surgery is complete, an occlusion device closes and seals the access site with a biocompatible implant. The occlusion device can be re-opened if necessary.

In accordance with some embodiments of the heart surgery system, the occlusion device is adapted and configured to be implanted and placed into the interior of the left ventricle via the port system previously attached to the outer wall of the heart.

Hence, the occlusion device is an appropriate closure mechanism for the apex, which can be used to replace purse string sutures in TAVI procedures as they are done today.

The heart surgery system disclosed herein improves safety, decreases procedure time and reduces the technical challenges associated with minimally invasive procedures. This is achieved by minimizing the incision size to gain access to the

beating heart and eliminating the need for conventional sutures. Moreover, with the heart surgery system disclosed herein, an adoption of minimally invasive therapeutic heart procedures can be expanded to a greater number of surgeons and as a result, many underserved patients will receive needed treatment for valve disease and end-stage heart failure.

An exemplary embodiment of a port system disclosed herein is described in the following with reference to Figs. 3 to 7. The exemplary port system comprises a flange-like base member 11 which is configured to be manually fixed to the outer wall of a patient's viscus, for example, to the outer wall of the left ventricle at the apex of the beating heart. As will be described in more detail below, the port system disclosed herein may serve as an apparatus for providing access to a viscus of a patient required for delivering therapeutic devices into the viscus for a structural repair procedure.

An exemplary embodiment of the flange-like base member 11 is illustrated in Figs. 3a to 3c. Figs. 4a and 4b illustrate the flange-like base member 11 in accordance with Figs. 3a to 3c fixed to the outer wall of a viscus (here: the outer wall of the left ventricle at the apex of the beating heart).

The base member 11 has a first surface 11a, an opposite second surface 11b, and a channel 12 extending through the base member 11. In accordance with the exemplary embodiment depicted in Fig. 3a, the base member 11 is a flange-like member configured to be manually fixed to the outer wall of, for example, the left ventricle at the apex of the heart of a patient. In this regard, reference is also made to Fig. 4a which illustrates the exemplary embodiment of the base member 11 in accordance with Fig. 3a, wherein the base member 11 is fixed to the outer wall of a viscus 220.

In more detail, the base member 11 shown in Fig. 3a is a flange-like member comprising a base plate 15 and a port 25 fixed to the base plate 15. As will be described in more detail with reference to Fig. 5, the port 25 of the flange-like base member 11 is configured to form a releasable connection with a tubular member 16 of the apparatus 10 for providing access in order to couple the tubular member 16 with the base member 11.

In accordance with some embodiments disclosed herein and as depicted in Fig. 3a, the base plate 15 of the base member 11 is preferably circular, wherein the port 25

is arranged at a center of the base plate 15. The port 25 is arranged on the first surface 11a of the base plate 15 and surrounds at least partly the opening of the channel 12 which extends through the base plate 15 of the base member 11.

As schematically illustrated in Fig. 3a, on the second surface 11b of the base plate 15 which corresponds to the second surface of the base member 11, sealing arrangement 14b is provided for preventing leakage of fluid, in particular blood, between the second surface 11b of the base member 11 and the outer wall of a viscus 220 (see Fig. 4a).

Preferably, the base plate 15 and the port 25 of the base member 11 are made of a biocompatible material. At least the base plate 15 of the base member 11 may be made of a rigid material, in particular metal, for example titanium, or a rigid plastic material.

As illustrated in Fig. 3a, the base plate 15 of the base member 11 is provided with an arrangement 26 for fixing the base member 11 to the outer wall of a viscus 220. In more detail, in the exemplary embodiment depicted in Fig. 3a, the fixing arrangement 26 comprises a plurality of eyelets for receiving a thin wire or thread required for suturing the base member 11 to the outer wall of the viscus 220. In this regard, reference is also made to Fig. 4a which illustrates the exemplary embodiment of the base member 11 in accordance with Fig. 3a, wherein the base member 11 is fixed to the outer wall of a viscus 220.

In more detail, the eyelets of the fixing arrangement 26 are preferably uniformly distributed around an outer circumference of the base plate 15.

In accordance with some embodiments disclosed herein, the base plate 15 of the base member 11 is made of a polymer material, in particular a flexible polymer material. Preferably, the base plate 15 is at least partly reinforced such as to allow suturing the base plate 15 of the base member 11 to the outer wall of a viscus 220. In this regard, it is conceivable that fibers are integrated in the polymer material for reinforcement.

As illustrated, for example, in Fig. 4a, the second surface 11b of the base plate 15 of the base member 11 is in contact with the outer wall of a viscus 220 when the base member 11 is fixed to the outer wall of the viscus, in particular the outer wall of the left ventricle 220 at the apex 224 of the beating heart 202.

In accordance with some embodiments disclosed herein, the second surface 11b of the base member 11 is at least partly formed such as to be adapted to and to match the anatomy of the outer wall of the viscus, in particular the outer wall of the left ventricle 220 at the apex 224 of the beating heart 202, thereby preventing fluid leakage. In more detail, the second surface 11b of the base member 11 is preferably at least partly curved thereby matching the anatomy of the outer wall of the viscus, in particular the outer wall of the left ventricle 220 at the apex 224 of the beating heart 202.

In accordance with some embodiments disclosed herein, the base member 11 of the apparatus 10 is provided with a coverage 9. An exemplary embodiment of such a coverage 9 is illustrated in Fig 3b. The embodiment of the coverage 9 illustrated in Fig. 3b is designed in accordance with the flange-like base member 11 shown in Fig. 3a. In this regard, reference is also made to Fig. 3c which illustrates the exemplary embodiment of the base member 11 in accordance with Fig. 3a and the exemplary embodiment of the coverage 9 in accordance with Fig. 3b in an assembled condition.

In general, the coverage 9 may be configured such as to cover the base plate 15 of the base member 11 at least partly thereby also covering the fixing arrangement 26 of the base plate 15, which is used for fixing the base plate 15 to the outer wall of the viscus, in particular the outer wall of the left ventricle 220 at the apex 224 of the beating heart 202. In this regard, the base member 11 may preferably exhibit a smooth outer surface when implanted in the body of a patient.

In more detail, the exemplary embodiment of the coverage 9 for the base member 11 illustrated in Fig. 3b is a ring-shaped member comprising an opening 8 for receiving the port 25 of the base member 11 in an assembled condition (see Fig. 3c).

The coverage 9 further comprises an arrangement 7 for fixing the coverage 9 to the base plate 15 of the base member 11. In accordance with the exemplary embodiment of the coverage 9 depicted in Fig. 3b, the arrangement 7 for fixing the coverage 9 to the base plate 15 of the base member 11 provides a positive locking of the coverage 9 and the base plate 15 in an assembled condition (see Fig. 3c). In this regard, reference is made, for example, to Fig. 4c which illustrates the

exemplary embodiment of the base member 11 with the assembled coverage 9 in accordance with Fig. 4a in a side-sectional elevation.

Fig. 4a illustrates the exemplary embodiment of the base member 11 in accordance with Fig. 3a, wherein the base member 11 is fixed to the outer wall of a viscus, in particular the outer wall of the left ventricle 220 at the apex 224 of the beating heart 202. On the other hand, Fig. 4b illustrates the exemplary embodiment of the base member 11 in accordance with Fig. 4a with assembled coverage 9.

The base member 11 fixed to the outer wall of the viscus (outer wall of the left ventricle 220) provides a platform securely attached to the viscus, wherein this platform is adapted and configured to be implanted and placed into the interior of the patient's body.

In accordance with some embodiments disclosed herein, the base member 11 comprises a first coupling arrangement 13 for receiving corresponding a second coupling arrangement 18 provided at a tubular member 16 for connecting the tubular member 16 with the base member 11 (see Fig. 5).

In more detail, in accordance with some aspects of the present disclosure, the port system serves as an apparatus for providing access to a viscus of a patient required for delivering therapeutic devices into the viscus for a structural repair procedure. An exemplary embodiment of a port system which serves as apparatus 10 for providing access to a viscus of a patient is illustrated in Fig. 5 in a side-sectional elevation.

As illustrated, in the exemplary embodiment depicted in Fig. 5, the apparatus 10 comprises a base member 11 assembled with a coverage 9 in accordance with Fig. 4b and a tubular member 16 coupled to the base member 11.

In accordance with some embodiments disclosed herein, the second coupling arrangement 18 of the tubular member 16 is complementary to the first coupling arrangement 13 of the base member 11 for allowing a releasable coupling between the base member 11 and the tubular member 16. In this regard, it is conceivable that the first and second coupling arrangements 13, 18 are configured, for example, to form a thread connection, a clip connection, a magnetic connection, or a bayonet lock.

Reference is made to Fig. 5 which illustrates an exemplary embodiment of an apparatus 10 for providing access to a viscus, in particular for providing access to the beating heart 202 of a patient in accordance with the present disclosure. In more detail, the exemplary embodiment of the apparatus 10 illustrated in Fig. 5 comprises a base member 11 assembled with a coverage 9, wherein the base member 11 is fixed to the outer wall of a viscus, in particular the outer wall of the left ventricle 220, and the coverage 9 is connected with the fixed base member 11.

The apparatus 10 further comprises a tubular member 16 coupled to the base member 11. The tubular member 16 is at least partly hollow and defines a lumen 17. A first end 16a of the tubular member 16 is provided with a second coupling arrangement 18 configured to be coupled with a first coupling arrangement 13 provided at the first surface 11a of the base member 11.

In an assembled condition illustrated in Fig. 5, the lumen 17 defined by the tubular member 16 and the channel 12 extending through the base member 11 (see Figs. 3a, c) communicate with each other thereby defining a passage 24 through which an elongate medical instrument 30, 30' is movable in the direction of the viscus wall, in particular in the direction of the outer wall of the left ventricle 220.

In this regard, reference is made, for example, to Fig. 6 which illustrates the exemplary embodiment of an apparatus 10 in accordance with Fig. 5, wherein an elongate medical instrument 30' is received within the passage 24 defined by the base member 11 and the tubular member 16 coupled to the base member 11.

The tubular member 16 is preferably provided with a sealing arrangement for preventing leakage of fluid, in particular blood, through a second end 16b of the tubular member 16, the second end 16b of the tubular member 16 being opposite to the first end 16a, i.e. the end of the tubular member 16 which is coupled to the base member 11 in an assembled condition.

In accordance with some embodiments disclosed herein, the sealing arrangement for preventing leakage of fluid through the second end 16b of the tubular member 16 comprises a mechanical seal 19 arranged in the interior of the lumen 17 defined by the tubular member 16. The mechanical seal 19 is configured to allow passing an elongate medical instrument 30, 30' there through. In this regard, reference is made to Fig. 6 which illustrates the exemplary embodiment of the apparatus 10 in accordance with Fig. 5, wherein an elongate medical instrument 30' is received

within the passage 24 defined by the base member 11 and the tubular member 16 coupled to the base member 11.

In more detail, the mechanical seal 19 arranged in the interior of the lumen 17 defined by the tubular member 16 is preferably self-adjustable to the outer diameter of the elongate medical instrument 30, 30', when the elongate medical instrument 30, 30' passes through the interior of the lumen 17 (see Fig. 6).

In accordance with some embodiments disclosed herein, the mechanical seal 19 arranged in the interior of the lumen 17 defined by the tubular member 16 comprises at least one, preferably at least three and more preferably at least six sealing lips which are movably connected to the inner wall of the lumen 17 defined by the tubular member 16. The at least one sealing lip is preferably pre-tensioned such as to close the lumen 17 thereby preventing leakage of fluid through the second end 16b of the tubular member 16.

In accordance with the exemplary embodiment of the tubular member 16 illustrated, for example, in Fig. 5, the sealing arrangement of the tubular member 16 also comprises at least one additional sealing lip 20 arranged inside the tubular member 16. In accordance with the exemplary embodiment depicted in Fig. 5, the at least one additional sealing lip 20 is a sprung sealing lip.

Moreover, it is conceivable that the sealing arrangement of the tubular member 16 comprises at least one circular seal or O-ring arranged inside the tubular member 16.

In accordance with some embodiments disclosed herein, the base member 11 of the apparatus 10 is provided with a sealing arrangement 14a for preventing leakage of fluid, in particular blood, through the coupling between the first end 16a of the tubular member 16 and the first surface 11a of the base member 11. As illustrated schematically, for example, in Fig. 5, the sealing arrangement 14a of the base member 11 may comprise a mechanical seal, in particular gasket, washer or circular seal or O-ring. In some embodiments disclosed herein, the sealing arrangement 14a of the base member 11 comprises a self-sealing seal, in particular cone.

As will be described in more detail with reference to Figs. 5 to 7, the exemplary embodiment of the apparatus 10 for providing access simplifies and standardize the

technique for opening a viscus, in particular the outer wall of the left ventricle 220 at the apex 224 of the beating heart 202 during cardiac surgery. In this regard, the apparatus 10 as disclosed herein makes a transapical or transventrical access procedure required for delivering therapeutic devices to the heart more routine for all surgeons.

As illustrated in Fig. 5, the apparatus 10 comprises a sealed port system constituted by the base member 11 fixed to the outer wall of the viscus to be treated and a tubular member 16 which is connected with the base member 11 in a sealed manner such that the lumen 17 defined by the tubular member 16 and the channel 12 extending through the base member 11 communicate with each other and thereby form a passage 24 for receiving an elongate medical instrument 30, 30'.

In more detail, Fig. 5 illustrates an exemplary embodiment of the apparatus 10, wherein the sealed port system comprising a base member 11 and a tubular member 16 connected to the base member 11 is mounted on the outer wall of the left ventricle 220 at the apex 224 of the beating heart 202 prior to puncture the wall of the ventricle 220.

Referring to Fig. 5, a first funnel-shaped element 21 is provided at the second end 16b of the tubular member 16 in order to simplify an insertion of an elongate medical instrument 30, 30' into the interior of the tubular member 16 (see Fig. 6 and Fig. 8). Moreover, a second funnel-shaped element 22 is provided at the first end 16a of the tubular member 16 in order to simplify an insertion of an elongate medical instrument 30, 30' into the channel 12 of the base member 11 when the tubular member 16 is coupled with the base member 11.

In the embodiment depicted in Fig. 5, the first and second funnel-shaped elements 21, 22 are separate elements connected with the respective ends 16a, 16b of the tubular member 16. It is also conceivable, however, that the first and second funnel-shaped elements 21, 22 are integrally formed with the tubular member 16.

For providing access, for example during structural heart repair procedures, the base plate 15 of the base member 11 is manually fixed to the outer wall of the heart 202, preferably at the apex of the heart 202. In this regard, reference is made to Fig. 4b.

Thereafter, the tubular member 16 is coupled with the port 25 provided at the first surface 11a of the base member 11 (see Fig. 5).

Then, an elongate medical puncture device 30', for example, a puncture needle, stylet or trocar, is inserted into the passage 24 formed by the lumen 17 of the tubular member 16 and the channel 12 of the base member 11, said passage 24 serving as a guidance for the medical puncture device 30' (see Fig. 6). In this regard, the wall of the heart is punctured as can be seen from Fig. 7 by opening an initially placed channel into the heart wall rather than stamping out a hole.

Preferably, a guidewire will be placed through the medical puncture device 30'. Then, the apparatus 10 is ready to insert a catheter system or another delivery system used for implanting a valve prosthesis.

In more detail, Fig. 6 illustrates the exemplary embodiment of the apparatus 10 in accordance with Fig. 5, wherein a medical puncture device 30', for example a puncture needle, stylet or trocar, is received within the passage 24 defined by the base member 11 and the tubular member 16 coupled to the base member 11. In Fig. 6, the wall of the left ventricle 220 at the apex 224 of the beating heart 202 is punctured by the medical puncture device 30' at an area accessible by the medical puncture device 30', when the medical puncture device 30' is passed through the passage 24 formed by the lumen 17 of the tubular member 16 and the channel 12 provided in the base member 11.

Accordingly, the port system disclosed herein is a medical instrument which allows a puncture of the wall of the left ventricle 220 at the apex 224 of the beating heart 202 by using, for example, the well-known Seldinger Method.

Fig. 7 illustrates the exemplary embodiment of the apparatus 10 in accordance with Fig. 6 after removing the medical puncture device 30' from the passage 24 defined by the base member 11 and the tubular member 16 of the apparatus 10. Accordingly, in the state depicted in Fig. 7 the apparatus 10 serves as a system for performing direct cardiac catheterization, in particular transapical or transventrical catheterization, because the apparatus 10 provides a platform securely attached to the outer wall of the left ventricle 220 by means of which therapeutic devices, such as a heart valve prosthesis of left ventricular assist devices, can be delivered into the left ventricle 220 of the beating heart 202 without loss of blood or exposure to air.

In more detail, the passage 24 formed by the lumen 17 defined by the tubular member 16 and the channel 12 provided in the base member 11 communicates with the opening provided in the wall of the left ventricle 220 by puncturing as illustrated in Fig. 6. A catheter delivery system can be delivered through the puncture 49 in the wall of the left ventricle 220 of the beating heart 202 in order to perform structural repair procedures. Once a therapeutic device has been delivered and surgery is complete, an occlusion device closes and seals the access site with a biocompatible implant.

Reference is made to Fig. 8 which illustrates the port system, i.e. the exemplary embodiment of the apparatus 10 in accordance with Fig. 7, wherein a tip 31 of a catheter delivery system 30 is past through the puncture 49 previously performed by a medical puncture device 30' (see Fig. 6). In the tip 31 of the catheter delivery system 30 schematically illustrated in Fig. 8, an exemplary embodiment of a surgical closure apparatus is accommodated in a collapsed state.

Fig. 9 illustrates the exemplary embodiment of the port system in accordance with Fig. 8, wherein the surgical closure apparatus is at least partly released from the tip 31 of the catheter delivery system 30. Accordingly, the surgical closure apparatus is adapted and configured to be implanted and placed into the interior of the left ventricle 220 via the apparatus 10 (port system) previously attached to the outer wall of the left ventricle 220 at the apex 224 of the beating heart 202.

Reference is made to Figs. 12 and 13 illustrating aspects of an exemplary embodiment of a surgical closure apparatus disclosed herein.

The surgical closure apparatus disclosed herein comprises an expandable or self-expandable occlusion device 50. The occlusion device 50 is introducible into the body of a patient in a minimally invasive fashion via the passage 24 formed by the lumen 17 of the tubular member 16 and the channel 12 of the base member 11 and the puncture 49 of the viscus wall (left ventricle 220 of the beating heart 202) performed by a medical puncture device 30' (see Fig. 6). For this reason, the occlusion device 50 exhibits a collapsed shape as the occlusion device 50 is being inserted into the patient's body (see Fig. 8), and an expanded shape as the occlusion device 50 is in the implanted state (see Fig. 9 and 10).

In more detail and as illustrated in Fig. 13, the occlusion device 50 comprises a retention area 51 which exhibits a flattened umbrella-shaped contouring in the expanded state of the occlusion device 50. The retention area 51 may consist of a braiding of thin wires or threads given a suitable form, for example, by means of a moulding and heat treatment procedure.

Alternatively and as illustrated in Figs. 12 and 13, the retention area 51 of the occlusion device 50 may consist of a foldable support frame 52 and a flexible membrane 53 fixed to the foldable support frame 52. Preferably, the foldable support frame 52 is composed of nitinol or of another shape-memory material, for example, a shape-memory polymer, preferably based on a polyanhydride matrix or on polyhydroxycarboxylic acid. Also, it is conceivable that the foldable support frame 52 is formed from a shape-memory polymer of block copolymer form.

The flexible membrane 53 fixed to the foldable support frame 52 at the retention area 51 of the occlusion device 50 is preferably composed of silicone, polyurethane or a polymer containing material.

Preferably, the flexible membrane 53 and/or the support frame 52 of the occlusion device 50 are/is at least partly formed of a biologically degradable material. Such biological degradable material may comprise a polymer composite which exhibits a hydrolytically degradable polymer, in particular polyhydroxycarboxylic acids or corresponding copolymers. Alternatively, the biologically degradable material may comprise a polymer composite which exhibits enzymatically degradable polymers.

Also, it is conceivable that the biologically degradable material comprises the polymer composite which exhibits a biodegradable thermoplastic amorphous polyurethane-copolyester polymer network. Moreover, the biologically degradable material may comprise a polymer composite which exhibits biodegradable elastic polymer network, obtained from cross-linking of oligomer diols with diisocyanate.

As schematically illustrated in Figs. 8 to 10, the occlusion device 50 is inserted into the ventricle of the heart 202 by using a catheter delivery system 30 comprising a guiding stylet 32 and an insertion tube 33. After inserting the occlusion device 50 and expanding the retention area 51 of the occlusion device 50, the insertion tube 33 of the catheter delivery system 30 is removed (see Fig. 9).

Thereafter, the connection between the tubular member 16 and the base member 11 of the apparatus 10 is released and the tubular member 16 is removed from the patient's body (see Fig. 10). The bleeding through the puncture 49 of the heart wall is then sealed unfolding the retention area 51 of the occlusion device 50. This can be initiated, for example, by pulling a guidewire which is screwed into the retention area 51 of the occlusion device 50. However, other means for manipulating the retention area 51 of the occlusion device 50 are also conceivable.

For fixing the retention area 51 of the occlusion device 50, a fixing arrangement is provided. The fixing arrangement is configured to fix the retention area 51 of the occlusion device 50 to the base member 11 which is already arranged at and fixed to the outer wall of the viscus.

In more detail, in accordance with some embodiments disclosed herein, the fixing arrangement may comprise a tie element 55 fixed to the retention area 51 of the occlusion device 50. The tie element 55 is configured to extend at least partly into the puncture 49 of the viscus wall when the occlusion device 50 is in its implanted state (see Fig. 10 and Figs. 11a to 11c).

The fixing arrangement further comprises a locking element 56 configured to be coupled to the tie element 55 such that the retention area 51 of the occlusion device 50 and the locking element 56 are positioned on the two sides of the puncture 49 to be occluded in the viscus wall (here: heart wall).

As illustrated in Figs. 11a to 11c, in accordance with some embodiments disclosed herein, the locking element 56 may comprise a heat portion 57 having a diameter larger than the diameter of the channel 12 extending through the base member 11 of the apparatus 10. Moreover, the locking element 56 preferably comprises a tie element 58 fixed to the heat portion 57. The tie element 58 fixed to the heat portion 57 is connectable to the tie element 55 fixed to the retention area 51 of the occlusion device 50.

After fixing the locking element 56 to the retention area 51 of the occlusion device 50, the guiding stylet 32 is removed (see Figs. 11a to 11c).

In the implanted state of the occlusion device 50 (see Figs. 11a to 11c) the retention area 51 of the occlusion device 50 and, in particular, the support frame 52 with the membrane 53 attached thereto, is located inside the viscus (here: inside

the left ventricle 220 of the beating heart 202). The occlusion device 50 is fixed in the implantation area by means of the locking element 56.

In accordance with some embodiments disclosed herein, the locking element 56 comprises a disk-like heat portion 57.

As illustrated in Fig. 14, the disk-like heat portion 57 of the locking element 56 may comprise a tie element 58 fixed to the heat portion 57. The tie element 58 of the locking element 56 is connectable to a corresponding tie element 55 fixed to the retention area 51 of the occlusion device 50. Accordingly, in the implanted state of the medical closure system, the retention area 51 of the occlusion device 50 and the locking element 56 are positioned on the two sides of the puncture 49 to be occluded in the viscus.

The tie element 55 fixed to the retention area 51 of the occlusion device 50 and the tie element 58 fixed to the heat portion 57 of the locking element 56 are preferably provided with a threaded area 60, 60' respectively configured to be engageable with each other. Alternatively, any other engagement of the two tie elements is conceivable.

The tie element 55 fixed to the retention area 51 of the occlusion device 50 is preferably also configured to be connectable with the tip of a stylet, catheter or cannular 32 for implanting the occlusion device 50 and positioning the retention area 51 of the occlusion device 50 (see Fig. 10).

After implanting the medical closure system as illustrated in Figs. 11a to 11c, the volume bordered by the two sides of the puncture 49 to be occluded in the viscus may be filled with a corresponding filling material in order to tidily occlude the puncture 49. For this purpose, the locking element 56 may be provided with at least one port for supplying the filling material in the volume. It is also conceivable that naturally occurring tissue material grows into the volume via holes 59 provided in the locking element 56.

The disclosed solution is not limited to the embodiments described with reference to the accompanying drawings. Also just as conceivable in fact are combinations of the individual features as specifically described.

List of reference numerals

7	arrangement for fixing
8	opening
9	coverage
10	apparatus
11	base member
11a	first surface of base member
11b	second surface of base member
12	channel
13	first coupling arrangement
14b	sealing arrangement
14a	sealing arrangement
15	base plate
16	tubular member
16a	first end of tubular member
16b	second end of tubular member
17	lumen
18	second coupling arrangement
19	mechanical seal
20	additional sealing lip/sprung sealing lip
21	first funnel shaped element
22	second funnel shaped element
24	passage
25	port
26	fixing arrangement
30'	elongate medical instrument/medical puncture device
30	catheter delivery system
31	tip
32	guiding stylet
33	insertion tube
49	puncture
50	occlusion device
51	retention area
52	support frame
53	flexible membrane
55	tie element
56	locking element
57	heat portion
58	tie element
59	holes
60	threaded area
60'	threaded area
100	stent
180	guidewire
202	heart
204	descending aorta
206	ascending aorta
210	mitral valve
212	aortic valves
220	viscus wall, left ventricle
222	right ventricle
224	left ventricular apex

Claims

1. Apparatus (10) for providing access to a viscus (220) of a patient required for delivering therapeutic devices into the viscus (220) for structural repair procedures, the apparatus (10) comprising:
   - a base member (11) having a first surface (11a) and an opposite second surface (11b) and a channel (12) extending there through, the base member (11) being configured to be manually fixed to the outer wall of the viscus (220); and
   - a tubular member (16) defining a lumen (17), the tubular member (16) having a first end (16a) and an opposite second end (16b) and being configured to be coupled with its first end (16a) to the first surface (11a) of the base member (11) such that the lumen (17) and the channel (12) communicate with each other thereby defining a passage (18) through which an elongate medical instrument (30, 30') is movable in the direction of the viscus wall.

2. The apparatus (10) according to claim 1,
wherein the base member (11) comprises a first coupling arrangement (13) and the tubular member (16) comprises a second coupling arrangement (18), the second coupling arrangement (18) being

complementary to the first coupling arrangement (13) for allowing a releasable coupling between the base member (11) and the tubular member (16).

3. The apparatus (10) according to claim 2,
wherein the first and second coupling arrangements (13, 18) are configured to form a thread connection, a clip connection, a magnetic connection or a bayonet lock.

4. The apparatus (10) according to one of the claims 1 to 3,
wherein the tubular member (16) is provided with a sealing arrangement for preventing leakage of fluid, in particular blood, through the second end (16b) of the tubular member (16).

5. The apparatus (10) according to claim 4,
wherein the sealing arrangement comprises a sealing foam, the sealing foam (19) being configured to allow passing an elongate medical instrument (30, 30') there through.

6. The apparatus (10) according to claim 5,
wherein the sealing foam is self-expandable when absorbing fluid, in particular blood.

7. The apparatus (10) according to one of the claims 4 to 6,
wherein the sealing arrangement comprises a mechanical seal (19) arranged in the interior of the lumen (17), the mechanical seal (19) being configured to allow passing an elongate medical instrument (30, 30') there through.

8. The apparatus (10) according to claim 7,
wherein the mechanical seal (19) is self-adjustable to the outer diameter of the elongate medical instrument (30, 30'), when the elongate medical instrument (30, 30') passes through the interior of the lumen (17).

9. The apparatus (10) according to claim 7 or 8,
wherein the mechanical seal (19) comprises at least one, preferably three

and more preferably at least six sealing lips which are movably connected to the inner wall of the lumen (17), wherein the at least one six sealing lip is preferably pre-tensioned such as to close the lumen (17).

10. The apparatus (10) according to one of the claims 4 to 9, wherein the sealing arrangement comprises at least one additional sealing lip (20), in particular sprung sealing lip, arranged inside the tubular member (16).

11. The apparatus (10) according to one of the claims 4 to 10, wherein the sealing arrangement comprises at least one circular seal or O-ring arranged inside the tubular member (16).

12. The apparatus (10) according to one of the claims 1 to 11, wherein the base member (11) is provided with a sealing arrangement (14a) for preventing leakage of fluid, in particular blood, through the coupling between the first end (16a) of the tubular member (16) and the first surface (11a) of the base member (11).

13. The apparatus (10) according to claim 12, wherein the sealing arrangement (14a) of the base member (11) comprises a mechanical seal, in particular gasket, washer, circular seal or O-ring.

14. The apparatus (10) according to claim 12, wherein the sealing arrangement (14a) of the base member (11) comprises a self-sealing seal, in particular cone.

15. The apparatus (10) according to one of the claims 1 to 14, wherein the base member (11) is provided with a sealing arrangement (14b) for preventing leakage of fluid, in particular blood, between the second surface (11b) of the base member (11) and the outer wall of the viscus (220).

16. The apparatus (10) according to one of the claims 1 to 15, wherein the base member (11) comprises a base plate (15) and a port (25) fixed to the base plate (15), the port (25) being configured to form a

releasable connection with the tubular member (16) for coupling the tubular member (16) with the base member (11).

17. The apparatus (10) according to claim 16,
wherein the base plate (15) is circular or approximately circular, and
wherein the port (25) is arranged at the center of the base plate (15).

18. The apparatus (10) according to claim 16 or 17,
wherein the port (25) is arranged on the first surface (11a) of the base plate (15) and surrounds at least partly the opening of the channel (12) extending through the base member (11).

19. The apparatus (10) according to one of the claims 16 to 18,
wherein the base plate (15) and the port (25) are made of a biocompatible material.

20. The apparatus (10) according to one of the claims 16 to 19,
wherein the base plate (15) is made of a rigid material, in particular metal, for example titanium, or a rigid plastic material.

21. The apparatus (10) according to one of the claims 16 to 20, in particular claim 20, wherein the base plate (15) is provided with an arrangement (26) for fixing the base member (11) to the outer wall of the viscus (220).

22. The apparatus (10) according to claim 21,
wherein the fixing arrangement (26) comprises at least one and preferably a plurality of holes and/or eyelets for receiving a thin wire or thread required for suturing the base member (11) to the outer wall of the viscus (220).

23. The apparatus (10) according to claim 22,
wherein the holes and/or eyelets are preferably uniformly distributed around an outer circumference of the base plate (15).

24. The apparatus (10) according to one of the claims 16 to 19, wherein the base plate (15) is made of a polymer material, in particular a flexible polymer material.

25. The apparatus (10) according to claim 24, wherein the base plate (15) is at least partly reinforced such as to allow suturing the base member (11) to the outer wall of the viscus (220).

26. The apparatus (10) according to claim 24 or 25, wherein fibers are integrated into the polymer material for reinforcement.

27. The apparatus (10) according to one of the claims 16 to 26, in particular claims 13 to 20, wherein the second surface (11b) of the base member (11) is at least partly formed such as to be adapted to the anatomy of the outer wall of the viscus (220), the second surface (11b) being in contact with the outer wall of the viscus (220) when the base member (11) is fixed to the outer wall of the viscus (220).

28. The apparatus (10) according to one of the claims 16 to 27, in particular claim 26, wherein the second surface (11b) of the base member (11) is at least partly curved.

29. The apparatus (10) according to one of the claims 1 to 28, wherein a first funnel-shaped element (21) is provided at the second end (16b) of the tubular member (16), the first funnel-shaped element (21) being configured such as to simplify an insertion of the elongate medical instrument (30, 30') into the interior of the tubular member (16).

30. The apparatus (10) according to one of the claims 1 to 29, wherein a second funnel-shaped element (22) is provided at the first end (16a) of the tubular member (16), the second funnel-shaped element (22) being configured such as to simplify an insertion of the elongate medical instrument (30, 30') into the channel (12) of the base member (11) when the tubular member (16) is coupled with the base member (11).

31. The apparatus (10) according to claim 29 or 30,
wherein the first funnel-shaped element (21) and/or the second funnel-shaped element (22) are/is integrally formed with the tubular member (16).

32. The apparatus (10) according to claim 29 or 30,
wherein the first funnel-shaped element (21) and/or the second funnel-shaped element (22) are/is a separate element connected with the respective end (16a, 16b) of the tubular member (16).

33. The apparatus (10) according to one of the claims 1 to 32,
wherein the base member (11) is at least partly formed of a biologically degradable material.

34. The apparatus (10) according to claim 33,
wherein the biologically degradable material comprises a polymer composite which exhibits a hydrolytically degradable polymer, in particular poly-hydroxycarboxylic acids or corresponding copolymers.

35. The apparatus (10) according to claim 33,
wherein the biologically degradable material comprises a polymer composite which exhibits enzymatically degradable polymers.

36. The apparatus (10) according to claim 33,
wherein the biologically degradable material comprises a polymer composite which exhibits a biodegradable thermoplastic amorphous polyurethane-copolyester polymer network.

37. The apparatus (10) according to claim 33,
wherein the biologically degradable material comprises a polymer composite which exhibits a biodegradable elastic polymer network, obtained from cross-linking of oligomer diols with diisocyanate.

38. The apparatus (10) according to one of the claims 1 to 37,
wherein the channel (12) provided in the base member (11) has an inner diameter defining the maximum achievable diameter of an access hole

which can be realized in the wall of the viscus (220) by an elongate medical instrument (30, 30'), in particular medical puncture device (30'), which is inserted into the passage (18) defined by the channel (12) of the base member (11) and the lumen (17) of the tubular member (16).

39. The apparatus (10) according to one of the claims 1 to 38, wherein the elongate medical instrument (30, 30'), which is insertable into the passage (18) defined by the lumen (17) of the tubular member (16) and the channel (12) provided in the base member (11), is selected from the group consisting of: a catheter, a cannula, a dilator, a needle, a guidewire, an elongate probe, and a medical puncture device (30'), in particular puncture needle, stylet or trocar.

40. The apparatus (10) according to one of the claims 1 to 39, wherein the apparatus (10) is configured for providing transapical or transventrical access to the heart of a patient required for delivering therapeutic devices to the heart for structural heart repair procedures, and wherein the base member (11) of the apparatus (10) is configured to be manually fixed to the outer wall of a ventricle at the apex of the heart.

41. System for performing direct cardiac catheterization, in particular transapical or transventrical catheterization, the system comprising:

- an apparatus (10) according to one of the claims 1 to 40, wherein the base member (11) of the apparatus (10) is configured to be manually fixed to the outer wall of a ventricle of the heart, in particular to the outer wall of a ventricle at the apex of the heart, and wherein the passage (18) formed by the lumen (17) of the tubular member (16) and the channel (12) of the base member (11) serves as a guidance for a medical puncture device (30'), in particular puncture needle, stylet or trocar, adapted for puncturing the wall of the heart, and
- a surgical closure apparatus for closing the area of the heart wall punctured by the medical puncture device (30').

42. The system according to claim 41, wherein the surgical closure apparatus comprises an expandable or self-expandable occlusion device (50), the occlusion device (50) being

introducible into the ventricle of the heart in a minimally invasive fashion via the passage (18) formed by the lumen (17) of the tubular member (16) and the channel (12) of the base member (11) and the puncture (49) of the heart wall performed by the medical puncture device (30'), wherein the occlusion device (50) exhibits a collapsed shape as the occlusion device (50) is being inserted into the ventricle of the heart, and an expanded shape as the occlusion device (50) is in the implanted state.

43. The system according to claim 42,
wherein the occlusion device (50) comprises a retention area (51), the retention area (51) exhibits a flattened umbrella-shaped contouring in the expanded state of the occlusion device (50).

44. The system according to claim 43,
wherein the retention area (51) consists of a braiding of thin wires or threads given a suitable form by means of a moulding and heat treatment procedure.

45. The system according to claim 44,
wherein the braiding is composed of nitinol or of another shape-memory material.

46. The system according to claim 44,
wherein the braiding is formed from a shape-memory polymer, preferably based on a polyanhydride matrix or on polyhydroxycarboxylic acids.

47. The system according to claim 44,
wherein the braiding is formed from a shape-memory polymer of a block copolymer form.

48. The system according to one of the claims 43 to 47,
wherein at least one fabric insert is arranged at the retention area (51).

49. The system according to claim 43,
wherein the retention area (51) consists of a foldable support frame (52) and a flexible membrane (53) fixed to the foldable support frame (52).

50. The system according to claim 49,
wherein the foldable support frame (52) is composed of nitinol or of another shape-memory material.

51. The system according to claim 49,
wherein the foldable support frame (52) is formed from a shape-memory polymer, preferably based on a polyanhydride matrix or on polyhydroxycarboxylic acids.

52. The system according to claim 49,
wherein the foldable support frame (52) is formed from a shape-memory polymer of a block copolymer form.

53. The system according to one of the claims 49 to 52,
wherein the flexible membrane (53) is composed of silicone, polyurethane or a polymer containing material.

54. The system according to one of the claims 49 to 53,
wherein the flexible membrane (53) is at least partly formed of a biologically degradable material.

55. The system according to one of the claims 42 to 54,
wherein the occlusion device (50) is at least partly formed of a biologically degradable material.

56. The system according to claim 55,
wherein the biologically degradable material comprises a polymer composite which exhibits a hydrolytically degradable polymer, in particular polyhydroxycarboxylic acids or corresponding copolymers.

57. The system according to claim 55,
wherein the biologically degradable material comprises a polymer composite which exhibits enzymatically degradable polymers.

58. The system according to claim 55,
wherein the biologically degradable material comprises a polymer composite which exhibits a biodegradable thermoplastic amorphous polyurethane-copolyester polymer network.

59. The system according to claim 55,
wherein the biologically degradable material comprises a polymer composite which exhibits biodegradable elastic polymer network, obtained from cross linking of oligomer diols with diisocyanate.

60. The system according to one of the claims 43 to 59,
wherein the occlusion device (50) comprises a fixing arrangement for fixing the retention area (51) to the base member (11) of the apparatus (10) for providing access.

61. The system according to claim 60,
wherein the fixing arrangement comprises a tie element (55) fixed to the retention area (51), the tie element (55) being configured to extend at least partly into the puncture (49) of the heart wall when the occlusion device (50) is in its implanted state.

62. The system according to claim 61,
wherein the fixing arrangement comprises a locking element (56) configured to be coupled to the tie element (55) such that the retention area (51) and the locking element (56) are positioned on the two sides of the puncture (49) to be occluded in the heart wall.

63. The system according to claim 62,
wherein the locking element (56) comprises a heat portion (57) having a diameter larger than the diameter of the channel (12) extending through the base member (11) of the apparatus (10) for providing access.

64. The system according to claim 63,
wherein the locking element (56) comprises a tie element (58) fixed to the heat portion (57), the tie element (58) fixed to the heat portion (57) being connectable to the tie element (55) fixed to the retention area (51).

65. The system according to claim 64,
wherein the tie element (55) fixed to the retention area (51) and the tie element (58) fixed to the heat portion (57) of the locking element (56) are respectively provided with an area (60, 60') configured to be engageable with each other, in particular a threaded area.

66. The system according to one of the claims 61 to 65,
wherein the tie element (55) fixed to the retention area (51) is configured to be connectable with the tip of a stilett, catheter or cannula (32) for implanting the occlusion device (50) and positioning the retention area (51).

67. The system according to one of the claims 62 to 66,
wherein the locking element (56) is provided with at least one port for supplying a filling material in the volume bordered by the two sides of the puncture (49) to be occluded in the heart wall and the interior wall of the puncture (49).

68. The system to one of the claims 62 to 67,
Wherein the locking element (56) is provided with at least one whole (59) for allowing ingrowth of natural tissue material into the volume bordered by the two sides of the puncture (49) to be occluded.

69. Method for minimally-invasive surgery, in particular minimally-invasive cardiac surgery, the method comprising the steps of:

i) providing an apparatus (10) according to one of the claims 1 to 40;

ii) fixing the base member (11) of the apparatus (10) to the outer wall of a viscus (220) to be treated;

iii) connecting the tubular member (16) of the apparatus (10) with the base member (11) such that the lumen (17) of the tubular member (16) and the channel (12) provided in the base member (11) communicate with each other and form a passage (18); and

iv) puncturing the viscus wall at an area accessible by a medical puncture device (30'), in particular puncture needle, stilett or trocar, by passing

the medical puncture device (30') through the passage (18) formed by the lumen (17) of the tubular member (16) and the channel (12) provided in the base member (11).

70. The method according to claim 69, further comprising the step of:

v) passing a catheter into the viscus (220) through the puncture (49) in the viscus wall performed by the medical puncture device (30') for performing structural repair procedures.

71. The method according to claim 70, further comprising the step of:

vi) closing the area of the viscus wall punctured by the medical puncture device (30') by using a surgical closure apparatus (10).

AMENDED CLAIMS
received by the International Bureau on 10 October 2013 (10.10.2013)

1. System for performing direct cardiac catheterization, in particular transapical or transventrical catheterization, the system comprising:

- an apparatus (10) for providing access to a viscus (220) of a patient required for delivering therapeutic devices into the viscus (220) for structural repair procedures; and
- a surgical closure apparatus,

wherein the apparatus (10) comprises:

- a base member (11) having a first surface (11a) and an opposite second surface (11b) and a channel (12) extending there through, the base member (11) being configured to be manually fixed to the outer wall of the viscus (220); and
- a tubular member (16) defining a lumen (17), the tubular member (16) having a first end (16a) and an opposite second end (16b) and being configured to be coupled with its first end (16a) to the first surface (11a) of the base member (11) such that the lumen (17) and the channel (12) communicate with each other thereby defining a passage (18) through which an elongate medical instrument (30, 30') is movable in the direction of the viscus wall,

wherein the base member (11) of the apparatus (10) is configured to be manually fixed to the outer wall of a ventricle of the heart, in particular to the outer wall of a ventricle at the apex of the heart, and

wherein the passage (18) formed by the lumen (17) of the tubular member (16) and the channel (12) of the base member (11) serves as a guidance for a medical puncture device (30'), in particular puncture needle, stylet or trocar, adapted for puncturing the wall of the heart, and
wherein the surgical closure apparatus is configured to close the area of the heart wall punctured by the medical puncture device (30').

2. The system according to claim 1,
wherein the base member (11) comprises a first coupling arrangement (13) and the tubular member (16) comprises a second coupling arrangement (18), the second coupling arrangement (18) being complementary to the first coupling arrangement (13) for allowing a releasable coupling between the base member (11) and the tubular member (16).

3. The system according to claim 2,
wherein the first and second coupling arrangements (13, 18) are configured to form a thread connection, a clip connection, a magnetic connection or a bayonet lock.

4. The system according to one of the claims 1 to 3,
wherein the tubular member (16) is provided with a sealing arrangement for preventing leakage of fluid, in particular blood, through the second end (16b) of the tubular member (16).

5. The system according to claim 4,
wherein the sealing arrangement comprises a sealing foam, the sealing foam (19) being configured to allow passing an elongate medical instrument (30, 30') there through.

6. The system according to claim 5,
wherein the sealing foam is self-expandable when absorbing fluid, in particular blood.

7. The system according to one of the claims 4 to 6, wherein the sealing arrangement comprises a mechanical seal (19) arranged in the interior of the lumen (17), the mechanical seal (19) being configured to allow passing an elongate medical instrument (30, 30') there through.

8. The system according to claim 7, wherein the mechanical seal (19) is self-adjustable to the outer diameter of the elongate medical instrument (30, 30'), when the elongate medical instrument (30, 30') passes through the interior of the lumen (17).

9. The system according to claim 7 or 8, wherein the mechanical seal (19) comprises at least one, preferably three and more preferably at least six sealing lips which are movably connected to the inner wall of the lumen (17), wherein the at least one six sealing lip is preferably pre-tensioned such as to close the lumen (17).

10. The system according to one of the claims 4 to 9, wherein the sealing arrangement comprises at least one additional sealing lip (20), in particular sprung sealing lip, arranged inside the tubular member (16).

11. The system according to one of the claims 4 to 10, wherein the sealing arrangement comprises at least one circular seal or O-ring arranged inside the tubular member (16).

12. The system according to one of the claims 1 to 11, wherein the base member (11) is provided with a sealing arrangement (14a) for preventing leakage of fluid, in particular blood, through the coupling between the first end (16a) of the tubular member (16) and the first surface (11a) of the base member (11).

13. The system according to claim 12, wherein the sealing arrangement (14a) of the base member (11) comprises a mechanical seal, in particular gasket, washer, circular seal or O-ring.

14. The system according to claim 12,
wherein the sealing arrangement (14a) of the base member (11) comprises a self-sealing seal, in particular cone.

15. The system according to one of the claims 1 to 14,
wherein the base member (11) is provided with a sealing arrangement (14b) for preventing leakage of fluid, in particular blood, between the second surface (11b) of the base member (11) and the outer wall of the viscus (220).

16. The system according to one of the claims 1 to 15,
wherein the base member (11) comprises a base plate (15) and a port (25) fixed to the base plate (15), the port (25) being configured to form a releasable connection with the tubular member (16) for coupling the tubular member (16) with the base member (11).

17. The system according to claim 16,
wherein the base plate (15) is circular or approximately circular, and
wherein the port (25) is arranged at the center of the base plate (15).

18. The system according to claim 16 or 17,
wherein the port (25) is arranged on the first surface (11a) of the base plate (15) and surrounds at least partly the opening of the channel (12) extending through the base member (11).

19. The system according to one of the claims 16 to 18,
wherein the base plate (15) and the port (25) are made of a biocompatible material.

20. The system according to one of the claims 16 to 19,
wherein the base plate (15) is made of a rigid material, in particular metal, for example titanium, or a rigid plastic material.

21. The system according to one of the claims 16 to 20, in particular claim 20,
wherein the base plate (15) is provided with an arrangement (26) for fixing the base member (11) to the outer wall of the viscus (220).

22. The system according to claim 21,
wherein the fixing arrangement (26) comprises at least one and preferably a plurality of holes and/or eyelets for receiving a thin wire or thread required for suturing the base member (11) to the outer wall of the viscus (220).

23. The system according to claim 22,
wherein the holes and/or eyelets are preferably uniformly distributed around an outer circumference of the base plate (15).

24. The system according to one of the claims 16 to 19,
wherein the base plate (15) is made of a polymer material, in particular a flexible polymer material.

25. The system according to claim 24,
wherein the base plate (15) is at least partly reinforced such as to allow suturing the base member (11) to the outer wall of the viscus (220).

26. The system according to claim 24 or 25,
wherein fibers are integrated into the polymer material for reinforcement.

27. The system according to one of the claims 16 to 26,
in particular claims 13 to 20, wherein the second surface (11b) of the base member (11) is at least partly formed such as to be adapted to the anatomy of the outer wall of the viscus (220), the second surface (11b) being in contact with the outer wall of the viscus (220) when the base member (11) is fixed to the outer wall of the viscus (220).

28. The system according to one of the claims 16 to 27, in particular claim 26,
wherein the second surface (11b) of the base member (11) is at least partly curved.

29. The system according to one of the claims 1 to 28, wherein a first funnel-shaped element (21) is provided at the second end (16b) of the tubular member (16), the first funnel-shaped element (21) being configured such as to simplify an insertion of the elongate medical instrument (30, 30') into the interior of the tubular member (16).

30. The system according to one of the claims 1 to 29, wherein a second funnel-shaped element (22) is provided at the first end (16a) of the tubular member (16), the second funnel-shaped element (22) being configured such as to simplify an insertion of the elongate medical instrument (30, 30') into the channel (12) of the base member (11) when the tubular member (16) is coupled with the base member (11).

31. The system according to claim 29 or 30, wherein the first funnel-shaped element (21) and/or the second funnel-shaped element (22) are/is integrally formed with the tubular member (16).

32. The system according to claim 29 or 30, wherein the first funnel-shaped element (21) and/or the second funnel-shaped element (22) are/is a separate element connected with the respective end (16a, 16b) of the tubular member (16).

33. The system according to one of the claims 1 to 32, wherein the base member (11) is at least partly formed of a biologically degradable material.

34. The system according to claim 33, wherein the biologically degradable material comprises a polymer composite which exhibits a hydrolytically degradable polymer, in particular poly-hydroxycarboxylic acids or corresponding copolymers.

35. The system according to claim 33, wherein the biologically degradable material comprises a polymer composite which exhibits enzymatically degradable polymers.

36. The system according to claim 33,
wherein the biologically degradable material comprises a polymer composite which exhibits a biodegradable thermoplastic amorphous polyurethane-copolyester polymer network.

37. The system according to claim 33,
wherein the biologically degradable material comprises a polymer composite which exhibits a biodegradable elastic polymer network, obtained from cross-linking of oligomer diols with diisocyanate.

38. The system according to one of the claims 1 to 37,
wherein the channel (12) provided in the base member (11) has an inner diameter defining the maximum achievable diameter of an access hole which can be realized in the wall of the viscus (220) by an elongate medical instrument (30, 30'), in particular medical puncture device (30'), which is inserted into the passage (18) defined by the channel (12) of the base member (11) and the lumen (17) of the tubular member (16).

39. The system according to one of the claims 1 to 38,
wherein the elongate medical instrument (30, 30'), which is insertable into the passage (18) defined by the lumen (17) of the tubular member (16) and the channel (12) provided in the base member (11), is selected from the group consisting of: a catheter, a cannula, a dilator, a needle, a guidewire, an elongate probe, and a medical puncture device (30'), in particular puncture needle, stylet or trocar.

40. The system according to one of the claims 1 to 39,
wherein the apparatus (10) is configured for providing transapical or transventrical access to the heart of a patient required for delivering therapeutic devices to the heart for structural heart repair procedures, and wherein the base member (11) of the apparatus (10) is configured to be manually fixed to the outer wall of a ventricle at the apex of the heart.

41. The system according to one of the claims 1 to 40, wherein the surgical closure apparatus comprises an expandable or self-expandable occlusion device (50), the occlusion device (50) being introducible into the ventricle of the heart in a minimally invasive fashion via the passage (18) formed by the lumen (17) of the tubular member (16) and the channel (12) of the base member (11) and the puncture (49) of the heart wall performed by the medical puncture device (30'), wherein the occlusion device (50) exhibits a collapsed shape as the occlusion device (50) is being inserted into the ventricle of the heart, and an expanded shape as the occlusion device (50) is in the implanted state.

42. The system according to claim 41, wherein the occlusion device (50) comprises a retention area (51), the retention area (51) exhibits a flattened umbrella-shaped contouring in the expanded state of the occlusion device (50).

43. The system according to claim 42, wherein the retention area (51) consists of a braiding of thin wires or threads given a suitable form by means of a moulding and heat treatment procedure.

44. The system according to claim 43, wherein the braiding is composed of nitinol or of another shape-memory material.

45. The system according to claim 43, wherein the braiding is formed from a shape-memory polymer, preferably based on a polyanhydride matrix or on polyhydroxycarboxylic acids.

46. The system according to claim 43, wherein the braiding is formed from a shape-memory polymer of a block copolymer form.

47. The system according to one of the claims 42 to 46, wherein at least one fabric insert is arranged at the retention area (51).

48. The system according to claim 42,
wherein the retention area (51) consists of a foldable support frame (52) and a flexible membrane (53) fixed to the foldable support frame (52).

49. The system according to claim 48,
wherein the foldable support frame (52) is composed of nitinol or of another shape-memory material.

50. The system according to claim 48,
wherein the foldable support frame (52) is formed from a shape-memory polymer, preferably based on a polyanhydride matrix or on polyhydroxycarboxylic acids.

51. The system according to claim 48,
wherein the foldable support frame (52) is formed from a shape-memory polymer of a block copolymer form.

52. The system according to one of the claims 48 to 51,
wherein the flexible membrane (53) is composed of silicone, polyurethane or a polymer containing material.

53. The system according to one of the claims 48 to 52,
wherein the flexible membrane (53) is at least partly formed of a biologically degradable material.

54. The system according to one of the claims 41 to 53,
wherein the occlusion device (50) is at least partly formed of a biologically degradable material.

55. The system according to claim 54,
wherein the biologically degradable material comprises a polymer composite which exhibits a hydrolytically degradable polymer, in particular polyhydroxycarboxylic acids or corresponding copolymers.

56. The system according to claim 54,
wherein the biologically degradable material comprises a polymer composite which exhibits enzymatically degradable polymers.

57. The system according to claim 54,
wherein the biologically degradable material comprises a polymer composite which exhibits a biodegradable thermoplastic amorphous polyurethane-copolyester polymer network.

58. The system according to claim 54,
wherein the biologically degradable material comprises a polymer composite which exhibits biodegradable elastic polymer network, obtained from cross linking of oligomer diols with diisocyanate.

59. The system according to one of the claims 42 to 58,
wherein the occlusion device (50) comprises a fixing arrangement for fixing the retention area (51) to the base member (11) of the apparatus (10) for providing access.

60. The system according to claim 59,
wherein the fixing arrangement comprises a tie element (55) fixed to the retention area (51), the tie element (55) being configured to extend at least partly into the puncture (49) of the heart wall when the occlusion device (50) is in its implanted state.

61. The system according to claim 60,
wherein the fixing arrangement comprises a locking element (56) configured to be coupled to the tie element (55) such that the retention area (51) and the locking element (56) are positioned on the two sides of the puncture (49) to be occluded in the heart wall.

62. The system according to claim 61,
wherein the locking element (56) comprises a heat portion (57) having a diameter larger than the diameter of the channel (12) extending through the base member (11) of the apparatus (10) for providing access.

63. The system according to claim 62,
wherein the locking element (56) comprises a tie element (58) fixed to the heat portion (57), the tie element (58) fixed to the heat portion (57) being connectable to the tie element (55) fixed to the retention area (51).

64. The system according to claim 63,
wherein the tie element (55) fixed to the retention area (51) and the tie element (58) fixed to the heat portion (57) of the locking element (56) are respectively provided with an area (60, 60') configured to be engageable with each other, in particular a threaded area.

65. The system according to one of the claims 60 to 64,
wherein the tie element (55) fixed to the retention area (51) is configured to be connectable with the tip of a stilett, catheter or cannula (32) for implanting the occlusion device (50) and positioning the retention area (51).

66. The system according to one of the claims 61 to 65,
wherein the locking element (56) is provided with at least one port for supplying a filling material in the volume bordered by the two sides of the puncture (49) to be occluded in the heart wall and the interior wall of the puncture (49).

67. The system to one of the claims 61 to 66,
Wherein the locking element (56) is provided with at least one whole (59) for allowing ingrowth of natural tissue material into the volume bordered by the two sides of the puncture (49) to be occluded.

STATEMENT UNDER ARTICLE 19 (1)

Independent claim 1 of the redrafted claims filed in accordance with Art. 19 PCT is directed to a system for performing direct cardiac catheterization, comprising an apparatus for providing access to a viscus of a patient and a surgical closure apparatus. Such a system is not known from the prior art cited in the International Search Report. In fact, the conventional systems known from the cited prior art are not provided with a surgical closure apparatus for closing the area of the heart wall punctured by a medical puncture device. Such a surgical closure apparatus, however is essential in practice in order to complete a cardiac catheterization process. In this regard, independent claim 1 as filed in accordance with Art. 19 PCT is neither anticipated by nor made obvious from the prior art documents, even if they were combined with each other.

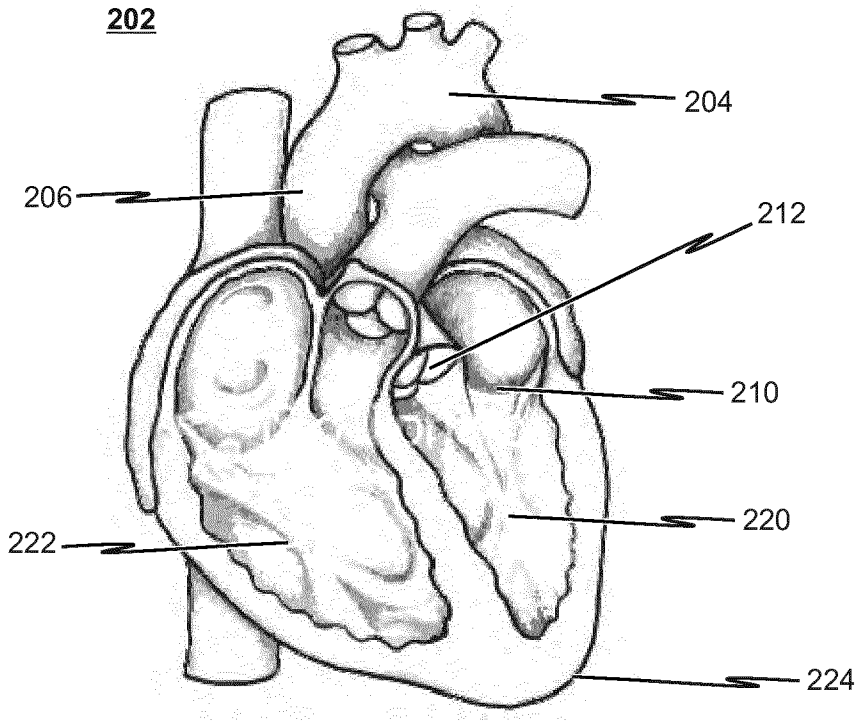

Fig. 1

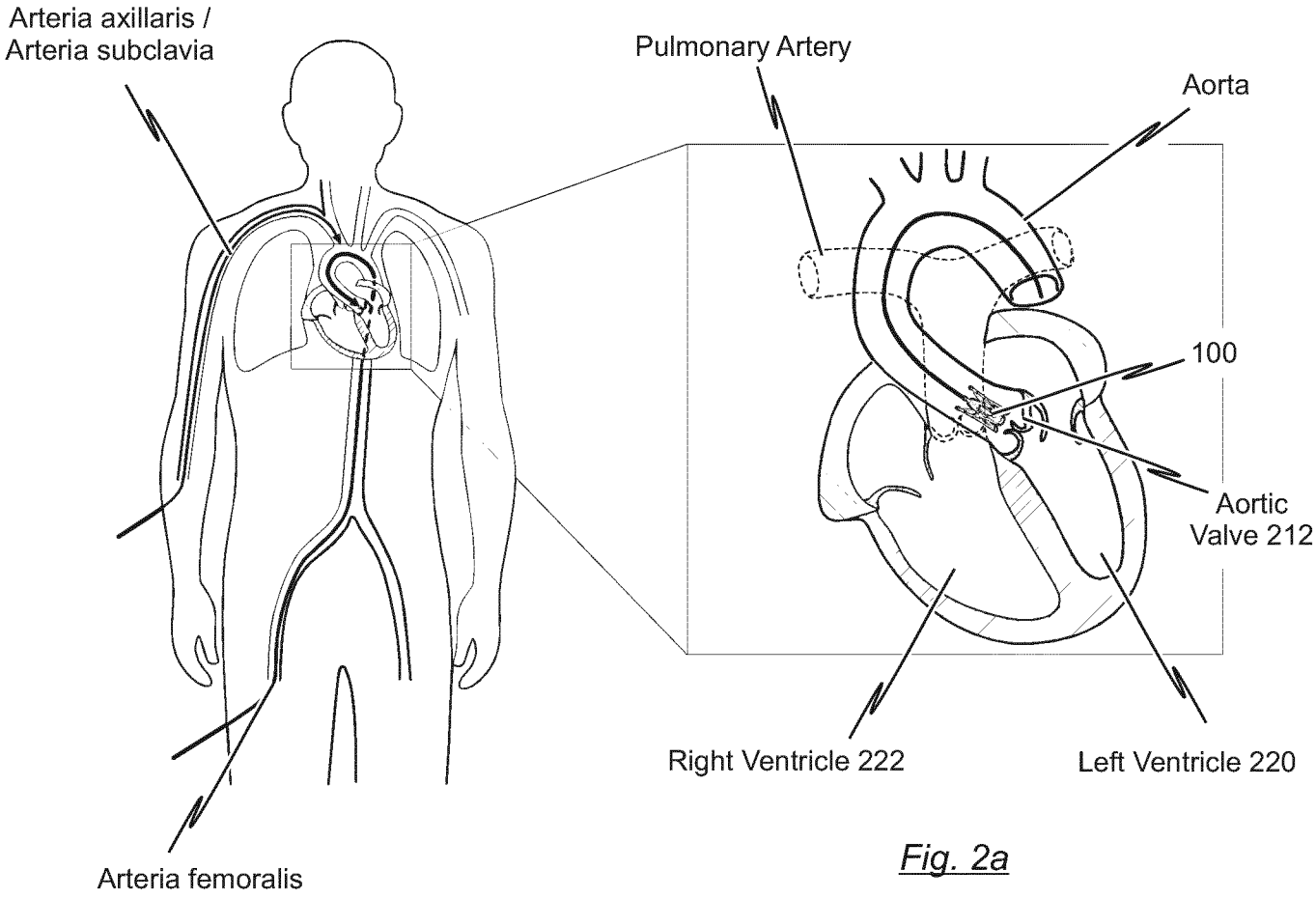
Arteria axillaris /
Arteria subclavia
Pulmonary Artery
Aorta
100
Aortic
Valve 212
Right Ventricle 222
Left Ventricle 220
Arteria femoralis

Fig. 2a

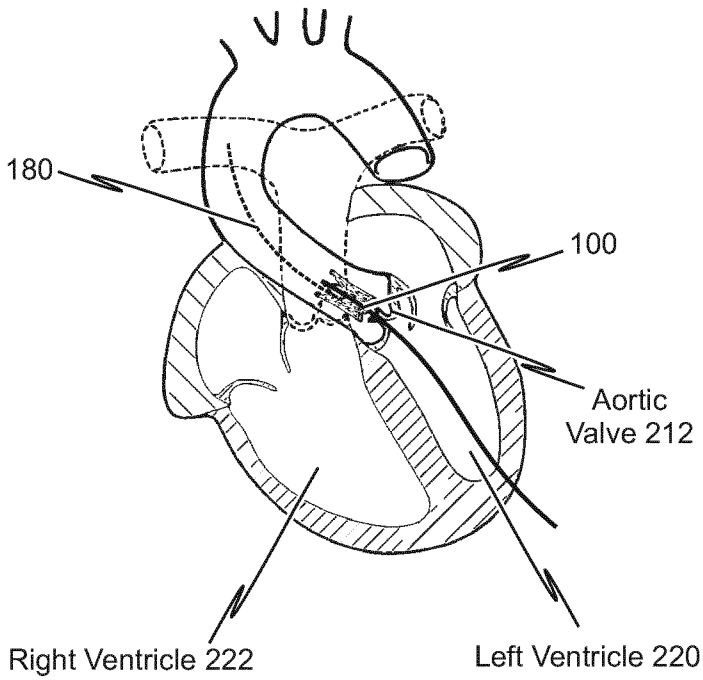
180
100
Aortic
Valve 212
Right Ventricle 222
Left Ventricle 220

Fig. 2b

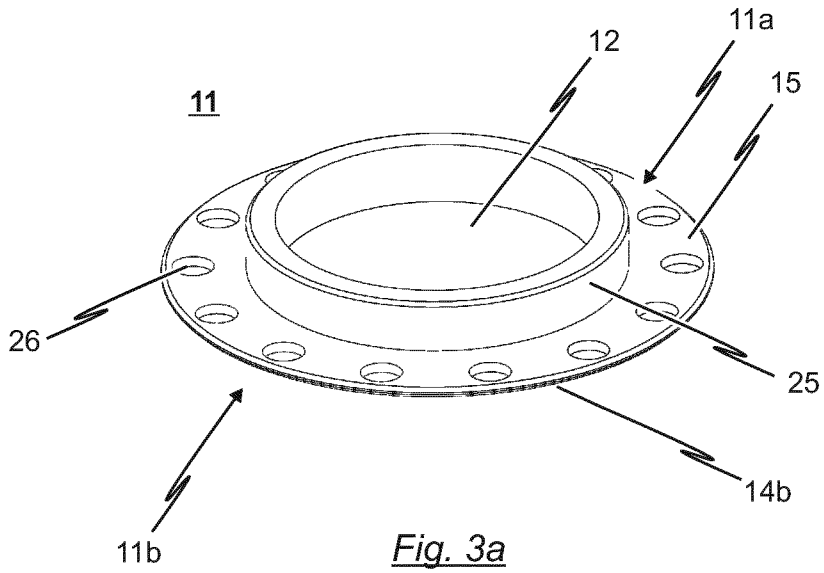

Fig. 3a

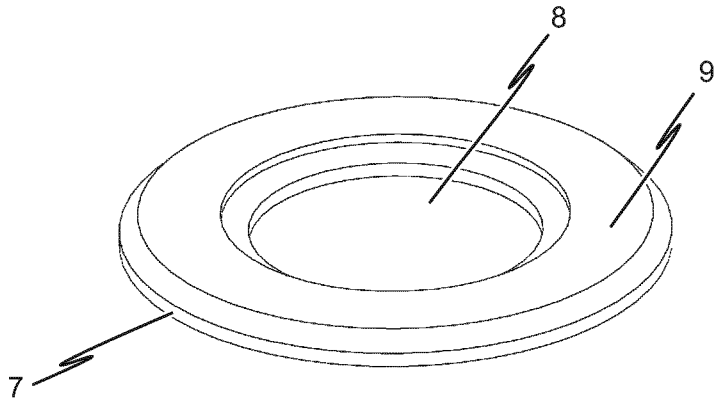

Fig. 3b

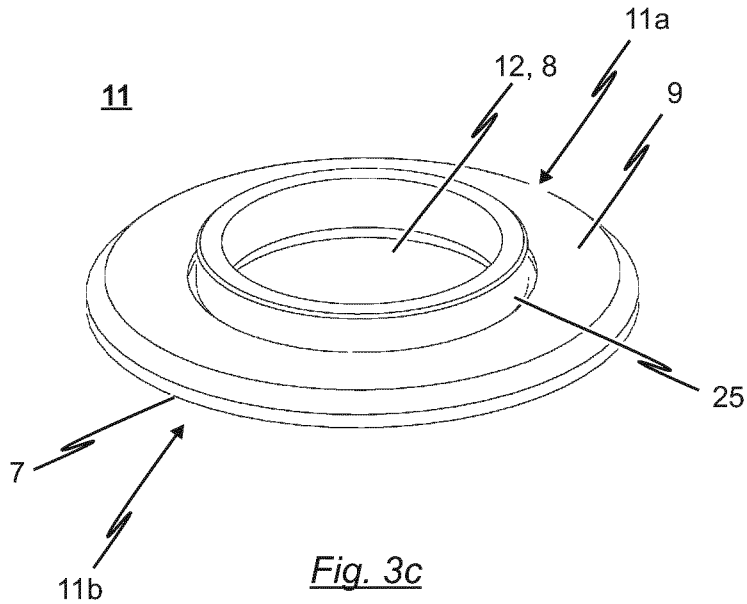

Fig. 3c

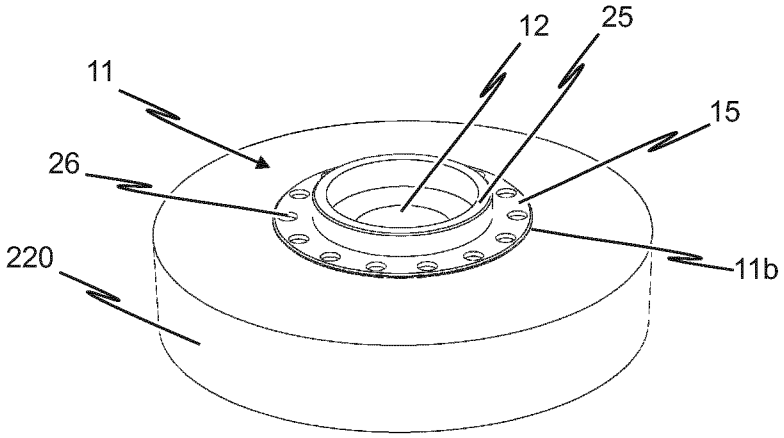

Fig. 4a

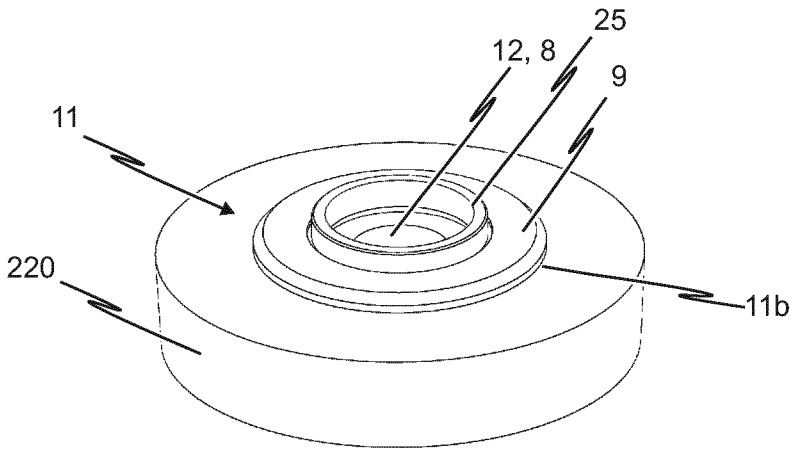

Fig. 4b

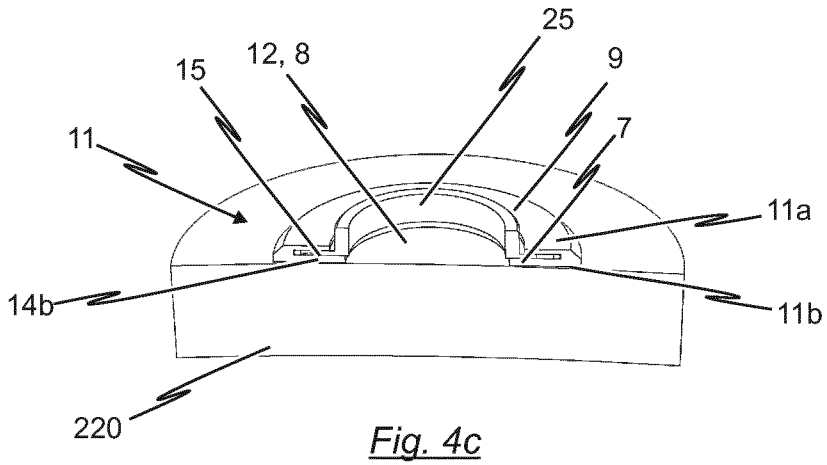

Fig. 4c

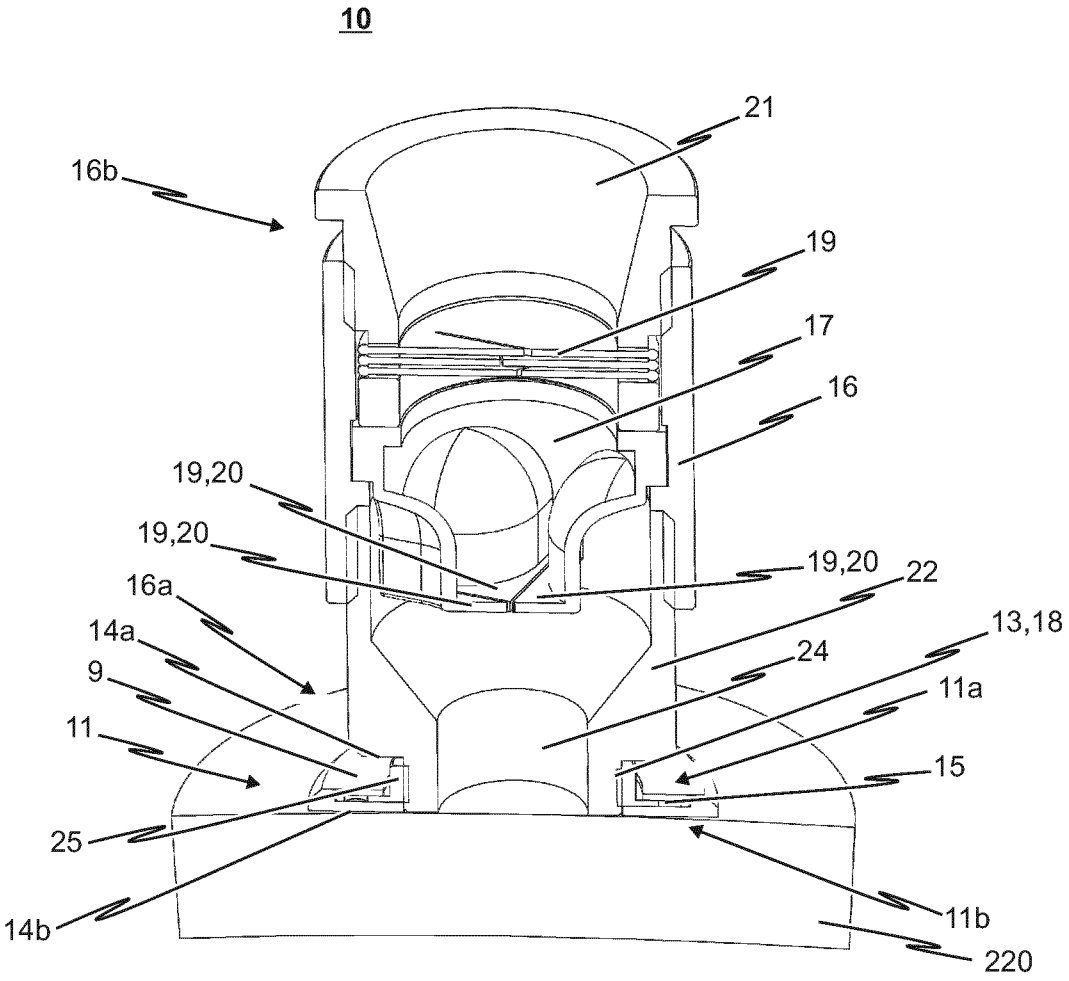
10
21
16b
19
17
16
19,20
19,20
19,20
22
16a
13,18
14a
24
9
11a
11
15
25
11b
14b
220

Fig. 5

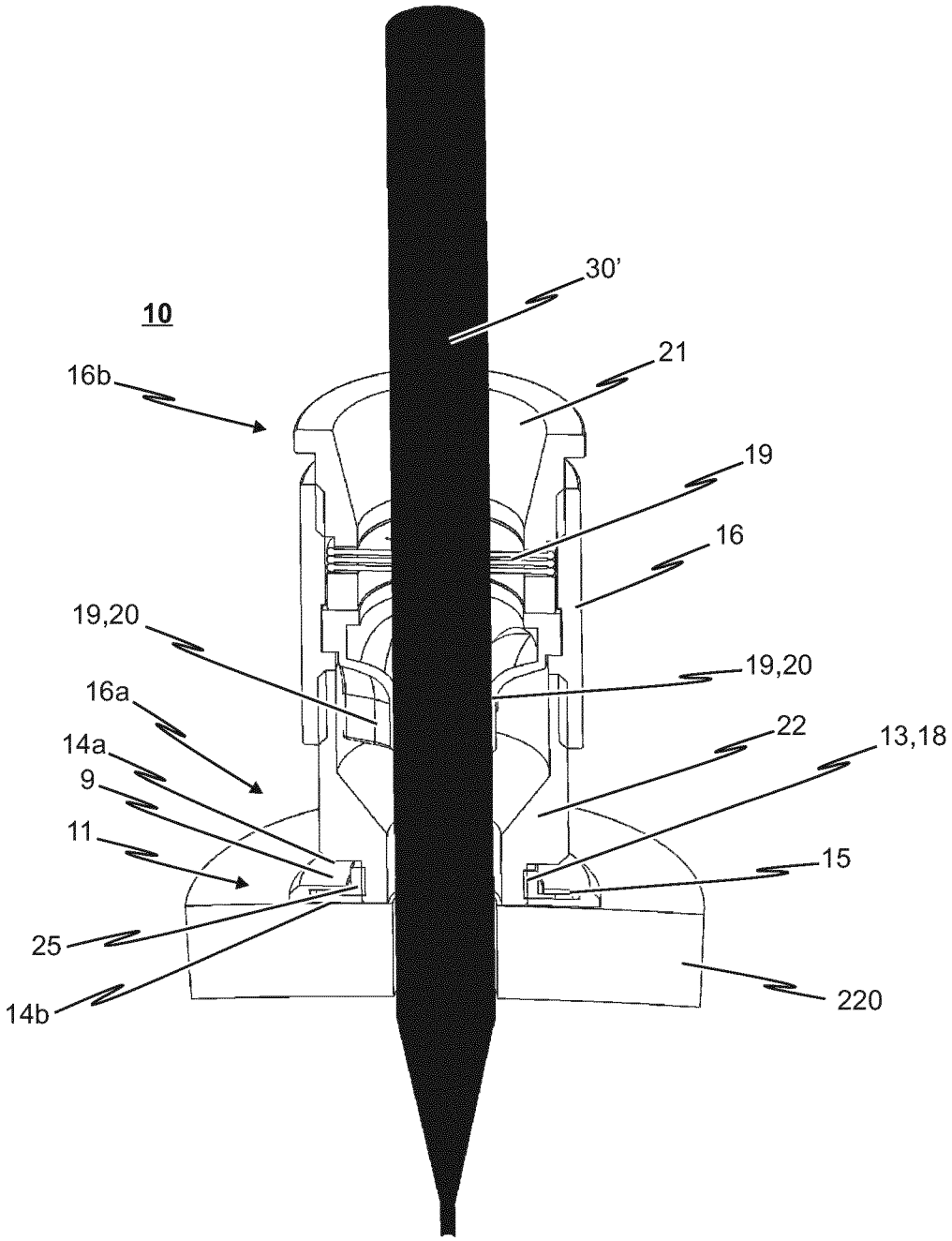

Fig. 6

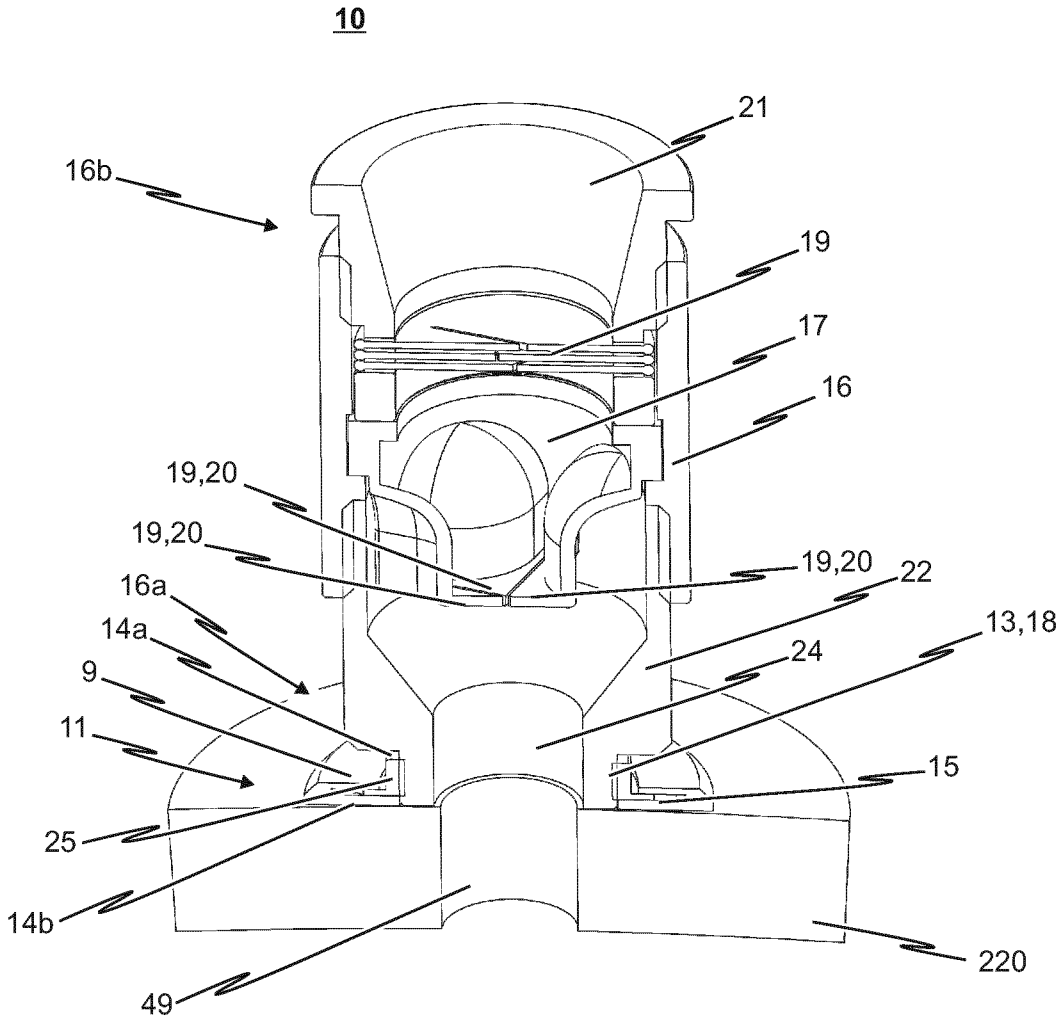
10
21
16b
19
17
16
19,20
19,20
19,20
22
16a
13,18
14a
24
9
11
15
25
14b
220
49

Fig. 7

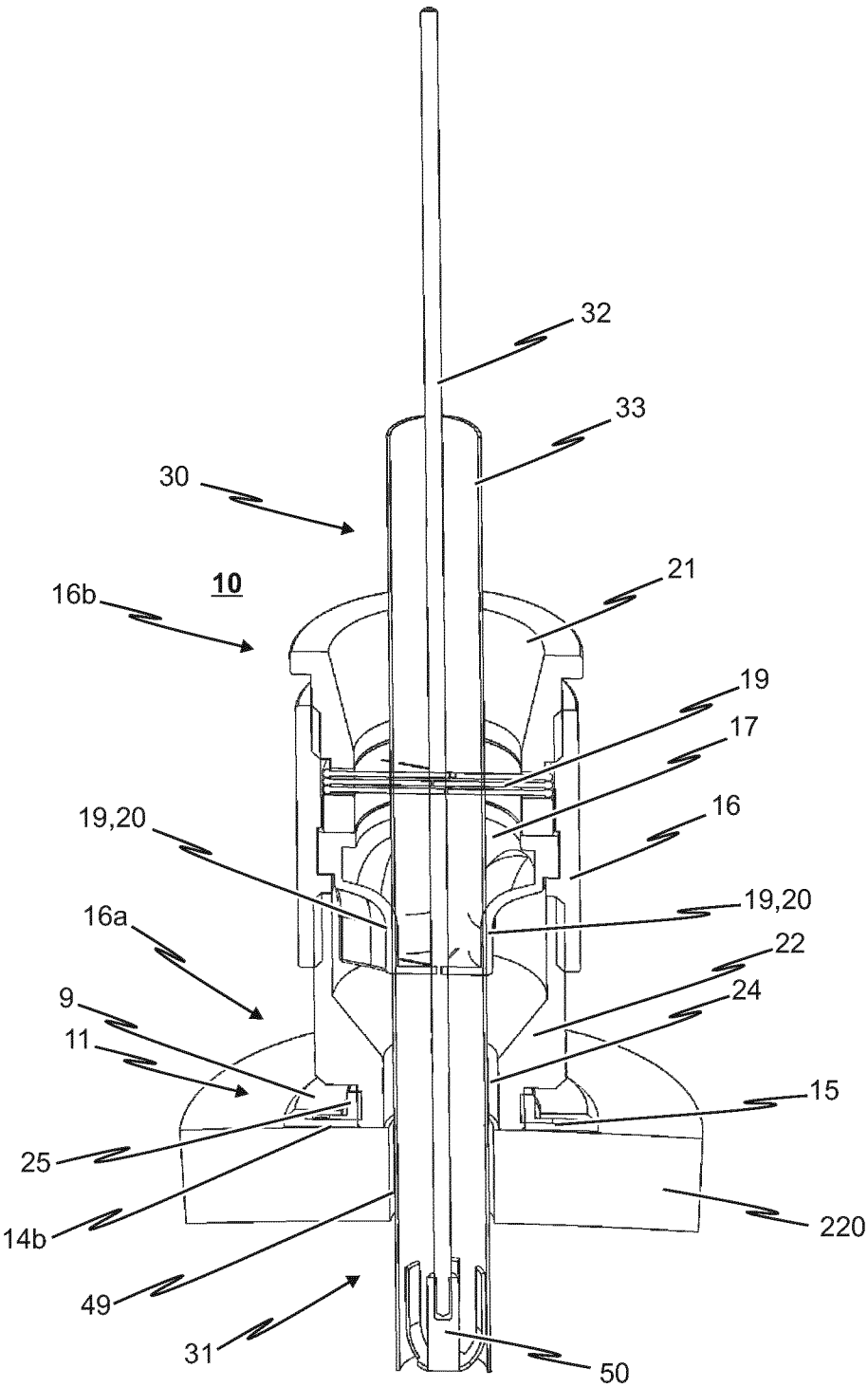
32
33
30
10
16b
21
19
17
16
19,20
19,20
16a
22
24
9
11
15
25
220
14b
49
31
50

Fig. 8

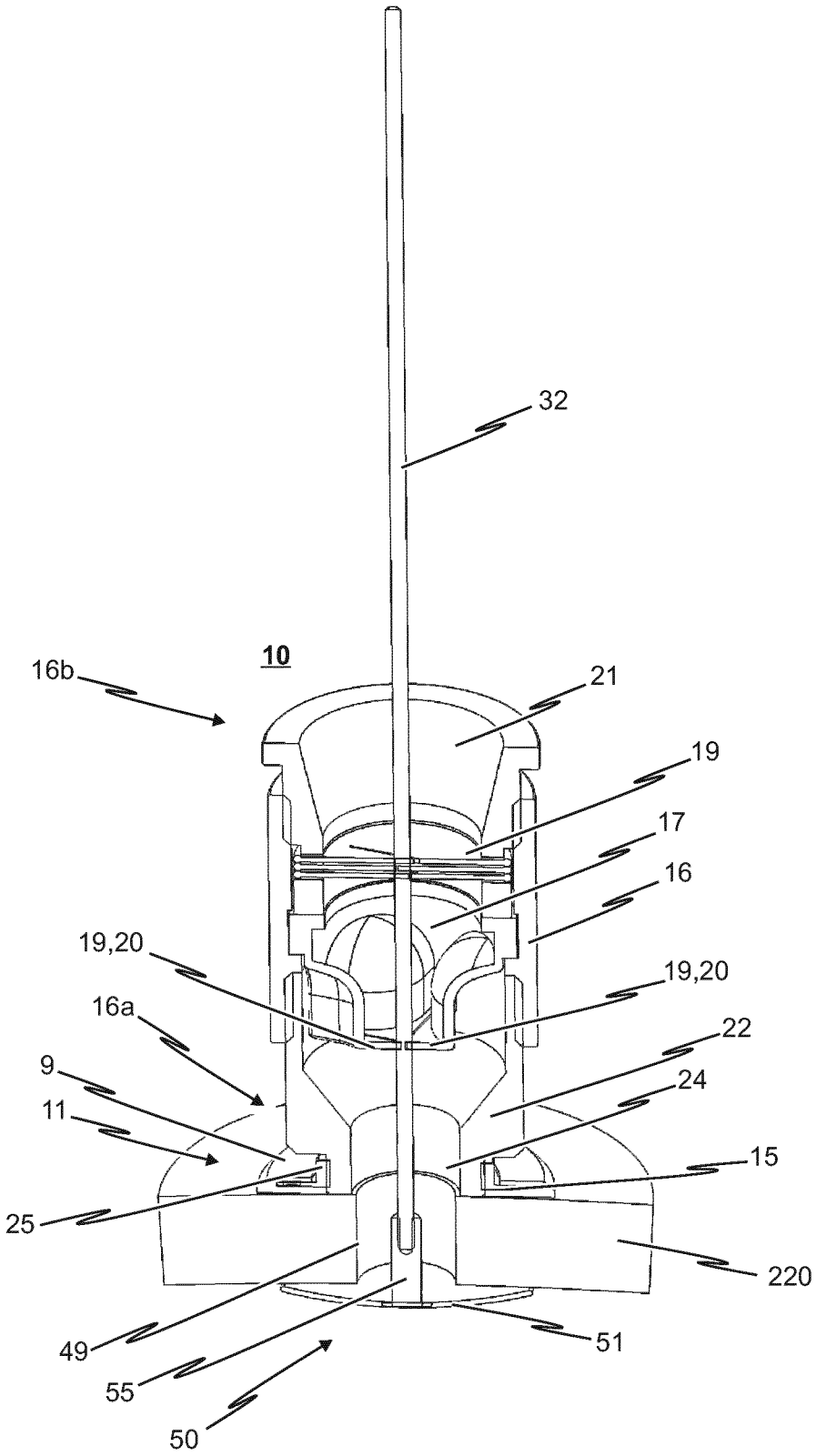

Fig. 9

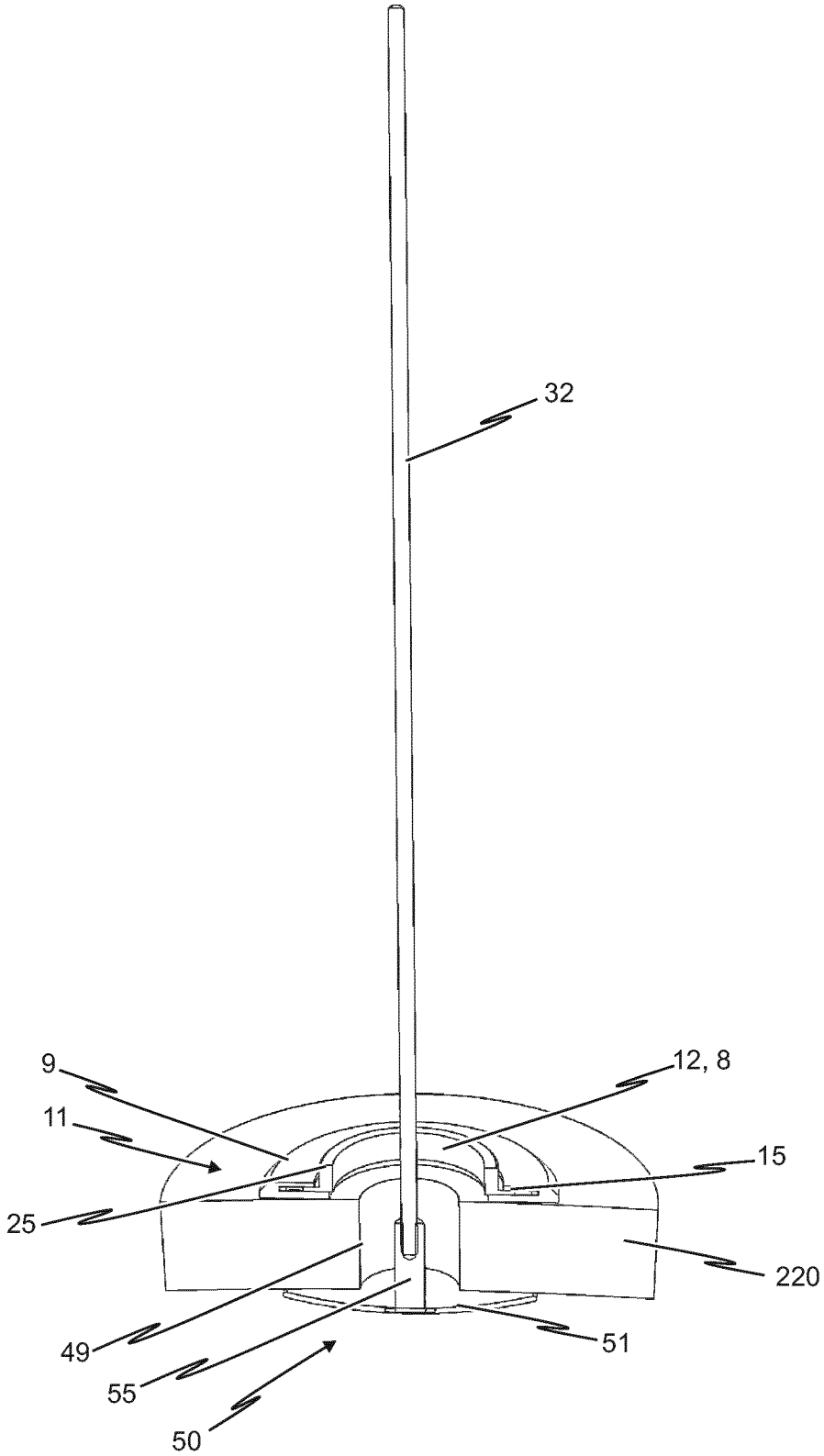

Fig. 10

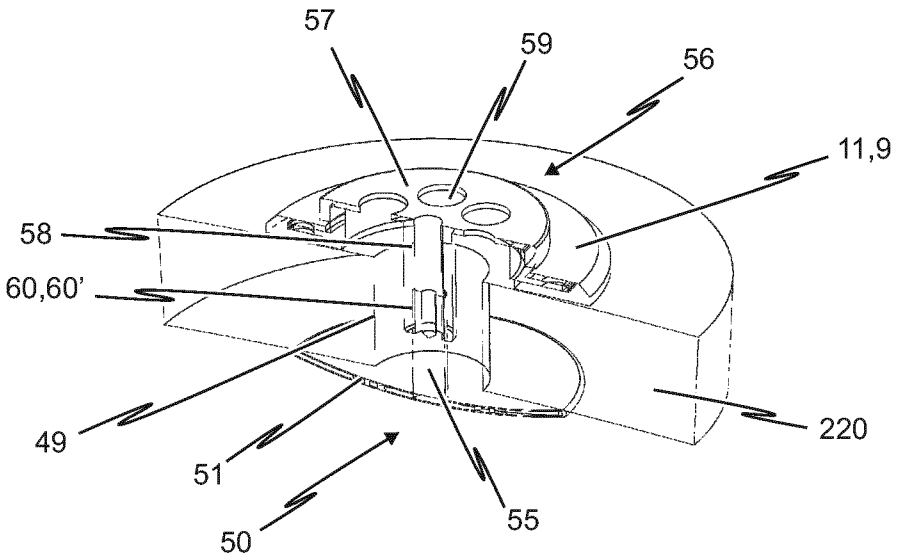

Fig. 11a

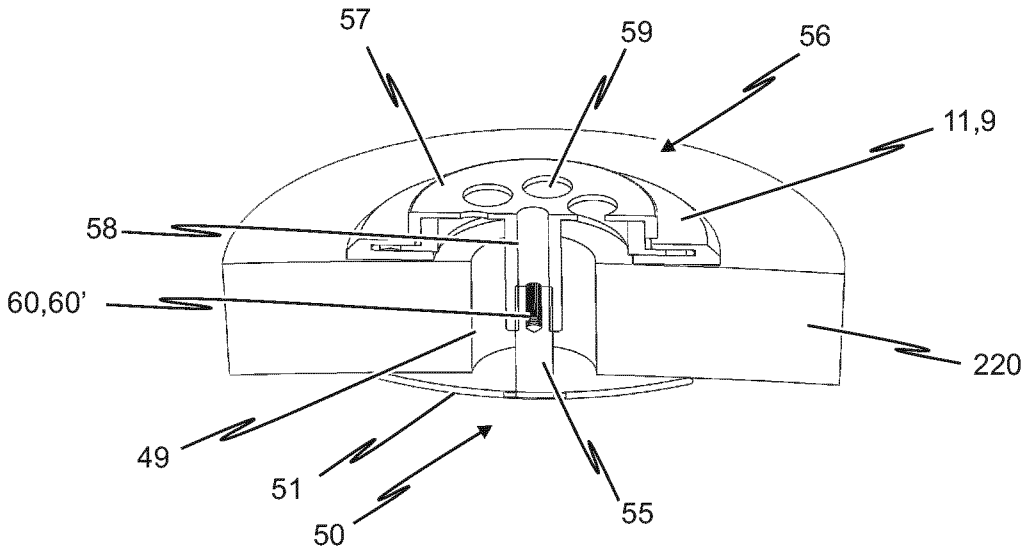

Fig. 11b

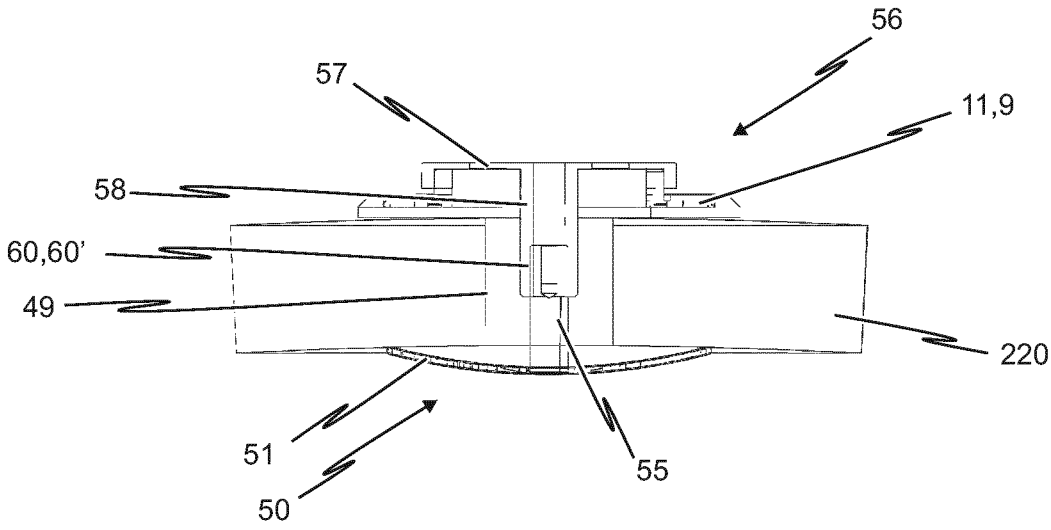

Fig. 11c

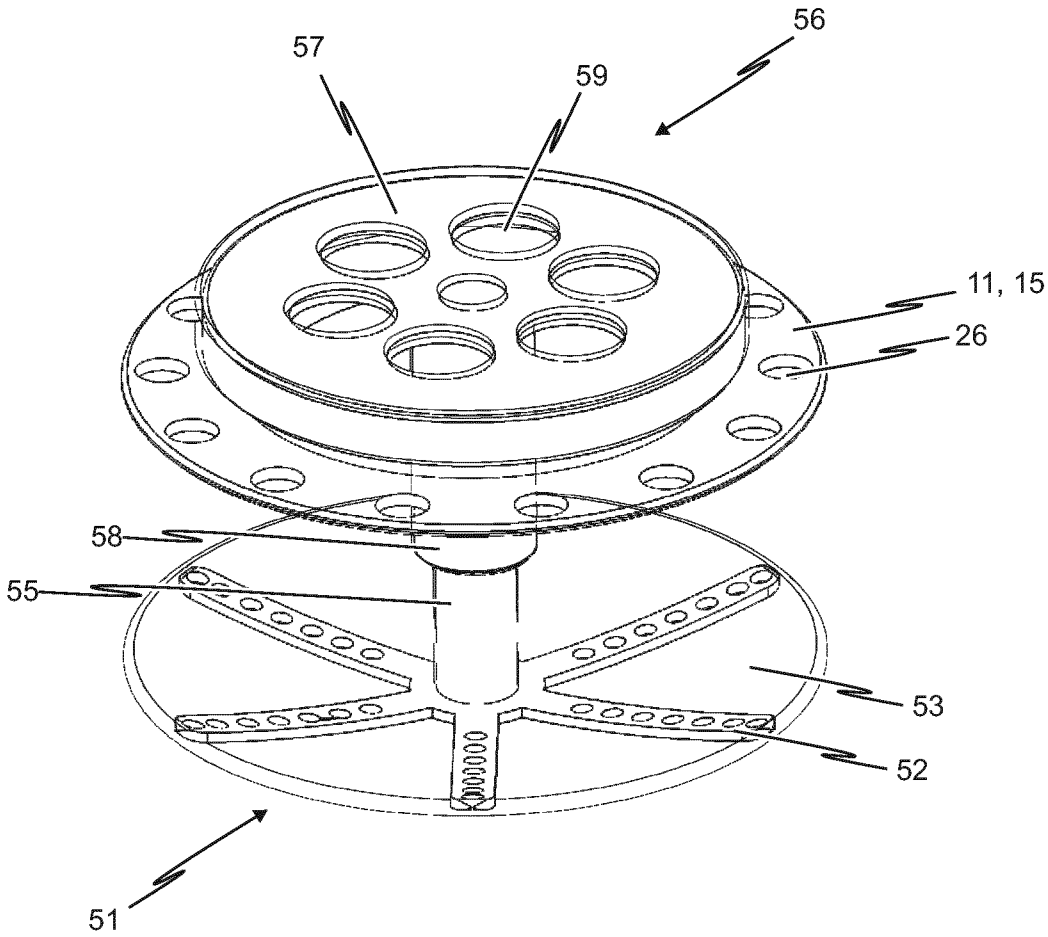

Fig. 12

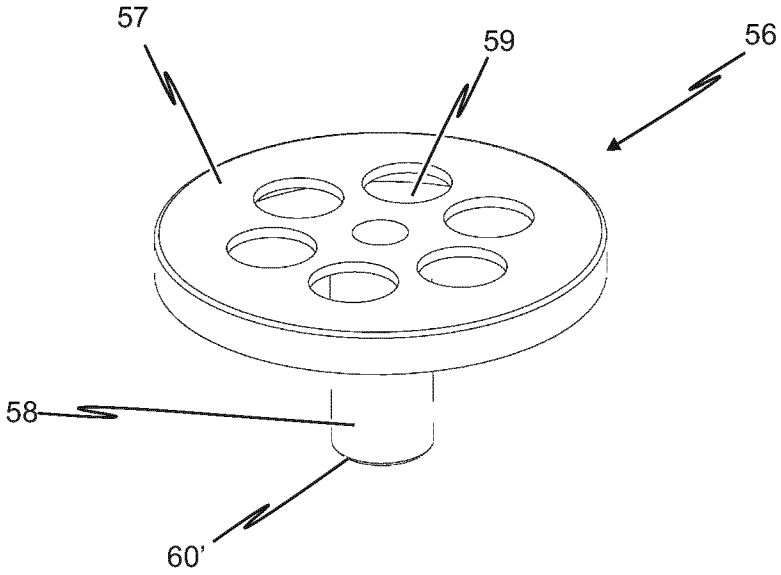

Fig. 14

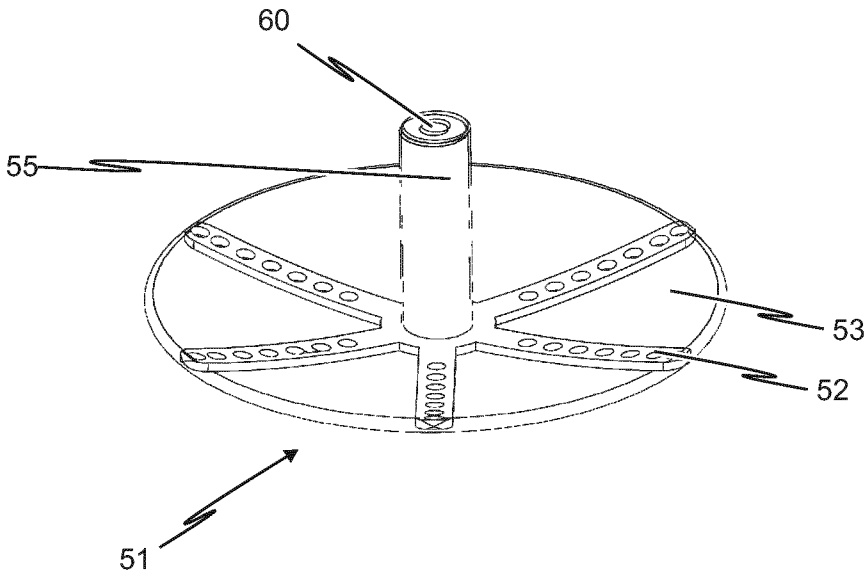

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/057427

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 A61B17/34
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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2011/060386 A2 (THORATEC CORPORATION) 19 May 2011 (2011-05-19) abstract; figures 25-26b,41a-42c page 24, line 28 - page 25, line 20 page 37, line 18 - page 38, line 7	1-40 41-68
X A	US 2002/045846 A1 (KAPLON ET AL.) 18 April 2002 (2002-04-18) abstract; figures paragraphs [0033] - [0046], [0051], [0052]	1-4,7,8, 39,40 41

-/--

[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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 July 2013	09/07/2013

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	Giménez Burgos, R

1

Form PCT/ISA/210 (second sheet) (April 2005)

International application No
PCT/EP2013/057427

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/137609 A1 (GUIRAUDON) 23 June 2005 (2005-06-23)	1-4,7,8, 10-13, 15,16, 19-21, 24-28, 38-40
A	abstract; figures 1,5,17,18,28-34 paragraphs [0086] - [0088], [0104] - [0107]	41

X	WO 2004/030515 A2 (ETHICON, INC.) 15 April 2004 (2004-04-15)	1,2,4,7, 8,10-13, 15-27, 38-40
A	abstract; figures 4-23	41

Y	US 5 350 399 A (ERLEBACHER ET AL.) 27 September 1994 (1994-09-27) abstract; figures column 5, line 30 - column 5, line 19 column 9, lines 4-11	41-68

A	WO 00/78226 A1 (RADI MEDICAL SYSTEMS A B) 28 December 2000 (2000-12-28) abstract; figures 1,2 page 6, line 5 - page 7, line 27	41-68

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2013/057427

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 69-71
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2013/057427

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011060386 A2	19-05-2011	AU 2010320038 A1	31-05-2012
		CA 2780817 A1	19-05-2011
		EP 2498838 A2	19-09-2012
		JP 2013510691 A	28-03-2013
		US 2011118766 A1	19-05-2011
		US 2011125256 A1	26-05-2011
		US 2011144680 A1	16-06-2011
		US 2012010455 A1	12-01-2012
		WO 2011060386 A2	19-05-2011
US 2002045846 A1	18-04-2002	NONE	
US 2005137609 A1	23-06-2005	CA 2547796 A1	30-06-2005
		EP 1696993 A1	06-09-2006
		US 2005137609 A1	23-06-2005
		US 2008161826 A1	03-07-2008
		WO 2005058408 A1	30-06-2005
WO 2004030515 A2	15-04-2004	AU 2003272572 A1	23-04-2004
		CA 2500054 A1	15-04-2004
		EP 1562486 A2	17-08-2005
		ES 2398383 T3	15-03-2013
		JP 2006501023 A	12-01-2006
		US 2004092965 A1	13-05-2004
		WO 2004030515 A2	15-04-2004
US 5350399 A	27-09-1994	CA 2078530 A1	24-03-1993
		EP 0534696 A1	31-03-1993
		JP H05212038 A	24-08-1993
		US 5350399 A	27-09-1994
WO 0078226 A1	28-12-2000	EP 1196092 A1	17-04-2002
		JP 2003502097 A	21-01-2003
		US RE44297 E1	11-06-2013
		US 6860895 B1	01-03-2005
		WO 0078226 A1	28-12-2000