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(54) Title: MEDICAL IMPLANT AND METHOD FOR HEART VALVE REPAIR

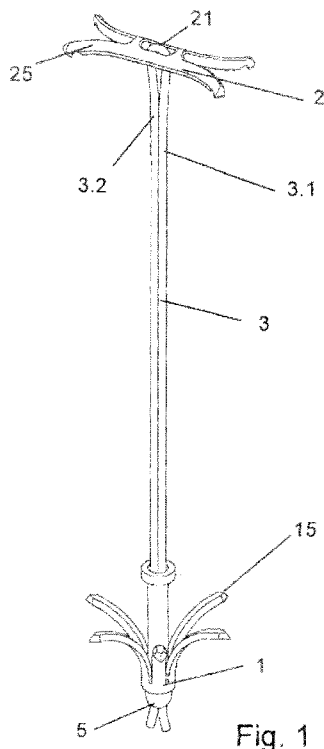


Fig. 1

(57) Abstract: According to an aspect of the invention, an implant is provided, the implant being a sutureless implant for replacing damaged natural chordae tendineae of a human or possibly animal heart, the implant comprising a distal implant part (1), a proximal implant part (2) and an artificial chord (3), wherein the distal implant part (1) is configured to fit in a lumen of an implant delivery device and comprises a self-spreading portion spreading radially outside when the distal implant part is released from the lumen, the self-spreading portion being capable of anchoring the distal implant part in human muscle tissue; wherein the proximal implant part (2) is configured to fit in the lumen of the implant delivery device and comprises a self-spreading portion, spreading radially outside when the proximal implant part is released from the lumen, the self-spreading portion being capable of bearing on a tissue portion of leaflet tissue, and wherein the distal implant part (1) and the proximal implant part (2) are connected by the chord (3).

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MEDICAL IMPLANT AND METHOD FOR HEART VALVE REPAIR

FIELD OF THE INVENTION

The invention is in the field of surgical, for example minimally invasive or interventional cardiology, devices for heart valve repair. It more particularly relates to an implant for repairing an atrioventricular heart valve, in particular the mitral
5 heart valve or also the tricuspid heart valve, 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 is a damaging of the tendons (chordae tendineae) that connect the leaflets of
10 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 fibres, such as Gore-tex® fibres. 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

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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. It has also been described that it is possible to attach the suture to and through the apex of the heart, however, as also described, results are not as good as if sutures are attached to the papillary muscles, which is the physiologic site. A second disadvantage is that the success of the operation depends strongly on the skill of the surgeon, especially in terms of length adjustment and time invested while the heart is arrested. A further disadvantage is that the fibres sutured to the leaflet may cause long-time damage.

In WO 2012/040865, approaches are presented according to which a distal anchor attached to a filament serving as artificial chord is used that can be shot across the left ventricle. Also tools for fixing an artificial chord to the leaflet and tools for temporary fixation of the leaflet of the beating heart are illustrated.

US 2011/0011917 describes methods and devices for cardiac valve repair. The devices may comprise a dart anchor with self-expandable legs for being secured into cardiac tissue and a staple to be deployed into tissue of the leaflet, which staple may be secured to a tensile member that is also connected to the dart anchor. A pledget may be used to spread loads, i.e. to prevent the leaflet tissue from being injured by the staple. US 2011/0011917 also discloses an anchor with an eyelet in which a chord can slide. This anchor is to be attached to a leaflet.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an implant for repairing an atrioventricular, in particular the mitral or also the tricuspid, heart valve, and an according method, which implant and method overcome drawbacks of prior art

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devices and methods and which are easy to implant, suited also for interventional surgery and provide a reliable and well tissue-compliant repair.

According to an aspect of the invention, an implant is provided, the implant being a sutureless implant for replacing damaged natural chordae tendineae of a human or possibly animal heart, the implant comprising a distal implant part, a proximal
5 implant part and an artificial chord,

- 10 - wherein the distal implant part is configured to fit in a lumen of an implant delivery device and comprises a self-spreading portion spreading radially outside when the distal implant part is released from the lumen, the self-spreading portion being capable of anchoring the distal implant part in human tissue, especially muscle tissue;
- 15 - wherein the proximal implant part is configured to fit in the lumen of the implant delivery device and comprises a self-spreading portion spreading radially outside when the proximal implant part is released from the lumen, the self-spreading portion being capable of bearing on a tissue portion of leaflet tissue, and
- wherein the distal implant part and the proximal implant part are connected by the chord.

20 The lumen into which the implant parts fit in a non-spread state is tube-shaped and may be a lumen of a bendable tube of a minimally invasive surgical apparatus (such as a catheter) or of another surgical instrument such as a needle. An interior diameter of the lumen may be at most 2 mm or at most 1.5 mm, especially at most 1.2 mm, for example 1 mm or possibly less. After spreading, the respective implant parts are more bulky, thus, the distal implant part or the proximal implant part or both have

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dimensions that cause them not to fit into the lumen any more without being deformed into a de-spread state.

The implant parts may be designed so that they may rest one next to the other for being released sequentially. For example, the instrument (catheter, other instrument)
5 may first be advanced to the tissue in or into which the distal implant part is to be released. After release of the distal implant part, the instrument may be moved to the leaflet, where the proximal implant part is released.

The distal implant part may comprise a shaft portion extending proximally from a distal head and a plurality of implant legs that in the non-released state lie against the
10 shaft portion also projecting proximally (backward) from the distal head and in the implanted state project to the proximal side and may be bent radially outward away from the shaft portion. The chord is attached to the proximal end of the shaft portion or is guided in the shaft portion and is attached to a distal portion of the shaft portion. By this, the orientation of the distal implant part once it is implanted is stabilized:
15 when the chord is pulled, the anchor is forced into its desired orientation, thus the shaft portion has a stabilizing effect: the orientation of the distal implant is automatically aligned with the direction of the pulling forces acting on the implant.

The number of legs may be an even number. This has the advantage that every leg has a well-defined counterpart, and this results in a balanced configuration. In an
20 embodiment, the number is at least four, or at least six, especially six. It has been found that six legs may provide an especially stable anchoring. As an alternative to an even number, the distal anchor may have an odd number of legs.

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The chord may be fastened to the distal implant part in a manner that it is knotless at least at the proximal end. For example, it may be fastened to the distal end (by a knot, by crimping, welding, soldering, gluing and/or an other technique) and guided axially through the distal implant part, thus through the shaft portion if applicable.

- 5 In some embodiments, the legs are sharpened. To this end, they are for example provided, at their outer (especially proximally-outwardly facing) ends, with at least one facet that is at a non-perpendicular angle to their axis. Especially, in
embodiments, between two facets a radially-outwardly facing edge may be formed that eases penetration of the respective leg into surrounding tissue when the legs are
10 released. In addition or as an alternative, the sharpening of the legs may form a tip at the legs' outer ends that when the legs are released and bent outwardly faces radially-outwardly.

- The legs may be self-expandable, so that in a released state the legs project from the shaft portion to be bent away therefrom by the effect of an elastic force, especially
15 due to superelasticity. To this end, the material of the distal implant part or at least of a portion thereof may be of a shape memory material.

- In addition or as an alternative, the ends of the legs of the distal implant part may be shaped in a way that the legs are being stretched further away from the shaft in case a pulling force is applied. This may lead to an improved anchoring in the tissue. Thus,
20 in this concept it is a barb-like effect that contributes to the anchoring of the distal implant part in the tissue.

A result of this optional feature is that there is a reduced tendency of the distal implant part to cut into the muscle tissue when subject to pulling forces.

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The legs may be of equal lengths. In special embodiments, the legs may have different lengths. Especially, the distal implant part may have at least one leg of a first length and at least one leg of a second, different length. A combination of short and long legs may add to the anchoring strength in that anchoring takes place in
5 different depths within the muscle.

The distal implant part may in embodiments have a blunt distal end, i.e. be shaped so that it does not itself have the capability of piercing through muscle tissue. In these embodiments, the instrument from which the distal implant part (and in many embodiments also the proximal implant part) is released is piercing, for example a
10 needle. Embodiments in which the distal implant part has a blunt distal end feature the advantage that damage to muscle tissue arising from the distal implant part advancing further into tissue after the operation can be excluded or at least made improbable.

In embodiments, the implant may be composed of a shaft piece forming a shaft
15 portion and a crown piece with the legs. Such a shaft piece may form a distal collar. The crown piece may be mounted surrounding the shaft piece and possibly, if applicable, abutting distally against the collar, so that a distal end of the crown piece and the collar together constitute a head of the above-described kind.

The distal implant part may be of a suitable material that has the necessary elastic
20 properties for the self-spreading portion (such as the legs) to spread when released. It may especially be made of a shape memory material having superelastic properties, such as Nitinol or an other shape memory metal or of a shape memory plastic. In embodiments where the distal implant part has several pieces, such as a shaft piece and a crown piece, at least the portion (such as the crown piece) that has the legs may
25 be of a shape memory material.

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In addition to a shaft portion and the legs, the distal implant part may further comprise a proximal collet piece. This collet piece may in the non-released state be arranged proximally of the proximal ends of the legs and have a radial extension that approximately corresponds to the radial extension of the legs in the non-released state or be higher than the latter. Thereby it has the effect of protecting the parts during mounting of the implant from the (relatively sharp, due to the reduced dimensions) legs, especially of protecting the chord. Also, during implantation it may contribute to defining an orientation of the implant and thereby ensure proper release.

The proximal implant part in contrast to prior art approaches may be configured to lie flat on a surface of the leaflet tissue, with the chord extending from the proximal implant part through the leaflet tissue and through the ventricle to the proximal 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). This is in contrast to prior art approaches that teach to clamp the leaflet by a leaflet anchor or to other prior art approaches that teach to suture the leaflet.

Especially, the proximal implant part may be configured to only lie on the leaflet 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 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

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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 on one side of the leaflet only and not for example extend through the leaflet. The side on which
5 the proximal implant part lies on the leaflet tissue is the atrium-facing upper side of the leaflet.

Especially, the proximal implant part is free of any clamping mechanism and does not comprise any portion that bears against the ventricle-facing lower surface of the leaflet.

10 As such, the proximal implant part is capable of coupling distally facing forces (forces towards the side of the ventricle) into the leaflet but its structure would not allow to couple proximally-facing forces into the leaflet (the proximal implant part cannot pull the leaflet towards the atrium side) and vice versa. The proximal implant part may have a central body and a plurality of arms that lie against each other or
15 against a shaft portion in the non-released state and are bent radially outward in the released state. The central body and the outwardly extending arms together form an abutment surface. In the released state the proximal implant part may lie flat on the leaflet surface.

In an embodiment, the proximal implant part, and especially the arms thereof,
20 comprises/comprise an optional protrusion (hook/piercing protrusion or other structure) at the abutment surface. Such a hook may assure that there is no relative movement of the proximal implant part and the leaflet tissue surface once implantation has been carried out. This may foster the necessary ingrowth. If the

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structure comprises a protrusion, a piercing depth of such protrusion will in many embodiments be smaller than a thickness of the leaflet.

5 The proximal implant part may be of a suitable material that has the necessary elastic, for example super-elastic properties for the self-spreading portion (such as the arms) to spread when released. It may especially be made of a shape memory material, such as Nitinol or an other shape memory metal or of a shape memory plastic.

10 Alternative materials for the distal and/or proximal implant part are polymer-based materials (plastics), such as PEEK. A special class of materials is resorbable (biodegradable) materials, such as polylactide polymers or biodegradable alloys, for example biodegradable magnesium or iron alloys. The principle of applying a bioresorbable implant part relies on the fact that during the time of resorption, the tissue will grow to integrate the chord, whereby after a certain time the implant part(s) will not be required any more.

15 More in general, any suitable material that is biocompatible and preferably radiopaque can be used.

20 The attachment of the chord to the proximal implant part may be knotless. In an embodiment, the proximal implant part is shaped so that the chord is doubled by being guided from the distal implant part through the proximal implant part and back to the distal implant part. Especially, the proximal implant part may comprise two openings through which the chord is guided from the distal to the proximal side and back to the distal side. Especially, the openings may be located centrally with respect both, to lateral and to axial directions so that when the chord is pulled the force is

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evenly distributed over the abutment surface and there is no tilting momentum (no torque) when the proximal implant part is being pulled.

5 In an alternative group of embodiments, the attachment of the chord to the distal implant part may be knotless, with the chord being doubled by being guided from the proximal implant part through the distal implant part and back to the proximal implant part. To this end, the distal implant part may for example comprise a horizontal through opening through the shaft portion through which the chord is guided.

10 Generally, the chord may be coupled to the proximal implant part in a manner that a pulling force on the chord does not transmit any torque on the proximal implant part lying flat on the leaflet.

- 15 - In embodiments with a single chord portion running between the proximal and distal implant parts, this may be achieved by placing the location of attachment of the chord in a center of area of with respect to the abutment surface.
- In embodiments with a plurality of chord portions running between the proximal and distal implant parts, this may be achieved by placing the center between the locations of attachment of the chord (for example the through openings through which the chord runs) at the location of the center of area with respect to the abutment surface.
- 20 - An optional additional knot (especially with a diameter greater than the openings through which the chord runs) of the chord between the proximal and distal implant parts may define a length of the distance between the proximal and distal implant parts.

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- In both, embodiments with a single chord portion and embodiments with a plurality of chord portions, it is also possible to provide a displaceable know that allows for an in-situ adjustment of the maximum distance between the distal and proximal implant parts.

- 5 Also, in this embodiment and in other embodiments the chord may be mounted displaceably with respect to the proximal implant part. In embodiment in which the chord has a fixed length, this allows to store the chord proximally of the proximal implant part in the instrument. This is also an option in embodiments with only one chord portion running between the distal and proximal implant parts, namely if the
- 10 chord runs through a (for example centrally located) opening of the proximal implant part, with a knot proximally of the opening.

In embodiments in which the chord is not displaceable with respect to the proximal implant part, it may be attached to the proximal implant part by a knot, by crimping or welding or clamping or other fastening technique.

- 15 Generally, the chord may have a fixed, defined chord length, or may have an adjustable chord length. If the chord length is adjustable, the connection of the chord to the proximal implant part may be performed by the surgeon, for example by knotting.

- 20 In cross section, the proximal implant part in a non-released state may have the shape of a circular segment, for example with a central angle of around 180° or more than 180° . Especially, such a central angle may be at least 120° or at least 90° .

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The present invention also concerns a distal implant part with the according properties discussed and claimed in the present text and a proximal implant part with the according properties discussed and claimed in the present text – thus the herein described and claimed distal and proximal implant parts each may be used together
5 with other implant parts or for example in combination with suturing, etc.

The invention further concerns a method of implanting an implant of the kind described and claimed in this text, the method comprising piercing a leaflet of the heart tissue, advancing a tube containing the proximal and distal implant parts through the pierced leaflet and through the heart's ventricle, releasing the distal
10 implant part into tissue, especially muscle tissue of the ventricle, retracting the tube to the leaflet, releasing the proximal implant part proximally of the leaflet, and retracting the tube.

In embodiments, the tissue into which the distal implant part is released is the muscle tissue of the papillary muscle.

15 This method can be carried out in a minimally invasive or interventional manner, on a beating heart, with the tube (that may have a distal tip to be a needle) inserted through a system of catheters. Alternatively, the method may be carried out by conventional surgery of the open, non-beating heart.

BRIEF DESCRIPTION OF THE DRAWINGS

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

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- Fig. 1 an implant;
- Fig. 2 a distal implant part;
- Fig. 3 an exploded view of elements of the distal implant part of Fig. 2;
- Fig. 4 a proximal implant part;
- 5 - Fig. 5 a cannulated needle forming, in its interior, the lumen, with the implant before the implant is released from the lumen; and
- Fig. 6 the implant implanted after operation.

DESCRIPTION OF EMBODIMENTS

The implant illustrated in **Figure 1** comprises a distal implant part 1, a proximal
10 implant part 2 and a chord 3 connecting the proximal and distal implant parts. The
chord is guided from a distal end of the distal implant part to the proximal implant
part and through the proximal implant part back to the distal end of the distal implant
part, so that the chord 3 is doubled and has two chord portions 3.1, 3.2 between the
proximal and distal implant parts. Within the distal implant part and between the
15 distal and proximal ends thereof, the chord portions 3.1, 3.2 are guided in a shaft 13,
and they are secured by a knot 5 distally of the distal implant part.

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In **Figures 2 and 3**, the distal implant part 1 is shown in somewhat more detail. In the depicted embodiment, it is composed of a shaft piece 8 and a crown piece 9 as well as an optional collet piece 11. The shaft piece 8 acts as a stabilizer that helps orientating the distal implant part 1 in a longitudinal manner, aligned and with the proximal end pointing towards the leaflet. It comprises is a tube-like shaft 13 with a longitudinal through opening 14 through which the chord 3 on is passed. At the distal end, the shaft piece 8 may optionally further comprises a collar (not shown) around the shaft. The crown piece 9 is placed on/around the shaft 13 and is designed to fulfill, together with the shaft piece 8 the anchor function. To this end, the crown piece comprises, attached to a distal head portion 12, a plurality of backwardly (proximally) protruding legs 15 that after release of the distal implant part spread against and inside the tissue of the papillary muscle.

The collet piece 11 is mounted at the proximal end of the shaft and in the depicted embodiment is an initially a separate piece. Alternatively, it would be possible to provide a collet directly on the shaft and one-piece with it.

The (proximodistal) axis 19 is also illustrated in the Figure.

The distal implant part 1, or at least the crown piece thereof, may optionally be made of a shape memory material, such as a shape memory metal, for example Nitinol.

In contrast to the depicted embodiment, the distal implant part may be one piece with the legs being firmly attached to the rest of the distal implant part.

In the depicted embodiment, the legs of the distal implant part are pointed at the outermost surface. More in particular, the legs are each provided with a plurality of

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facets 17 that meet at edges, wherein there is at least one edge 18 and/or a tip 16 that faces outwardly and helps easing penetration into the tissue.

Figure 4 depicts the proximal implant part 2. The proximal implant part is elongate defining a longitudinal axis 29. It has a central body 21 and four arms 25 one-piece with the central body and extending outwardly from the central body.

The lower side of the central body and the arms forms an abutment surface that rests against the leaflet tissue after implantation.

The chord 3 mechanically couples the proximal implant part 2 and the distal anchor part 1 with each other and defines a maximum distance between these implant parts.

10 To this end, the proximal implant part has a first chord opening 22 and a second chord opening 23 separated by a bridge 24. The chord runs through the first chord opening, over the bridge and back to the second chord opening so that it is looped through the proximal implant part. The bridge 24 has rounded features so that the chord can slide along it easily without being damaged. The first and second openings

15 are positioned so that the center of the abutment area is in the middle between them.

As a consequence, if a force tries to pull away the proximal implant part 2 from the distal implant part 1, the chord 3 couples a counter force into the proximal implant part, which counter force acts on the center of area of the proximal implant part abutment surface, at least with respect to longitudinal directions. Because the

20 openings 22, 23 lie on the axis 29, the counter force also acts on the center with respect to lateral directions.

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As a consequence, a pulling by the chord acting on the proximal implant part will not cause any torque on the proximal implant part.

While in the depicted configuration the chord 3 is doubled and looped through the proximal implant part, this effect could for example also be achieved if the chord was
5 one-way only and attached to a spot of the center of area or runs through a single opening in the center of area.

The arms 25 of the proximal implant part 2 are bent outwardly away from the axis. Thereby, the proximal implant part is better supported by the leaflet tissue. On the abutment surface, the arms each comprise an optional hook feature 27.

10 In embodiments, the central body may further have, close to the transition to the arms 25 has shallow lateral recesses (not shown) that cause a waist to make the proximal implant part more flexible to the outward bending of the arms.

Figure 5 shows the implant prior to its release from the lumen from which it is implanted. The lumen is constituted by a hollow tube 40 that has a distal tip 41 and is
15 thus a cannulated needle. An inner diameter of the hollow tube is 1 mm.

The distal implant part 1 and the proximal implant part 2 are both arranged inside the tube 40. In the figure, the tube 40 is shown transparent so that the elements inside it are visible in the figure. The tube 40 in addition to the distal and proximal implant parts also contains the chord 3 that runs from the distal implant part 1 through the
20 openings 22, 23 and forms a loop proximally of the proximal implant part.

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Further, the system comprises an anchor carrier 51. The anchor carrier reaches from proximally of the proximal implant part 2 to distally of the proximal implant part. It forms a seat for the proximal implant part, defines its orientation in the tube and secures the proximal implant part against escaping to distal directions.

- 5 The system comprises a pushing mechanism for moving the anchor carrier and the implant parts relative to the tube at least into distal directions (this includes the possibility of retracting the tube into a proximal direction while holding the parts still with respect to the tissue). Such a pushing mechanism may be flexible to bending movements but will be capable of transmitting axial forces. Such a pusher may
- 10 optionally be one-piece with the anchor carrier, i.e. the most distal portion of such a pusher may be the anchor carrier or may be constituted by a separate piece proximally of the anchor carrier; then optionally the anchor carrier may be fastened to the pusher so that anchor carrier may be retracted into the tube by pulling the pusher after the proximal implant part has been released.
- 15 In the depicted embodiment, the system further comprises a sleeve 28 inside the tube 40, the sleeve encompassing the anchor carrier and the implant prior to the implant's release. The purpose of such an optional sleeve is to protect the implant parts (including the chord) from the needle-like tip distal tip 41 of the tube and also to reduce the risk of injuries of the heart tissue.
- 20 **Figure 6** shows the distal implant part 1 anchored in the papillary muscle. The artificial chord 3 runs through the ventricle and through an opening of the leaflet; the proximal implant part is placed on the proximal side of the leaflet 61, with the abutment surface resting on the leaflet tissue. By this, the implant assists the natural chordae 63 if they are damaged or otherwise not sufficient for the mitral valve to
- 25 close sufficiently.

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WHAT IS CLAIMED IS:

1. An implant for replacing or supplementing damaged natural chordae tendineae of a human or animal heart, the implant comprising a distal implant part, a proximal implant part and an artificial or allograft or xenograft chord,
 - 5 - wherein the distal implant part is configured to fit in a lumen of an implant delivery device and comprises a self-spreading portion spreading radially outside when the distal implant part is released from the lumen, the self-spreading portion being capable of anchoring the distal implant part in tissue;
 - wherein the proximal implant part is configured to fit in the lumen of the
10 implant delivery device and comprises a self-spreading portion spreading radially outside when the proximal implant part is released from the lumen, the proximal implant part being capable of bearing on a tissue portion of leaflet tissue, and
 - wherein the distal implant part and the proximal implant part are connected
15 by the chord.
2. The implant according to claim 1, wherein an interior diameter of the lumen is at most 2 mm, preferably at most 1.5 mm.
3. The implant according to claim 1 or 2 being designed so that the distal and proximal implant parts may rest axially spaced next to one another for being
20 released sequentially.

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4. The implant according to any one of the previous claims, wherein the distal implant part comprises a shaft portion and a plurality of legs that in a non-released state lie against the shaft portion.
5. The implant according to claim 4, wherein the shaft portion and the legs both extend proximally from distal head, wherein in a released state the legs are bent radially outwardly away from the shaft portion.
6. The implant according to claim 4 or 5, wherein the chord is attached to a proximal end of the shaft portion.
7. The implant according to claim 4 or 5, wherein the chord runs through the shaft portion from a proximal portion thereof to a distal portion thereof and is fixed at the distal portion.
8. The implant according to claim 7, wherein the chord is fixed at the distal end of the shaft by a knot or by welding.
9. The implant according to any one of claims 4 to 8, wherein the chord is knotless at least at the proximal end of the shaft portion.
10. The implant according to any one of claims 4 to 9, wherein the number of legs is six or eight.

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11. The implant according to any one of claims 4 to 10, wherein at least one of the legs is provided with a sharpening at their respective outer ends.
12. The implant according to claim 11, wherein the legs comprise at least one facet that is at a non-perpendicular angle to a leg axis.
- 5 13. The implant according to claim 12, wherein the legs comprise an edge that faces radially-outwardly with respect to a distal implant part axis.
14. The implant according to any one of claims 4 to 13, wherein the shaft portion is hollow.
15. The implant according to any one of the previous claims, wherein the distal
10 implant part has a blunt distal end.
16. The implant according to any one of the previous claims, wherein at least the self-spreading portion of the distal implant part is made of a shape memory material.
17. The implant according to any one of the previous claims, wherein the distal
15 implant part comprises a plurality of legs that are shaped in a way that by pulling on the chord the legs are caused to spread radially.
18. The implant according to any one of the previous claims, wherein the proximal implant part is configured to lie flat on a leaflet surface with the chord

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extending from the proximal implant part through the leaflet tissue and through the ventricle to the proximal implant part.

19. The implant according to claim 18, wherein the proximal implant part has a distally-facing abutment surface shaped to lie flat on the leaflet tissue.
- 5 20. The implant according to claim 19, wherein the proximal implant part has at least one hook feature on the abutment surface, the hook feature preventing shifting movements of the proximal implant part relative to leaflet tissue and thereby fostering tissue ingrowth.
- 10 21. The implant according to any one of the previous claims, wherein the proximal implant part has a central body and a plurality of arms extending, in a released state, outwardly from the central body.
22. The implant according to claim 21, wherein the arms extend from the central body in a direction of an axis of the proximal implant part and are bent, in the released state, radially-outwardly from the axis.
- 15 23. The implant according to claim 22, wherein the number of the arms is four and wherein pairs of the arms lie against each other in a non-released state.
24. The implant according to any one of the previous claims, wherein attachment of the chord to the proximal implant part is knotless.

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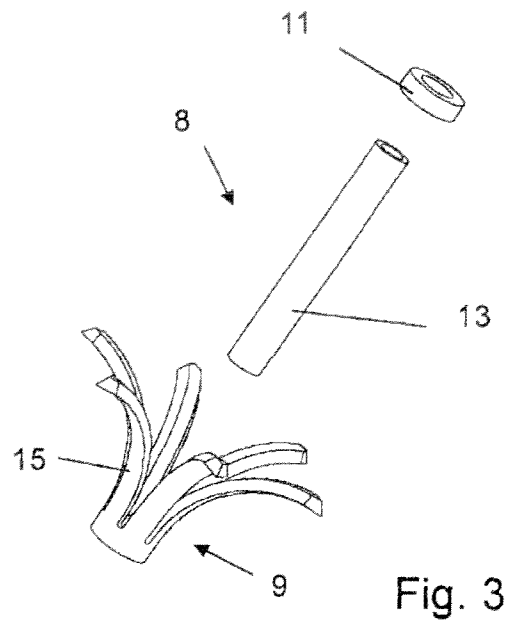
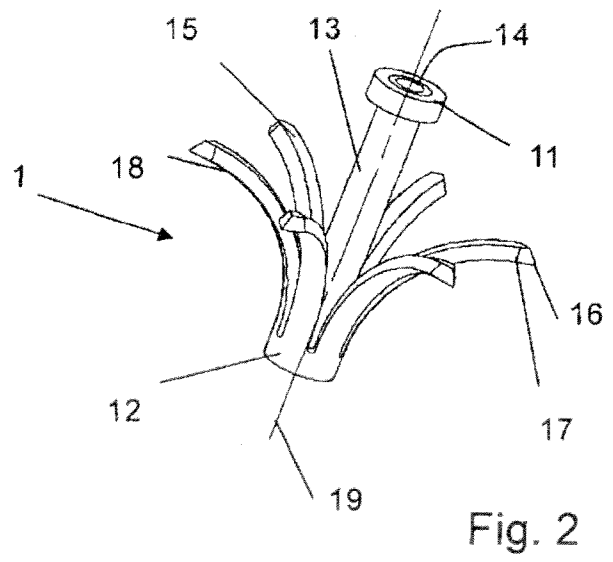
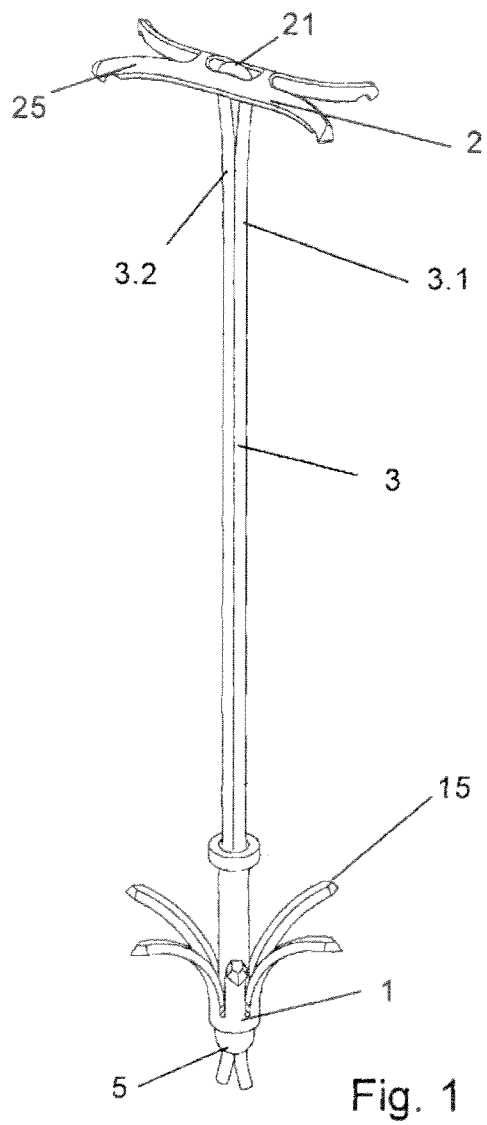
25. The implant according to any one of the previous claims, wherein two chord portions run between the proximal implant part and the distal implant part.
26. The implant according to claim 25, wherein the chord runs from the distal implant part through the proximal implant part back to the distal implant part.
- 5 27. The implant according to claim 26, wherein the chord runs through a first opening of the proximal implant part and a second opening of the proximal implant part.
28. The implant according to claim 26 or 27, wherein the chord is displaceable with respect to the proximal implant part.
- 10 29. The implant according to claim 25, wherein the chord runs from the proximal implant part through the distal implant part back to the proximal implant part.
30. The implant according to any one of the previous claims, wherein the proximal implant part is coupled to the chord in a manner that a pulling force on the chord does not transmit cause any torque on the proximal implant part lying
15 flat on the leaflet.
31. The implant according to claim 30, wherein the proximal implant part comprises two through openings through which the chord runs, wherein a middle between the two through openings is at a location of the center of area of the abutment surface.

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32. The implant according to any one of the previous claims, wherein in a non-released state the proximal implant part in cross section has the shape of a circular segment.
33. The implant according to any one of the previous claims, wherein the chord is not attached to the proximal implant part and is assembled with the proximal and distal implant parts to be attached during operation, whereby a length of the chord is adjustable.
34. A method of replacing or supplementing damaged natural chordae tendineae of a human or animal heart of a patient in need thereof, the method comprising the steps of:
- providing an implant, the implant comprising a distal implant part, a proximal implant part and an artificial or allograft or xenograft chord;
 - Providing a tubular element and arranging the distal implant part and the proximal implant part in the tubular element;
 - advancing the tubular element from an atrial side to a leaflet of an atrioventricular valve of the heart, piercing the leaflet and advancing the tubular element through the pierced leaflet and through the ventricle towards tissue;
 - releasing the distal implant part from the tubular element and thereby implanting it in the tissue;
 - retracting the tubular element and releasing the proximal implant part proximally of the leaflet, on the atrial side thereof; and
 - removing the tubular element;

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- wherein either the proximal implant part and the distal implant part are connected by the chord, or the method comprises the additional step of connecting the proximal and distal implant parts by the chord.
35. The method according to claim 34, wherein releasing the proximal implant part comprises letting a self-expanding portion of the proximal implant part expand.
36. The method according to claim 34 or 35, wherein releasing the proximal implant part comprises causing the proximal implant part to lie flat on an atrial side of the leaflet.
37. The method according to any one of claims 34 to 36, wherein releasing the proximal implant part comprises moving tubular element relative to the anchor carrier in a proximal direction until the proximal implant part is outside of the tubular element, whereby the proximal implant part is released automatically from the anchor carrier.



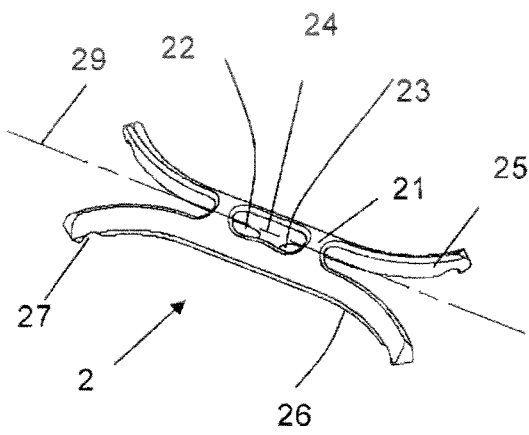


Fig. 4

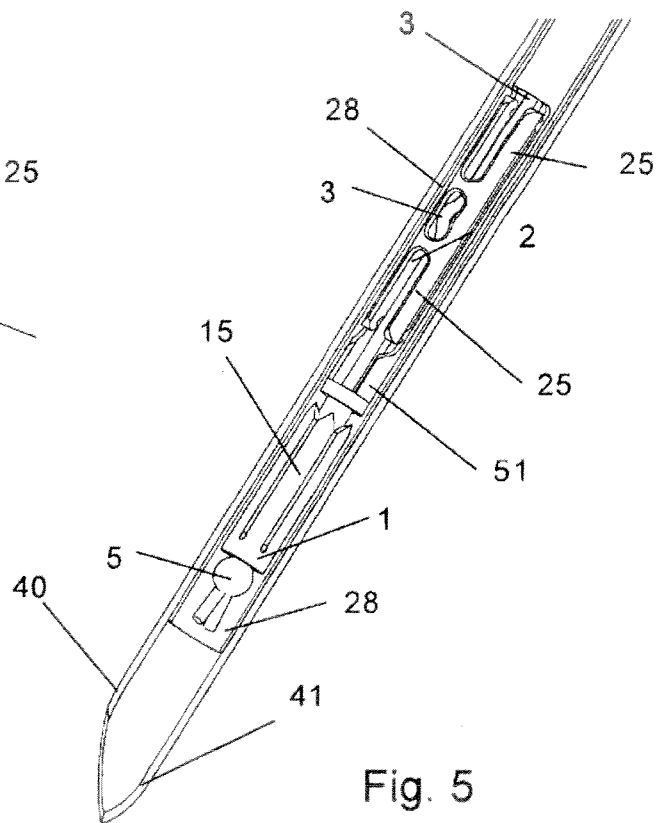


Fig. 5

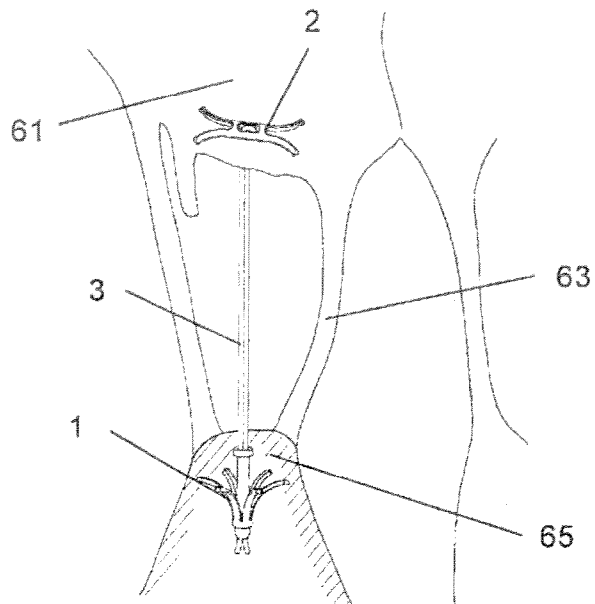


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No

PCT/CH2016/000136

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/24 A61B17/04
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/040865 A1 (WEBER ALBERTO [CH]; VOGEL ROLF [CH]; VANDENBERGHE STIJN [CH]; CARREL T) 5 April 2012 (2012-04-05)	1-14, 16-19, 24,26, 30,32,33
Y	page 21, line 3 - page 22, line 2 page 23, lines 4-20 page 27, lines 8-15 figures 3a-3c, 6a-6c, 7a-7b, 13a-15b -----	15, 20-22, 25-27, 29,31
X	US 2011/011917 A1 (LOULMET DIDIER [US]) 20 January 2011 (2011-01-20)	1-8, 10-19, 21,22, 24,25, 30,32,33
Y	paragraphs [0047], [0049] - [0050], [0053] - [0055]; figures 4A-4E,8G-8H ----- -/--	15,21,22



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

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

"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

12 January 2017

Date of mailing of the international search report

24/01/2017

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Prechtel, A

INTERNATIONAL SEARCH REPORT

International application No

PCT/CH2016/000136

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/118151 A1 (DAVIDSON MICHAEL J [US]) 24 May 2007 (2007-05-24)	1-3, 16-19, 21-23, 25,26, 28-30, 32,33
Y	paragraphs [0098], [0134] - [0140]; figures 50B, 50C, 53-60 -----	20, 25-27, 29,31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH2016/000136

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.: 34-37
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/CH2016/000136

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012040865 A1	05-04-2012	NONE	
US 2011011917 A1	20-01-2011	NONE	
US 2007118151 A1	24-05-2007	US 2007118151 A1	24-05-2007
		WO 2007062054 A2	31-05-2007