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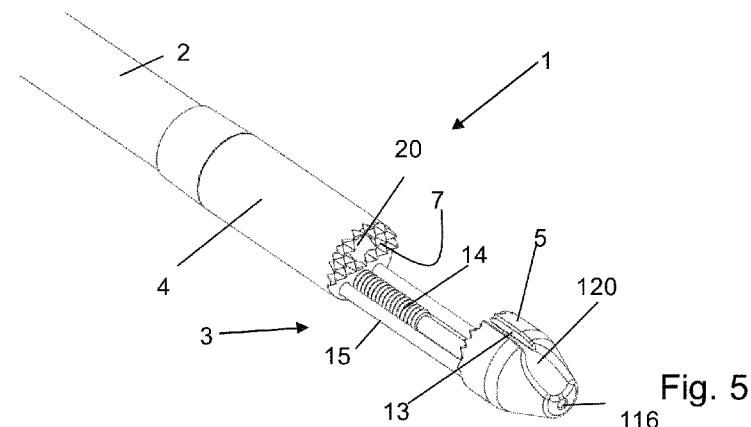


Fig. 5

(57) Abstract: The invention is in the field of minimally invasive surgical and interventional cardiology devices for heart valve repair. It particularly relates to an instrument for repairing an atrioventricular heart valve, mitral heart valve or also the tricuspid heart valve in a minimally invasive manner, and to an according method. In particular the instrument comprises a first tube having a tube axis defining an axial direction; arranged at a distal part of the first tube and contiguous to the first tube, a leaflet grabbing structure, the leaflet grabbing structure comprising a main body and a jaw, the jaw being movable relative to the main body; wherein the jaw comprises a first proximally facing abutment surface and the main body comprises a second, distally facing abutment surface; the instrument further comprising a needle wherein the needle is cannulated and forms an inner tube, and wherein the needle is releasable from the first tube and movable relative to the main body in axial directions, whereby the leaflet grabbing structure is capable of clamping a leaflet of the heart valve between the first and second abutment surfaces; and wherein the jaw has a being formed to allow the needle to extend there through while the leaflet is being clamped.

INSTRUMENT FOR REPAIRING AN ATRIOVENTRICULAR HEART VALVE

FIELD OF THE INVENTION

The invention is in the field of minimally invasive surgical and interventional cardiology devices for heart valve repair. It particularly relates to an instrument for 5 repairing an atrioventricular heart valve, mitral heart valve or also the tricuspid heart valve in a minimally invasive manner, and to an according method.

BACKGROUND OF THE INVENTION

Prolapses of a leaflet of the mitral valve into the left atrium and resulting valve insufficiency can cause serious dysfunctions of the heart. One reason for such prolapse 10 are damaged tendons (chordae tendineae) that connect the leaflets of the mitral valve to the papillary muscle through the left ventricle. Such damage may for example be a result of a myocardial infarction, tissue degeneration or infectious disease.

A repair of such a prolapse demands the leaflet or leaflets to be re-connected to the papillary muscle, for example by synthetic fibers, such as Gore-Tex® fibers. Such an 15 approach in accordance with the state of the art demands suturing the implant to a papillary muscle. A first disadvantage of such a repair process is that it is only possible while the heart is inactive, thus the surgical repair demands that the heart is stopped and drained of blood, while a cardiopulmonary bypass is used. A second disadvantage is that the success of the operation depends strongly on the skill of the surgeon. A 20 further disadvantage is that the fibers sutured to the leaflet may cause long-time damage.

Most laparoscopic and minimally invasive techniques and tools that have been developed are not usable for the requirements of mitral valve repair on a beating heart. While certain annuloplasty techniques and instruments that can suture an annuloplasty ring as part of vascular repair or heart bypass surgery may be used in conjunction with 5 a beating heart, these annuloplasty procedures.

WO 2009/052528 A2 refers to a device for performing minimally invasive valve leaflet repair in a beating heart performing a clamping mechanism adapted to grasp and release the valve leaflet. Therefore the instrument includes a needle assembly and a suture cartridge. Before starting the operation a suture to be used has to be threaded 10 through openings on the cartridge assembly. The mechanism performed by that instrument includes drawing a suture through the leaflet and using a prolene suture to tension the first suture. Subsequently, each suture has to be secured on the epicardium adjacent to a ventriculotomy using a knot and pledget. The complete mechanism is time consuming and prone to error. In addition, methods that are based on sutures 15 feature the disadvantage that suturing in minimally invasive setups is difficult, and therefore sufficiently reliable stability is often difficult to achieve.

WO 2017/066890 A2 discloses an instrument for repairing an atrioventricular heart valve and an according method, wherein the instrument implements a leaflet grabbing mechanism. The leaflet grabbing mechanism comprises a first arm with a proximally 20 facing abutment surface and a second arm with a distally facing abutment surface, wherein the arms are movable with respect to one another so that the leaflet can be grabbed and clamped between the first and second abutment surfaces. It has been found that this structure causes problems during orientation and placement of the instrument using echocardiography. Furthermore, the control mechanism is rather 25 complicated.

While these inventions represent a significant advance over open heart techniques for heart valve repair, it would be advantageous to further improve upon these techniques.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an instrument for repairing an atrioventricular heart valve, in particular the mitral heart valve or also the tricuspid heart valve, and an according method, which instrument and method overcome drawbacks of prior art devices and methods and which ensure easy implantation, are suited also for transcatheter procedures and provide a reliable and well tissue-compliant repair. The transcatheter procedure is carried out in a minimally invasive manner on the beating heart, the leaflet has to be held still for the operation, and the instrument and method should provide solutions for this. Especially, it should easily be possible to check the orientation and placement of the instrument using echocardiopathy.

These objects are achieved by the invention as defined in the claims. In accordance with an aspect of the invention, an instrument implementing a leaflet grabbing mechanism by a leaflet grabbing structure is provided. The leaflet grabbing mechanism comprises a first, proximally facing abutment surface and a second, distally facing abutment surface, wherein the abutment surfaces are movable with respect to one another so that the leaflet can be grabbed and clamped between the first and second abutment surfaces. The instrument is suitable for transcatheter procedures.

The present invention refers to an instrument for repairing an atrioventricular heart valve in a minimally invasive manner, the instrument comprises a first tube having a tube axis defining an axial direction and a leaflet grabbing structure being arranged at

a distal part of the first tube and contiguous to the first tube. The leaflet grabbing structure may comprise a main body and a jaw, whereby the leaflet grabbing structure is capable of clamping a leaflet of the heart valve between the first and second abutment surfaces. Thereby the jaw is movable relative to the main body, and

5 comprises a first proximally facing abutment surface. The main body comprises a second, distally facing abutment surface. The instrument may further comprise a needle and in particular a cannulated needle forming an inner tube. The needle is releasable from the first tube and movable relative to the main body in axial directions. The main body and the jaw have a channel which is formed to allow the needle to

10 extend there through while the leaflet is being clamped. The channel may have a position that is not central with respect to the tube axis. This position of the channel is chosen to allow the needle to puncture the leaflet relatively far away from the leaflet-edge. The instrument according to the present invention is in particular suitable for transcatheter procedures.

15 One embodiment refers to the instrument, wherein the jaw is movable in a straight axial direction. Thereby the axial direction is defined by the tube axis. This means that the jaw and the main body are separable by a movement of the jaw in axial direction (the jaw moves away from the main body; distal movement). Of course, the jaw and the main body may also be joined or merged by a movement of the jaw in axial direction (towards the main body, proximal movement). This can be used to grab a leaflet of the valve.

20 The needle of the instrument is cannulated to form a needle tube (called “inner tube” herein). Within the needle, the chord and for example parts of an implant may be arranged. The chord may be pre-mounted to the implant parts, with a fixed or adjustable length. An adjustable length may for example be possible by a slidable knot. Alternatively, the chord may have to be mounted to the implant parts or one of the implant parts in a separate method step. The present invention refers to embodiments,

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wherein the cannulated needle of the instrument is arranged in an interior of the leaflet grabbing structure and is movable with respect to the leaflet grabbing structure in axial directions to be released from the interior. Therefore, the grabbing structure has a channel, wherein the cannulated needle may be arranged in or may be advanced

5 through the interior of this channel. Said channel may continue at least partially the lumen of the first tube and run parallel to the tube axis through the main body as well as the jaw. The parts of the channel within the main body and the jaw can fit together so that in the closed position of the leaflet grabbing structure the lumen is continuous. The cannulated needle may be advanced through the lumen of said channel within the

10 leaflet grabbing structure to pierce the leaflet when it is clamped between the first and second abutment surfaces.

The main body of the instrument according to the present invention may further comprise a counter portion releasable from the first tube and being movable relative to the main body in axial directions, the counter portion comprising a distally-facing

15 second abutment surface that is pressable, by a force pointing towards a distal direction, against the first abutment surface. One embodiment refers to the instrument according to the invention, wherein the cannulated needle is arranged in an interior of the counter portion and is movable with respect to the counter portion in axial directions to be released from the interior of the counter portion to pierce the leaflet

20 when it is clamped between the first and second abutment surfaces. The counter portion may be straight with respect to the axis and be movable in a straight axial direction.

In alternative embodiments, the grabbing structure does not have a counter portion of the main body, but the main body itself forms as the counter portion by having the

25 distally facing second abutment surface.

In each case, the grabbing of the leaflet may be done by a relative movement of the jaw and the part (main body; separate counter portion) that has the second abutment surface. In general the main body and the jaw may be arranged to be opened and closed again. Therefore the jaw can be moved in axial direction relative to the main body,

5 either bidirectional (back and forth) or at least unidirectional (away from the main body). In addition, a counter portion, where it exists, can be moved in axial direction, either bidirectional (back and forth) or at least unidirectional (towards the jaw). Alternatively, the main body and the jaw may be formed to be closed only. In this case the main body and the jaw are constructed to be introduced into the patient in an open

10 form (with a certain distance) and either the jaw or the main body, respectively a part of the main body such as a counter portion, can be axially moved towards the other part.

The second abutment surface may be constituted by a press pad formed by a distal end face of a counter portion that is releasable from the first tube and/or the main body and

15 axially movable relative to the main body. The counter portion or at least a distal end part thereof may for example be essentially tube shaped (cylindrical) or have the shape of a slitted tube to release the needle from it while the leaflet is being clamped. The counter portion may also have a rectangular, pentagonal or hexagonal cross-sectional area.

20 The press pad formed by the counter portion or by the main body itself may have a circular outer contour or may also be angular (such as rectangular or pentagonal or hexagonal etc.). The press pad may, especially at its distal end, be provided with a cushion to prevent the tissue from becoming damaged. The channel for the needle within the grabbing structure may be located within the main body (and, if applicable, its counter portion) and the jaw. The dimensions of the channel located in the jaw and the main body are adapted to each other so that the distally facing abutment surface and the proximally facing abutment surface of the jaw (in the leaflet grabbing position)

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have a substantial overlap while an axial continuation of the lumen within the counter portion coincides with the innermost portion of the channel so that a needle released from inside the counter portion while the same is pressed against the jaw is not impeded. More in particular, the mouths of the channel main body section and the

5 channel jaw section essentially coincide when the grabbing structure is in the closed position, with the exception of a slight axial offset accounting for the thickness of the grabbed leaflet.

More in particular, the cannulated needle of the instrument may be arranged in an interior of the main body and be movable with respect to the main body in axial

10 directions to be released from the interior of the main body (including, if applicable, the counter portion) to pierce the leaflet when it is clamped between the first and second abutment surfaces. The instrument and in particular the leaflet grabbing structure is formed in a way that the needle in a fully extended position protrude from the distal end of the leaflet grabbing structure, and in particular the distal opening of

15 the jaw. This is important to be able to set the implant in a proper way, in particular to set the distal part of the implant in the ventricle, e.g. the papillary muscle via a transfemoral (retrograde) procedure.

In embodiments, the first and/or second abutment surfaces are structured. The structures may be selected to increase the grip of the grabbing mechanism. Therefore

20 the structures may comprise notches, ripples, pyramids, or frustum of pyramids. It is particular suitable to structure the abutment surfaces in a way that complementary structures on both surfaces arise. Thus the first and second abutment surfaces may fit into each other.

In embodiments the first and second abutment surfaces (in the clamped position)

25 define a plane being perpendicular to the tube axis. The abutment surfaces may also

be formed to define a plane forming an angle between 20 and 90° and preferably between 30 and 80° with the tube axis. Also non-plane (curved) abutment surfaces are possible.

In embodiments, the first and second abutment surfaces encompass at least two

5 different sections each section matching to the respective sections of the corresponding surface. The sections can differ in the structure of the surface, e.g. only one section has surface structures, such as ripples or pyramids, and the other section(s) are formed by smooth surfaces. In addition or alternatively the sections may differ in the angle formed by the tube axis and the plane defined by the respective sections of the surfaces

10 when the surfaces abut against each other. One embodiment refers to first and second abutment surfaces formed to comprise two sections defining a plane that forms an angle with the tube axis of 90° or nearly 90° and a third section being arranged between these two sections which defines a plane forming an angle with the tube axis between 30° and 75°. This embodiment facilitates leaflet grabbing by providing a large surface

15 area for leaflet grabbing together with an optimized grip. Therefore abutment surfaces defining a plane being oblique to the tube axis conduce to increase the area of the leaflet to be grasped. The three-sections structure of the abutment surfaces, or any other structure with abutment surfaces not perpendicular to the axis, in particular, is/are suitable to increase the distance of the area to be grasped from the edge of the leaflet.

20 Another embodiment of the invention refers to an instrument wherein the grabbing structure comprises at least one fold-out structure, for example a fold-out support such as wire loop or wire support to support the process of bringing the grabber into a correct orientation with respect to the leaflet and/or to increase the area of the leaflet which may be grasped and/or to stabilize the leaflet after grasping. Such a fold-out

25 feature may be attached to the main body and/or the jaw in a way to be on the same level as the abutment surface(s). For example, a fold-out structure may be one fold-out support attached to the jaw or attached to the main body. Alternatively, the

grabbing structure can comprise two fold-out supports. These can be in form of wire loops, one fixed to the jaw and one to the main body. Another possibility are two fold-out supports, both fixed either to the main body or the jaw to form one supporting structure. In case that more than one fold-out support is attached it is preferred that

5 these wire supports are all fixed parallel in regard to the plane formed by the first and second abutment surface in closed position. Therefore it is preferred that in closed position the abutment surfaces and optionally the one or more fold-out supports define the same plane. In addition, the fold-out supports can be arranged to be folded against the grabbing structure, for example at least partially in grooves of the grabbing

10 structure and can swing out before or during opening of the grabbing structure, for example upon being released from the outer tube.

The instrument according to the present invention may further comprise an anchor carrier arranged within the inner tube of the needle and being axially movable relative to it, the anchor carrier being configured to carry at least a part of an implant that is

15 secured or capable of being secured to an artificial chord. In an embodiment, the implant comprises a distal implant part and a proximal implant part and a chord, wherein the chord is configured to connect and for example in the assembled state connects the proximal and distal implant parts. In a tubular element (which may be the cannulated needle or an implant sleeve inside the cannulated needle), the distal and

20 proximal implant parts are arranged beside one another with the proximal implant part for example arranged proximally of the distal implant part, so that the tubular element prevents the proximal implant part from escaping from the anchor carrier as long as the anchor carrier is within the tubular element. Especially, the anchor carrier may axially extend within the tubular element from proximally of the proximal implant part

25 to at least a distal end of the proximal implant part and may have a distal foot portion (stop feature) that prevents the proximal implant part from slipping out towards distally as long as it is within the tubular element. For example, the anchor carrier may comprise an anchor receiving recess (seat) proximally of the distal foot portion.

Implants of this kind are described in WO 2017/066888, and systems that comprise an anchor carrier of this kind are described in WO 2017/066889. In embodiments, instruments or sets according to the present invention may comprise an implant as described and claimed in WO 2017/066888 and/or an anchor carrier system as 5 described and claimed in WO 2017/066889.

The grabbing structure including the main body and the jaw can be made of a metal, an alloy such as stainless steel or a polymeric material such as polyether ether ketone (PEEK). It is preferred that the grabbing structure, in particular a polymeric grabbing structure, comprises at least one marker made of a radiopaque material. This at least 10 one marker is helpful to trace or visualize the position of the grabbing structure using X-rays. Alternatively, a radiopaque polymeric material may be used to make the grabbing structure. A polymeric material may be made radiopaque by coupling a molecule containing a dense atom (e.g. an iodine-containing molecule) onto the polymer backbone. High radiopacity of a polymeric material may alternatively be 15 achieved by combining a polymeric resin and a powdered radiopaque agent having uniformly shaped particles of a specific particle size distribution (e.g. dense metal powders or Barium sulfate (BaSO₄)).

There may also be marker which are attached to the main body and/or the jaw and which are suitable to trace the opening and closing of the grabbing structure using X-rays. The marker may be formed as strips, tapes, points or patches within the grabbing structure or attached to the grabbing structure. The marker may also be formed as small 20 antennas or wire loops and being attached to the grabbing structure. These loops or antennas can protrude from the grabbing structure and increase the visibility using echography. Especially, they may ease determining the orientation around the axis 25 (azimuthal position) during operation, which determination in view of the often necessarily rotationally cylindrical (rotationally cylindrical because of the

transcathether approach) overall shape of the grasping device would otherwise be difficult.

Generally, markers can be made of a radiopaque polymer, an alloy, or metal, such as a platinum-iridium alloy or tantalum.

- 5 One embodiment of the grabbing structure comprises indentations or grooves wherein marker can be attached. The marker may be attached by adhesive bonding. It is preferred that at least one marker (or indentation) is located on the lateral side of the main body and at least one on the lateral side of the jaw. These markers (or indentations) are preferably located near the abutment surface or along the edge of the
- 10 abutment surface and in parallel. This allows the operator (for example surgeon) to determine the orientation of the grabbing structure. Using X-ray the markers show further if the grabbing structure is closed or open and the width of the opening. A preferred form of the marker (or indentation) is curved or banana-like strip.

In embodiments, the surface of the grabbing structure or parts of the surface of the 15 grabbing structure has a textured surface finish comprising for example convex microstructures or striated parts. Said microstructures are curved or rounded outward like the exterior of a sphere or circle. Another embodiment of the present invention refers to a grabbing structure, wherein at least a part of the surface of the grabbing structure has a roughness average Ra between 1 – 40 μm , preferably between 5 and 20 μm . Thereby surface roughness as a component of surface texture is quantified by the deviations in the direction of the normal vector of a real surface from its ideal form. The arithmetic average roughness, Ra is the arithmetic average value of filtered roughness profile determined from deviations about the center line within the evaluation length and the most widely used one-dimensional roughness parameter.

The present invention refers further to a kit (set) comprising an instrument as well as an implant suitable to be implanted by the instrument and thus, repairing an atrioventricular heart valve in particular by replacing a damaged (ruptured) chordae. Thereby the implant is preferably designed as described herein. In further 5 embodiments, at least the proximal implant part and for example both/all implant parts may be carried by an anchor carrier which may be surrounded by the cannulated needle and possibly an additional sleeve within the cannulated needle. Therefore, a kit may comprise at least two of the following: the instrument, an anchor carrier with or without a protective sleeve, a catheter, and an implant (with or without the artificial 10 chord). The kit can be provided comprising the elements individually or in a preassembled or assembled manner.

Especially, the proximal implant part may be assembled with the anchor carrier in a manner that it can escape and is released automatically as soon as the proximal implant part and the portion of the anchor carrier to which it is mounted is outside of the tubular 15 element – for example without any active mechanism that causes the release, thus just by being moved out of the tubular element.

For example, the anchor carrier may axially extend within the tubular element from proximally of the proximal implant part to at least a center of the proximal implant part and for example at least to its distal end or further than its distal end. Especially, 20 the anchor carrier may extend over the full (proximodistal) length of the proximal implant part, for example substantially as described in WO 2017/066889.

In embodiments, the anchor carrier may form a seat for the proximal implant part, out of which the proximal implant part can escape by being moved in radial direction once it is released from the tubular element, i.e. the seat is open towards one radial direction

but blocks the second implant part with respect to axial directions as long as it is kept in the seat by the tubular element.

The seat for this purpose may have a structure adapted to the shape of the proximal implant part in the initial (not spread) state. Especially, the anchor carrier may have a 5 distal foot portion with a channel for the chord, and, proximally thereof, a seat portion (also referred to as shaft portion in this text) in which the cross section is reduced to accommodate the proximal implant part. Proximally of the seat portion, the anchor carrier may have a pusher portion that has a larger cross section than the seat portion so that a pushing movement of the anchor carrier also pushes the second implant part 10 forward as long as the second implant part is still located in the seat and not yet released.

In case the anchor carrier also carries the distal implant part in addition to the proximal implant part, it may be such that the implant parts are arranged beside one another, with the proximal implant part arranged proximally of the distal implant part. The inner 15 tube or a sleeve element inside the inner tube may prevent the proximal implant part from escaping from the anchor carrier as long as the anchor carrier is within the inner sleeve or tube element.

The grabbing structure, as mentioned comprises a channel arranged so that the cannulated needle may be advanced through this channel so that at least part of the 20 needle can distally protrude out of the grabbing structure. The first abutment surface may be constituted by a region around the innermost portion of the channel of the proximally facing surface of the jaw. And the second abutment surface may be constituted by a region around the innermost portion of the channel of the distally facing surface of the main body.

The channel is preferably further formed in a way that a chord, for example extending between a released distal implant part (that will be released distally of the jaw while the leaflet is being grabbed; implanted within the ventricle or a ventricle tissue) and a proximal implant part (that will be released on the atrial side of the leaflet, e.g. as 5 anchor lying on the leaflet) can extend there through and be released by a lateral (radial) relative movement. Therefore, the channel may at least partially be open to a side (“side” or “lateral” in this text unless otherwise specified are used to denote directions that are radial with respect to the tube axis). Thus, the channel may extend to a lateral surface of the grabbing structure. Therefore the channel may be connected 10 to the lateral surface with a for example slit-shaped recess. Thus, the grabbing structure may comprise a slit between a lateral surface and the channel for advancing the cannulated needle. The present invention, therefore, refers to an instrument, wherein the channel is open to a single lateral side.

15 The opening (recess) of the channel to the single lateral side or the recess of the channel may only be located within the jaw. In this case the recess or slit runs preferably along the complete length of the jaw.

It may alternatively run through a portion of the main body and from the main body to the distal end of the jaw. Thereby the recess runs along the complete length of the jaw and a distal section of the main body. This allows that one part of the implant can be 20 released distal of the leaflet and the other part can be released proximally of the leaflet while the leaflet is being grasped. The recess may optionally be relatively narrow, but the recess may have a wider implant release portion at the location where the proximal implant part is released while the leaflet is being clamped. The width of the recess or of its implant release portion may be between 0.4 and 0.8 mm or even extend up to a 25 full width of the channel, and the diameter of the channel may between 1.2 and 2 mm, preferably between 1.4 and 1.8 mm.

For guiding the needle when the leaflet is pierced, especially in embodiments with a comparably wide recess (or recess implant release portion) open to a lateral side, the device may further comprise a needle guide tube encompassing the needle and being guided within the channel. Such a needle guide tube is axially movable independently 5 of the main body and the jaw and independently of the needle at least to some extent and may be retracted relative to the needle for release of the proximal implant part.

Therefore one specific embodiment of the present invention refers to an instrument for repairing an atrioventricular heart valve in a minimally invasive manner, wherein the instrument comprises a first tube having a tube axis defining an axial direction and 10 arranged at a distal part of the first tube and contiguous to the first tube, a leaflet grabbing structure. The leaflet grabbing structure comprises a main body and a jaw, wherein the jaw is movable relative to the main body and comprises a first proximally facing abutment surface and the main body comprises a second, distally facing abutment surface so that the leaflet grabbing structure is capable of clamping a leaflet 15 of the heart valve between the first and second abutment surfaces. The instrument comprises further a needle wherein the needle is cannulated, forms an inner tube, and is releasable from the first tube and movable relative to the main body in axial directions. The main body and the jaw of said embodiment have a channel with a recess extending to a lateral surface wherein the recess runs through a distal portion of the 20 main body and the complete jaw.

The main body and the jaw of the instrument may work together to form cooperatively a grasping device. Therefore, the jaw is movable relative to the main body. This movement may be produced by the operator via an operating structure, such as an operating rod. In embodiments, the operating rod is a push-pull wire. In other 25 embodiments, the operating rod is a threaded rod. One embodiment refers to an instrument as described herein comprising an operating rod suitable to operate the axial movement of the jaw and to adjust the distance between the main body and the jaw.

Alternatively the movement may be facilitated by a cable, e.g. made of nitinol, which may be partially surrounded by a threaded sleeve, e.g. made of stainless steel. At the distal end of the rod or cable, a stop element may be attached. This stop element attaches the cable or rod to the jaw and allows axial movement of the jaw facilitated

5 by movement of the cable or rod.

To ensure that the jaw is only moved in axial directions, the instrument may comprise at least one guiding rod (stabilizing rod) and in particular at least two stabilizing rods. The at least one guiding rod or the at least two guiding rods may be arranged to run parallel to the threaded rod (and the tube axis). The guiding rod(s) are displaceable

10 relative to the jaw and/or the main portion to ensure a guided axial movement but in contrast to the operating structure (for example operating rod) is not equipped for being operated from outside (from the handle part).

The instrument according to the present invention is suitable for transcatheter procedures used for repairing heart valves. Therefore, the instrument according to the

15 present invention may further comprise a guide catheter surrounding the first tube and providing a conduit to the first tube to reach the heart valve to be treated. Another additional tube of the instrument may be a steerable catheter. Steerable or deflectable catheters are known in the art of minimally invasive surgery. It would also be possible to make an interior tube steerable. Therefore, the instrument according to the present

20 invention may further comprise or being provided as a set together with a handle and a transseptal steerable catheter.

For usage within transcatheter procedures it is advantageous if the instrument according to the present invention may have a channel for a guide wire. Thus, the present invention refers to an instrument comprising an over the wire grabbing structure. A guide wire is a device used to enter tight spaces, e.g., obstructed valves or

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channels, within the body, or to assist in inserting, positioning, and moving a catheter (called Seldinger Technique). Therefore the invention refers to embodiments wherein the main body and the jaw further comprise a guide wire channel suitable to incorporate a guide wire. This guide wire channel is for example located central within 5 the grabbing structure. Alternatively, depending on the available space, the guide wire channel may be arranged off-center. The guide wire channel runs parallel to the tube axis (if it is arranged centrally coinciding therewith) from the proximal end of the main body to the distal end of jaw.

One embodiment of the present invention refers to an instrument for repairing an 10 atrioventricular heart valve in a minimally invasive manner, the instrument comprising a first tube having a tube axis defining an axial direction and being arranged at a distal part of the first tube and contiguous to the first tube, a leaflet grabbing structure, the leaflet grabbing structure comprising a main body and a jaw, the jaw being movable relative to the main body; wherein the jaw comprises a first proximally facing 15 abutment surface and the main body comprises a second, distally facing abutment surface; the instrument further comprising a needle wherein the needle is cannulated and forms an inner tube, and wherein the needle is releasable from the first tube and movable relative to the main body in axial directions, whereby the leaflet grabbing structure is capable of clamping a leaflet of the heart valve between the first and second 20 abutment surfaces and wherein the grabbing structure has a channel having a position that is not central with respect to the tube axis and is formed to allow the needle to extend there through while the leaflet is being clamped. Within said embodiment the channel is open to a single lateral side. The instrument of this embodiment comprises further an operating rod suitable to operate the axial movement of the jaw and to adjust 25 the distance between the main body and the jaw as well as at least one stabilizing rod being arranged to run parallel to the operating rod. The main body and the jaw of that embodiment may further comprise a channel suitable to incorporate a guide wire.

The cannulated needle may be made of a metal such as stainless steel. The cannulated needle may be formed to be suitable to puncture a leaflet and a ventricle tissue, e.g. a papillary muscle or the free wall of the ventricle. Therefore the cannulated needle may have a sharpened distal end. In addition it is advantageously that the cannulated needle

5 has a certain flexibility. Therefore the cannulated needle may comprise a laser cut section proximally adjacent to the sharpened end. Therefore the distal end of the cannulated needle may be cut oblique to the tube axis. In embodiments, the cannulated needle is cut twice, with different gradients. The distal part of the cut defines a plane that forms with the tube axis an angle of 25 to 35° and the proximal part defines a

10 plane that forms with the an angle of 15 to 22 °. Within said laser cut section the cannulated needle comprises radial laser cuts, which do not cover the complete circumference of the needle (the cuts describe an open ring).

In embodiments, the needle has a sharpened distal end and proximally therefrom a laser cut section (for flexibility). The laser cut section may be up to 30 cm long and

15 may start 3 to 10 cm proximally of the distal end of the needle. After the laser cut section a polyimide tubing may be added having a length to reach a handle of the instrument.

A handle by which the surgeon operates the instrument may comprise a depth indicator to control the distance by which the needle has been deployed. In addition or as an

20 alternative, the needle may comprise at least one marking that indicates the penetration depth and that may be supervised by imaging methods.

Due to the described approach, the instrument may be an all passive construction making implantation on the beating heart possible without any active power source except the pulling and pushing of wires and steering of the steerable catheter by the

surgeon. Especially, it is not necessary that parts, such as an implant part, are actively shot out or similar. This makes possible a good control of the operation by the surgeon.

In embodiments, the instrument and in particular the cannulated needle of the instrument comprises the implant parts in a pre-assembled or pre-assemblable 5 configuration. Especially, the implant parts may comprise a distal implant part to be anchored in a ventricle tissue, such as muscle tissue, and a proximal implant part to be secured to the leaflet and for example to be arranged proximally of the leaflet, with the chord extending through a perforation of the leaflet to the distal implant part.

In embodiments, the proximal implant part may be configured to lie flat on a surface 10 of the leaflet tissue, with the chord extending from the proximal implant part through the leaflet tissue and through the ventricle to the distal implant part. To this end, the proximal implant part may for example comprise a flattish distally-facing abutment surface (distally-facing in the implanted state, i.e. facing to the side to which the chord runs). Especially, the proximal implant part may be configured to only lie on the leaflet 15 and to thereby being secured to it – without the proximal implant part having any fastening mechanism that extends within the leaflet or through the leaflet.

The proximal implant part may hold to the leaflet without any additional fastening mechanism (such as a suture) or artificial fastening means, only by the design of the implant as such that comprises the distally facing abutment surface lying on the leaflet 20 tissue – especially by the chord extending through the leaflet tissue and the ventricle to the distal implant part, possibly assisted by a distally-facing structure on the abutment surface that comprises portions that protrude into the tissue, without penetrating through it, and/or is indented with respect to it, to prevent shifting movements. The proximal implant part especially will, after implantation, be placed 25 on one side of the leaflet only and not for example extend through the leaflet. The side

on which the proximal implant part lies on the leaflet tissue is the atrium-facing upper side of the leaflet.

For bringing the leaflet grabbing structure from the closed position to open position or vice versa, the instrument may comprise a cable pull mechanism. Such a mechanism 5 may for example comprise a wire appropriately guided along the first tube and the main body and the jaw, with which it is appropriately connected to pull or push it.

Of course, other variants are possible. This includes the possibility that one or more springs automatically bring the leaflet grabbing structure into the open position, and an active mechanism, such as a cable pull mechanism, is provided to bring it back into 10 the closed position.

It is also possible that a spring mechanism is used to bring the grabbing structure into the closed position and to hold it there. Such a spring mechanism can be present everywhere in the device, for example in the handpiece held by the operator, or it may be within the outer tube that is inserted in the body. Such optional spring mechanism 15 for closing the leaflet grabbing structure has two possible advantages: firstly, it may close the grabbing structure automatically. Secondly it exerts a controlled and constant force on the leaflet while the leaflet is being held.

In embodiments, the instrument comprises a feedback indicator showing whether or 20 not the leaflet grabbing structure has grabbed the leaflet. Such indicator may for example comprise an optical means such as a light guide defining a light path to the distal end back, which light path is interrupted when the leaflet has been grabbed.

It has been found that the grabbing structure as described herein has a superior visibility in echography compared to devices of the prior art. Therefore, the present invention provides an instrument that provides the possibility of a good orientation using echography.

- 5 The invention also concerns a method of replacing or supplementing damaged natural chordae tendineae of a human or animal heart by using a device as described herein. Features that were described in this text referring to the instrument may also belong to the method, and vice versa. Especially, this method may comprise the steps of:
 - providing an instrument, the instrument comprising:
 - 10 o a first tube having a tube axis defining an axial direction;
 - o arranged at a distal part of the first tube and contiguous to the first tube, a leaflet grabbing structure, the leaflet grabbing structure comprising a main body and a jaw, the jaw being movable relative to the main body;
 - o wherein the jaw comprises a first proximally facing abutment surface and the main body comprises a second, distally facing abutment surface;
 - 15 o the instrument further comprising a needle wherein the needle is cannulated and forms an inner tube, and wherein the needle is releasable from the first tube and movable relative to the main body in axial directions,
 - o whereby the leaflet grabbing structure is capable of clamping a leaflet of the heart valve between the first and second abutment surfaces;
 - 20 o and wherein the grabbing structure has a channel being formed to allow the needle to extend there through while the leaflet is being clamped and which may have a position that is not central with respect to the tube axis;
 - advancing the tube from an atrial side towards a leaflet of an atrioventricular valve of the heart,
 - clamping the leaflet between the first and second abutment surfaces;
 - puncture the leaflet using the cannulated needle while the leaflet is being clamped;
 - securing an artificial chord to the clamped leaflet; and

- removing the first tube and the leaflet grabbing structure.

The step of securing the artificial chord, may refer to a method comprising the following steps:

- providing a system arranged within the cannulated needle of the instrument,
5 respectively the inner tube within the needle, the system comprising:
 - o a tubular element having an outer, distal end,
 - o a distal implant part arranged in the tubular element,
 - o the chord, being an artificial or allograft or xenograft chord arranged in the tubular element,
 - o a proximal implant part arranged in the tubular element, and
 - o an anchor carrier arranged in the tubular element,
 - o the distal implant part and the proximal implant part being arranged in the tubular element beside one another,
 - o the proximal implant part being assembled with the anchor carrier inside
10 the tubular element so that the tubular element prevents the proximal implant part from escaping from the anchor carrier as long as the anchor carrier is within the tubular element,
- advancing the cannulated needle with the tubular element from an atrial side to a leaflet of an atrioventricular valve of the heart, piercing the leaflet and advancing the cannulated needle through the pierced leaflet and through a tissue within the ventricle, such as a papillary muscle;
20
- releasing tubular element from the needle and the distal implant part from the tubular element and thereby implanting the distal implant part in the tissue;
- retracting the tubular element (together with the needle) and releasing the proximal implant part proximally of the leaflet, on the atrial side thereof; and
25
- removing the tubular element,
- wherein either the proximal implant part and the distal implant part are connected by the chord in the system, or the method comprises the additional step of connecting the proximal and distal implant parts by the chord.

Specifically, the present invention can provide a minimally invasive treatment or repairing an atrioventricular heart valve. The methods comprises in particular a transcatheter valve repairing method. The present invention is thereby compatible with 5 and directed to different access points to a (beating) heart, such as transapical and in particular also a transfemoral approach. Usually valve replacement requires an open heart procedure with a “sternotomy”, in which the chest is surgically separated for the procedure. Transcatheter procedures can be done through very small openings that leave all the chest bones in place. Therefore a transcatheter procedure provides 10 beneficial treatment options to people who are considered an intermediate or high risk patient for standard valve replacement surgery while also providing the added bonus of a faster recovery in most cases.

BRIEF DESCRIPTION OF THE DRAWINGS

15 Hereinafter, principles and embodiments of the invention are described referring to drawings. Same reference numbers in the drawings refer to same or analogous elements. The drawings show:

Fig.1: A schematic drawing of an instrument with a grabbing structure comprising a main body, a jaw and a counter portion.

20 Fig. 2: A schematic drawing of the instrument of Figure 1, wherein the counter portion has been moved in axial direction towards the jaw.

Fig. 3: A schematic drawing of the instrument of Figure 1, wherein the needle has been moved in axial direction through the jaw.

Fig.4: A schematic drawing of an instrument according to the invention with a grabbing structure comprising a main body and a jaw.

Fig. 5: A schematic drawing of the instrument according to Fig. 4, wherein the view is changed.

5 Fig. 6: A schematic drawing of the instrument according to Fig. 4 in a closed configuration.

Fig. 7: A schematic drawing of the instrument according to Fig. 4, wherein the needle reaches through the jaw.

10 Figs. 8A-8C: Schematic drawings of the instrument of Figure 4 in open configuration in a perspective view with different orientations.

Figs. 9A-9C: schematic drawings of an instrument according to the invention, wherein the first and second abutment surfaces define a plane being oblique to the tube axis.

15 Figs. 10A and 10B: Two representations of a grabbing structure comprising support wires and lateral grooves for the attachment of marker stripes.

Fig. 11: A schematic drawing of a main body being part of an instrument according to the invention showing a lateral groove for a marker.

Fig. 12: A schematic drawing of a jaw being part of an instrument according to the invention showing a lateral groove for a marker.

Figs. 13 and 14: A grabbing structure with antennae, in an open and a closed configuration; "

5 Figs. 15-17: A main body of an alternative grabbing structure and the grabbing structure in two different states, respectively;

Figs. 18 and 19: Variants of the grabbing structure of Figs. 15-17 with markers; and

Figs. 20 and 21: A grabbing structure with wing-like fold-out structure, in a folded-in and a folded-out configuration, respectively.

10 DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following more detailed description of the embodiments of the instrument is a representative of exemplary embodiments of the technology, wherein similar parts are designated by same numerals throughout. Standard medical planes of reference and descriptive terminology are employed in this specification. In particular, proximal means toward the trunk, or, in the case of an inanimate object, toward a user and distal means away from the trunk, or, in the case of an inanimate object, away from a user.

Figures 1 to 3 show one exemplary embodiment of a grabbing structure being part of an instrument for repairing an atrioventricular heart valve. Figure 1 shows a grabbing

structure 3 comprising a main body 4 and a jaw 5 in an open position. The grabbing structure may be formed as a bullet tip grasper (bullet tip grabber). The grabbing structure may have a length of 0.75 to 1.2 cm. The jaw may be formed as a distal nosecone tip able to be advanced over two guiding rails to create a grasping opening.

5 As shown in figure 2, the main body comprises a second abutment surface 7 formed by a press pad at the distal end of a counter portion 19 that is releaseable from the main body as shown in Fig. 2. The press pad is movable in axial direction towards the jaw to grasp and hold a leaflet. As can be seen in Figure 3 a cannulated needle 8 forming an inner tube 9 can be advanced from a proximal end of the grabbing structure (within

10 a first tube which is not shown in Figures 1 – 3) through the main body, the counter portion and a channel within the jaw to protrude out of the grabbing structure. When the needle is advanced, it is able to puncture the grabbed leaflet. Within that needle, an implant may be arranged so that at least one part of the implant (distal implant part) may be implanted distally of the leaflet. The counter portion may be formed having a

15 base being tube shaped or being elongated with an angular cross section and a channel for the cannulated needle. The press pad at the distal end of the counter portion may be round with at least one cut out to be sliceable on the guiding rails.

Figures 4 to 8 and 8A-8C show an exemplary embodiment of an instrument 1 according to the present invention. The instrument is shown in different perspective views. The proximal end of the main body 4 is attached to a first tube 2. The grabbing structure 3, the needle 8 and the implant can be manipulated via the first tube. This tube may be an implant catheter. For accessing the heart, the instrument may comprise a further, outer catheter (for example a transseptal and guide catheter) that is for example capable of being advanced through a suitable vein into the right atrium and

20 from there into the left atrium, and from which the main body attached to the first tube 2 is deployed further into the left atrium to grab, together with the jaw, the leaflet. The tube may be a braided sheath with flexible section at the distal tip and a maneuvering section at the proximal end. For example, it may be a Pebax® Catheter including a

25 distal flexible section provides appropriate column strength and stiffness. The first tube

can provide depth translation through and with the transseptal and guide catheter providing trajectory alignment to the heart valve, such as a mitral valve. The first tube may further comprise at least one marker band, such as a platinum band.

In contrast to the structure shown in Figures 1-3, in the embodiment of Figs. 4-8, 8A-5 and the embodiments described hereinafter, there is no separate counter portion capable of being advanced relative to the main body, but the main body 4 itself serves as the counter portion by comprising the distally facing second abutment surface 7.

The main body 4 can comprise a channel 20 for the cannulated needle 8 and a (central) guide wire channel 16 for a guide wire. The guide wire channel continues within the 10 jaw 5 (see Figure 8 C and D; jaw guide wire channel portion 116 aligned with main body guide wire channel portion 16). The channel 20 for the cannulated needle is also continued within the jaw by the jaw portion 120 of the channel. This channel allows that the cannulated needle is advanced through the main body and the jaw and punctures the leaflet when held between the first and second abutment surfaces, and 15 that one part of the implant can be released and implanted within a ventricle tissue (see hereinafter).

In the embodiment of Figs. 4-8, 8A-8C, the channel, more specifically the jaw portion 120 of the channel, has a slit-like lateral opening 13. After implantation of at least the distal part of the implant this opening allows to release an artificial chord attached to 20 the implant parts carried by the cannulated needle. After withdrawal of the needle, the artificial chord can be released from the grabbing structure by a lateral movement.

The grabbing structure includes a mechanism to move the jaw in relation to the main body in axial directions. The mechanism comprises an operating structure such as an operating rod any may further comprise one or more guiding rods 15 (guiding rails).

In many embodiments, the operating structure is an operating rod (which can have a dimension to be bendable and therefore may be viewed as operating wire also) which is subject to axial movements from outside directly by the operator. Alternatively, as shown here, the movement may be facilitated by a threaded rod 14. In this alternative mechanism, the operator causes an axial movement by causing a rotation of the threaded rod. The embodiment with a threaded rod has the advantage of allowing a more precise determination of the axial position without the necessity of a feedback by means of monitoring but has the disadvantage that it may be sometimes difficult to transfer a rotational (torsional) movement across a comparably long distance of for example up to 1 m through the tubing..

Generally, while for illustration purposes most figures show an operating structure in the form of a threaded rod, a direct axial movement by an operating rod (operating wire) as well as an operating structure in the form of a threaded rod or other operating structures are options for all embodiments of the present invention.

The length of the grabbing structure in the open configuration may be 25 – 40 mm. Thereby the opening width is 8 to 15 mm, preferably 12 mm, the length of the main body is 10 – 20 mm and the jaw may have a length of 4 – 10 mm. The diameter of the grabbing structure may between 4.5 and 8 mm.

Figure 6 shows the grabbing structure in a closed or nearly closed configuration. Between the second abutment surface 7 of the main body 4 and the first abutment surface 6 of the jaw 5 a leaflet can be clamped and held.

Figure 7 shows the grabbing structure in a closed or nearly closed configuration and 5 with a cannulated needle 8 advanced to protrude distally from the jaw 5. The cannulated needle has a sharpened distal end 17.

The first abutment surface 6 and the second abutment surface 7 define a plane. This plane and the tube axis form an angle of 90° in the embodiment shown in Figs.4-8, 8A-8C. In alternative embodiments, see also the embodiments described hereinafter, 10 the angle may also be smaller.

As can be seen in Figures 8 A and B as well as in other figures, the first abutment surface 6 and/or second abutment surface 7 may be structured by having a surface structure 106, 107 forming a pattern of protrusions/indentations. Exemplarily, small pyramids having a square base are shown as the surface structures 106, 107. The 15 surface structures 106, 107 may be formed to be complementary. This means that the structures fit to each other in case the grabbing structure is in a closed configuration. Therefore, the structures allow to increase the grip but in closed configuration there exists no risk for unwanted clamping of other structures than the leaflet because no open spaces are left between the main body 4 and the jaw 5.

20 **Figures 9A-9C** show another embodiment of a grabbing structure 3 being part of an instrument 1 according to the present invention.

A first difference between the hereinbefore described embodiments and the embodiment of Figs. 9A-9C is that the abutment surfaces 6, 7 – which are parallel to each other – are not at a right angle to the axis 10 but have at least a section that is not perpendicular thereto. Especially, in the embodiment of Figs. 9A-9C, the abutment 5 surfaces are not perpendicular to the axis at the position where the channel for the cannulated needle 8 goes through them.

In the specific depicted embodiment, the first abutment surface and the second abutment surface comprise each three portions. In closed position (Figure 9A) the corresponding portions of these abutment surfaces thus define three planes. Two 10 planes form with the tube axis an angle of 90° or nearly 90°. The plane defined by a middle portion connecting the perpendicular portion forms with the tube axis an angle β of for example between 25 and 80°, for example between 30° and 60°. The cannulated needle 8 is pushed through the abutment surfaces within this section defining the plane being oblique in relation to the tube axis.

15 Other shapes of the abutment surfaces other than perpendicular are possible, including locally curved surfaces.

One possible feature of embodiments having abutment surfaces that are not perpendicular to the axis is also illustrated in Fig. 9B. The plane 206 defined by the abutment surfaces in vicinity of the channel for the cannulated needle is non-parallel 20 to the plane 117 defined by the distal end 17 of the needle 8. Thereby, when the needle pierces the grabbed leaflet, the distal needle end does not lie flat against the leaflet, but for example the tip pierces the leaflet first.

Especially, the middle plane 117 defined by the distal end may be inclined, with respect to the axis, in a direction different from the direction of inclination of the plane 206 defined by the abutment surfaces around the channel (being a middle plane of the mouth of the channel in the abutment surfaces) and for example inclined in 5 approximately the opposed direction, as illustrated in the shown embodiment.

The cannulated needle 8 may comprise a laser cut section 18 proximal of the sharpened distal end. Such section comprises a plurality of cuts in the otherwise cylindrical body, increases the flexibility of the needle and allows to implant one implant part within a ventricle tissue such as the ventricle wall or a papillary muscle. The laser cuts run on 10 the circumference of the needle in form of an open ring. Thus, the cuts may have the form of circle arcs. It is preferred that the laser cuts in form of circle arcs are arranged alternating, so that the not cut part on each circle varies in position.

The cannulated needle 8 is shown to be in advanced position so that the distal end of the cannulated needle protrudes over the distal end of the jaw 5. Anchor carrier or 15 implant carrier 11 is located within the needle and surrounded by an optional implant sleeve 12 or alternatively directly by the needle. The implant sleeve 12 and the implant carrier may be advanced to protrude distally from the needle. The implant carrier is designed to accommodate the implant parts. After the implant sleeve is withdrawn, the implant may be released. The implant carrier may have a lateral seat 61 at least for the 20 proximal implant part. A portion distally thereof serves as foot portion 62 for preventing the proximal implant part from slipping out of the implant sleeve 12 as long as the proximal implant part is within the implant sleeve 12 (or, if there is no implant sleeve 12 within at least the cannulated needle 8).

The implant sleeve and the implant carrier may be made from nitinol and may also comprise a laser cut section which may be formed in the same manner as the laser cut section of the cannulated needle.

An even further feature of the embodiment of Figs. 9A-9C – which may independently 5 of the other features described referring to these Figs be implemented in any embodiment – refers to markings. The main body 4 comprises a groove 21 for a marker stripe and the jaw 5 a groove 22 for another marker stripe. The grooves may be located near the edge of the abutment surfaces and may be curved. In these grooves a stripe of 10 a radiopaque material or of a material yielding a good contrast in echography (sonography) can be attached. For example stripes of a platinum-iridium alloy can stick in these grooves. Such strips look under X-radiation like two hooks and allow to determine the orientation of the grabbing structure as well as if and to what extent the grabbing structure is open.

15 **Figures 10A and 10B** each show a representation of another embodiment of a grabbing structure 3 being part of an instrument according to the present invention. Fig. 10A shows the grabbing structure in closed form, and Fig. 10B depicts the same in an open position.

20 The grabbing structure in addition to the features described hereinbefore comprises further a fold-out support, such as a wire support 23. A fold-out support or other fold-out structure is equipped to fold out and to protrude radially-outward out of the cylindrical volume defined by the outer surface of the main body and jaw, and for example out of the outer catheter (such as transseptal guide catheter). The fold-out structure may for example fold out automatically upon release from such outer catheter, upon the grabbing structure being opened and/or upon a trigger action 25 induced by the operator.

A fold-out support enhances the effective area for cooperating with the leaflet and hence may facilitate grasping the leaflet. It may be folded out from the jaw or from the main body. It is also possible to combine these two options. Especially, to be able to support the leaflet, the wires may increase the area of at least one abutment surface.

- 5 In the depicted embodiment, the fold-out support is a wire support consisting for example of two wires. In the open position the wires support the grasped leaflet, and thus promote the grasping of the leaflet. The wire support can consist of one wire loop or of two wires attached in parallel. Such wires may be bent at the free end. A wire support of two wires is preferably arranged to comprise a gap between the two wires
- 10 which is aligned with the recess 13 of the channel 120 so as to allow releasing the chord from the needle arrangement.

The wire support can be arranged in a way that it is closely attached to the grabbing structure in the closed position but can stick out in the open position. Therefore the free ends of the wires attached to the jaw may be located in support recesses 123 within

- 15 the main body. While the jaw moves away from the main body, the wires are pulled out and unfold or flip open. The wire supports may be made of a material having shape memory effect such as nitinol. Alternatively the wires may be made of a material being radiopaque or contain radiopaque marker.

A further feature of the embodiment of Figs. 10A and 10B as well as of embodiments

- 20 described hereinafter – which further feature may be implemented independent of the other features of this embodiment – is the absence of a threaded rod for causing the axial movement of the jaw relative to the main body. Instead, one or both of the rods 15 that serve as guiding rods may be connected to a push-pull operating mechanism (essentially a push-pull wire) and thereby also serve for operating.

5 **Figure 11** shows a drawing of a main body 4 of a grabbing structure comprising a channel 16 for a guide wire and the channel 20 for a cannulated needle. Besides the abutment surface 7 the main body comprises a groove 21. Within said groove 21 a radiopaque marker can be bond. There may be an analogous groove on the other side
5 of the main body. The groove can be 3 to 8 mm long, 0.15 to 0.5 mm deep and has a width between 1.5 and 4 mm.

10 **Figure 12** shows a drawing of a jaw 5 of a grabbing structure, the jaw being equipped for cooperating with a main body as shown in Fig. 11. The jaw comprises a channel for a cannulated needle, the channel having a recess 13 so that the channel is open to the top. Besides the abutment surface, the jaw comprises a groove 22. Within said groove 21 a radiopaque marker can be bond. There may be an analogous groove on the other side of the jaw. The groove can be 3 to 8 mm long, 0.15 to 0.5 mm deep and has a width between 1.5 and 4 mm.

15 **Figures 13 and 14** show a variant of the embodiments of Figures 9-12 in the closed condition and in the open condition of the grabbing structure, respectively. In contrast to the previously described embodiments, the grabbing structure comprises a fold-out structure in the form of at least one fold-out antenna. In the embodiment of Figs. 13 and 14, it comprises two fold-out antennae, both attached laterally to the main body. The antennae increase, by radially protruding away from the main body and/or the jaw
20 in the unfolded condition, the visibility when echography is applied. Much like a wire support of the above-described kind, such antenna can be arranged in a way that it is closely attached to the grabbing structure in the closed position but can stick out in the open position. Also the free end of the antenna may be seated in an according recess, such as an antenna recess 151 in the jaw. When the grabbing structure is deployed
25 from the outer catheter or when the jaw moves away from the main body, the antenna is folded out. Also the antenna may be made of a material having shape memory effect such as nitinol and/or of a material being radiopaque or contain radiopaque marker.

In the embodiments of Figures 4-14 described hereinbefore, the channel for the cannulated needle is open towards a single lateral side by there being formed a slit-shaped recess in the jaw, whereas the – proximal – main body does not have such feature. For releasing the proximal implant part, the proximal implant part – for 5 example carried by the anchor carrier as shown in Figs. 9A-9C – has to be deployed from the main body. If the proximal implant part is to lie proximally of the leaflet, deployment, therefore, may be done after the leaflet has been released from the grabbing structure.

10 The embodiments of **Figures 15-19** described hereinafter are equipped for the option of there being a proximal anchor release while the leaflet is still being grabbed. This makes additional control by the operator possible – i.e. both is possible: release of the proximal implant part while the leaflet is still being grabbed, or release of the proximal implant part after release of the leaflet.

15 To this end, not only the channel portion 120 in the jaw but also the main body channel portion 20 is open to a lateral side (i.e. the same side as the jaw channel portion) by the main body 4 having a recess 24 extending from the distal end. In the depicted embodiment, the recess has a narrow distal recess portion 25 and a broader proximal recess portion 26 serving as implant release portion. The length (axial extension) and width of the recess or, if present, of its implant release portion 26 are sufficient for the 20 proximal implant part to be released therethrough. Especially, the opening angle α of the main body recess portion or of its implant release portion may be at least 45° or at least 60° or at least 80° or more. The length is larger than the length of the proximal implant portion and hence larger than the length of the anchor carrier seat 61.

25 In Figures 16 and 17 a further optional feature is illustrated. Namely, the cannulated needle 8 is encompassed by a needle guide tube 71. The needle guide tube

encompasses the needle 8 essentially up to its distal end during the forward (towards distally) movement of the needle for piercing the leaflet while the leaflet is being clamped. The needle guide tube 71 is retracted thereafter for release of the proximal implant part. The needle guide tube 71 makes sure that the needle is guided towards 5 and into the jaw channel portion even if the leaflet causes a mechanical resistance against the forward movement/puncturing and even though the proximal recess portion is relatively wide open.

Figures 18 and 19 illustrate possible positions of markings that may be used to make sure that the axial positions of the anchor carrier 11 and of the implant release portion 10 26 are properly adjusted for implant release even if the device is too flexible for the operator to be able to define the relative positions precisely enough for the deployment of the proximal anchor just from markings on the handle device. In Fig. 84, the main body 4 comprises a circumferential (extending by 280° in the depicted embodiment) marker 84 the axial position of which defines an axial position of a central anchor 15 carrier marker 85. According to a second option, a distal anchor carrier marker 86 may be aligned with the side markers 81, 82 of the main body 4 and/or the jaw 5, which are present in the marker grooves 21, 22 described hereinbefore.

The embodiment of **Figures 20 and 21** comprises a fold-out structure that is constituted by wing-like elements 160 capable of being folded out from the main body 20 to assist orienting the grabbing structure with respect to the leaflet, especially by being visible by echography and/or radiography. Depending on the position and structure, a wing-like element may, in embodiments different from the one shown in Figs. 20 and 21, also act to enhance the effective area for supporting the leaflet and thereby also work as fold-out support. In the folded-in condition (Figure 20), the wing-like elements 25 160 are accommodated in a seat 161 so as to not protrude radially-outward out of the cylindrical volume defined by the outer surface of the main body and jaw, whereas in the folded-out condition (Figure 21) they radially protrude outward of this cylindrical

volume. The fold-out process may take place automatically upon the grabbing structure being released from the outer tube it is guided in.

WHAT IS CLAIMED IS:

1. An instrument for repairing an atrioventricular heart valve in a minimally invasive manner, the instrument comprising:

a tubular arrangement defining an axis and an axial direction;

5 a leaflet grabbing structure, the leaflet grabbing structure comprising a main body and a jaw;

wherein the jaw comprises a first proximally facing abutment surface and the main body comprises a second, distally facing abutment surface;

10 the instrument further comprising a needle, wherein the needle is cannulated and forms an inner tube, and wherein the needle is movable relative to the main body in axial directions,

whereby the leaflet grabbing structure is capable of clamping a leaflet of the heart valve between the first and second abutment surfaces;

15 and wherein the main body and the jaw have a channel being formed to allow the needle to extend there through while the leaflet is being clamped.

2. The instrument according to claim 1, wherein the channel has a position that is not central with respect to the tube axis.

3. The instrument according to claim 1 or 2, wherein the jaw is movable relative to the main body in the axial direction.

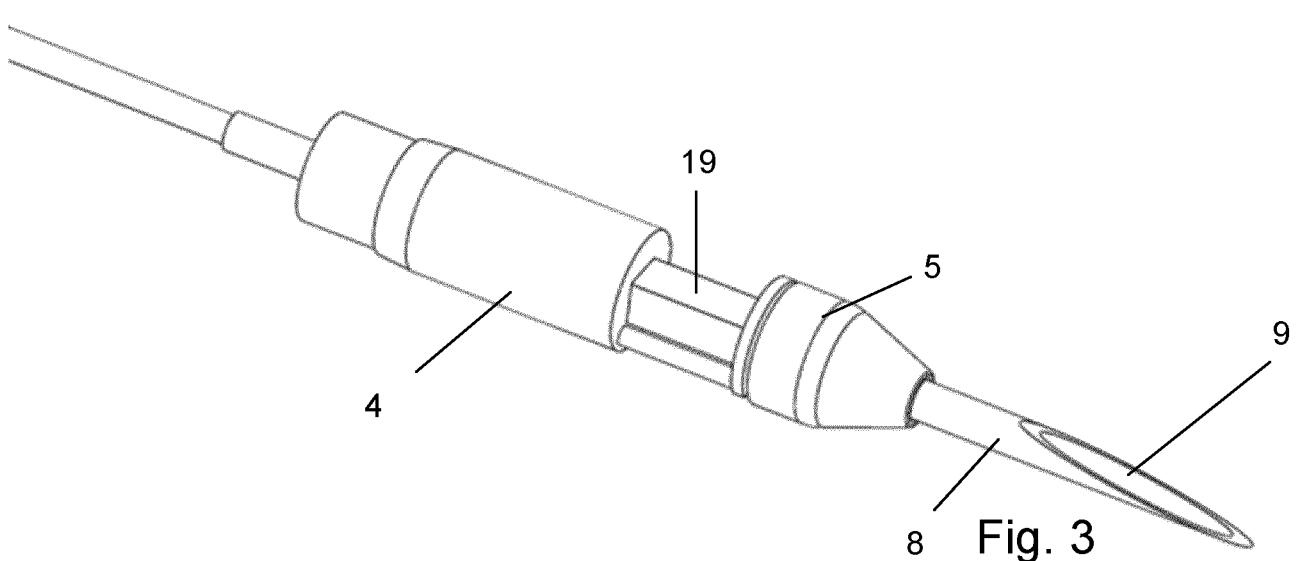
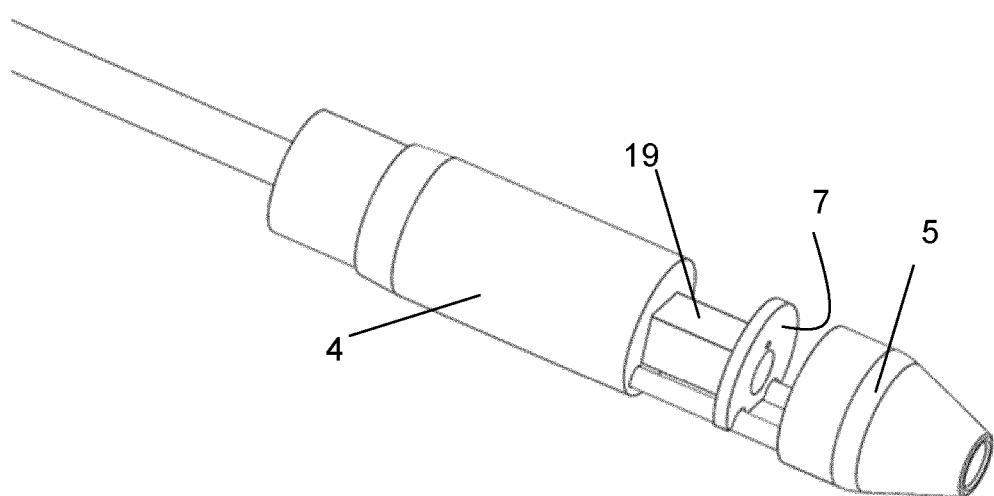
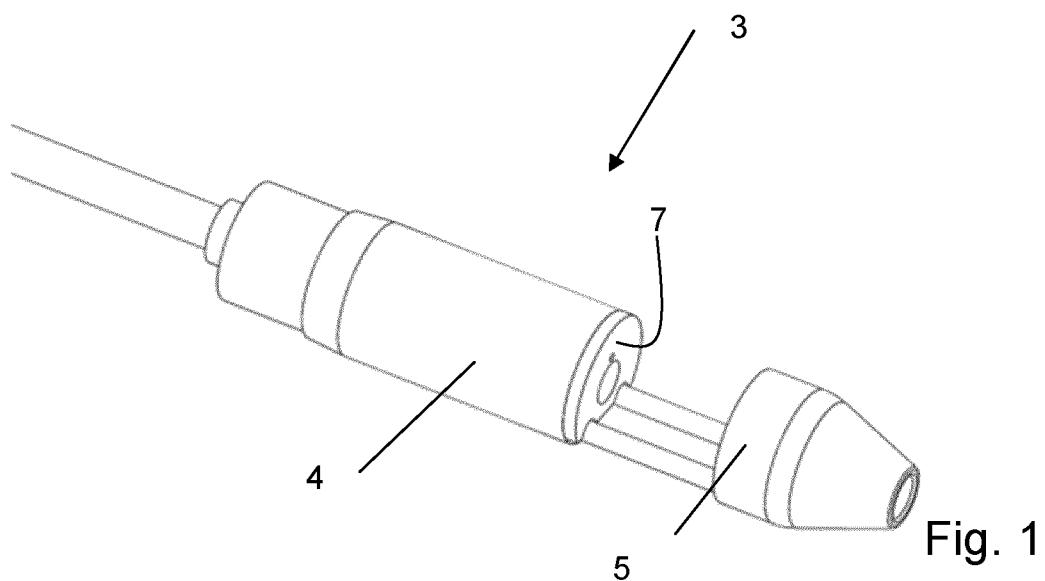
4. The instrument according to anyone of claims 1 - 3, wherein the instrument further comprises an anchor carrier being arranged within the inner tube and being axially movable relative to it, the anchor carrier being configured to carry at least a part of an implant that is secured or capable of being secured to an artificial chord.
5
5. The instrument according to claim 4, being configured for a distal implant part and a proximal implant part being arranged beside one another, with the proximal implant part arranged proximally of the distal implant part, wherein the anchor carrier forms an anchor seat is configured to carry the proximal implant part of the implant.,.
10
6. The instrument according to claim 5, wherein the inner tube or a sleeve element inside the inner tube prevents the proximal implant part from escaping from the anchor carrier as long as the anchor carrier is received in the anchor seat and is within the inner tube or sleeve element.
- 15 7. The instrument according to any one of claims 4-6, wherein the anchor carrier comprises a marker for determining a position by echography and/or radiography, and wherein the main body and/or the jaw comprises a marker for determining a position by echography and/or radiography, for determination of relative positions of the anchor carrier and of the main body and/or jaw.
- 20 8. The instrument according to any one of the previous claims, wherein the channel is open to a lateral side.

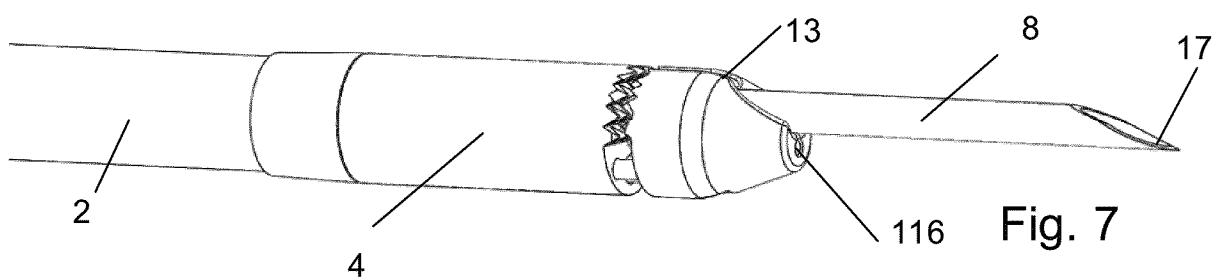
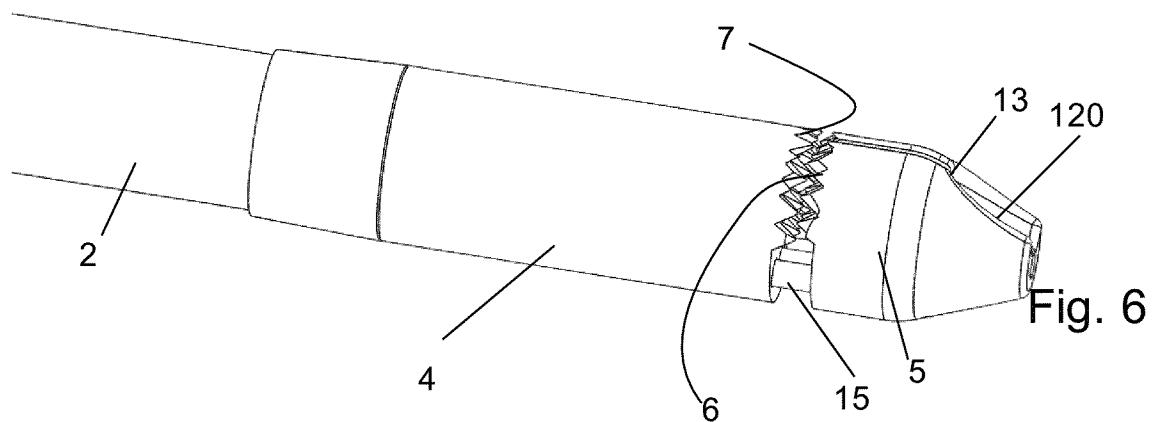
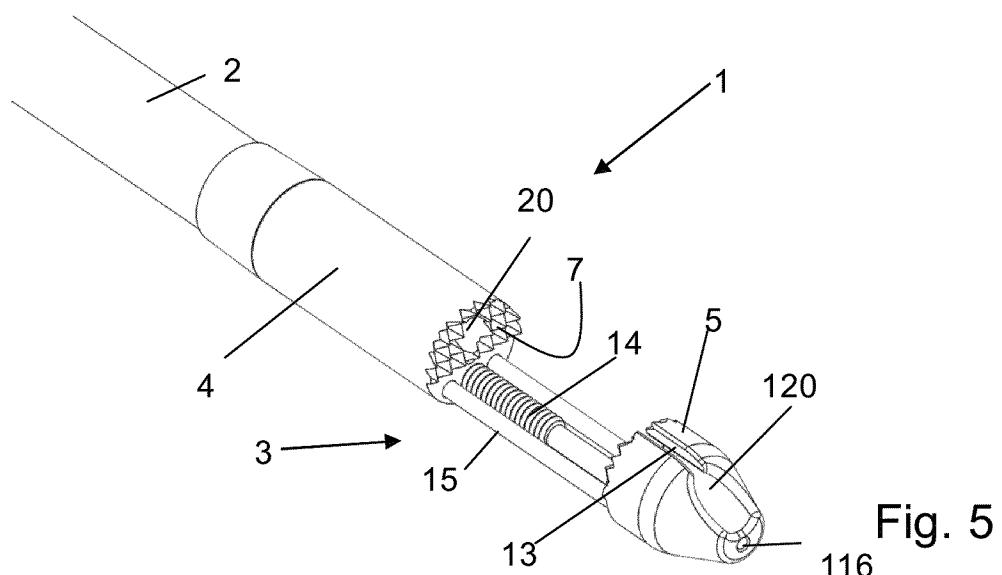
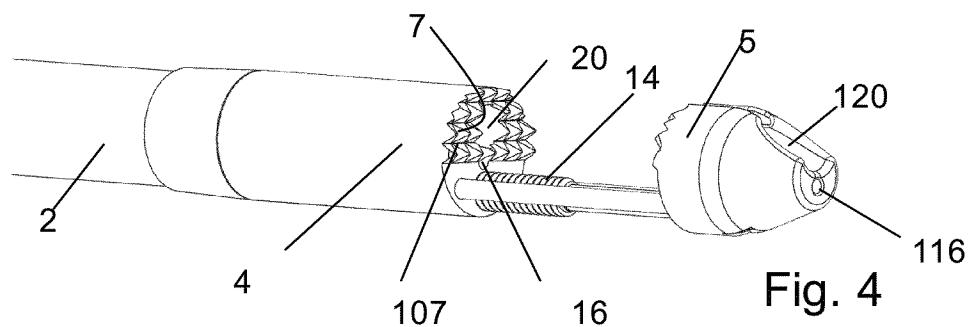
9. The instrument according to claim 8, wherein the channel has a main body channel and a jaw channel aligned with the main body channel, wherein the jaw channel is open to the lateral side along its full axial length.
10. The instrument according to claim 9, wherein also a distal portion of the main body channel is open to the lateral side..
5
11. The instrument according to claim 10, wherein the channel is open to the lateral side by a recess that has a distal recess portion and proximally thereof, an implant release portion, wherein the implant release portion of the recess runs in the main body, and wherein the implant release portion of the recess is wider than the distal recess portion.
10
12. The instrument according to claim 11, wherein the distal recess portion has a first sub-portion running in the jaw and a second sub-portion running in the main body, distally of the implant release portion.
13. The instrument according to any one of claims 10-12, wherein an opening angle α of a lateral recess by which the channel is open to the lateral side is at least 45° .
15
14. The instrument according to any one of claims 8-13, further comprising a needle guide being a tube encompassing the cannulated needle and being accommodated inside the channel.

15. The instrument according to any one of claims 8-14, wherein the channel is open a single lateral side.
16. The instrument according to any one of the previous claims, wherein the first and second abutment surfaces at a position around a mouth of the channel in the first and second abutment surfaces, define at least one plane being at an angle different from 90° to the tube axis.
5
17. The instrument according to claim 17, wherein a distal end of the needle defines a distal needle end plane that is at an angle different from 90° to the axis, and wherein the distal needle end plane and the plane defined by the first and second abutment surfaces are inclined in different directions.
10
18. The instrument according to any one of the previous claims, further comprising an operating mechanism suitable to operate the axial movement of the jaw relative to the main body and to adjust the distance between the main body and the jaw, wherein the operating mechanism comprises a push-pull rod or a threaded rod.
- 15 19. The instrument according to claim 18, further comprising at least one guiding rod configured to prevent non-axial movements of the jaw relative to the main body.
20. The instrument according to any one of the previous claims, wherein the main body and the jaw further comprise a guide wire channel suitable to incorporate a guide wire.

21. The instrument according to any one of the previous claims, wherein the needle has a sharpened distal end and proximally therefrom a laser cut section.
22. The instrument according to any one of the previous claims, wherein the tubular arrangement comprises a first tube, wherein the leaflet grabbing structure is arranged at a distal part of the first tube and is contiguous to the first tube, and wherein the needle is releasable from the first tube and movable relative to the main body in axial directions.
5
23. The instrument according to any one of the previous claims, wherein the tubular arrangement comprises an outer catheter being configured as a guide catheter, the outer catheter being dimensioned to accommodate the leaflet grabbing structure within an interior of the outer catheter.
10
24. The instrument according to any one of the previous claims wherein the jaw and the main body each comprise a marker for determining the relative positions of the jaw and the main body by echography and/or radiography.
- 15 25. The instrument according to any one of the previous claims, further comprising a fold-out structure equipped to fold out and to protrude, when folded out, radially-outward out of the cylindrical volume defined by the outer surface of the main body and jaw.
26. The instrument according to claim 25, wherein the fold-out structure is a fold-out support extending an area of at least one of the abutment surfaces.
20

27. A set, comprising an instrument according to any one of the previous claims, and further comprising an implant that has a proximal implant part, a distal implant part, and a chord connecting or equipped to connect the proximal implant part and the distal implant part.
- 5 28. A method of replacing or supplementing damaged natural chordae tendineae of a human or animal heart of a patient in need thereof, the method by using an instrument according any one of claims 1 – 26 or a set according to claim 27.





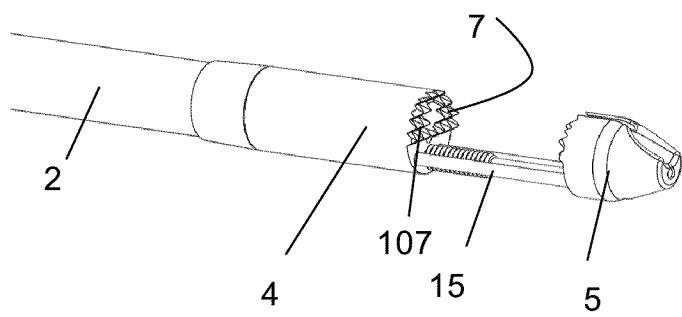


Fig. 8A

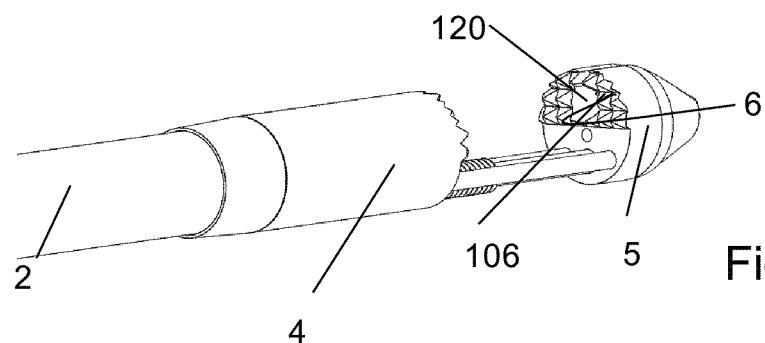


Fig. 8B

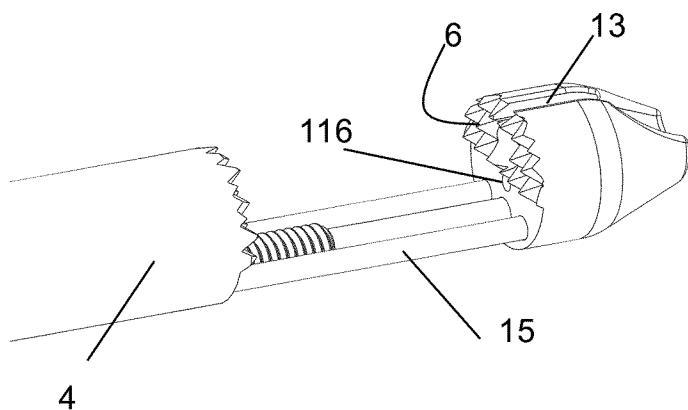


Fig. 8C

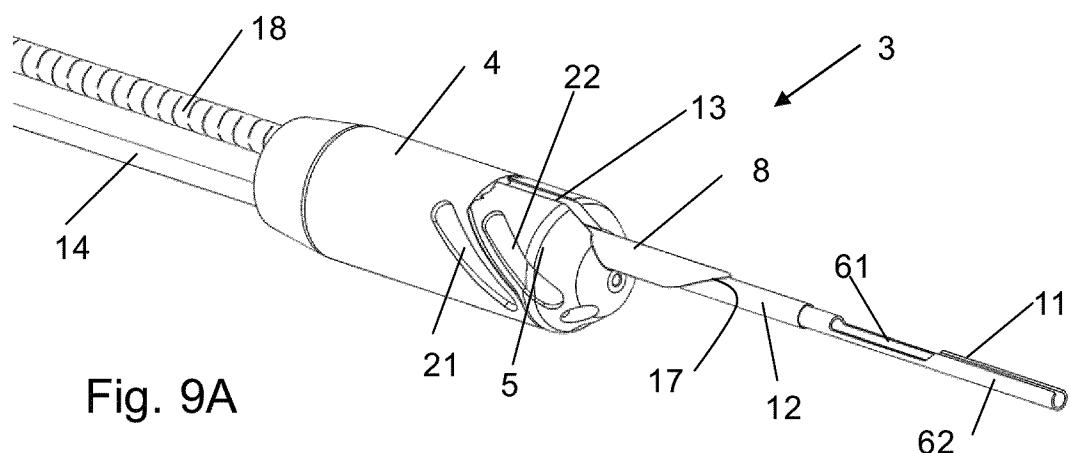


Fig. 9A

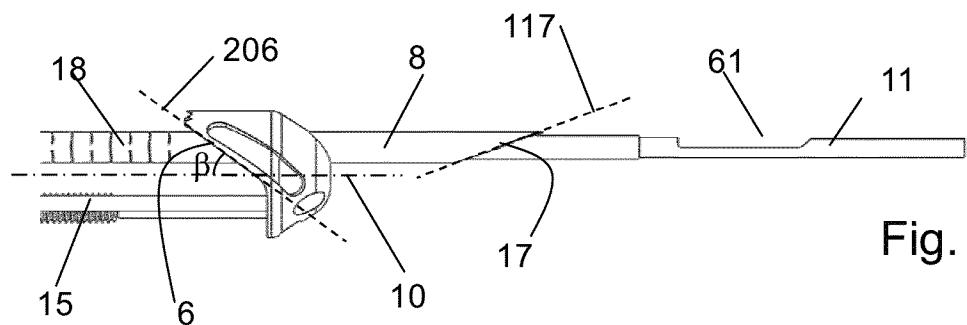


Fig. 9B

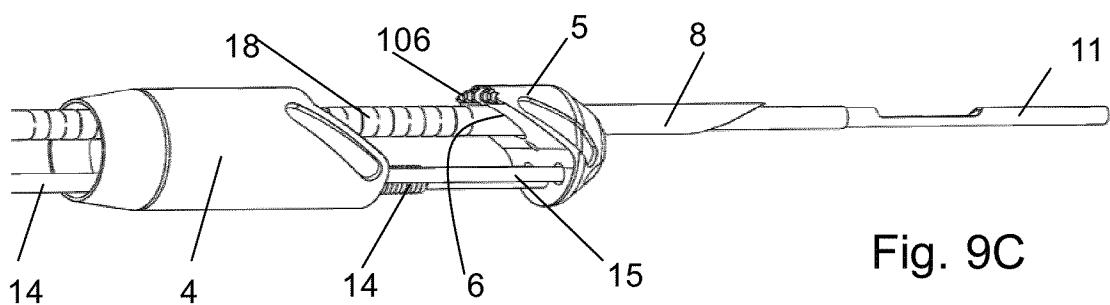


Fig. 9C

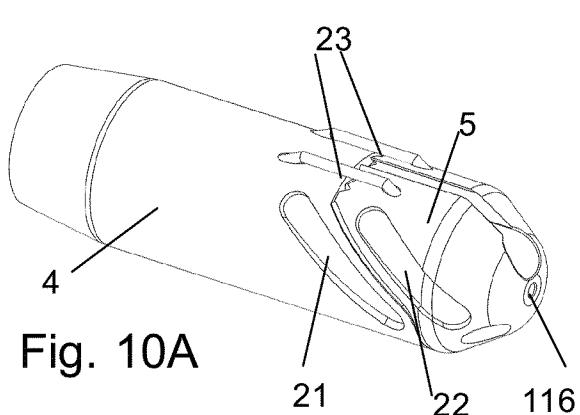


Fig. 10A

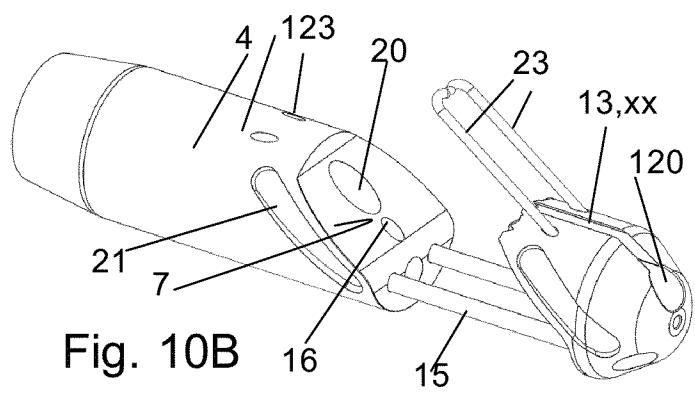


Fig. 10B

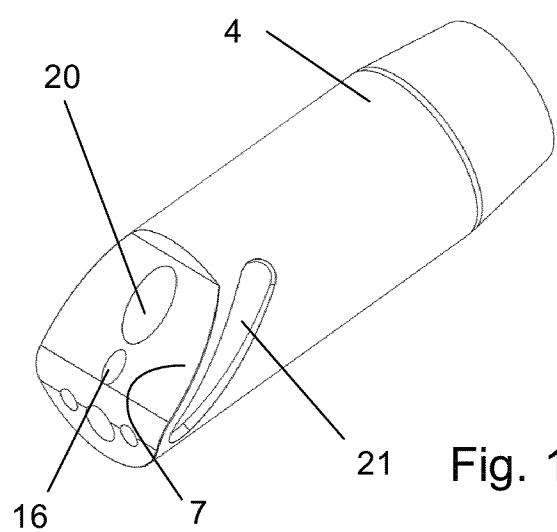


Fig. 11

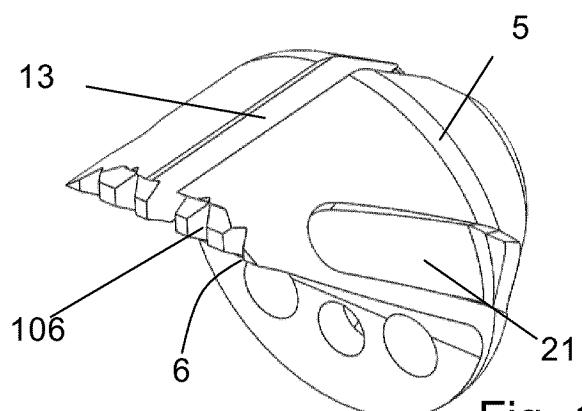


Fig. 12

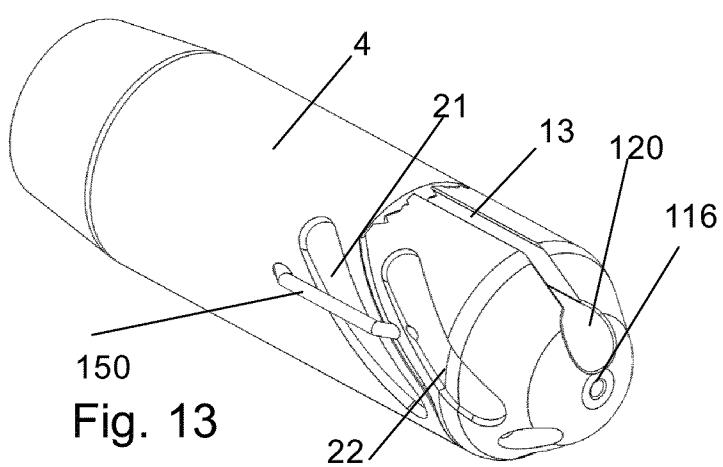


Fig. 13

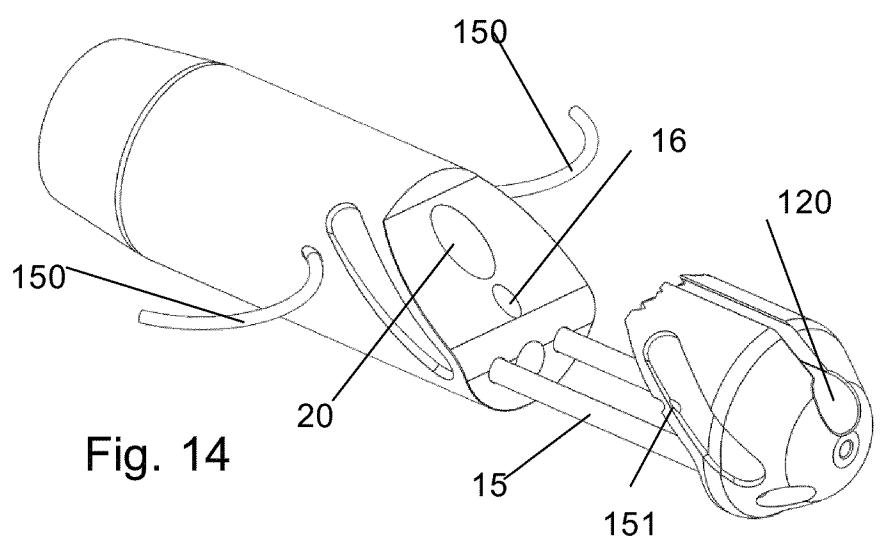
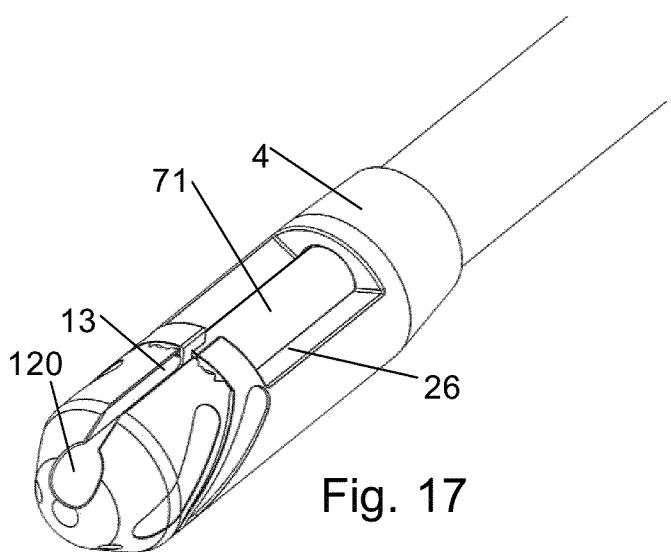
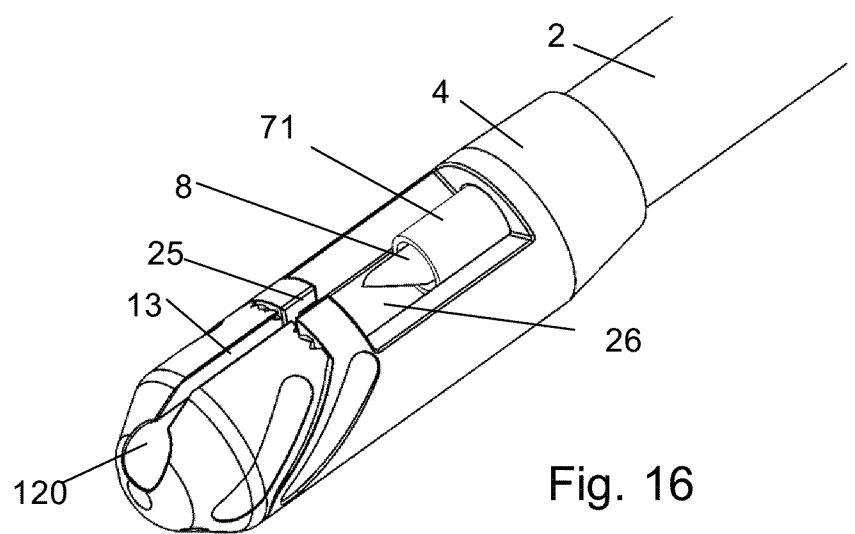
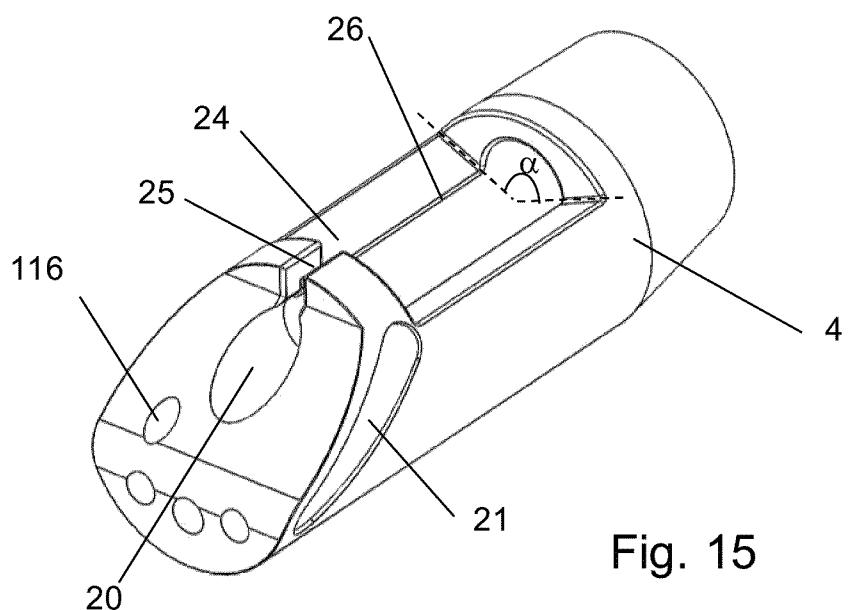


Fig. 14



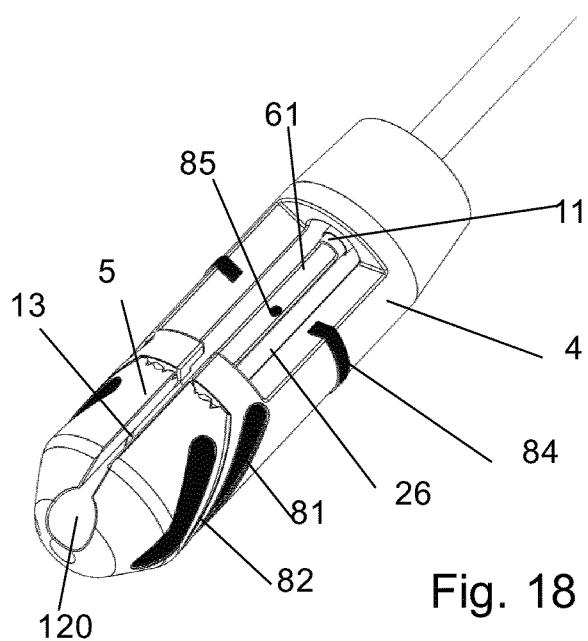


Fig. 18

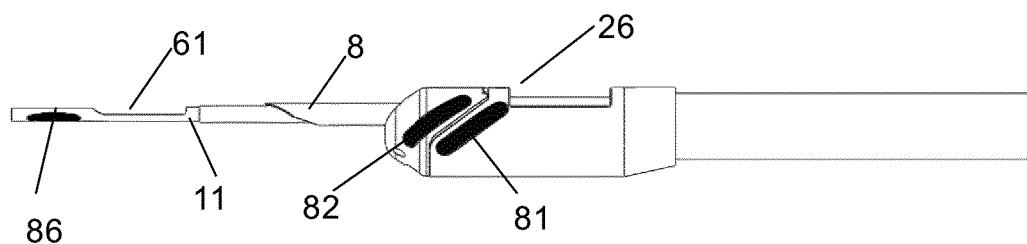


Fig. 19

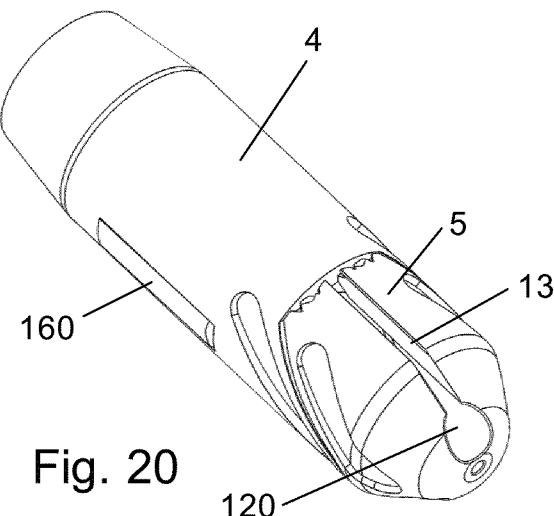


Fig. 20

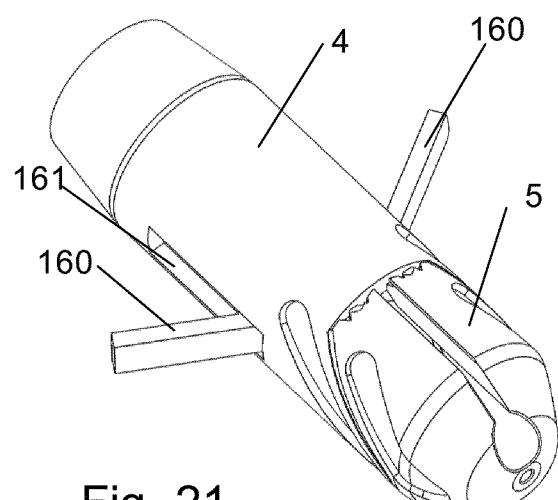


Fig. 21

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/057350

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24 A61B17/29 A61B17/06
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F 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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/049952 A1 (WEISS STEVEN J [US]) 1 March 2007 (2007-03-01)	1-3,16, 18,22,23
Y	paragraphs [0003], [0051] - [0055];	17,24,25
A	figures 7-13	4-15, 19-21, 26,27

Y	US 2009/105729 A1 (ZENTGRAF JOHN [US]) 23 April 2009 (2009-04-23) figure 4h	17

Y	WO 2008/112237 A2 (ST JUDE MEDICAL [US]; ALKHATIB YOUSEF [US]) 18 September 2008 (2008-09-18) figure 9	25

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Further documents are listed in the continuation of Box C.

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 28 May 2020	Date of mailing of the international search report 09/06/2020
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Erbel, Stephan

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/057350

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2004/044365 A1 (BACHMAN ALAN B [US]) 4 March 2004 (2004-03-04) figures 7A,7B paragraph [0031] -----	24
A	US 2009/299406 A1 (SWAIN CHRISTOPHER P [GB] ET AL) 3 December 2009 (2009-12-03) figures 15A,15B -----	1
A	US 2006/271073 A1 (LAM CANG C [US] ET AL) 30 November 2006 (2006-11-30) figure 3A -----	1
A	US 2012/184971 A1 (ZENTGRAF JOHN [US] ET AL) 19 July 2012 (2012-07-19) figures 1C,11 paragraphs [0002], [0056], [0057], [0064] -----	1
A	WO 2006/078694 A2 (MAYO FOUNDATION [US]; SPEZIALI GIOVANNI [US]) 27 July 2006 (2006-07-27) figure 5 paragraph [0018] -----	1
A	WO 2017/066890 A1 (COREMEDIC AG [CH]) 27 April 2017 (2017-04-27) page 5, line 15 - line 22 -----	1
A	US 2016/220372 A1 (MEDEMA RYAN [US] ET AL) 4 August 2016 (2016-08-04) paragraph [0033]; figures 6b, 6c -----	1
A	WO 2012/006161 A2 (SYNTHES USA LLC [US]; SYNTHES GMBH [CH] ET AL.) 12 January 2012 (2012-01-12) paragraph [0178]; figure 4D -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2020/057350

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. Claims Nos.: **28**
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 28

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery and therapy Claim 28 relates to a method for treating the human body by surgery and therapy. According to Rule 39.1 (iv) PCT the international search authority is not required to search subject matter falling under this category.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2020/057350

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
US 2007049952	A1 01-03-2007	AU 2006285160 A1 CA 2620764 A1 EP 1933719 A2 JP 2009505789 A US 2007049952 A1 WO 2007027451 A2			08-03-2007 08-03-2007 25-06-2008 12-02-2009 01-03-2007 08-03-2007
US 2009105729	A1 23-04-2009	AU 2008311754 A1 CA 2703129 A1 CN 101902975 A EP 2219530 A2 HK 1149183 A1 JP 5357167 B2 JP 2011500228 A US 2009105729 A1 US 2009105751 A1 US 2014364875 A1 US 2020138430 A1 WO 2009052528 A2			23-04-2009 23-04-2009 01-12-2010 25-08-2010 24-10-2014 04-12-2013 06-01-2011 23-04-2009 23-04-2009 11-12-2014 07-05-2020 23-04-2009
WO 2008112237	A2 18-09-2008	EP 2131788 A2 JP 2010521225 A US 2008228223 A1 US 2013253639 A1 US 2019216599 A1 WO 2008112237 A2			16-12-2009 24-06-2010 18-09-2008 26-09-2013 18-07-2019 18-09-2008
US 2004044365	A1 04-03-2004	AU 2003265916 A1 AU 2009202296 A1 CA 2495465 A1 EP 1542597 A1 JP 4560405 B2 JP 2005537110 A US 2004044365 A1 US 2006287657 A1 US 2011137326 A1 US 2012310333 A1 US 2013296894 A1 US 2016192925 A1 WO 2004021893 A1			29-03-2004 02-07-2009 18-03-2004 22-06-2005 13-10-2010 08-12-2005 04-03-2004 21-12-2006 09-06-2011 06-12-2012 07-11-2013 07-07-2016 18-03-2004
US 2009299406	A1 03-12-2009	NONE			
US 2006271073	A1 30-11-2006	NONE			
US 2012184971	A1 19-07-2012	CN 103347464 A EP 2658480 A1 US 10080659 B1 US 2012184971 A1 US 2015313713 A1 US 2019053902 A1 US 2019133766 A1 WO 2012141757 A1			09-10-2013 06-11-2013 25-09-2018 19-07-2012 05-11-2015 21-02-2019 09-05-2019 18-10-2012
WO 2006078694	A2 27-07-2006	AT 513516 T AU 2006206591 A1 CA 2595459 A1 CN 101495049 A			15-07-2011 27-07-2006 27-07-2006 29-07-2009

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2020/057350

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		EP 1845861 A2	24-10-2007
		HK 1137130 A1	26-08-2011
		JP 4960262 B2	27-06-2012
		JP 2008536528 A	11-09-2008
		US 2008188873 A1	07-08-2008
		US 2010174297 A1	08-07-2010
		US 2014039324 A1	06-02-2014
		US 2015148821 A1	28-05-2015
		US 2017290582 A1	12-10-2017
		US 2020121314 A1	23-04-2020
		WO 2006078694 A2	27-07-2006
<hr/>			
WO 2017066890	A1	27-04-2017	CN 108289662 A
			EP 3364884 A1
			JP 2018533398 A
			US 2018303614 A1
			WO 2017066890 A1
<hr/>			
US 2016220372	A1	04-08-2016	US 2016220372 A1
			US 2017105838 A1
			WO 2016126699 A1
<hr/>			
WO 2012006161	A2	12-01-2012	AU 2011276457 A1
			CA 2801935 A1
			CN 102958458 A
			EP 2588007 A2
			EP 2977013 A1
			JP 5960131 B2
			JP 6150929 B2
			JP 2013530772 A
			JP 2016185360 A
			KR 20130122932 A
			TW 201221107 A
			WO 2012006161 A2
<hr/>			