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(54) Title: MEMBRANE AUGMENTATION, SUCH AS OF FOR TREATMENT OF CARDIAC VALVES, AND FASTENING DEVICES FOR MEMBRANE AUGMENTATION

(57) Abstract: Disclosed are methods for augmenting tissue, for example membranes such as cardiac leaflets and tissue surrounding a cardiac valve, which in embodiments improve leaflet coaptation. Also disclosed are devices useful for augmenting tissue.

MEMBRANE AUGMENTATION, SUCH AS OF FOR TREATMENT OF CARDIAC VALVES, AND FASTENING DEVICES FOR MEMBRANE AUGMENTATION

RELATED APPLICATIONS

The present application gains benefit of the filing dates of US patent application Nos. 60/809,848 filed 1 June 2006; 60/814,572 filed 19 June 2006; 60/832,142 filed 21 July 2006; 60/832,162 filed 21 July 2006 and 60/860,805 filed 24 November 2006 all which are incorporated by reference as if fully set forth herein.

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to the field of surgery and especially to surgical fastening devices such as surgical staplers useful, for example, in augmenting cardiac valve leaflets or in augmenting tissue surrounding a cardiac valve, for example to allow displacement of the intact cardiac valve. The use of surgical fastening devices of the present invention allows performance of otherwise lengthy and complex surgeries quickly and efficiently, for example in order to improve leaflet coaptation, for example in order to treat ischemic mitral regurgitation.

The human heart **10**, depicted in cross sectional long axis view in Figure 1, is a muscular organ that pumps deoxygenated blood through the lungs to oxygenate the blood and pumps oxygenated blood to the rest of the body by rhythmic contractions of four chambers.

After having circulated in the body, deoxygenated blood from the body enters the right atrium **12** through the vena cava **14**. Right atrium **12** contracts, pumping the blood through a tricuspid valve **16** into the right ventricle **18**. Right ventricle **18** contracts, pumping the blood through the pulmonary semi-lunar valve **20** into the pulmonary artery **22** which splits to two branches, one for each lung. The blood is oxygenated while passing through the lungs and reenters the heart to the left atrium **24**.

Left atrium **24** contracts, pumping the oxygenated blood through the mitral valve **26** into the left ventricle **28**. Left ventricle **28** contracts, pumping the

oxygenated blood through the aortic semi-lunar valve **30** into the aorta **32**. From aorta **32**, the oxygenated blood is distributed to the rest of the body.

Physically separating left ventricle **28** and right ventricle **18** is interventricular septum **33**. Physically separating left atrium **24** and right atrium **12** is an interatrial septum.

Mitral valve **26**, depicted in Figure 2A (top view) and in Figure 2B (cross sectional long axis view) is defined by an approximately circular mitral annulus **34** that defines a mitral lumen **36**. Attached to the periphery of mitral annulus **34** is an anterior leaflet **38** and a smaller posterior leaflet **40**, leaflets **38** and **40** joined at commissures **41**. Each leaflet is between about 0.8 and 2.4 mm thick and composed of three layers of soft tissue.

The typical area of mitral lumen **36** in a healthy adult is between 4 and 6 cm^2 while the typical total surface area of leaflets **38** and **40** is approximately 12 cm^2. Consequently and as depicted in Figure 2B, leaflets **38** and **40** curve downwards into left ventricle **28** and coapt to accommodate the excess leaflet surface area, producing a coaptation surface **42** that constitutes a seal. The typical length of coaptation surface **42** in a healthy heart **10** of an adult is approximately 7-8 mm.

The bottom surface of anterior leaflet **38** and posterior leaflet **40** are connected to papillary muscles **44** at the bottom of left ventricle **28** by posterior chordae **46** and anterior chordae **48**.

During diastole, left atrium **24** contracts to pump blood downwards into left ventricle **28** through mitral valve **26**. The blood flows through mitral lumen **36** pushing leaflets **38** and **40** downwards into left ventricle **28** with little resistance.

During systole left ventricle **28** contracts to pump blood upwards into aorta **32** through aortic semi-lunar valve **30**. Mitral annulus **34** contracts pushing leaflets **38** and **40** inwards and downwards, reducing the area of mitral lumen **36** by about 20% to 30% and increasing the length of coaptation surface **42**. The pressure of blood in left ventricle **28** pushes against the bottom surfaces of leaflets **38** and **40**, tightly pressing leaflets **38** and **40** together at coaptation surface **42** so that a tight leak-proof seal is formed. To prevent prolapse of leaflets **38** and **40** upwards into left atrium **24**, papillary muscles **44** contract pulling the edges of leaflets **38** and **40** downwards through posterior chordae **46** and anterior chordae **48**, respectively.

As is clear from the description above, an effective seal of mitral valve **26** is dependent on a sufficient degree of coaptation, in terms of length, area and continuity of coaptation surface **42**. If coaptation surface **42** is insufficient or non-existent, there is mitral valve insufficiency, that is, regurgitation of blood from left ventricle **28** up into left atrium **24**. A lack of sufficient coaptation may be caused by any number of physical anomalies that allow leaflet prolapse (e.g., elongated or ruptured chordae **46** and **48**, weak papillary muscles **44**) or prevent coaptation (e.g., short chordae **46** and **48**, small leaflets **38** and **40**).

Mitral valve insufficiency leads to many complications including arrhythmia, atrial fibrillation, cardiac palpitations, chest pain, congestive heart failure, fainting, fatigue, low cardiac output, orthopnea, paroxysmal nocturnal dyspnea, pulmonary edema, shortness of breath, and sudden death.

There are a number of pathologies that lead to a mitral valve insufficiency including collagen vascular disease, ischemic mitral regurgitation, myxomatous degeneration of leaflets **38** and **40** and rheumatic heart disease.

In ischemic mitral regurgitation (resulting, e.g., from myocardial infarction, chronic heart failure, or surgical or catheter revascularization), leaflets **38** and **40** and chordae **46** and **48** have normal structure and the mitral valve insufficiency results from altered geometry of left ventricle **28**. As a result of ischemia, portions of the heart walls necrose. During healing, the necrotic tissue is replaced with unorganized tissue leading to remodeling of the heart which reduces coaptation through distortion of mitral annulus **34** and sagging of the outer wall of left ventricle **28** which displaces papillary muscles **44**.

In Figures 3A (top view) and 3B (cross sectional long axis view), The reduction of coaptation resulting from ischemia is depicted for a mitral valve **26** of an ischemic heart **50** that has undergone mild remodeling and suffers from ischemic mitral regurgitation. In Figure 3B is seen how an outer wall of left ventricle **28** sags outwards, displacing papillary muscles **44** downwards which, through chordae **46** and **48**, pulls leaflets **38** and **40** downwards and apart, reducing coaptation. The incomplete closure of mitral valve **26** is seen in Figures 3A and 3B.

Initially, ischemic mitral regurgitation is a minor problem, typically leading only to shortness of breath during physical exercise due to the fact that a small fraction of blood pumped by left ventricle **28** is pumped into left atrium **24** and not

through aortic semi-lunar valve **30**, reducing heart capacity. To compensate for the reduced capacity, left ventricle **28** beats harder and consequently remodeling continues. Ultimately leaflet coaptation is entirely eliminated as leaflets **38** and **40** are pulled further and further apart, leading to more blood regurgitation, further increasing the load on left ventricle **28**, and further remodeling. Ultimately, the left side of the heart fails and the person dies.

Apart from humans, mammals that suffer from mitral valve insufficiency include horses, cats, dogs, cows and pigs.

Currently, it is accepted to use open-heart surgical methods to improve mitral valve functioning by many different methods, including: modifying the subvalvular apparatus (e.g. lengthening the chordae) to improve leaflet coaptation; implanting an annuloplasty ring, e.g., as described in United States Patents 3,656,185, 6,183,512 and 6,250,308 to force mitral valve annulus **34** into a normal shape; or implanting devices in the mitral valve to act as prosthetic leaflets, e.g., United States Patent applications published as US 2002/065554, US 2003/0033009, US 2004/0138745 or US 2005/0038509.

Surgical augmentation of a mitral valve anterior leaflet **38** for improving mitral valve leaflet coaptation for treating ischemic mitral valve regurgitation is taught by Kincaid et al (Kincaid EH, Riley RD, Hines MH, Hammon JW and Kon ND in Ann. Thorac. Surg. 2004, 78, 564-568). An incision is made in the anterior leaflet almost from commissure to commissure. The edges of a roughly elliptical patch of material (e.g., bovine pericardium, 1 cm wide, 3 cm long) are sutured to either side of the incision augmenting the anterior leaflet by an amount roughly equal to the surface area of the patch. Additionally, a flexible annuloplasty ring is implanted to reshape the mitral annulus. Although effective, such augmentation is considered a complex surgical procedure performed only by cardiac surgeons having above average skill.

Open heart surgery of any kind is complex, requires long recovery time and is accompanied by a high rate of complications and death. The failure rate of the mitral valve function improvement operations is very high both due to objective reasons relating to patient condition and the subjective difficulty of performing such operations repeatedly correctly. Even when successfully performed, persons having undergone such surgeries have an increased chance of infection and stroke, and are

often required to use anticoagulant agents for the rest of their lives. Often there is a need to repeat the surgery after a few years.

Any significant reduction of time in an open heart surgery increases the chance of success of the operation. Further, any way in which a heart surgery may be performed more accurately will generally provide a consistently better prognosis.

It would be highly advantageous to have a quick and simple method for performing open heart operations such as augmenting cardiac valve leaflets or otherwise improving leaflet coaptation, to reduce mitral insufficiency, for example for treating subjects suffering from ischemic mitral valve regurgitation.

SUMMARY OF THE INVENTION

The present invention successfully addresses at least some of the shortcomings of the prior art by providing methods of tissue augmentation which in embodiments improves cardiac valve leaflet coaptation, which may be useful in treating conditions, for example mitral insufficiency such as ischemic mitral regurgitation. The present invention also provides surgical fastening devices such as surgical staplers and related components that allow procedures such as leaflet augmentation or cardiac valve displacement to be performed quickly, accurately and of consistent quality with less dependence on the skill level or degree of exhaustion of the performing surgeon.

In an embodiment of the present invention, augmentation of a membrane (increase of the surface area of the membrane) such as a cardiac valve leaflet (in a manner reminiscent to the taught by Kincaid et al) is performed more quickly and more easily than known in the art.

Thus, according to the teachings of the present invention there is provided a method of augmenting a membrane, comprising: a) slitting an in vivo membrane so as to produce a slit having a first slit edge and a second slit edge; b) providing a patch of tissue having a periphery as a membrane augmenting implant; c) placing the patch of tissue to define an overlap region comprising an overlap of a first portion of the periphery with the first slit edge and an overlap of a second portion of the periphery with the second slit edge; and d) securing the patch to the membrane around a plurality of locations of the overlap region substantially simultaneously, thereby augmenting the membrane by increasing a surface area of the membrane with the patch.

In embodiments, the in vivo membrane augmented is a leaflet of a cardiac valve. In embodiments, the cardiac valve is a mitral valve. In embodiments, the leaflet is a posterior mitral valve leaflet. In embodiments, the augmenting of a leaflet of a cardiac valve improves coaptation of the leaflets of the mitral valve.

In embodiments, the slit has a shape selected from the group consisting of straight, curved and wavy.

In embodiments, the slitting of the membrane and the placing of the patch is substantially simultaneous.

In embodiments, the slitting of the membrane, the placing of the patch and the securing of the patch to the membrane is substantially simultaneous.

In embodiments, the overlap region is substantially a closed curve circumscribing the slit. Typical suitable shapes of the overlap region include but are not limited to circles, ovals, ellipses, oblate ovals, oblate ellipses and oblate circles.

In embodiments, during the securing of the patch to the membrane, the area of the membrane circumscribed by the overlap region is less than the surface area of the patch circumscribed by the first portion and by the second portion of the patch.

In embodiments, the securing of the patch to the membrane comprises: i) piercing the patch and the membrane at the plurality of locations to make a plurality of holes in the overlap region substantially simultaneously; ii) passing lockable fasteners through the holes; and iii) locking the lockable fasteners so as to secure the patch to the first slit edge and the second slit edge through the overlap region.

In embodiments, the piercing of the patch and the membrane as well as the passing of the lockable fasteners through the holes is substantially simultaneously performed by driving a piercing element of the lockable fasteners (e.g., the legs of a staple) through the patch and the membrane.

In embodiments, the slitting of the membrane, the placing of the patch and the piercing of the patch and the membrane is substantially simultaneous.

In embodiments, locking a lockable fastener comprises deforming the lockable fastener, for example clinching a staple.

In embodiments, locking a lockable fastener comprises securing a locking component to the lockable fastener.

In embodiments, during the piercing of the patch and the membrane, the area of the membrane circumscribed by the holes through the first slit edge and the second

slit edge is less than the surface area of the patch circumscribed by the holes through the periphery of the patch. In embodiments, during the piercing, the patch is buckled.

According to the aspect of the present invention, the tissue surrounding a cardiac valve is augmented (e.g., the surface area of tissue between the valve annulus and the valve itself is increased) more quickly and more easily than known in the art. In embodiments, such augmenting allows the cardiac valve to be displaced, which in embodiments increases coaptation of the valve leaflets.

Thus according to the teachings of the present invention there is also provided a method of augmenting the tissue surrounding a cardiac valve, comprising: a) excising leaflets of a cardiac valve with an incision having a shape of a closed curve, so as to define a valve seat edge of the incision and a valve periphery edge of the incision; b) providing an implant including a wall, the wall delimited by two edges each in the shape of a closed curve and defining a lumen. (e.g., a tube or annulus) as a cardiac valve augmenting implant; c) placing the implant to define a proximal overlap region comprising an overlap of a first portion near a first edge of the implant with the valve seat edge d) placing the implant to define a distal overlap region comprising an overlap of a second portion near a second edge of the implant with the valve periphery edge; e) securing the first portion of the implant to the valve seat edge around a plurality of locations of the proximal overlap region; and f) securing the second portion of the implant to the valve periphery edge around a plurality of locations of the distal overlap region, substantially simultaneously, thereby augmenting a surface area of tissue surrounding the cardiac valve with the implant, and in embodiments allowing displacement of the cardiac valve. In embodiments, spare portions of the implant are trimmed. It is important to note that the steps of the method may be performed in any rational order and not necessarily in the order listed above. For example, in embodiments, **a** precedes **c** and/or **d** and/or **e** and/or **f**; **a** succeeds **c** and/or **d** and/or **e** and/or **f**; **c** precedes **d** and/ or **f**; **e** precedes **d** and/or **f**; **d** precedes **c** and/or **e**; **f** precedes **c** and/or **e**. It is important to note, as discussed below, in preferred embodiments one or more steps are substantially simultaneous.

In embodiments, the cardiac valve is a mitral valve. In embodiments, the augmentation of the tissue surrounding the valve improves coaptation of leaflets of the cardiac valve.

In embodiments, the incision is of a shape selected from the group consisting of circle, oval, ellipse, oblate oval, oblate ellipse and oblate circle.

In embodiments, securing the first portion of the implant to the valve seat edge around a plurality of locations of the proximal overlap region is performed substantially simultaneous for the plurality of location.

In embodiments, excising the leaflets, placing the implant to define the proximal overlap zone and securing the first portion of the implant to the valve seat edge are substantially simultaneous.

In embodiments, excising the leaflets, placing the implant to define the distal overlap zone, and securing the second portion of the implant to the valve periphery edge are substantially simultaneous.

In embodiments, excising the leaflets, placing the implant to define the proximal overlap zone, placing the implant to define the distal overlap zone, securing the first portion of the implant to the valve seat edge and securing the second portion of the implant to the valve periphery edge are substantially simultaneous.

In embodiments, the proximal overlap region is substantially a closed curve circumscribing the incision. Typical shapes of closed curves include, but are not limited to circles, ovals, ellipses, oblate ovals, oblate ellipses and oblate circles.

In embodiments, the distal overlap region is substantially a closed curve surrounded the incision. Typical shapes of closed curves include, but are not limited to circles, ovals, ellipses, oblate ovals, oblate ellipses and oblate circles.

In embodiments, the surface area of the walls of the implant between the proximal overlap region and the distal overlap region is greater than the surface area of the tissue between the proximal overlap region and the distal overlap region. In embodiments, during the placing of the implant, the wall of the implant is buckled.

In embodiments, securing the first portion of the implant to the valve seat edge comprises: i) piercing the implant and the tissue surrounding the valve seat edge at the plurality of locations to make a plurality of holes in the proximal overlap region substantially simultaneously; ii) passing lockable fasteners through the holes; and iii) locking the lockable fasteners so as to secure the implant to the valve seat edge through the proximal overlap region.

In embodiments, securing the second portion of the implant to the valve periphery edge comprises: i) piercing the implant and tissue surrounding the valve

periphery edge at the plurality of locations to make a plurality of holes in the distal overlap region substantially simultaneously; ii) passing lockable fasteners through the holes; and iii) locking the lockable fasteners so as to secure the implant to the valve periphery edge through the distal overlap region.

In embodiments, piercing the implant and the tissue and passing the lockable fasteners through the holes is substantially simultaneously performed by driving a piercing element of the lockable fasteners through the implant and the tissue.

In embodiments, locking a lockable fastener comprises deforming the lockable fastener, for example clinching a staple.

In embodiments, locking a lockable fastener comprises securing a locking component to the lockable fastener.

As noted above, an implant used in augmenting the tissue surrounding a cardiac valve in accordance with the teachings of the present invention includes a wall, the wall delimited by two edges each in the shape of a closed curve and defining a lumen. Suitable closed curve shapes of the edges of an implant include, but are not limited to circles, ovals, ellipses, oblate ovals, oblate ellipses and oblate circles. Any suitable material or combination of materials may be used for fashioning a wall of an implant, both synthetic and biological as is detailed hereinbelow.

In embodiments, an implant is substantially a flat sheet of material with a hole therethrough, where the first edge is the outer edge of the flat sheet and the second edge is the edge of the hole. In such embodiments, the first region, that which is secured to the valve seat edge of the incision is a portion of the sheet closer to the first edge (edge of the sheet) than the second region which is closer to the second edge (the edge of the hole) and to which the valve periphery edge of the incision is secured. In embodiments, the flat sheet of material is in the shape of an annulus or ring. In embodiments the two edges are of the same shape. In embodiments, the two edges describe shapes that are substantially concentric.

In embodiments, an implant is substantially a tube of material having a proximal end and a distal end with a lumen passing therebetween, where the first edge is the rim of the proximal end and the second edge is the rim of the distal end. In such embodiments, the first region, that which is secured to the valve seat edge of the incision is a portion of the tube closer to the first edge (proximal rim) than the second region which is closer to the second edge (distal rim) and to which the valve periphery

edge of the incision is secured. In embodiments, the tube is substantially parallel walled. In embodiments, the distal rim and the proximal rim are of substantially the same size. In embodiments, the distal end and the proximal end are coaxial. In embodiments, the distal end and the proximal end are not-coaxial. In embodiments, the proximal rim is substantially larger than the distal rim. In embodiments, the tubular wall is substantially a truncated cone. In embodiments, the distal end and the proximal end are coaxial. In embodiments, the distal end and the proximal end are not-coaxial. In embodiments, the tubular wall is substantially frustoconical. In embodiments, the ends of the truncated cone are substantially not parallel.

Embodiments of the methods of the present invention may be performed quickly and/or efficiently and/or more accurately with embodiments of fastening devices of the present invention.

According to the teachings of the present invention there is also provided a surgical fastening device useful for securing a cardiac valve and an implant together, comprising: a) a device body comprising a fastener magazine having a fastener ejection ring (in embodiments, the fastener ejection ring having the shape of a closed curve) and configured to project a plurality of tissue-piercing elements of one or more lockable fasteners (preferably, substantially in parallel to an axis) in the shape of a closed curve from the fastener magazine; and b) an anvil configured to act as a counterpoise during projection of the tissue-piercing elements which comprises an anvil head including an anvil head top surface having a shape of a closed-curve and a size substantially similar to that of the fastener ejection ring, wherein the anvil is securable to the device body through a stem surrounded by the fastener ejection ring, so that when secured, the anvil head surface is opposite the fastener ejection ring, wherein the anvil head comprises at least two mateable anvil head parts, wherein each mateable anvil head part spans a sector less than 360° of the closed curve of the anvil head. Typical lockable fasteners include, but are not limited to, staples, cotter pins, studs, rivets, and two-part rivets. In embodiments, the device is a stapler and the one or more lockable fasteners are staples.

Such a fastening device is useful for associating, for example, a mitral valve edge with an edge of an implant as described above. Generally, the anvil head parts are passed through the mitral valve annulus and around the chordae, and mated to constitute a whole anvil head on the distal (ventricular) side of the mitral valve with

the stem passing through the mitral valve lumen. When activated, the fastening device drives a plurality of lockable fastener substantially simultaneously through the edge of the implant and the mitral valve edge. The anvil is then taken apart and the parts withdrawn through the mitral valve lumen, while avoiding the chordae.

Thus, according to the teachings of the present invention, there is also provided an anvil for a surgical fastening device useful for securing a cardiac valve to an implant, comprising at least two mateable anvil head parts that when mated the anvil head parts constitute an anvil head that is substantially a closed curve including an anvil head top surface, wherein each the mateable anvil head part spans a sector less than 360° of the closed curve.

In embodiments, the closed curve shape of the anvil and which the fasteners are projected is of a shape selected from the group consisting of circle, oval, ellipse, oblate oval, oblate ellipse and oblate circle. It is understood that embodiments comprise also anvil heads that are not entirely closed curves but also substantially closed curves. For example, in embodiments the anvil head describes a split curve that constitute 350° of a closed curve where the 10° gap does not significantly adversely effect the functioning of the device. For example, in embodiments the anvil head is intermittent with a plurality of small gaps that do not significantly adversely effect the functioning of the device.

In embodiments, the anvil is of 2, 3, 4, 5, 6 or even more anvil head parts. That said, in a preferred embodiment, the anvil comprises two mateable anvil head parts, a first anvil head part and a second anvil head part, which when mated together spanning the entire circumference of the closed curve. In embodiments, the first anvil head part spans a sector of between about 120° and about 240° of the closed curve. In embodiments, the first anvil head part spans a sector of between about 160° and about 200° of the closed curve.

In embodiments, each anvil head part comprises an inwardly extending crosspiece. Such a crosspiece is generally relatively narrow, spanning no greater than about 45°, no greater than about 30°, no greater than about 15° and even no greater than about 10°.

In embodiments, an anvil comprises a stem attached to at least one the anvil head part through a crosspiece, the crosspiece inwardly extending from the anvil head part to the stem. In embodiments, the stem attached to only one the anvil head part. In

embodiments, the stem is split into a plurality of mateable parts, the parts attached to different anvil head parts, and configured so that when the anvil head parts are properly mated the stem parts are properly mated.

In embodiments, the top surface of the anvil comprises a tray for presenting locking components to engage lockable fasteners projected from the surgical fastening device, e.g., the locking components of two-part rivets.

In embodiments, the top surface of the anvil comprises features for facilitating deformation of lockable fasteners projected from the surgical fastening device, for example for a stapler typical deformation facilitation, deformation facilitating features comprise staple clinching grooves.

According to the teachings of the present invention there is also provided for a surgical fastening device useful for augmenting tissue (for example in accordance with the methods of the present invention), comprising: a) a device body including a fastener magazine functionally associated with a fastener ejection ring (in embodiments, in the shape of a closed curve) at a distal end of the device body and configured, upon triggering, to project a plurality of tissue-piercing elements of one or more lockable fasteners from the fastener magazine through the fastener ejection ring in a direction (preferably, substantially in parallel to an axis) in the shape of the closed curve; b) an anvil configured to act as a counterpoise during the projection of the tissue-piercing elements which comprises an anvil head including an anvil head top surface having a shape substantially of a closed curve and a size substantially similar to that of the fastener ejection ring, the anvil secured to the device body through a stem, so that when secured, the anvil head surface is opposite the fastener ejection ring; c) an implant container at the distal end of the device body including an outwardly directed opening (e.g., directed substantially in the direction substantially in parallel to the axis) surrounded by the fastener ejection ring; and d) a knife driver defining a part of a wall of the implant container configured, upon triggering, to push an object held in the implant container out through the opening. As is explained below, such a device is useful, for example, in implementing the methods of the present invention efficiently, in embodiments by allowing cutting of tissue and fastening an implant with one action.

In embodiments, the closed curve shape of the anvil and which the lockable fasteners are projected is of a shape selected from the group consisting of circle, oval,

ellipse, oblate oval, oblate ellipse and oblate circle. It is understood that embodiments comprise also anvil heads that are not entirely closed curves but also substantially closed curves, as discussed above.

Typical lockable fasteners include, but are not limited to, staples, cotter pins, studs, rivets, and two-part rivets. In embodiments, the device is a stapler and the one or more lockable fasteners are staples and, preferably, the anvil head top surface including a staple clinching groove ring opposite the fastener ejection ring when the anvil is secured to the device body.

In embodiments, the anvil head is reversibly detachable from the device body.

In embodiments, the device further comprises a trigger to trigger the projection of the tissue-piercing elements of the lockable fasteners contained in the fastener magazine and to trigger the pushing of an object held in the implant container by the knife driver. In embodiments, the trigger is configured to trigger the projection and the pushing simultaneously.

In embodiments, the device further comprises a cutting blade, physically separate from the device body and configured to be accommodated within the implant container together with an implant.

In embodiments, the anvil head top surface including a cutting blade accepting slot opposite the opening of the implant container when the anvil is secured to the device body, configured to accept the cutting blade.

In embodiments, the cutting blade is configured to make a single slit, for example having a shape selected from the group consisting of straight, curved and wavy. In embodiments, such a cutting blade allows implementation of the method of membrane augmentation in accordance with the teachings of the present invention. In embodiments, the anvil head top surface including a cutting blade accepting slot opposite the opening of the implant container when the anvil is secured to the device body, configured to accept the cutting blade.

In embodiments, the fastener magazine of the device is an outer fastener magazine, the fastener ejection ring is an outer fastener ejection ring, the device further comprises: e) a second fastener magazine functionally associated with an inner fastener ejection ring at a the distal end of the device body in the shape of a closed curve; wherein the implant container is in the shape of a closed curve surrounding the second fastener ejection ring; wherein the stem of the anvil is surrounded by the

second fastener ejection ring; and where, the device body is further configured, upon triggering, to project a plurality of tissue-piercing elements of one or more fasteners from the inner fastener magazine in the shape of the closed curve through the inner fastener ejection ring in the direction. In embodiments, the anvil head comprises at least two mateable anvil head parts, wherein each the mateable anvil head part spans a sector of the closed curve of the anvil head, in embodiments substantially as described above. In embodiments, the device further comprises a cutting blade physically separate from the device body and configured to be accommodated within the implant container together with an implant. In embodiments, the cutting blade is configured to make an incision having a closed curved shape, including but not limited to a shape selected from the group consisting of circle, oval, ellipse, oblate oval, oblate ellipse and oblate circle. In embodiments, the cutting blade is a linear strip of sufficient flexibility to be bent into the closed curve shape by the implant container. In embodiments, the cutting blade is a loop of sufficient flexibility to be collapsed to an elongated shape.

In embodiments of a device of the present invention, a device body is configured to accept a cartridge which includes fasteners, an implant and/or a cutting blade. For use, a cartridge is attached to the device body.

Thus, according to the teachings of the present invention there is also provided a cartridge for a surgical fastening device, comprising: a) a cartridge body with a distal end and a proximal end, configured for association with a surgical fastening device through the proximal end of the cartridge body; b) a fastener magazine functionally associated with a fastener ejection ring at the distal end of the cartridge body (preferably in the shape of a closed curve); c) a plurality of tissue-piercing elements of one or more lockable fasteners held in the fastener ejection magazine and directed towards the fastener ejection ring so as to describe a closed curve; d) an implant container at the distal end including an outwardly directed opening surrounded by the fastener ejection ring; e) contained within the implant container, an implant comprising a patch of tissue having a periphery wherein the periphery extends beyond the fastener ejection ring; and f) a cutting blade contained within the implant container and nestled in the implant with a cutting edge directed towards the opening of the implant container.

Typical lockable fasteners include, but are not limited to, staples, cotter pins, studs, rivets, and two-part rivets. In embodiments, the device is a stapler and the one or more lockable fasteners are staples.

In embodiments, the cutting blade is configured to make a single slit, for example having a shape selected from the group consisting of straight, curved and wavy. In embodiments, the cutting blade comprises a strip of a suitable material, e.g., stainless steel, titanium, titanium alloys and the like.

According to the teachings of the present invention there is also provided a cartridge for a surgical fastening device, comprising: a) a cartridge body with a distal end and a proximal end, configured for association with a surgical fastening device through the proximal end of the cartridge body; b) an outer fastener magazine functionally associated with an outer fastener ejection ring at the distal end of the cartridge body (preferably in the shape of a closed curve); c) a plurality of tissue-piercing elements of one or more lockable fasteners held in the outer fastener ejection magazine and directed towards the outer fastener ejection ring so as to describe a closed curve; d) an implant container in the shape of a closed curve at the distal end including an outwardly directed opening surrounded by the fastener ejection ring; e) an inner fastener magazine functionally associated with an inner fastener ejection ring at the distal end of the cartridge body (preferably in the shape of a closed curve) surrounded by the implant container; f) a plurality of tissue-piercing elements of one or more lockable fasteners held in the inner fastener ejection magazine and directed towards the inner fastener ejection ring so as to describe a closed curve; g) contained within the implant container, an implant including a wall, the wall delimited by two edges each in the shape of a closed curve, and defining a lumen, wherein a first of the two edges extends outwards beyond the outer fastener ejection ring and a second of the two edges extends inwards beyond the inner fastener ejection ring; and h) a cutting blade contained within the implant container and nestled in the implant with a cutting edge directed towards the opening of the implant container.

Typical lockable fasteners include, but are not limited to, staples, cotter pins, studs, rivets, and two-part rivets. In embodiments, the device is a stapler and the one or more lockable fasteners are staples.

In embodiments, the cutting blade is configured to make an incision having a closed curve shape single slit, for example having a shape selected from the group

consisting of circle, oval, ellipse, oblate oval, oblate ellipse and oblate circle. In embodiments, the cutting blade is a strip of sufficient flexibility to be bent into the implant container to have the desired closed curve shape. In embodiments, the cutting blade is a loop of sufficient flexibility to be collapsed to an elongated shape, as discussed above. The cutting blade comprises a suitable material, e.g., stainless steel, titanium, titanium alloys and the like.

As noted above and detailed below, lockable fasteners are used to implement embodiments of the present invention. Examples of lockable fasteners useful for implementing the teachings of the present invention that are lockable by deformation include, but are not limited to, staples, cotter pins, studs and rivets.

Examples of lockable fasteners useful for implementing the teachings of the present invention that are lockable by engagement with a discrete locking component (e.g., unidirectional locking rings) include, but are not limited to, two-part rivets.

According to the teachings of the present invention there is also provided a lockable fastener useful for securing the periphery of a cardiac valve to an implant material (for example, in accordance with a method of the present invention), comprising: a) a loop-shaped body with a bottom side defining a lumen and describing at least a 320° sector about an axis; and b) at least three elongated piercing elements protruding from the bottom side substantially parallel to the axis. In embodiments, the loop-shaped body describes at least a 340° sector about the axis and even a complete loop about the axis. In embodiments, the piercing elements are configured to deform so that the fastener is lockable by deformation of the piercing elements, preferably by bending, preferably in a direction tangential to the body, upon sufficiently forceful contact with an anvil when projected from an appropriately configured surgical fastening device. In embodiments, the fastener is lockable by securing at least one discrete locking component to the piercing elements (which are configured therefore). In embodiments, a set of at least two lockable fasteners such as above is provided, where the two fasteners are coaxially nestable, so that when coaxially nested, a coaxial gap between the outer edge of the body of the smaller fastener and the inner edge of the body of the larger fastener is at least 0.1 mm and preferably less than about 10 mm. Such a gap is configured to accommodate an implant and a cutting blade, as described above.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

As used herein, the terms "comprising" and "including" or grammatical variants thereof are to be taken as specifying the stated features, integers, steps or components but do not preclude the addition of one or more additional features, integers, steps, components or groups thereof. This term encompasses the terms "consisting of" and "consisting essentially of".

The phrase "consisting essentially of" or grammatical variants thereof when used herein are to be taken as specifying the stated features, integers, steps or components but do not preclude the addition of one or more additional features, integers, steps, components or groups thereof but only if the additional features, integers, steps, components or groups thereof do not materially alter the basic and novel characteristics of the claimed composition, device or method.

As used herein, the indefinite articles "a" and "an" mean "at least one" or "one or more".

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIG. 1 (prior art) is a schematic depiction of a healthy heart in cross section;

FIGS. 2A and 2B (prior art) depict a mitral valve of a healthy heart;

FIGS. 3A and 3B (prior art) depict a mitral valve of a heart suffering from ischemic mitral regurgitation related to incomplete coaptation of the leaflets of the mitral valve;

FIGS. 4A-4I depict a membrane augmenting stapler of the present invention and a use thereof for augmenting a mitral anterior leaflet;

FIG. 5A depicts cardiac valve leaflet augmentation in accordance with the teachings of copending PCT patent application identified by Attorney Docket No. 39351 using an annuloplasty ring with an associated membrane;

FIGS. 5B-5C depict mitral valve displacement in accordance with the teachings of copending PCT patent application identified by Attorney Docket No. 39351 using an annuloplasty ring with an associated membrane;

FIG. 5D depicts mitral valve displacement in accordance with the teachings of copending PCT patent application identified by Attorney Docket No. 39351 using a substantially tubular implant;

FIGS. 6A and 6B depict an embodiment of a cardiac valve periphery stapler including a multipart anvil comprising two anvil parts;

FIGS. 6C-6F depict an embodiment of a method of displacing a mitral valve with the help of a tubular implant where the mitral valve is secured to the implant with the help of the cardiac valve periphery stapler depicted in Figures 6A and 6B.

FIG. 7 depicts a multipart anvil of an embodiment of a cardiac valve periphery stapler comprising two anvil head parts neither of which includes a substantial portion of an anvil stem;

FIG. 8A depicts an embodiment of a valve displacement stapler of the present invention;

FIG. 8B depicts an embodiment of a cutting blade for use with a stapler of Figure 8A;

FIG. 8C depicts a frustoconical implant useful as an implant used in conjunction with a stapler of Figures 8A;

FIGS. 8D-8J depict an embodiment of a method of displacing a mitral valve with the help of a tubular implant where the mitral valve is secured to the implant with the help of the valve displacement stapler depicted in Figures 8A and 8B; and

FIGS. 9A-9G depicts fasteners useful in implementing the teachings of the present invention.

DESCRIPTION OF EMBODIMENTS

The present invention relates to methods and devices for tissue augmentation that in embodiments are useful for improving cardiac leaflet coaptation, especially of the mitral valve. Generally, according to the teachings of the present invention the subvalvular apparatus is preserved.

Embodiments of the present invention successfully address at least some of the shortcomings of the prior art by providing a simple method of augmenting membranes such as cardiac valve leaflets. Thus, the teachings of the present invention allow a cardiac leaflet to be augmented and therefore embodiments are useful for treating a condition where cardiac valve augmentation is beneficial, such as mitral valve insufficiency, for example ischemic mitral regurgitation.

Embodiments of the present invention successfully address at least some of the shortcomings of the prior art by providing a simple method of augmenting the tissue around a cardiac valve. In embodiments, this leads to cardiac valve displacement that improves leaflet coaptation and may be useful for treating ischemic mitral valve regurgitation. Thus, the teachings of the present invention allow a cardiac valve to be displaced and therefore embodiments are useful for treating a condition where cardiac valve displacement is beneficial, such as mitral valve insufficiency, for example ischemic mitral regurgitation.

By treating a condition is meant curing the condition, treating the condition, preventing the condition, treating symptoms of the condition, curing symptoms of the condition, ameliorating symptoms of the condition, treating effects of the condition, ameliorating effects of the condition, and preventing results of the condition.

As is understood from the above, embodiments of the present invention are useful in augmenting membranes, especially cardiac valve leaflets, especially for treating a condition where cardiac valve augmentation is beneficial and are also useful in displacing a cardiac valve especially for are useful for treating a condition where cardiac valve displacement is beneficial. In order to simplify understanding the teachings of the present invention embodiments of the present invention will be

discussed in the context of treating a mitral valve suffering from ischemic mitral regurgitation where the teachings of the present invention are directed to increasing leaflet coaptation and thus treat the ischemic mitral regurgitation.

Embodiments of the present invention relate to surgical fastening devices that project lockable fasteners such as staplers and components thereof useful in performing tissue augmentation and quickly and efficiently. In order to simplify understanding the teachings of the present invention embodiments of the present invention will be discussed with reference to surgical staplers, fastening devices that implant staples in the body in order to fasten or secure tissue. As is discussed below, in embodiments surgical fastening devices that deploy fasteners other than staplers are also useful in implementing the teachings of the present invention.

Staples are lockable fasteners well-known in the art. A typical staple consists of a length of wire or the like bent so as to describe a square U-shape, having two parallel legs and a perpendicular connecting crown, where the tips of the two legs constitute piercing elements.

A stapler is a device configured to drive and clinch one or more staples simultaneously through at least two layers of membrane in order to secure the layers together. The staples are held inside a staple magazine in a stapler body with the piercing elements pointing outwards of a staple ejection slot. Positioned across from the ejection slot at some distance is an anvil provided with clinching grooves across from each piercing element to act as a counterpoise.

For use, layers to be secured are pinched between the staple ejection slot and the anvil so that the piercing elements are perpendicular to the surface of the layers. When the stapler is activated, a drive blade presses downwards on the staple crown applying a force parallel to the axis of the piercing elements, driving the piercing elements down through the layers until the piercing elements clear the last of the layers and enter the clinching grooves. As the drive blade presses downwards further, the piercing elements and the legs are forced to curve inwards so that the staple is bent into a loop shape where the layers are clamped between the curved legs and the staple crown, locking the staple

Surgical staplers are well known in the art, see for example, Examples of prior art surgical staplers of the type described can be found in U.S. Patent Nos. 2,853,074, 3,874,384, 3,079,608, 3,225,996, 3,489,330, 3,604,561 and 3,873,016.

Membrane Augmentation such as Cardiac Leaflet Augmentation

A first embodiment of the present invention relates to augmentation of membrane such as a cardiac leaflet, for example a posterior mitral valve leaflet. An embodiment of membrane augmentation in accordance with a method of the present invention is discussed with reference to Figures 4A-4I.

An embodiment of a surgical fastening device, such as a membrane augmenting stapler **52** depicted in Figures 4A-4I, is provided allowing quick cardiac leaflet augmentation where, with one simple stapling action a leaflet is slit and a periphery of an implant that acts as a patch secured to the periphery of the slit.

In Figure 4A is depicted a distal end of stapler body **54** of membrane augmenting stapler **52** from below showing an anvil attachment tube **56**, a cutting edge **58** of a cutting blade **60** positioned inside an implant container **62** and an oblate elliptical staple ejection ring **64** surrounding implant container **62**.

In Figure 4B is depicted an anvil **66** of membrane augmenting stapler **52** viewed from above. On a top surface **68** of an anvil head **70** is apparent blade-accepting slot **72** surrounded by clinching groove ring **74**. Attached to anvil head **70** by crosspiece **76** is anvil stem **78** configured to reversibly lockingly engage anvil attachment tube **56** of stapler body **54**.

In Figure 4C is depicted anvil **66** coupled to stapler body **54** in cross-section where stem **78** engages anvil attachment tube **56** so that blade-accepting slot **72** is positioned across from cutting blade **60** and clinching groove ring **74** is positioned across staple ejection ring **64**. Held inside implant container **62** and surrounding cutting blade **60** is patch **80** of tissue as a membrane augmenting implant, which edges **82** project outwards past staple ejection ring **64** to be held flush against the bottom face of distal end **54**.

Distal end of stapler body **54** is circular and configured to fit inside a mitral valve lumen, having a diameter of about 3 cm.

Cutting blade **60** is a 3 mm high, 2 cm long and 0.3 mm thick stainless steel strip sharpened to define a 50 micron broad cutting edge **58**. Fixed (e.g., by laser welding) on the side of cutting blade **60** opposing cutting edge **58** is curved implant shield **84** fashioned of a 0.5 mm thick, 2 cm long and 2 mm broad sheet of stainless steel.

Inside stapler magazine **63** which opens out to constitute staple ejection ring **64** are held plurality (e.g., 12) staples **86** of 0.5 mm broad 0.5 mm thick stainless steel wire bent in a square U-shape with legs pointing towards staple ejection ring **64** and with crowns of staples **86** contacting a drive blade **92** of membrane augmenting stapler **52**.

Patch **80** is a 1 cm wide by 2.5 cm long patch of commercially-available cross-linked bovine pericardium pushed into implant container **62** between a knife driver **94** and implant shield **84** of cutting blade **60** so that cutting blade **60** is contained within implant container **62** and nestled in patch **80**. Patch **80** is held flush with the distal end of stapler body **54** with the help of a tacky biocompatible adhesive (as well known in the art, see for example U.S. Patent Nos. 6,126,919 or 6,325,810). It is seen that patch **80** is buckled to accommodate cutting blade **60**.

For use, a mitral valve **26** of a subject having ischemic mitral regurgitation, e.g., as depicted in Figures 3, is exposed. For example, as described in Kincaid et al, mitral valve **26** is exposed through a median sternotomy, aortic and bicaval cannulation, moderate hypothermic cardiopulmonary bypass, and cold-blood retrograde cardioplegia. Alternative approaches include right or left thoracotomies. During the procedure, the heart may be fibrillating or arrested. Mitral valve **26** is exposed in the usual way, for example right-sided or left-sided left atriotomy, a transseptal incision with or without left atrial roof opening.

As depicted in Figure 4D, anvil is maneuvered through mitral valve annulus **34** and between chordae **46** to be placed underneath anterior leaflet **38**. Stem **78** engages anvil attachment tube **56** and is locked in place so that anterior leaflet **38** is located between stapler body **54** and anvil head **70**.

In Figure 4E, membrane augmenting stapler **52** is triggered in the usual way, pulling anvil head **70** and the distal end of stapler body **54** together to clamp anterior leaflet **38** therebetween. In such a way, patch **80** is placed against leaflet **38** so as to define an overlap region of patch **80** with leaflet **38**. Cutting edge **58** of cutting blade **60** is directed towards the region circumscribed by the overlap region while legs **88** of staples **86** are directed towards the overlap region. Substantially simultaneously, drive blade **92** presses against crowns **90** of staples **86**, forcing staples **86** out of the stapler magazine so that legs **88** to penetrate patch **80** near patch edges **82** in the overlap region and subsequently to pass through anterior leaflet **38**. Substantially

simultaneously, knife driver **94** presses against implant shield **84** through patch **80**. Implant shield **84** prevents cutting blade **60** from damaging patch **80** and rather cutting blade **60** is forced downwards to slice into anterior leaflet **38**.

In Figure 4F, legs **88** of staples **86** are depicted having penetrated through patch **80** and anterior leaflet **38** to enter clinching groove ring **74** while cutting blade **60** is depicted having cut clear through anterior leaflet **38**.

In Figure 4G, as drive blade **92** and knife driver **94** descend further, cutting blade **60** is pushed down to fall into blade accepting slot **72** while legs **88** of staples **86** are bent by contact with clinching groove ring **74** to curve inwards, forcing staples **86** into a loop shape that substantially clamps and holds together anterior leaflet **38** and patch **80**.

In Figure 4H, the trigger of membrane augmenting stapler **52** is released, allowing stapler body **54** and anvil head **70** to move apart and away from anterior leaflet **38** augmented with patch **80**. Anvil **66** is disengaged from stapler body **54** and maneuvered out from between chordae **46** and out through mitral lumen **36** together with cutting blade **60**.

As depicted in Figure 4I, the augmentation of anterior leaflet **38** improves coaptation, in analogy to the disclosed in Kincaid et al.

In embodiments, a mitral valve annulus supporting device such as an annuloplasty ring is deployed to reshape the mitral annulus in addition to augmentation of the valve leaflet as discussed above, whether prior or subsequent to the augmentation.

An embodiment of the teachings of the present invention has been discussed above with reference to augmentation of an anterior leaflet **38** of a mitral valve **26** as such embodiments may prove useful in treating ischemic mitral regurgitation, a common pathological condition. In non-depicted embodiments other cardiac leaflets are augmented in an analogous fashion, such as a mitral valve posterior leaflet **40** or leaflets of other cardiac valves such as of a tricuspid valve **16**, a semi-lunar valve **20** or an aortic semi-lunar valve **30**. In embodiments a membrane other than a cardiac valve is augmented.

Membrane augmenting stapler **52** discussed above is configured to produce and patch a single straight slit in a membrane, for example by the fact that cutting blade **60** is straight. In non-depicted embodiments, a membrane augmenting fastening

device of the present invention is configured to produce and patch a curved slit, for example by including a curved cutting blade. A mitral valve leaflet that is augmented in accordance with the teachings of the present invention with the help of an implant secured to patch a curved slit is forced to buckle upwards which, in embodiments, provides an exceptionally high degree of coaptation.

Membrane augmenting stapler **52** discussed above is configured to augment a membrane such as a posterior leaflet of a mitral valve with an asymmetrically oblate elliptical graft, for example, by the fact that staple ejection ring **64** defines an asymmetrically oblate elliptical closed curve. In non-depicted embodiments, a membrane augmenting fastening device of the present invention is configured to augment a membrane with an implant having an alternative shape. Alternative shapes include, but are not limited to, circles, ellipses, ovals, ovoids as well as symmetrically and asymmetrically oblate ovals, ellipses or circles.

In some cases, it is not convenient for a medical professional such as a surgeon to associate, immediately before a surgical procedure, an implant such as **80** and a cutting blade such as **60** with a fastening device **52** as described above. In embodiments, a cartridge comprising a cartridge body, a staple magazine including a staple ejection ring loaded with staples, and an implant container containing an implant and a cutting blade, substantially as described above is provided, that is to say a cartridge comprising an implant container containing an implant surrounding a cutting blade so that a cutting edge of the blade faces outwards from the container In embodiments, such a cartridge also comprises a knife driver and/or a staple drive blade. Preferably, such a cartridge is provided packaged and sterile for use. Such a cartridge is configured to be secured to a properly configured fastening device and then used substantially as described above.

Stapler useful for cardiac valve attachment

As noted above and depicted in Figures 3, in a heart **50** suffering from ischemic mitral regurgitation mitral valve **26** and associated chordae **46** and **48** are patent. The insufficient coaptation of leaflets **38** and **40** that leads to the regurgitation of blood is a result of deformation of mitral valve annulus **34** and misdirected pulling forces applied through chordae **46** and **48** to leaflets **38** and **40**, both resulting from

necrosis and consequent deformation of the wall of left ventricle **28**. In such cases, the regurgitation may be treated by improving leaflet coaptation.

In copending PCT patent application identified by Attorney Docket No. 39351 of the Inventor are disclosed annuloplasty rings including a membrane that at least partially covers the lumen of the annuloplasty ring. Therein is taught, and as is depicted in Figure 5A, that a mitral valve leaflet **38** is detached, an annuloplasty ring **91** with an attached membrane **93** implanted in the usual way, attached membrane **93** trimmed to cover a sector defined by a chord having a length approximately that of detached leaflet **38**, and leaflet **38** reattached to membrane **93** effectively augmenting leaflet **38**, that in embodiments such as depicted in Figure 5A improves leaflet coaptation **42**.

In copending PCT patent application identified by Attorney Docket No. 39351 of the Inventor are also disclosed annuloplasty rings including an annular membrane that at least partially covers the lumen of the ring and has a central void through the membrane defining a lumen. Therein is taught, and as is depicted in Figure 5B, that a mitral valve **26** is detached intact from a respective mitral valve annulus, so as to leave the valve leaflets **38** and **40** associated through commissures **41**. An annuloplasty ring **91** is implanted in the usual way. Membrane **93** is trimmed so that the lumen therethrough is approximately the size of detached mitral valve **26**. The periphery of mitral valve **26** is secured near an inner rim of membrane **93**. In such a way, the tissue surrounding mitral valve **26** is augmented and mitral valve **26** displaced and allowed to settle downwards into left ventricle **28**, which allows realignment of leaflets **38** and **40** that, in embodiments such as depicted in Figure 5C, improves leaflet coaptation **42**.

In copending PCT patent application identified by Attorney Docket No. 39351 of the Inventor a similar augmentation of tissue surrounding a mitral valve is achieved with a substantially tubular implant which includes an annuloplasty ring at neither, either or both a proximal end (attached to mitral valve annulus) or distal end (to which mitral valve is attached). In Figure 5D is depicted tubular implant **95** including an annuloplasty ring **97** at distal end **99** to which mitral valve **26** is attached and not at proximal end **101** attached to mitral valve annulus **34**.

The three above-discussed procedures, as well as other procedures known in the art such as the implantation of prior art annuloplasty rings, require placing many

sutures around the entire periphery of both a mitral valve annulus and of the outer edge of the circular implant. Further, for the procedures taught in copending PCT patent application identified by Attorney Docket No. 39351 where an intact mitral valve is displaced, implantation requires placing many sutures around the periphery of the mitral valve and the inner rim of the membrane or the distal end of the tubular implant. Such suturing is difficult and time consuming. It is not simple to tension all sutures equally. It is not simple to evenly distribute the sutures about the mitral valve, the mitral valve annulus and/or the implant such that there is no deformation. Thus, it is possible that attachment will be incorrect, providing less than ideal results which may lead, for example, to leakage.

In an embodiment of the present invention, a mitral valve periphery stapler is provided allowing quick and/or simple and/or accurate securing of a mitral valve (e.g., an intact mitral valve) to an implant (such as an annular graft, an annuloplasty ring as described above or a tubular implant as described above or the like). The utility of a mitral valve periphery stapler of the present invention results, in part, from an anvil head which allows maneuvering of the anvil head between the mitral valve chordae. An embodiment of such a mitral valve periphery stapler useful for securing a mitral valve detached from a respective mitral valve annulus to an implant such as taught in copending PCT patent application identified by Attorney Docket No. 39351 is discussed with reference to Figures 6A-6F.

In Figure 6A is depicted a distal end of stapler body **54** of mitral valve periphery stapler **96** from below showing two concentric circular staple ejection rings **64** surrounding an anvil-engaging pin **98**.

In Figure 6B are depicted the two parts **100a** and **100b** of a two-part anvil **100** of mitral valve periphery stapler **96**, separated (above) as well as assembled to constitute a single anvil (below). First part **100a** of anvil **100** of mitral valve periphery stapler **96** includes a portion **78a** of stem **78**, a crosspiece **76a** protruding at a 30° angle downwards from perpendicular from stem portion **78a** to attach to one end of anvil head portion **104a**. Second part **100b** of anvil **100** of mitral valve periphery stapler **96** includes a portion **78b** of stem **78**, a crosspiece **76b** protruding at a 30° angle downwards from perpendicular from stem portion **78b** to attach to one end of anvil head portion **104b**. Each of anvil head parts **104a** and **104b** constitute a 180° sector of anvil head **104**.

Anvil parts **100a** and **100b** are configured to mate, together constituting an anvil **100** having a circular planar anvil head **104**. When mated, on top surface **68** of anvil head **104** are apparent two concentric clinching groove rings **74**. When mated, threads **106** are constituted at the end of stem **78**. A distal end **107** of a stem extension piece **108** is configured to engage threads **106** holding anvil parts **100a** and **100b** together. Further, a proximal end **109** of stem extension piece **108** is configured to reversibly lockingly engage anvil engaging pin **98**.

Analogously to the discussed above for membrane augmenting stapler **52**, when anvil **100** (assembled by joining anvil parts **100a** and **100b**) and stapler body **54** of mitral valve periphery stapler **96** are associated through stem extension piece **108** by engaging anvil engaging pin **98** with proximal end **109** of stem extension piece **108** and by screwing distal end **107** of a stem extension piece **108** over threads **106** of anvil **100**, clinching groove rings **74** are positioned across staple ejection rings **64**.

In embodiments, staple ejection rings **64** are circular and of a diameter that is suitable for fastening a desired implant to the periphery of an intact detached mitral valve **26** as is discussed below (e.g., 45 mm). Consequently, the distal end of stapler body **54** is generally small enough to pass through a mitral valve annulus.

Analogously to the discussed above with reference to membrane augmenting stapler **52**, inside both staple magazines **63** opening out to constitute staple ejection rings **64** of mitral valve periphery stapler **96** are held a plurality of staples **86** of 1 mm broad 0.5 mm thick stainless steel wire bent in a square U-shape with legs **88** pointing towards a staple ejection ring of a staple ejection ring **64** and with crowns **90** of staples **86** contacting one of two drive blades **92** of mitral valve periphery stapler **96**, each drive blade associated with one of the two stapler magazines **63** and staple ejection rings **64**.

For use, a mitral valve **26** of a subject having ischemic mitral insufficiency, e.g. as depicted in Figures 3, is exposed in the usual way as discussed above.

Mitral valve **26** is detached intact from mitral valve annulus **34**, so as to leave the valve leaflets **38** and **40** associated through commissures **41** with subvalvular apparatus including chordae **46** and **48** intact. Each of anvil head parts **104a** and **104b** of anvil **100** is separately passed through mitral valve annulus **34** and mitral valve lumen **36** and maneuvered with a rotating motion around chordae **46** and **48** so that stem portions **78a** and **78b** remain in left atrium **24**.

In Figure 6C, anvil parts **100a** and **100b** are mated so as to constitute an assembled anvil **100** where chordae **46** and **48** are encircled by annular anvil head **104**. Stem extension piece **108** is screwed onto stem **78** to engage threads **108** so as to hold anvil **100** together. A tubular implant **110** such as taught in copending PCT patent application identified by Attorney Docket No. 39351 and similar to implant **95** depicted in Figure 5D is placed over stem extension piece **108** and stem **78** of anvil **100** so that a distal end **112** is nearer anvil head **104** than a proximal end **114**.

In Figure 6D, anvil engaging pin **98** of stapler body **54** is coupled to the distal end of stem extension piece **108** so that the periphery of mitral valve **26** and distal end **112** of tubular implant **110** is located between stapler body **54** and anvil head **100**.

Once assembled as depicted in Figure 6D, mitral valve periphery stapler **96** is triggered in the usual way, pulling anvil head **100** and the distal end of stapler body **54** together to clamp the periphery of mitral valve **26** therebetween. Substantially simultaneously, the two drive blades **92** press against crowns **90** of staples **86**, forcing legs **88** to penetrate tubular implant **110** and to pass through mitral valve **26**.

Analogously to the discussed above with reference to membrane augmenting stapler **52**, legs **88** of staples **86** pass through tubular implant **110** and mitral valve **26**. and are bent inwards by contact with clinching groove rings **74** to curve inwards, forcing staples **86** into a loop shape that substantially clamps and holds together tubular implant **110** and mitral valve **26**. Mitral valve periphery stapler **96** is released, allowing stapler body **54** and anvil head **100** to move apart. Stem extension piece **108** is disengaged from stapler body **54** and unscrewed from stem **78**. Anvil head **104** is taken apart and anvil head parts **104a** and **104b** removed through lumen **36** of mitral valve **26**.

In Figure 6E, mitral valve **26** is depicted secured to distal end **112** of tubular implant **110** with two concentric circles of staples **86**.

In Figure 6F, proximal end **114** of tubular implant **110** is depicted secured to mitral valve annulus **34** in the usual way with sutures. As depicted above in Figure 5C, such displacement of mitral valve **26** improves mitral valve leaflet coaptation.

As discussed above, mitral valve **26** is first detached from mitral valve annulus **34** and subsequently secured to an implant (distal end **112** of tubular implant **110**). In embodiments, a mitral valve is first secured to an implant, for example in accordance

with the teachings of the present invention, and subsequently detached from a mitral valve annulus.

As discussed above, distal end **112** of tubular implant **110** is first secured to a mitral valve **26** and subsequently proximal end **114** is secured to mitral valve annulus **34**. In embodiments, a proximal end of a tubular implant is first secured to a mitral valve annulus and subsequently a distal end of a tubular implant is secured to a mitral valve.

Mitral valve periphery stapler **96** discussed above is configured and used to attach the annular distal end **112** of tubular implant **110** such as disclosed in copending PCT patent application identified by Attorney Docket No. 39351 to the periphery of an intact mitral valve detached from a respective mitral valve annulus. In non-depicted embodiments, a mitral valve periphery stapler such as **96** is used to attach the inner rim of an annular implant such as disclosed in copending PCT patent application identified by Attorney Docket No. 39351 or the inner rim of an annular graft (e.g., a ring of tissue) to the periphery of an intact mitral valve detached from a respective mitral valve annulus, substantially in accordance with the teachings of copending PCT patent application identified by Attorney Docket No. 39351. In analogy to the discussed immediately hereinabove, in embodiments, an outer periphery of an annular implant is first secured to a mitral valve annulus and subsequently an inner rim is secured to a mitral valve.

In mitral valve periphery stapler **96** discussed above, annular anvil head **104** of anvil **100** is split into two parts **104a** and **104b**, each defining an equal 180° sector of annular anvil head **104**. In embodiments, each part of an annular anvil head defines a different sized sector.

In mitral valve periphery stapler **96** discussed above, annular anvil head **104** of anvil **100** is split into two parts **104a** and **104b**. In embodiments, an annular anvil head is split into more than two parts, e.g., three, four, five, six or even more parts.

In mitral valve periphery stapler **96** discussed above, stem **78** of anvil **100** is split and is made up of two parts **78a** and **78b** that are parts of anvil parts **100a** and **100b**, respectively. In embodiments, a stem of a multi-part anvil is a single piece that is not split, see below.

In mitral valve periphery stapler **96** discussed above, parts of stem **78** of anvil **100** are a part **100a** or **100b** of anvil **100** that comprises a part **104a** or **104b** of anvil

head **104**. In embodiments, a stem is a separate component that is not a part of an anvil that comprises a part of an anvil head, as depicted in Figure 7.

In mitral valve periphery stapler **96** discussed above, crosspieces **76a** or **76b** protrude at a 30° angle downwards from perpendicular from a respective stem portion **78a** or **78b** to attach to one end of anvil head portion **104a** or **104b**. In embodiments, crosspieces protrude downwards from perpendicular at an angle different from 30°. In embodiments, crosspieces protrude upwards from perpendicular. In embodiments, crosspieces protrude substantially perpendicularly from stem **78**, see below.

In mitral valve periphery stapler **96** discussed above, top surface **68** of anvil head **104** defines a plane substantially perpendicular to stem **78**. In embodiments, a plane defined by a top surface of an anvil head is not perpendicular to a respective stem but is tilted, in embodiments up to about 30° and even up to about 60° relative to the stem. In embodiments, such tilting makes maneuvering of the anvil head parts through a mitral valve lumen more convenient.

In mitral valve periphery stapler **96** discussed above, top surface **68** of anvil head **104** is substantially planar. In embodiments, a top surface of an anvil head is not planar. For example, in embodiments, top surface **68** has a saddle contour similar to that of a patent mitral valve annulus.

In mitral valve periphery stapler **96** discussed above, crosspieces **76a** and **76b** attach to one end of an anvil head portion **104a** and **104b** respectively. In embodiments, a crosspiece attaches to a respective anvil head portion not at an end of an anvil head portion rather, for example, in the middle of a respective anvil head portion, see below.

In mitral valve periphery stapler **96** discussed above, anvil head **104** and stapler body **54** are configured to attach an implant with the help of two concentric circular rows of staples. In embodiments, a stapler of the present invention is configured to attach an implant with the help of one row of staples, as depicted in Figure 7. In embodiments, a stapler of the present invention is configured to attach an implant with the help of three or more rows of staples.

In mitral valve periphery stapler **96** discussed above, anvil head **104** and stapler body **54** are configured to attach an implant with the help of substantially circular rows of staples. In embodiments, an anvil head and stapler body are configured to attach an implant with the help of one or more rows of staples that

define a closed curve that is not a circle, for example an oval, an ellipse, an ovoid, or a symmetrically or asymmetrically oblate circle, oval or ellipse.

Stapler useful for augmentation of tissue around a cardiac valve

As noted above and depicted in Figures 5B and 5C, in copending PCT patent application identified by Attorney Docket No. 39351 is disclosed the augmentation of the tissue around an intact mitral valve allowing displacement of the mitral valve with the help of a substantially annular membrane. As noted above and depicted in Figures 5D and 6F, in copending PCT patent application identified by Attorney Docket No. 39351 is disclosed the augmentation of the tissue around an intact mitral valve allowing displacement of the mitral valve with the help of a substantially tubular implant. In both cases, the displacement allows the mitral valve to settle downwards into the left ventricle, which allows realignment of the leaflets and chordae that in embodiments improves leaflet coaptation as depicted in Figures 5C and 5D

In embodiments of the present invention, features discussed hereinabove are combined in a single fastening device to allow simple and/or repeatable augmentation of the tissue surrounding a cardiac valve as discussed above. Specifically, a fastening device is provided including a cutting blade configured to produce a cut in the shape of a closed curve that is contained between two rows of lockable fasteners such as staples, each row defining a closed curve. With one action, e.g., one triggering of the fastening device:

1) native leaflets of a valve are attached to one edge of an implant (e.g., an inner edge of an annular implant or a distal end of a tubular implant);

2) another edge of an implant (e.g., an outer edge of an annular implant or a proximal end of a tubular implant) is attached to the native valve annulus or tissue near the annulus; and

3) the native leaflets are detached from the native annulus.

An embodiment of a surgical fastening device allowing augmentation of tissue surrounding a cardiac valve in accordance with the teachings of the present invention, stapler **116** is discussed with reference to Figures 8A-8J.

In Figure 8A is depicted a distal end of stapler body **54** of stapler **116** in partial cross section engaged with a first part **118a** of two-part anvil **118** and a second part **118b** of anvil **118** not attached thereto.

First part **118a** of anvil **118** includes a one-piece stem **78** from which protrudes a crosspiece **76a** which connects to the middle of a first semicircular part **104a** of anvil head **104** so that top surface **68** of anvil head **104** is perpendicular to stem **78**. Second part **104b** of anvil head **104** substantially comprises a crosspiece **76b** which connects to the middle of a semicircular part **104b** of anvil head **104**. Second part **118b** includes two slots **120** and a peg **122** which are configured to slidingly engage, respectively, tabs **124** and a hole **126** in first part **104a** of anvil head **104**. Both anvil-head parts **104a** and **104b** are semicircular and comprise a 180° sector of assembled anvil head **104**. Apparent on top surface **68** of anvil head parts **104a** and **104b** is an outer staple clinching groove ring **130b**, encircling a circular blade accepting slot **128**, encircling an inner staple clinching groove ring **130b**.

In stapler body **54** are seen an outer staple magazine **131a** opening out to constitute an outer staple ejection ring **132a** (45 mm diameter) opposite outer staple clinching groove ring **130b**, encircling circular implant container **134** (42.5 mm diameter) opposite circular blade accepting slot **128**, encircling an inner staple magazine **131b** opening out to constitute an inner staple ejection ring **132b** (41.5 mm diameter) opposite inner staple clinching groove ring **130b**. Distal end of stapler body **54** is circular and configured to fit inside a mitral valve lumen, having a diameter of about 50 mm.

Inside staple magazines **131a** and **131b** associated with staple ejection rings **132a** and **132b** are held a plurality of staples **86** of 0.5 mm broad 0.5 mm thick square cross-section stainless steel wire bent in a square U-shape with legs **88** pointing towards the opening of staple ejection rings **132a** and **132b** and with crowns **90** of staples **86** contacting drive blades **92a** and **92b**, respectively, of stapler **116**.

Inside circular implant container **132** are cutting blade **136**, implant shield **138** and a frustoconical graft **140**, which contacts knife driver **142**.

Cutting blade **136**, Figure 8B, is a 2 mm high and 0.5 mm thick 272 mm long flexible stainless steel strip sharpened to define a 50 micron broad cutting edge **58** and bent into a circle to fit inside circular implant container **134** so that the two ends of

cutting blade **136** abut. Implant shield **138** is a 250 mm long flexible Nitinol wire with a 1.5 mm diameter and a 0.5 mm axial slot configured to accept cutting blade **136**.

Frustoconical implant **140**, Figure 8C, is a 6 mm (dimension *a*) broad strip of commercially available 0.5 mm thick crosslinked serous tissue such as bovine pericardium fashioned in the usual way (e.g., with the help of adhesive or sutures) to form the frustoconical shape of implant **140** 5.4 mm high (dimension *b*), a proximal end **144** of 46 mm (dimension *c*) and a distal end **146** of 40.5 mm (dimension *d*).

As seen in Figure 8A, frustoconical implant **140** is pushed into implant container **134** between a knife driver **142** on one side and implant shield **138** / cutting blade **136** on another side so that implant **140** is buckled and cutting blade **136** nestled therein. Proximal end **144** of implant **140** projects outwards past outer staple ejection ring **132a**. Distal end **146** of implant **140** projects inwards past inner staple ejection ring **132b**. Ends **144** and **146** of implant **140** are held flush with the distal end of stapler body **54** with the help of a tacky biocompatible adhesive.

For use, a mitral valve **26** of a subject having ischemic mitral insufficiency, e.g., as depicted in Figures 3, is exposed in the usual way as discussed above.

In Figures 8D and 8E, each of anvil parts **118a** and **118b** of anvil **118** is separately passed through mitral valve lumen **36** and maneuvered with a rotating motion around chordae **46** and **48** so that stem **78** remains in left atrium **24**. Anvil parts **118a** and **118b** are mated by pushing tabs **124** into slots **120** and peg **122** into hole **126** so as to constitute an assembled anvil **118** where chordae **46** and **48** are encircled by annular anvil head **119**, Figure 8F.

Anvil **118** is engaged with stapler body **54** and locked in place so that anterior leaflet **38** and posterior leaflet **40** are located between stapler body **54** and anvil head **104**.

In Figure 8G, stapler **116** is triggered in the usual way, pulling anvil head **104** and the distal end of stapler body **54** together to clamp leaflets **38** and **40** therebetween.

In such a way, implant **140** is placed against mitral valve **26** so as to define two overlap regions of implant **140** with mitral valve **26**: an outer overlap region closer to mitral valve annulus **34** with proximal end **144** of implant **140** and an inner overlap region closer to the center of mitral valve lumen **36** with distal end **146** of implant **140**. The cutting edge of cutting blade **136** is directed towards the region

between the two overlap regions. Legs **88** of staples **86** held in outer staple magazine **131a** associated with outer staple ejection ring **132a** are directed towards the outer overlap region. Legs **88** of staples **86** held in inner staple magazine **131b** associated with inner staple ejection ring **132b** are directed towards the inner overlap region.

In Figure 8H, substantially simultaneously, drive blade **92a** presses against crowns **90** of staples **86** held in outer staple magazine **131a** associated with outer staple ejection ring **132a**, forcing legs **88** to penetrate implant **140** near proximal end **144** and to pass through leaflets **38** and **40** in the outer overlap region. Substantially simultaneously, drive blade **92b** presses against crowns **90** of staples **86** held in inner staple magazine **131b** associated with inner staple ejection ring **132b**, forcing legs **88** to penetrate implant **140** near distal end **146** and to pass through leaflets **38** and **40** in the inner overlap region. Substantially simultaneously, knife driver **142** presses against implant shield **138** through implant **140**. Implant shield **138** prevents cutting blade **136** from damaging implant **140** and rather cutting blade **136** is forced downwards to slice into leaflets **38** and **40** between the two overlap regions.

Analogously to the discussed above for membrane augmentation stapler **52**, legs **88** of staples **86** penetrate through leaflets **38** and **40** to enter clinching groove rings **130a** and **130b** while cutting blade **136** cuts clear through leaflets **38** and **40**. Ultimately, cutting blade **136** and implant shield **136** fall into blade accepting slot **128** while legs **88** of staples **86** are bent by contact with clinching groove rings **130a** and **130b** to curve inwards, forcing staples **86** into a loop shape that substantially clamps and holds leaflet **38** and **40** together with implant **140**.

Subsequently, the trigger of stapler **116** is released, allowing stapler body **54** and anvil head **104** to move apart and away from leaflets **38** and **40**. Anvil **118** is disengaged from stapler body **54**. Implant shield **138** and cutting blade **136** are dissociated and removed separately, for example with a forceps, from blade accepting slot **128** in anvil **118** and out through lumen **36** of mitral valve **26**.

As depicted in Figure 8I (side cross section), Figure 8J (top view) and analogously to the depicted in Figures 5C and 5D, the tissue surrounding mitral valve **26** is augmented allowing mitral valve **26** to displace downwards into left ventricle **28**, that improves coaptation **42** as discussed above with reference to mitral valve periphery stapler **96**.

Stapler **116** discussed above is configured to augment the tissue surrounding a cardiac valve by excising the valve intact with a circular incision while substantially simultaneously securing an implant to the edges of the excision with two concentric rows of lockable fasteners, one encircling the incision and one encircled by the incision. In embodiments, (one or more of) the incisions and two rows of lockable fasteners are not concentric. In embodiments, (one or more of) the incisions and two rows of fasteners are not circular but have an alternatively-shaped closed curve. Alternative shapes include, but are not limited to, circles, ellipses, ovals, ovoids as wells as symmetrically and asymmetrically oblate ovals, ellipses or circles.

In embodiments of the method of the present invention, a mitral valve annulus supporting device such as an annuloplasty ring to reshape the mitral annulus is deployed to reshape the mitral annulus in addition to displacement of the valve, whether prior or subsequent to displacement of the valve in accordance with the teachings of the present invention.

In the embodiment discussed above, the teachings of the present invention have been discussed with reference to displacement of a mitral valve **26** as embodiments of the present invention may prove useful in treating ischemic mitral regurgitation, a common pathological condition. In non-depicted embodiments other cardiac valves such as of a tricuspid valve **16**, a semi-lunar valve **20** or an aortic semi-lunar valve **30** may be displaced.

In the embodiment discussed above cutting blade **136** is a sharpened stainless steel strip sharpened to define cutting edge and flexible enough to bent into a circle to fit inside circular implant container **134**. In embodiments, a cutting blade is a loop in the shape of a closed curve having sufficient flexibility to be collapsed to an elongated shape (e.g., long and narrow). In such embodiments, the cutting blade is removed from the left ventricle by collapsing to an elongated shape (for example, with forceps) and then pulling out through the mitral valve lumen.

In the embodiment discussed above, the teachings of the present invention have been discussed where a mitral valve is displaced by implantation of a frustoconical tubular implant. In non-depicted embodiments, other shaped implants are implanted including annular implants, tubular implants that are cylindrical and tubular implants that are not frustoconical (distal and proximal ends are not parallel).

Generally a suitable implant includes a wall, the wall delimited by two edges each in the shape of a closed curve and defining a lumen.

In some cases, it is not convenient for a medical professional such as a surgeon to associate, immediately before a surgical procedure, an implant such as **140** and a cutting blade such as **136** with a fastening device such as **116** as described above. In embodiments, a cartridge comprising a cartridge body, an outer fastener magazine functionally associated with an outer fastener ejection ring holding a plurality of staplers directed towards the outer fastener ejection ring; surrounded by the implant container, an implant container in the shape of a closed curve at the distal end including an outwardly directed opening surrounded by the fastener ejection ring; surrounded by the implant container an inner fastener magazine functionally associated with an inner fastener ejection ring holding a plurality of staplers directed towards the inner fastener ejection ring where contained within the implant container, is an implant as described above where a first of the two edges extends outwards beyond the outer fastener ejection ring and a second of the two edges extends inwards beyond the inner fastener ejection ring; and a cutting blade contained within the implant container and nestled in the implant with a cutting edge directed towards the opening of the implant container. In embodiments, such a cartridge also comprises a knife driver and/or a staple drive blade associated with the inner staple magazine and/or a staple drive blade associated with the outer staple magazine. Preferably, such a cartridge is provided packaged and sterile for use. Such a cartridge is configured to be secured to a properly configured fastening device and then used substantially as described above.

It is important to note that a person weighing between 60 and 100 kg has a usual cardiac output of about 4 to 6 l blood / minute and about 15 l blood / minute during maximum effort. It is known that a mitral valve lumen having a diameter of at least about 28 mm diameter is needed to transfer 15 l blood minute without undue stress. Thus, generally it is desirable that the diameter of an inner staple ejection ring such as **132b** or of a staple ejection ring **64** of a mitral valve periphery stapler such as **96** be at least 28 mm in diameter.

Persons suffering from ischemic mitral regurgitation generally have a mitral valve lumen of about 55 mm in diameter. Thus, embodiments of a valve displacement stapler of the present invention, such as stapler **116** having an outer staple ejection

ring such as **132a** less than 55 mm can easily be treated, where some leaflet area is lost.

One skilled in the art of fastening devices such as staplers is able, without undue experimentation, to implement the teachings of the present invention including manufacturing a stapler of the present invention. For example, in embodiments, anvils of staplers of the present invention such as anvil **66**, **100** or **118** are fashioned from a hard material such as known in the field of similar medical devices such as surgical staplers, for example, stainless steel, titanium or alloys thereof.

In the embodiments discussed above, stapler **52** and **116** are configured so that a cutting blade **60** and staples **86** contact tissue substantially simultaneously. That said, in non-depicted embodiments, cutting blade **60** contacts tissue prior to staples **86**. That said, in embodiments, staples **86** contacts tissue prior to cutting blade **60**.

In the embodiments discussed above, a cutting blade **60** is retained in at least a portion of a blade accepting slot **128** so that cutting blade **60** is prevented from falling into the body of a subject (e.g., a left ventricle **28**) during the stapling process. That said, in non-depicted embodiments, cutting blade **60** is not actively prevented from falling into the body of a subject.

In the embodiments discussed above, the implants used in implementing the teachings of the present invention, both the patch of tissue used for augmenting a cardiac leaflet and the lumen-defining implant are fashioned substantially from commercially available cross linked bovine pericardium. When implementing the teachings of the present inventions, the implants, whether as patches, or as lumen-defining implants such as sheets with holes, annuli, tubes or other, may comprise any suitable material or combination of materials, whether synthetic or biological. Preferably at least one material from which an implant is fashioned is impermeable to prevent the flow of blood through the implant once implanted.

Typical synthetic materials suitable for fashioning an implant of the present invention include but are not limited to fluorinated hydrocarbons such as polytetrafluoroethylene, urethane, elastomer, polyamide and polyester.

Sources of typical biological materials suitable for fashioning an implant of the present invention include but are not limited to materials from a human source, an equine source, a porcine source or a bovine source. In embodiments, biological materials used for fashioning an implant of the present invention include but are not

limited to autologous tissue, homologous tissue and heterologous tissue. Specific examples include venous tissue, arterial tissue, serous tissue, dura mater, pleura, peritoneum, pericardium and aortic leaflet.

In the embodiments discussed above, the lockable fasteners, staples **86**, are substantially of stainless steel. In non-depicted embodiments, lockable fasteners are fashioned from a material other than stainless steel that is suitable for implantation in the body. Suitable materials from which to fashion lockable fasteners used in implementing the teachings of the present invention include metals such as stainless steel, silver, silver alloys and titanium alloys as well as non-metal, plastic and polymer materials, see for example, U.S. Patent No. 5,324,307 and references cited therein.

In the embodiments discussed above, the lockable fasteners, staples **86**, are substantially of a square U-shape. In embodiments, staples **86** are of a different shape, for example of a skewed square U-shape, a rounded U-shape or an M-shape (Figure 9A).

In the embodiments discussed above, the lockable fasteners used to implement the teachings of the present invention are staples having two functionally associated legs that penetrate tissue where locking is achieved by deforming the staple, that is bending together of the legs to clamp layers of tissue together. In embodiments, alternative types of lockable fasteners are used in implementing the teachings of the present invention. Generally, lockable fasteners useful in implementing the teachings of the present invention, when implanted, have no part that extends beyond, extends over or encircles an edge of treated membranes but rather pass through the membranes. Generally, lockable fasteners useful in implementing the augmentation of the tissue surrounding a cardiac valve, when implanted, have no part that extends beyond, extends over or passes through a valve lumen so as to avoid substantial interference with leaflet functioning.

In embodiments, alternative lockable fasteners are, like staples, configured to lock by deformation and include, but are not limited to, fasteners such as cotter pins (e.g., Figure 9B), studs (e.g., Figure 9C) and rivets (e.g., Figure 9D). One skilled in the art is able, upon perusal of the specification, to modify the teachings of the present invention to fashion a fastening device that uses an alternative lockable fastener, such

as the listed above, including with the appropriately configured anvil to deform the fastener.

In embodiments, alternative lockable fasteners are configured to lock by engaging a discrete locking component such as retaining rings, constricting rings and unidirectional locking rings and include, but are not limited to two-part rivets (e.g., Figure 9E). One skilled in the art is able, upon perusal of the specification, to modify the teachings of the present invention to fashion a fastening device that uses an alternative fastener that locks with the help of a locking component, such as the listed above. In such embodiments, instead of, or together with, an anvil that acts as a counterpoise to deform a fastener, an analogous component is used which functions as a "tray" to align and orient locking components to allow coupling of a fastener with a respective locking component.

In the embodiments discussed above, a fastening device such as a stapler is configured to implant a plurality of discrete lockable fasteners to define a closed curve. In embodiments, a fastening device is configured to implant a single lockable fastener defining a closed curve, where the single fastener is provided with three or more piercing members. In such embodiments, a fastener comprises a) a loop-shaped body with a bottom side defining a lumen and describing at least a 320° sector about an axis; and b) at least three (in embodiments, four, five, six and even more, e.g., 10 or 20) of elongated piercing elements protruding from the bottom side substantially parallel to the axis.

In embodiments, the loop-shaped body describes at least a 340° sector about the axis and even a complete loop about the axis.

In embodiments, the fastener is lockable by deformation of the (preferably by bending, preferably in a direction tangential to the body) upon sufficiently forceful contact with an anvil when projected from an appropriately configured fastening device so as to lock in place in a manner analogous to a staple, see for example, the lockable fastener depicted in Figure 9F comprising a loop-shaped body describing a complete closed curve (a circle).

In embodiments, the fastener is lockable by securing at least one discrete locking component to the piercing elements. For example, the lockable fastener depicted in Figure 9G comprises a loop-shaped body describing a 340° sector of a closed curve (a circle) and is configured to be locked by passing the piercing elements

through the holes (provided with pawls to allow only unidirectional passage of the piercing elements) in a one-piece locking ring (split to allow maneuvering around the chordae) which is discrete from the fastener body.

For treating human subjects suffering, for example, from mitral insufficiency, in accordance with the teachings of the present invention it is preferred that the lumen of such a lockable fastener have a diameter of at least about 25mm and even at least about 28 mm to allow for sufficient flow of blood therethrough. For treating human subjects suffering, for example, from mitral insufficiency, in accordance with the teachings of the present invention, it is preferred that the loop-shaped body have an outer diameter of not more than about 60 mm, and even not more than 55 mm, to allow implantation in a mitral valve annulus without discomfort or damage.

In embodiments, the loop-shaped body and/or the piercing elements are between about 0.1 mm and about 2 mm broad in a radial direction from the axis, which are typical dimensions for surgical staples.

In an embodiment exceptionally useful for implementing augmentation of tissue surrounding a cardiac valve with the help of embodiments of devices of the present invention similar to stapler **116**, a set of at least two lockable fasteners such as above is provided, where the two fasteners are coaxially nestable, so that when coaxially nested, a coaxial gap between the outer edge of the body of the smaller fastener and the inner edge of the body of the larger fastener is at least 0.1 mm and preferably less than about 10 mm. Such a coaxial gap is configured to accommodate an implant and a cutting blade, as described above with reference to stapler **116**.

The various embodiments of the present invention, especially the methods of augmenting tissue, have been described herein primarily with reference to treatment of living human subjects. It is understood, however, that embodiments of the present invention are performed for the veterinary treatment of a non-human mammal, especially horses, cats, dogs, cows and pigs.

The various embodiments of the present invention, especially the methods of augmenting tissue, have been described herein primarily with reference to treatment of living subjects. It is understood that application of the present invention for training and educational purposes (as opposed to treating a condition) falls within the scope of the claims, whether on a living non-human subject or on a dead subject, whether on a

human cadaver or on a non-human body, whether on an isolated cardiac valve, or on a valve in a heart isolated (at least partially) from a body, or on a body.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

WHAT IS CLAIMED IS:

1. A surgical fastening device useful for securing a cardiac valve to an implant, comprising:

a) a device body comprising a fastener magazine having a fastener ejection ring configured to project a plurality of tissue-piercing elements of one or more fasteners in the shape of a closed curve from said fastener magazine; and

b) an anvil configured to act as a counterpoise during said projection of said tissue-piercing elements which comprises an anvil head including an anvil head top surface having a shape of a closed-curve and a size substantially similar to that of said fastener ejection ring, said anvil configured to be reversibly secured to said device body through a stem surrounded by said fastener ejection ring, so that when secured, said anvil head surface is opposite said fastener ejection ring

wherein said anvil head comprises at least two mateable anvil head parts, wherein each said mateable anvil head part spans a sector of said closed curve of said anvil head.

2. The device of claim 1, wherein said one or more fasteners are selected from the group consisting of staples, cotter pins, studs, rivets, and two-part rivets.

3. An anvil for a surgical fastening device useful for securing a cardiac valve to an implant, comprising at least two mateable anvil head parts that when mated said anvil head parts constitute an anvil head that is substantially a closed curve including an anvil head top surface, wherein each said mateable anvil head part spans a sector of said closed curve.

4. The anvil of claim 3, comprising two mateable anvil head parts, a first anvil head part and a second anvil head part, when mated together spanning the entire circumference of said closed curve.

5. The anvil of claim 4, wherein said first anvil head part spans a sector of between about 120° and about 240° of said closed curve.

6. The anvil of claim 3, each said anvil head part comprising an inwardly extending crosspiece.

7. The anvil of claim 6, a said crosspiece spanning no greater than about 45°.

8. The anvil of claim 3, further comprising a stem attached to at least one said anvil head part through a crosspiece.

9. The anvil of claim 8, said stem attached to only one said anvil head part.

10. The anvil of claim 8, said stem split into a plurality of mateable parts, said parts attached to different said anvil head parts, configured so that when said anvil head parts are properly mated said stem parts are properly mated.

11. The anvil head of claim 3, said top surface comprising a tray for presenting locking components to engage fasteners projected from the surgical fastening device.

12. The anvil head of claim 3, said top surface comprising features for facilitating deformation of fasteners projected from the surgical fastening device.

13. A surgical fastening device useful for augmenting tissue, comprising:
a) a device body including a fastener magazine functionally associated with a fastener ejection ring at a distal end of said device body configured, upon triggering, to project a plurality of tissue-piercing elements of one or more fasteners from said fastener magazine through said fastener ejection ring in the shape of a closed curve;
b) an anvil configured to act as a counterpoise during said projection of said tissue-piercing elements which comprises an anvil head including an anvil head top surface having a shape of a closed curve and a size substantially similar to that of said fastener ejection ring, said anvil secured to said device

body through a stem, so that when secured, said anvil head surface is opposite said fastener ejection ring;

c) an implant container at said distal end including an outwardly directed opening surrounded by said fastener ejection ring; and

d) a knife driver defining a part of a wall of said implant container configured, upon triggering, to push an object held in said implant container out through said opening.

14. The device of claim 13, wherein said one or more fasteners are staples.

15. The device of claim 14, said anvil head top surface including a staple clinching groove ring opposite said fastener ejection ring when said anvil is secured to said device body.

16. The device of claim 13, wherein said one or more fasteners are selected from the group consisting of staples, cotter pins, studs, rivets, and two-part rivets.

17. The device of claim 13, wherein said anvil head is reversibly detachable from said device body.

18. The device of claim 13, further comprising a trigger to trigger said projection of said tissue piercing elements and to trigger said pushing by said knife driver.

19. The device of claim 18, said trigger configured to trigger said projection and said pushing, substantially simultaneously.

20. The device of claim 13, further comprising a cutting blade, physically separate from said device body and configured to be accommodated within said implant container together with an implant.

21. The device of claim 20, wherein said cutting blade is configured to make a single slit.

22. The device of claim 20, said anvil head top surface including a cutting blade accepting slot opposite said opening of said implant container when said anvil is secured to said device body, configured to accept said cutting blade.

23. The device of claim 13,

wherein said fastener magazine is an outer fastener magazine, said fastener ejection ring is an outer fastener ejection ring;

further comprising:

e) a second fastener magazine functionally associated with an inner fastener ejection ring at a said distal end of said device body in the shape of a closed curve;

wherein said implant container is in the shape of a closed curve surrounding said second fastener ejection ring;

wherein said stem of said anvil is surrounded by said second fastener ejection ring; and

where, said device body is further configured, upon triggering, to project a plurality of tissue-piercing elements of one or more fasteners from said inner fastener magazine through said inner fastener ejection ring in said direction in the shape of said closed curve.

24. The device of claim 23, wherein said anvil head comprises at least two mateable anvil head parts, wherein each said mateable anvil head part spans a sector of said closed curve of said anvil head.

25. The device of claim 23, further comprising a cutting blade, physically separate from said device body and configured to be accommodated within said implant container together with an implant.

26. The device of claim 25, where said cutting blade is configured to make an incision having a closed curved shape.

27. The device of claim 25, wherein said cutting blade is a linear strip of sufficient flexibility to be bent into said implant container.

28. The device of claim 25, wherein said cutting blade is a loop of sufficient flexibility to be collapsed to an elongated shape.

29. The device of claim 25, said anvil head top surface including a cutting blade accepting slot opposite said opening of said implant container when said anvil is secured to said device body, configured to accept said cutting blade.

30. A cartridge for a surgical fastening device, comprising:

a) a cartridge body with a distal end and a proximal end, configured for association with a surgical fastening device through said proximal end;

b) a fastener magazine functionally associated with a fastener ejection ring at said distal end of said cartridge body in the shape of a closed curve;

c) a plurality of tissue-piercing elements of one or more fasteners held in said fastener ejection magazine and directed towards said fastener ejection ring;

d) an implant container at said distal end including an outwardly directed opening surrounded by said fastener ejection ring;

e) contained within said implant container, an implant comprising a patch of tissue having a periphery wherein said periphery extends beyond said fastener ejection ring; and

f) a cutting blade nestled in said implant with a cutting edge directed towards said opening of said implant container.

31. The cartridge of claim 30, wherein said one or more fasteners are selected from the group consisting of staples, cotter pins, studs, rivets, and two-part rivets.

32. The cartridge of claim 30, wherein said cutting blade is configured to make a single slit.

33. A cartridge for a surgical fastening device, comprising:

a) a cartridge body with a distal end and a proximal end, configured for association with a surgical fastening device through said proximal end;

b) an outer fastener magazine functionally associated with an outer fastener ejection ring at said distal end of said cartridge body in the shape of a closed curve;

c) a plurality of tissue-piercing elements of one or more fasteners held in said outer fastener ejection magazine and directed towards said outer fastener ejection ring;

d) an implant container in the shape of a closed curve at said distal end including an outwardly directed opening surrounded by said fastener ejection ring;

e) an inner fastener magazine functionally associated with an inner fastener ejection ring at said distal end of said cartridge body in the shape of a closed curve surrounded by said implant container;

f) a plurality of tissue-piercing elements of one or more fasteners held in said inner fastener ejection magazine and directed towards said inner fastener ejection ring;

g) contained within said implant container, an implant including a wall said wall delimited by two rims each in the shape of a closed curve, and defining a lumen, wherein a first said rim extends outwards beyond said outer fastener ejection ring and a second said rim extends inwards beyond said inner fastener ejection ring; and

h) a cutting blade nestled in said implant with a cutting edge directed towards said opening of said implant container.

34. The cartridge of claim 33, wherein said one or more fasteners are selected from the group consisting of staples, cotter pins, studs, rivets, and two-part rivets.

35. The cartridge of claim 33, where said cutting blade is configured to make an incision having a closed curved shape.

36. The cartridge of claim 33, wherein said cutting blade is a linear strip of sufficient flexibility to be bent into said implant container.

37. The cartridge of claim 33, wherein said cutting blade is a loop of sufficient flexibility to be collapsed to an elongated shape.

38. A lockable fastener useful for securing the periphery of a cardiac valve to an implant material, comprising:

a) a loop-shaped body with a bottom side defining a lumen and describing at least a 320° sector about an axis; and

b) at least three elongated piercing elements protruding from said bottom side substantially parallel to said axis.

39. The fastener of claim 38, said piercing elements configured to deform upon sufficiently forceful contact with an anvil when projected from an appropriately configured surgical fastening device so as to lock in place.

40. The fastener of claim 38, a said piercing element configured to engage a discrete locking component.

41. A set of lockable fasteners, comprising at least two fasteners of claim 38 configured to be coaxially nestable, so that when coaxially nested, a coaxial gap between an outer edge of a said loop-shaped body of a smaller said fastener and an inner edge of a said loop-shaped body of a larger said fastener is at least 0.1 mm.

42. A method of augmenting a membrane, comprising:

a) slitting an in vivo membrane so as to produce a slit having a first slit edge and a second slit edge;

b) providing a patch of tissue having a periphery as a membrane augmenting implant;

c) placing said patch of tissue to define an overlap region comprising an overlap of a first portion of said periphery with said first slit edge and an overlap of a second portion of said periphery with said second slit edge; and

d) securing said patch to said membrane around a plurality of locations of said overlap region substantially simultaneously

thereby augmenting said membrane by increasing a surface area of said membrane with said patch.

43. The method of claim 42, wherein said slitting and said placing is substantially simultaneous.

44. The method of claim 42, wherein said slitting, said placing and said securing is substantially simultaneous.

45. The method of claim 42, wherein said overlap region is substantially a closed curve circumscribing said slit.

46. The method of claim 42, wherein during said securing the area of said membrane circumscribed by said overlap region is less than the surface area of said patch circumscribed by said first portion and by said second portion of said patch.

47. The method of claim 42, wherein said securing comprises:

i) piercing said patch and said membrane at said plurality of locations to make a plurality of holes in said overlap region substantially simultaneously;

ii) passing lockable fasteners through said holes; and

iii) locking said lockable fasteners so as to secure said patch to said first slit edge and said second slit edge through said overlap region.

48. The method of claim 42, wherein said in vivo membrane is a leaflet of a cardiac valve.

49. A method of augmenting the tissue surrounding a cardiac valve, comprising:

a) excising leaflets of a cardiac valve with an incision having a shape of a closed curve so as to define a valve seat edge of said incision and a valve periphery edge of said incision;

b) providing an implant including a wall, the wall delimited by two edges each in the shape of a closed curve and defining a lumen as a cardiac valve augmenting implant;

c) placing said implant to define a proximal overlap region comprising an overlap of a first portion near a first edge of said implant with said valve seat edge

d) placing said implant to define a distal overlap region comprising an overlap of a second portion near a second edge of said implant with said valve periphery edge;

e) securing said first portion of said implant to said valve seat edge around a plurality of locations of said proximal overlap region; and

f) securing said second portion of said implant to said valve periphery edge around a plurality of locations of said distal overlap region, substantially simultaneously

thereby augmenting a surface area of tissue surrounding said cardiac valve with said implant.

50. The method of claim 49, wherein said securing said first portion of said implant to said valve seat edge around a plurality of locations of said proximal overlap region is performed substantially simultaneously for said plurality of locations.

51. The method of claim 49, wherein:

said excising;

said placing said implant to define said proximal overlap zone; and

said securing said first portion of said implant to said valve seat edge

are substantially simultaneous.

52. The method of claim 49, wherein:

said excising;

said placing said implant to define said distal overlap zone; and
said securing said second portion of said implant to said valve periphery edge are substantially simultaneous.

53. The method of claim 49, wherein:
said excising;
said placing said implant to define said proximal overlap zone;
said placing said implant to define said distal overlap zone;
said securing said first portion of said implant to said valve seat edge; and
said securing said second portion of said implant to said valve periphery edge are substantially simultaneous.

54. The method of claim 49, wherein said proximal overlap region is substantially a closed curve circumscribing said incision.

55. The method of claim 49, wherein said distal overlap region is substantially a closed curve surrounded by said incision.

56. The method of claim 49, wherein the surface area of said walls of said implant between said proximal overlap region and said distal overlap region is greater than the surface area of tissue between said proximal overlap region and said distal overlap region.

57. The method of claim 49, wherein said securing said first portion of said implant to said valve seat edge comprises:

i) piercing said implant and tissue surrounding said valve seat edge at said plurality of locations to make a plurality of holes in said proximal overlap region substantially simultaneously;
ii) passing lockable fasteners through said holes; and
iii) locking said lockable fasteners so as to secure said implant to said valve seat edge through said proximal overlap region.

58. The method of claim 49, wherein securing said second portion of said implant to said valve periphery edge comprises:

i) piercing said implant and tissue surrounded said valve periphery edge at said plurality of locations to make a plurality of holes in said distal overlap region substantially simultaneously;

ii) passing lockable fasteners through said holes; and

iii) locking said lockable fasteners so as to secure said implant to said valve periphery edge through said distal overlap region.

59. The method of claim 49, wherein said cardiac valve is a mitral valve.

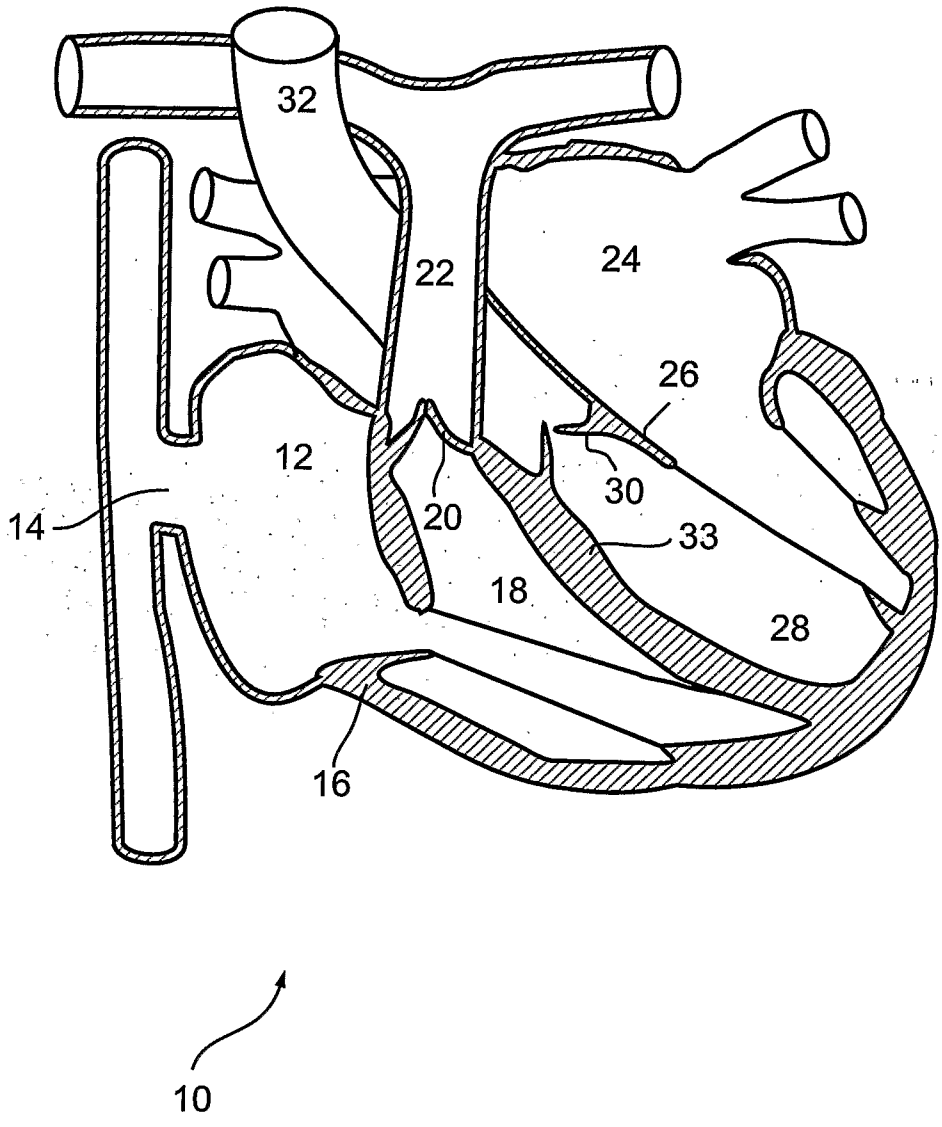


Fig. 1(Prior Art)

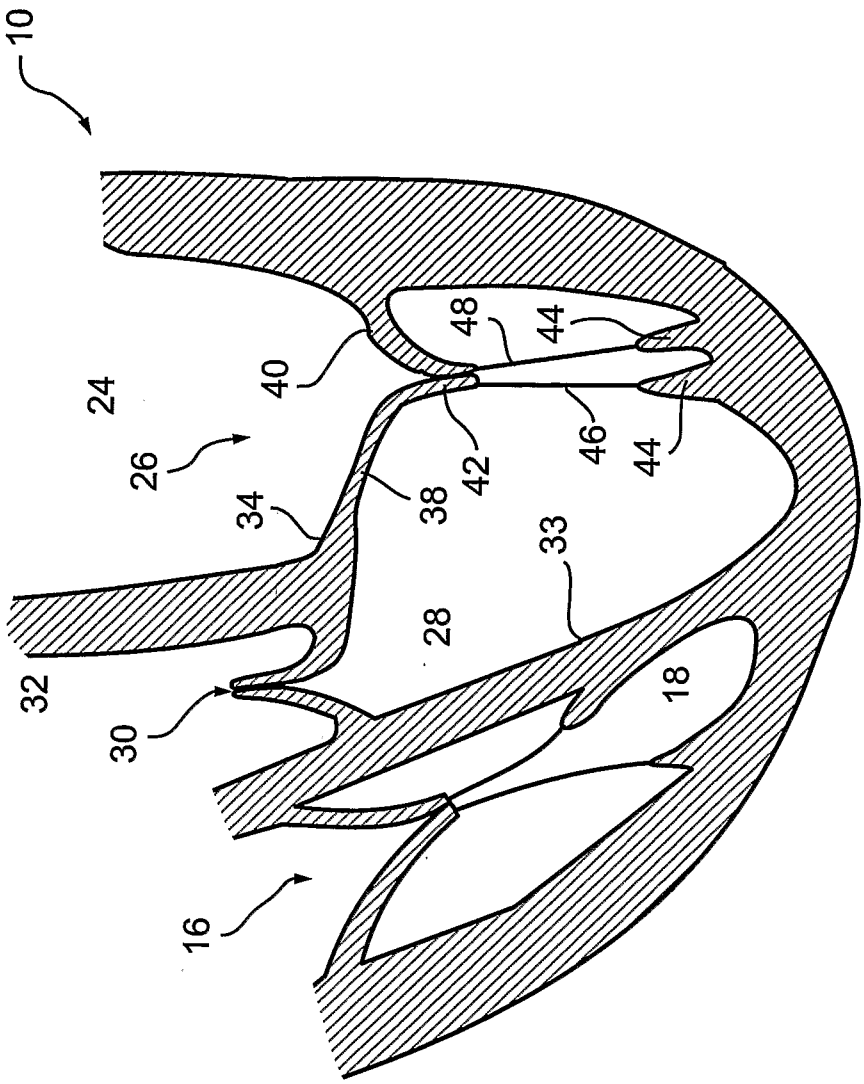


Fig. 2b (Prior Art)

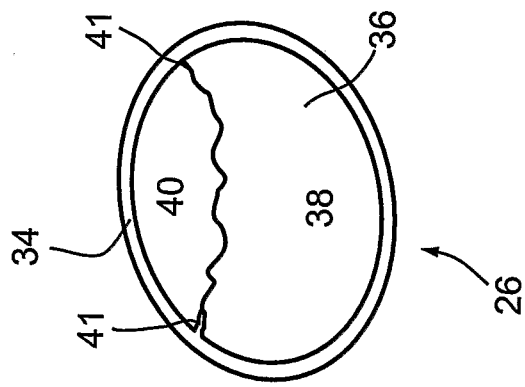


Fig. 2a (Prior Art)

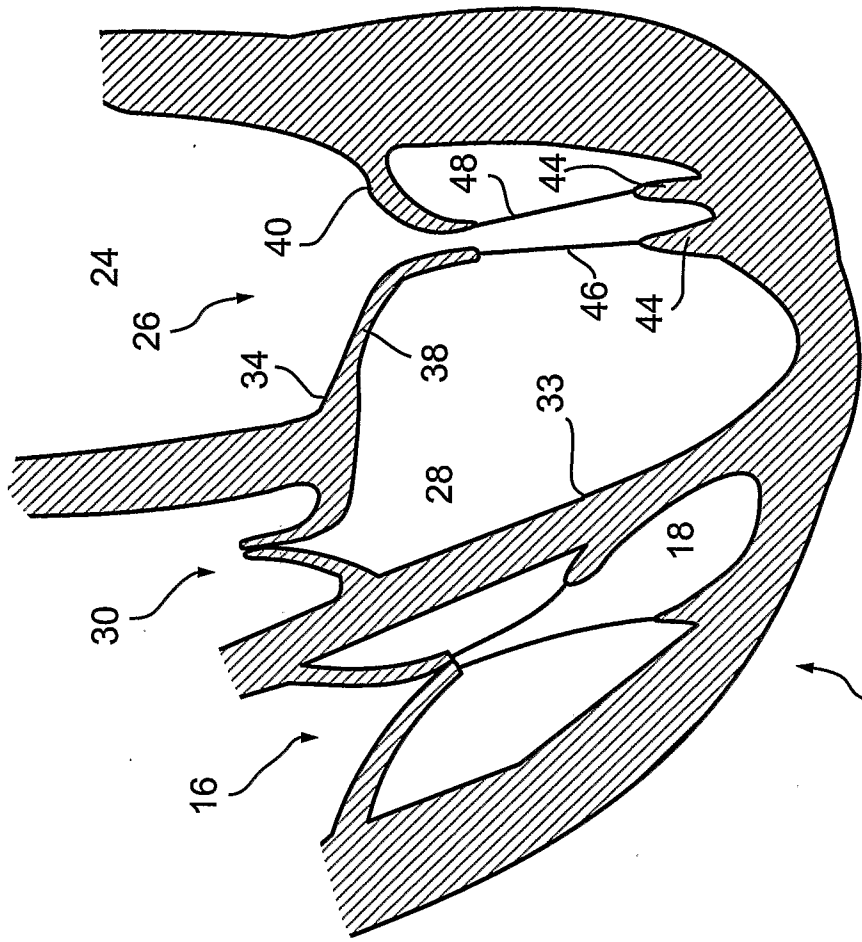


Fig. 3b (Prior Art)

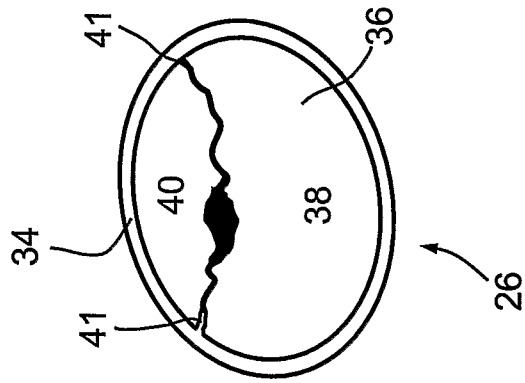
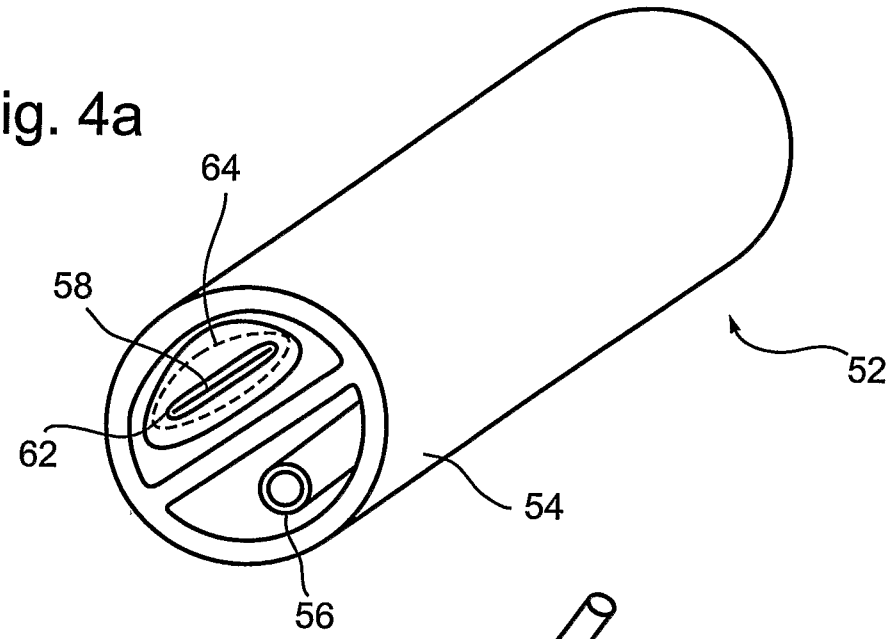


Fig. 3a (Prior Art)

Fig. 4a



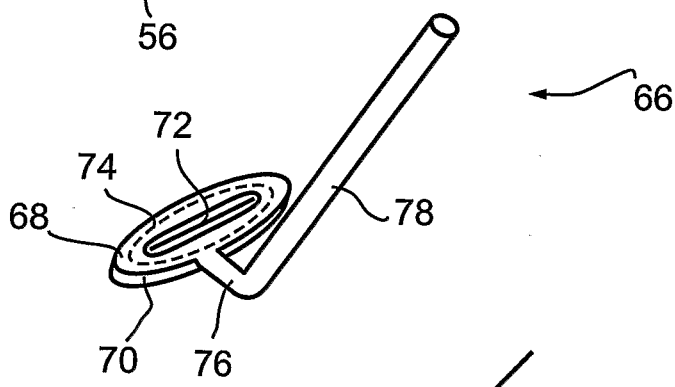


Fig. 4b

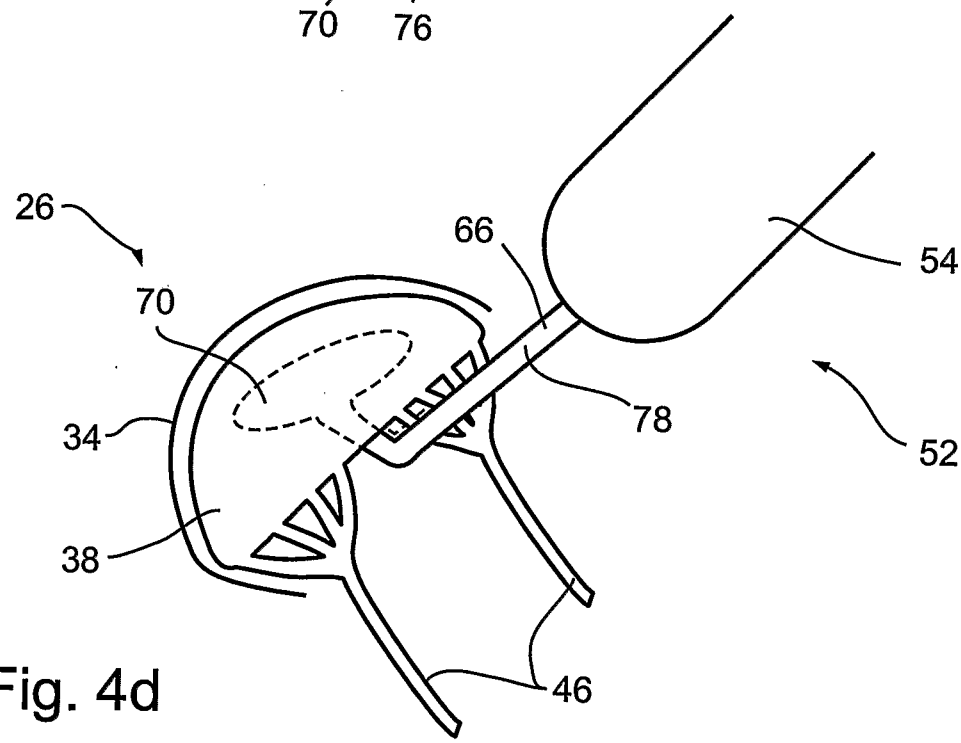


Fig. 4d

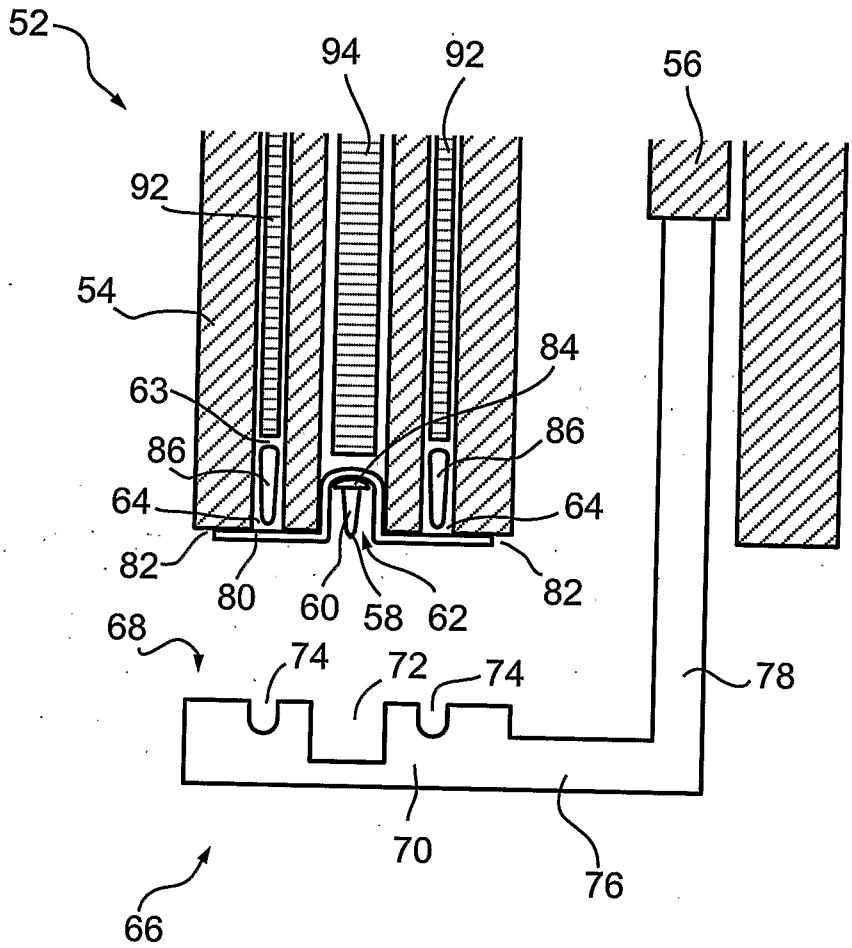

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Fig. 4c

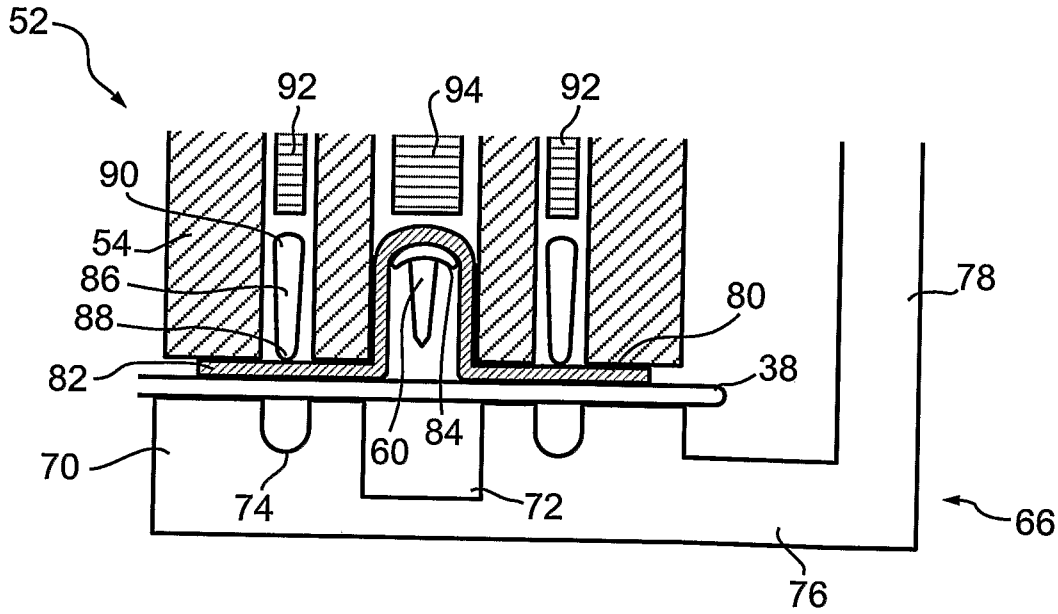
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Fig. 4e

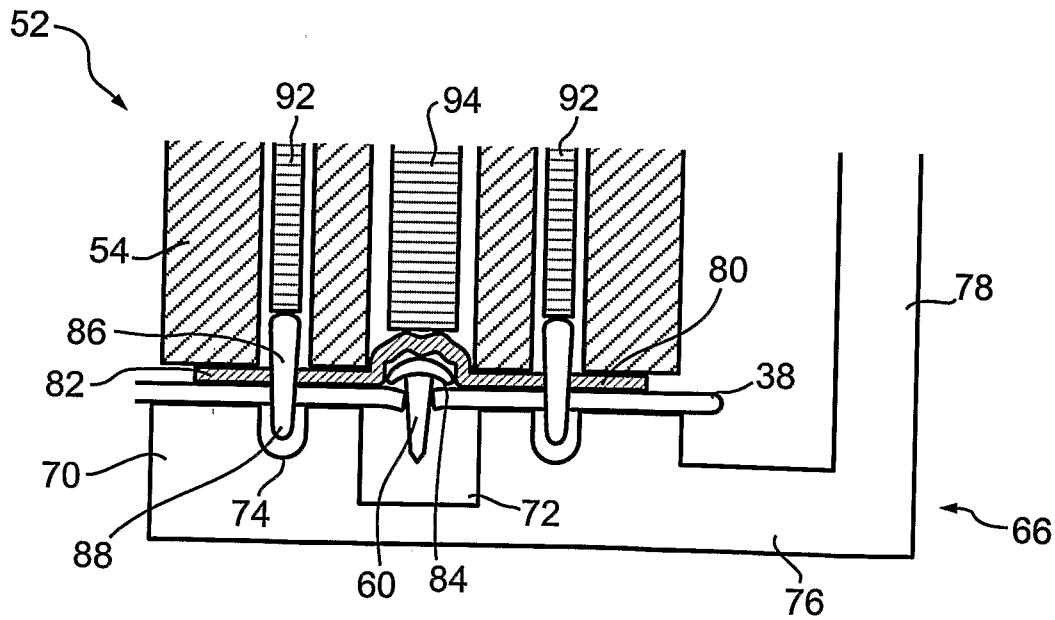
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Fig. 4f

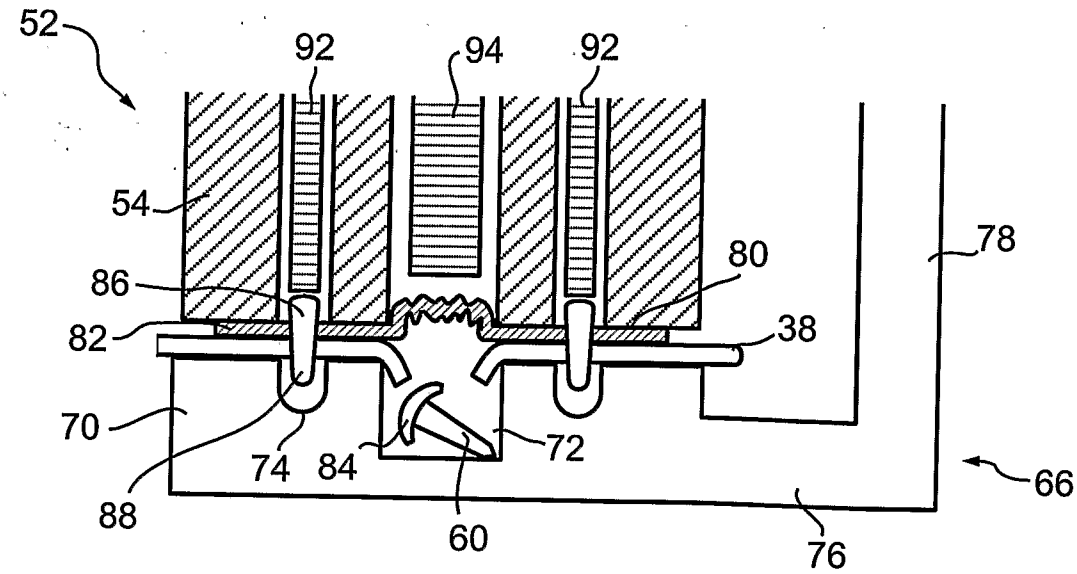
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Fig. 4g

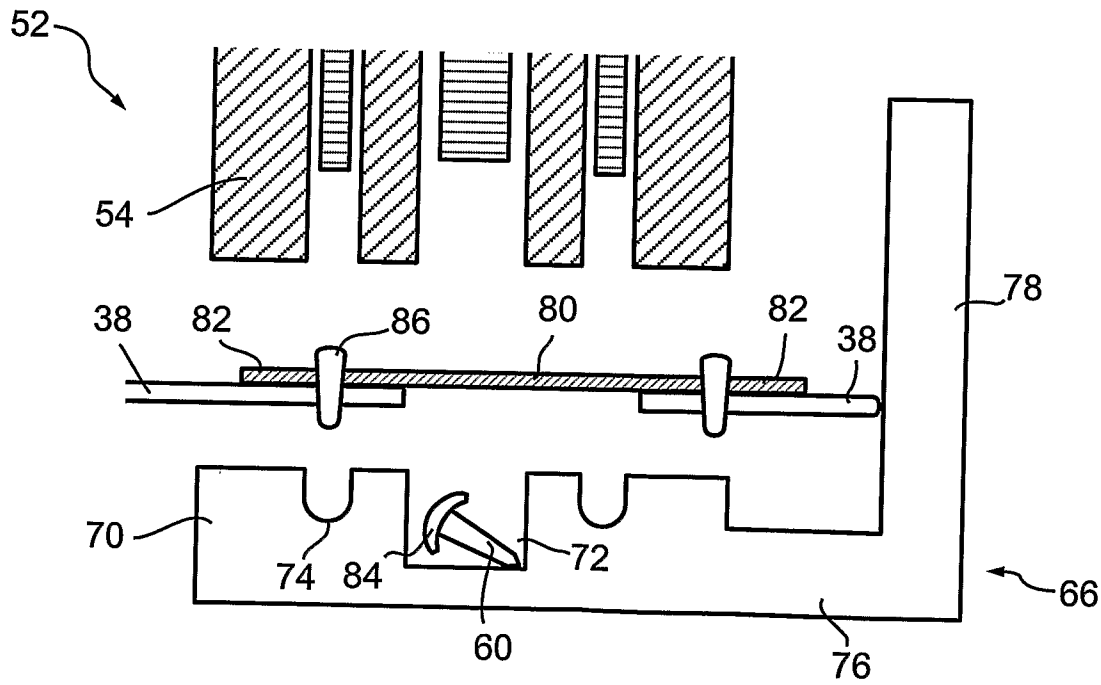
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Fig. 4h

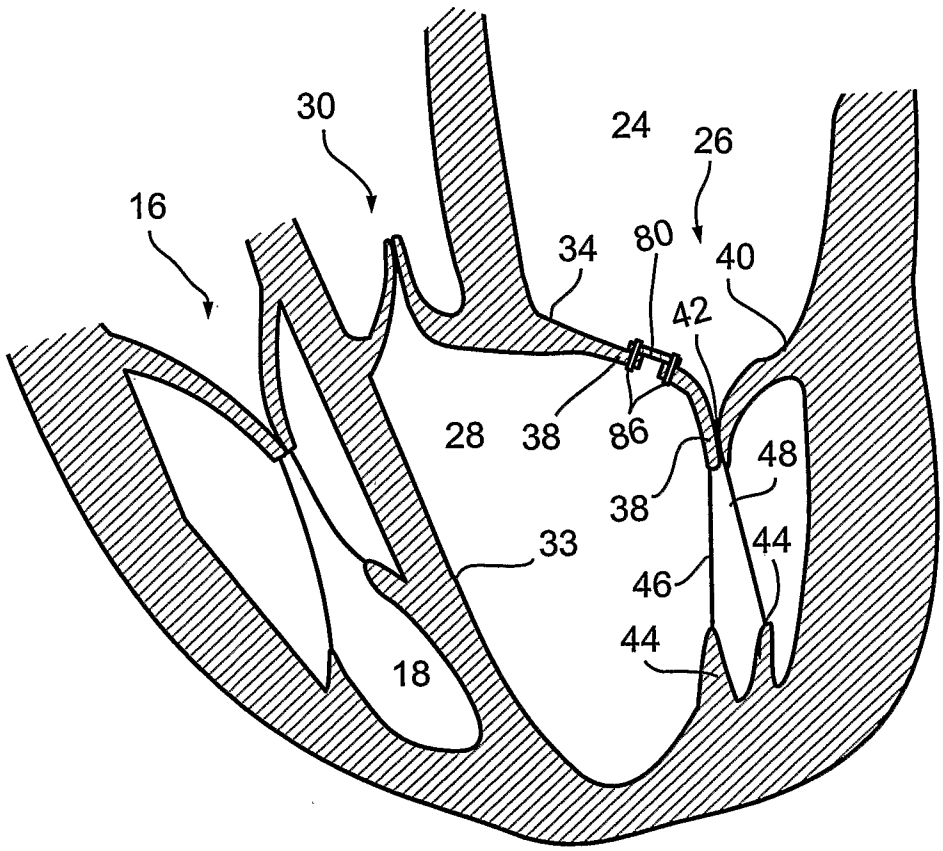

Fig. 4i

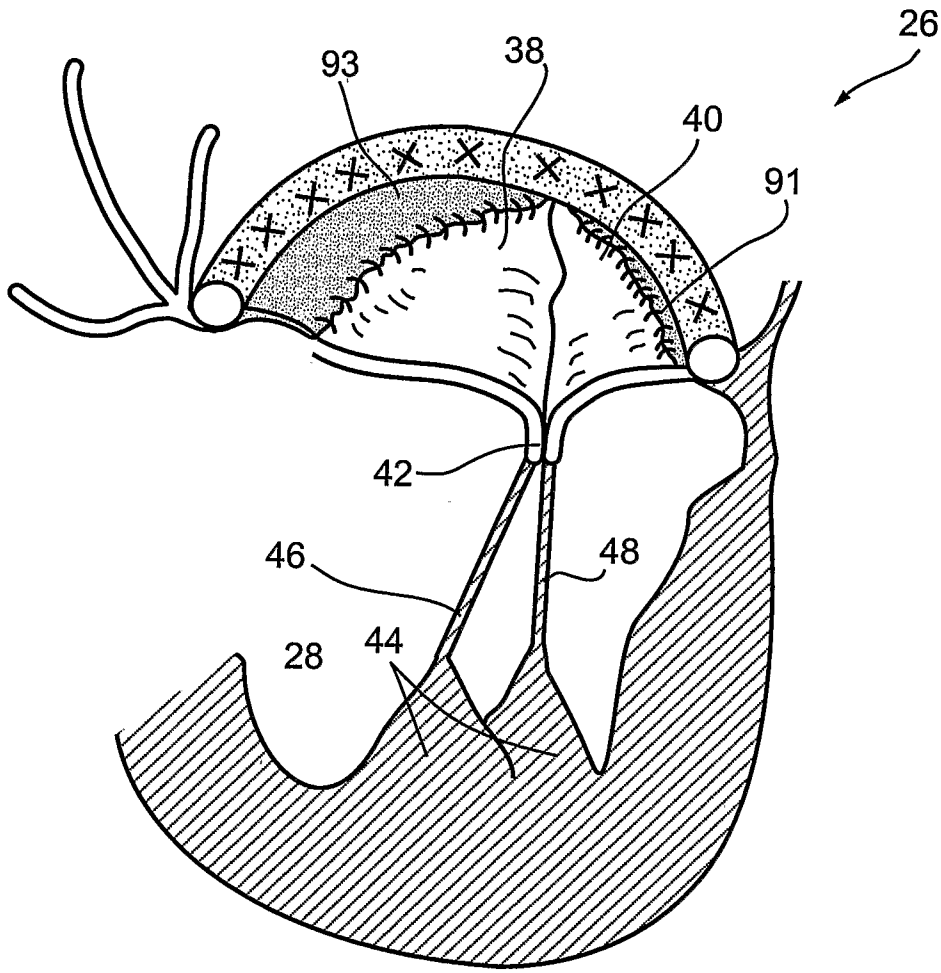

Fig. 5a

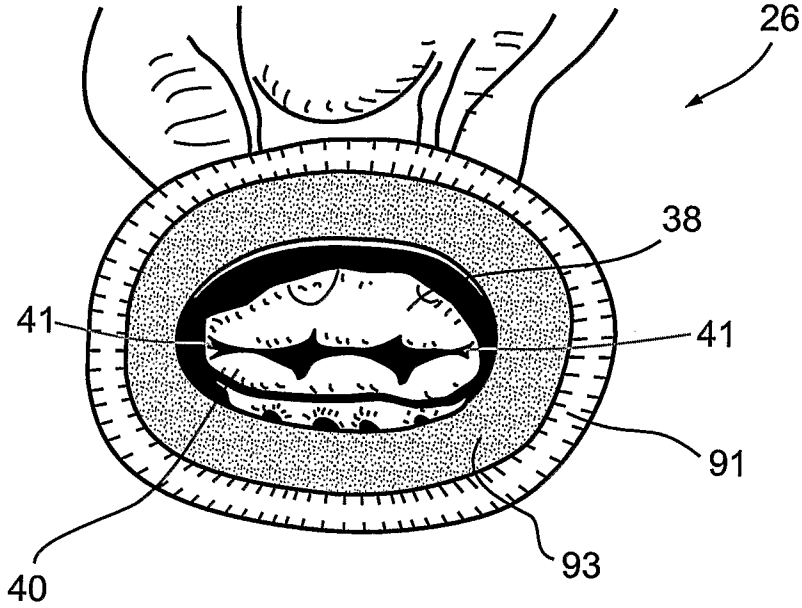

Fig. 5b

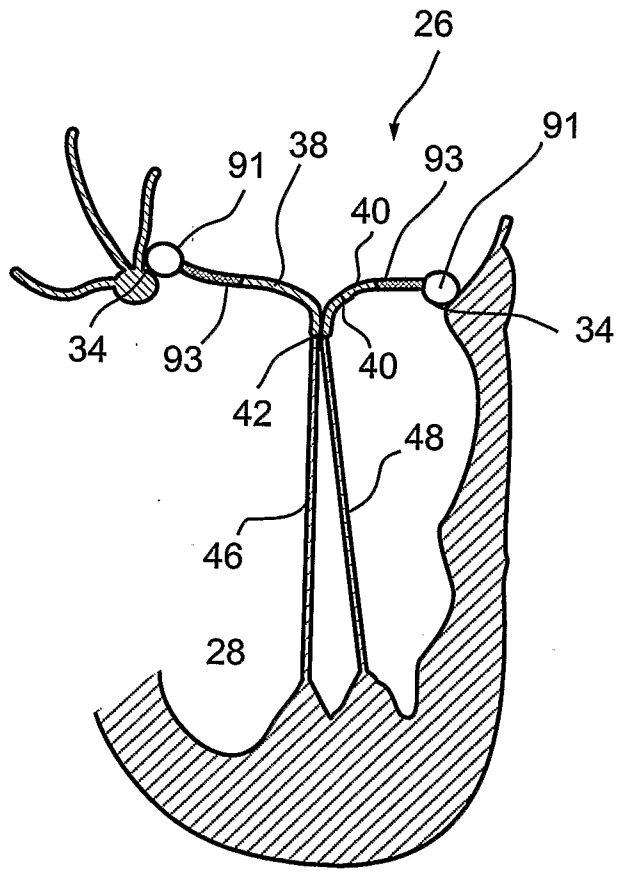

Fig. 5c

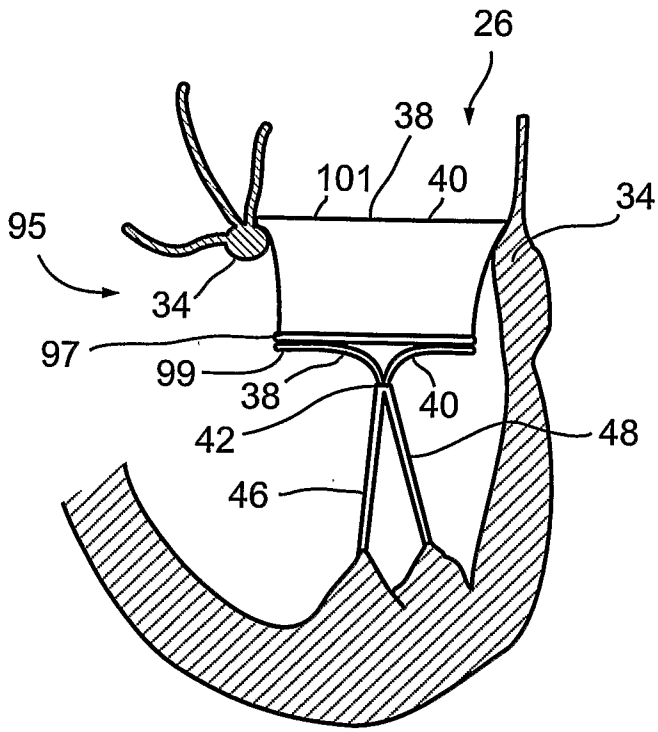

Fig. 5d

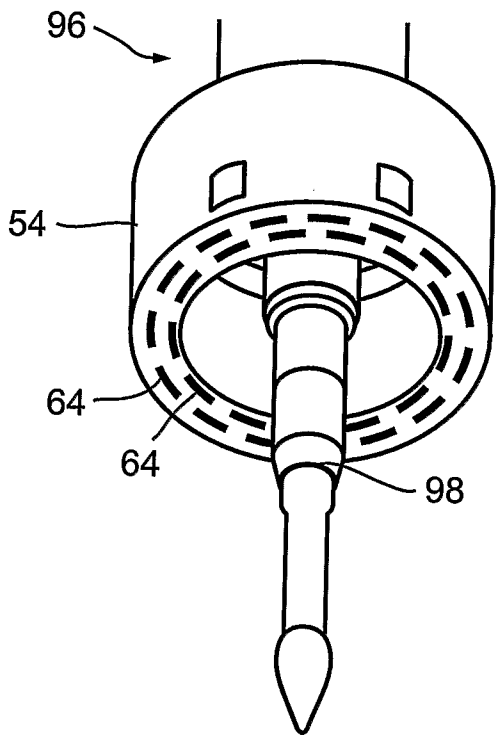

Fig. 6a

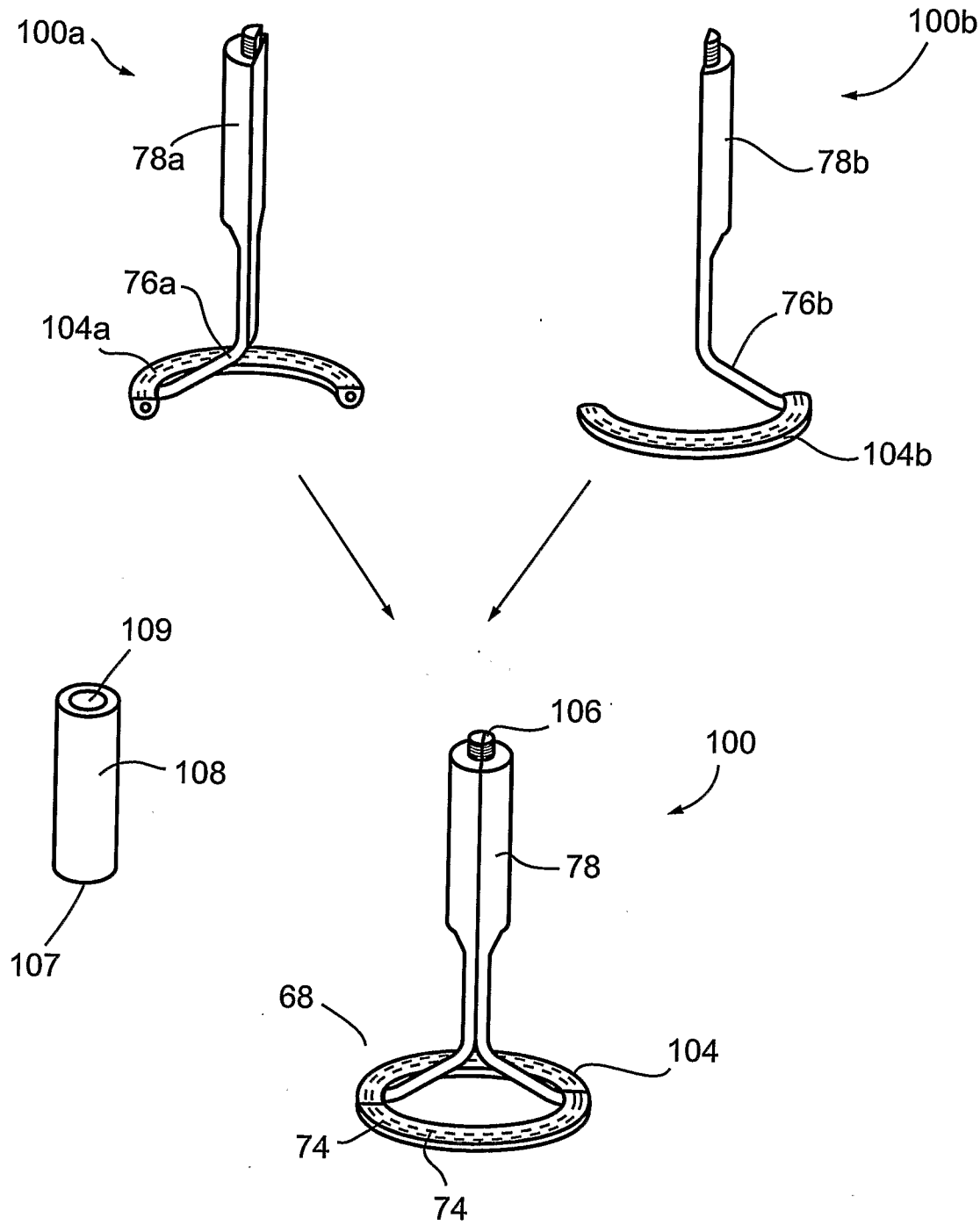
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Fig. 6b

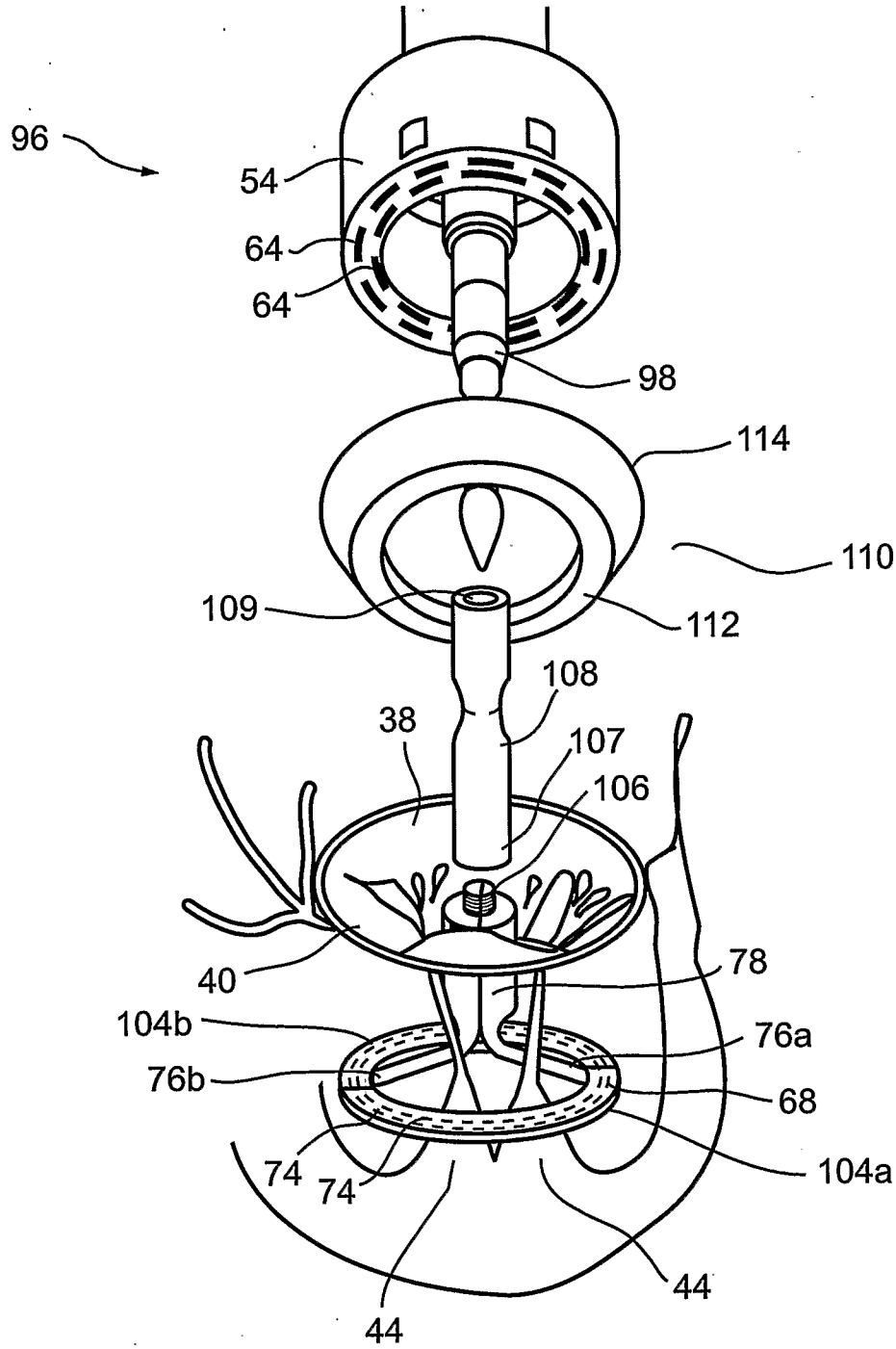
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Fig. 6c

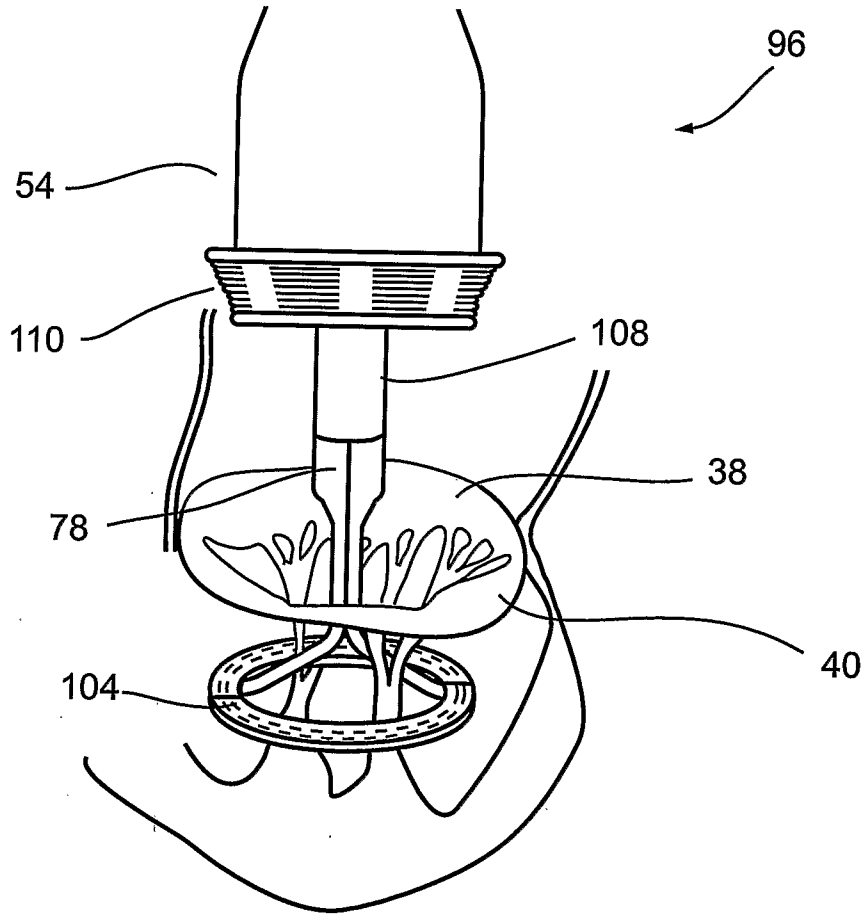

Fig. 6d

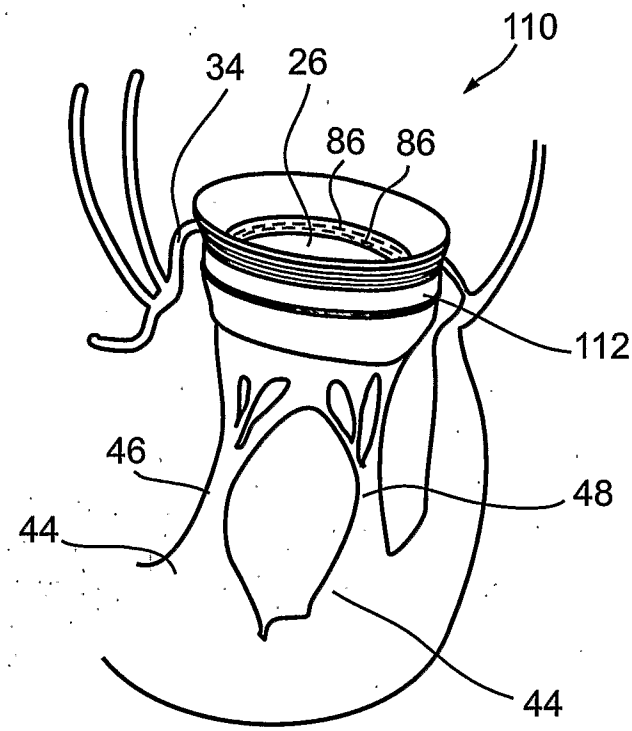

Fig. 6e

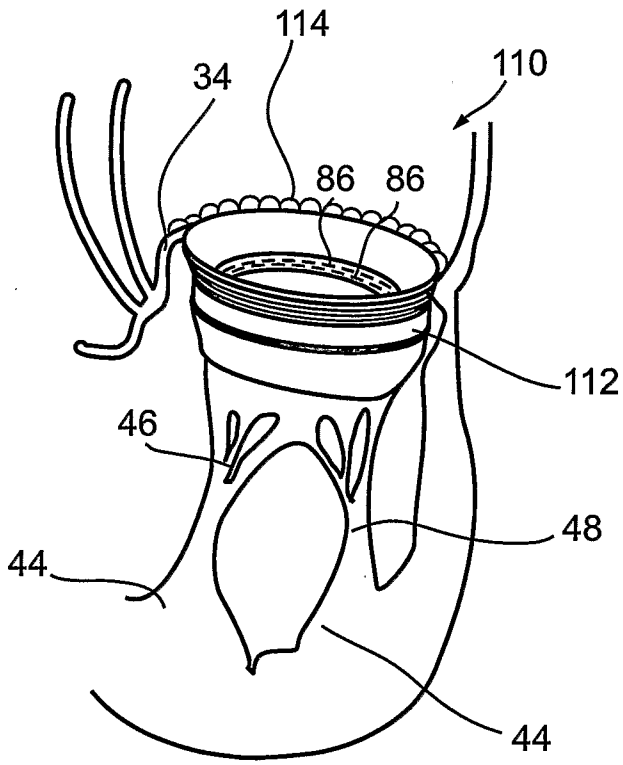

Fig. 6f

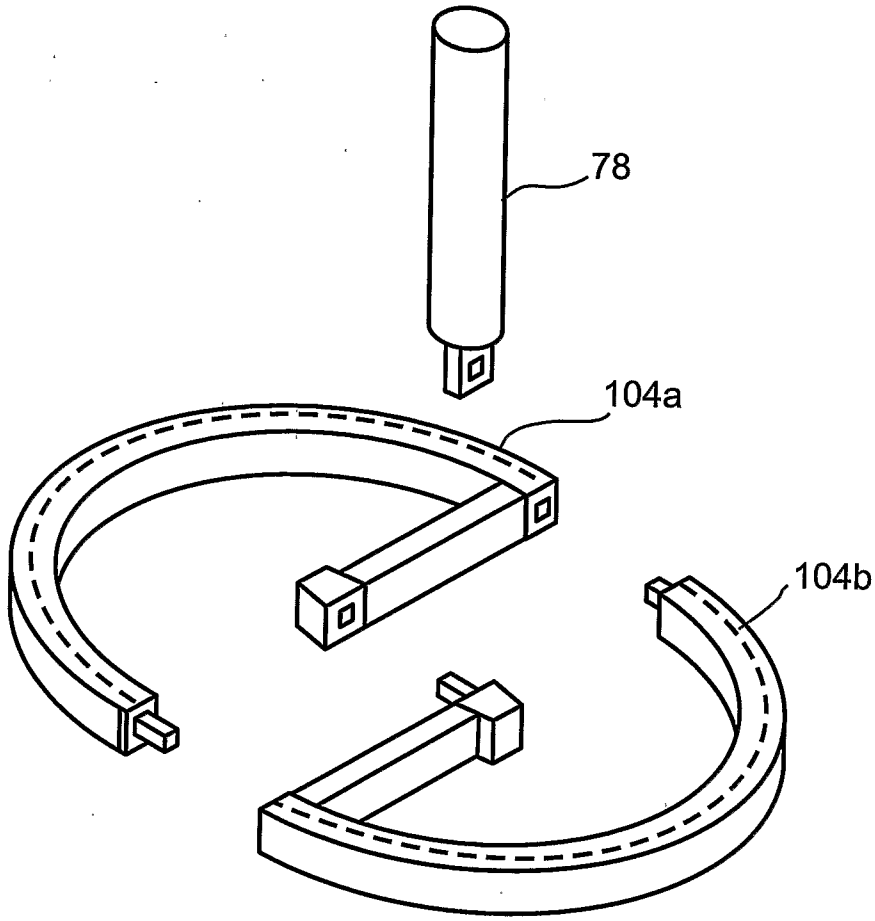

Fig. 7

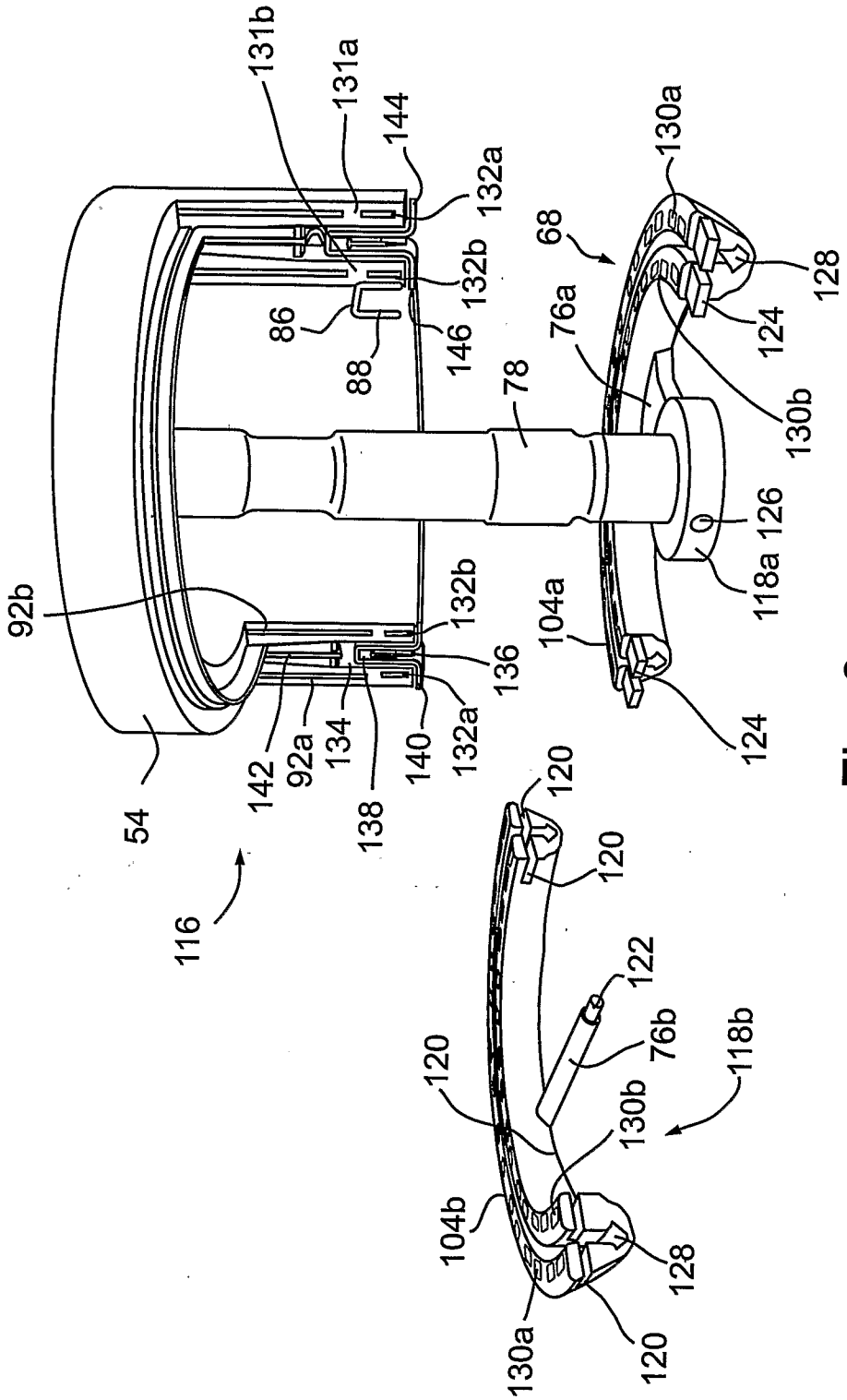
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Fig. 8a

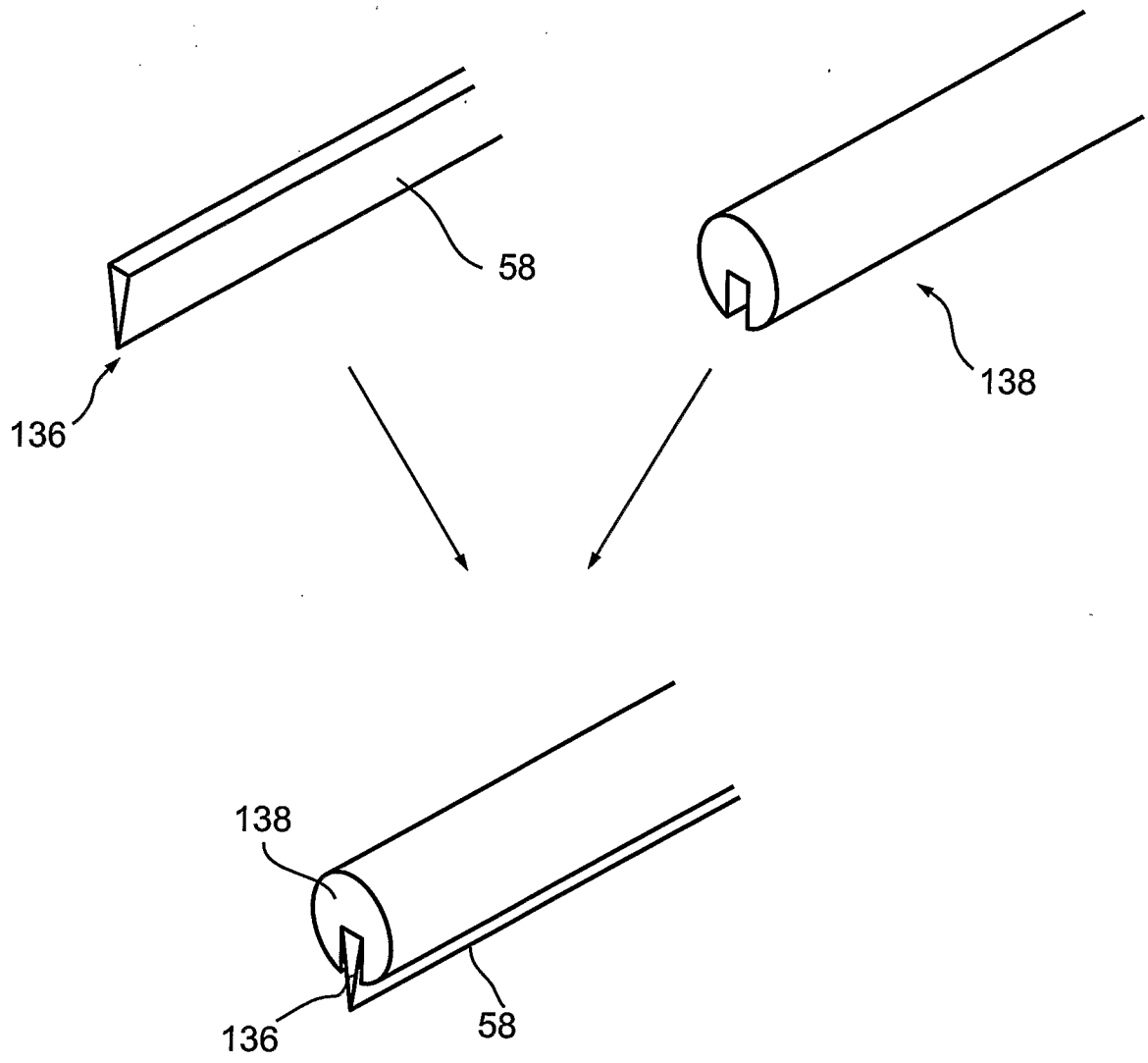


Fig. 8b

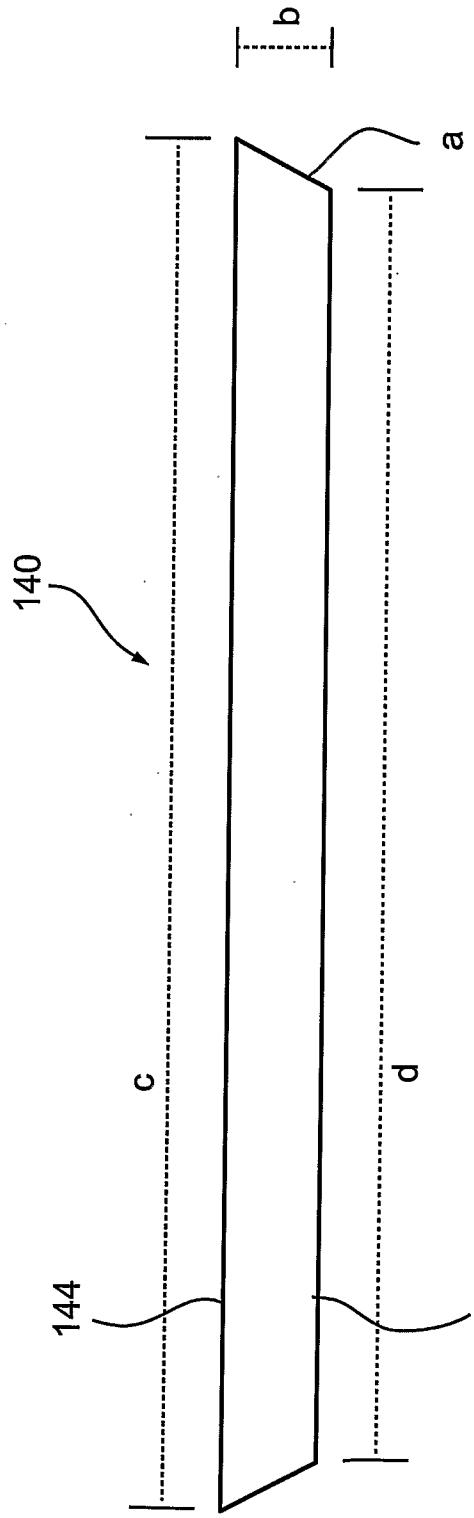


Fig. 8c

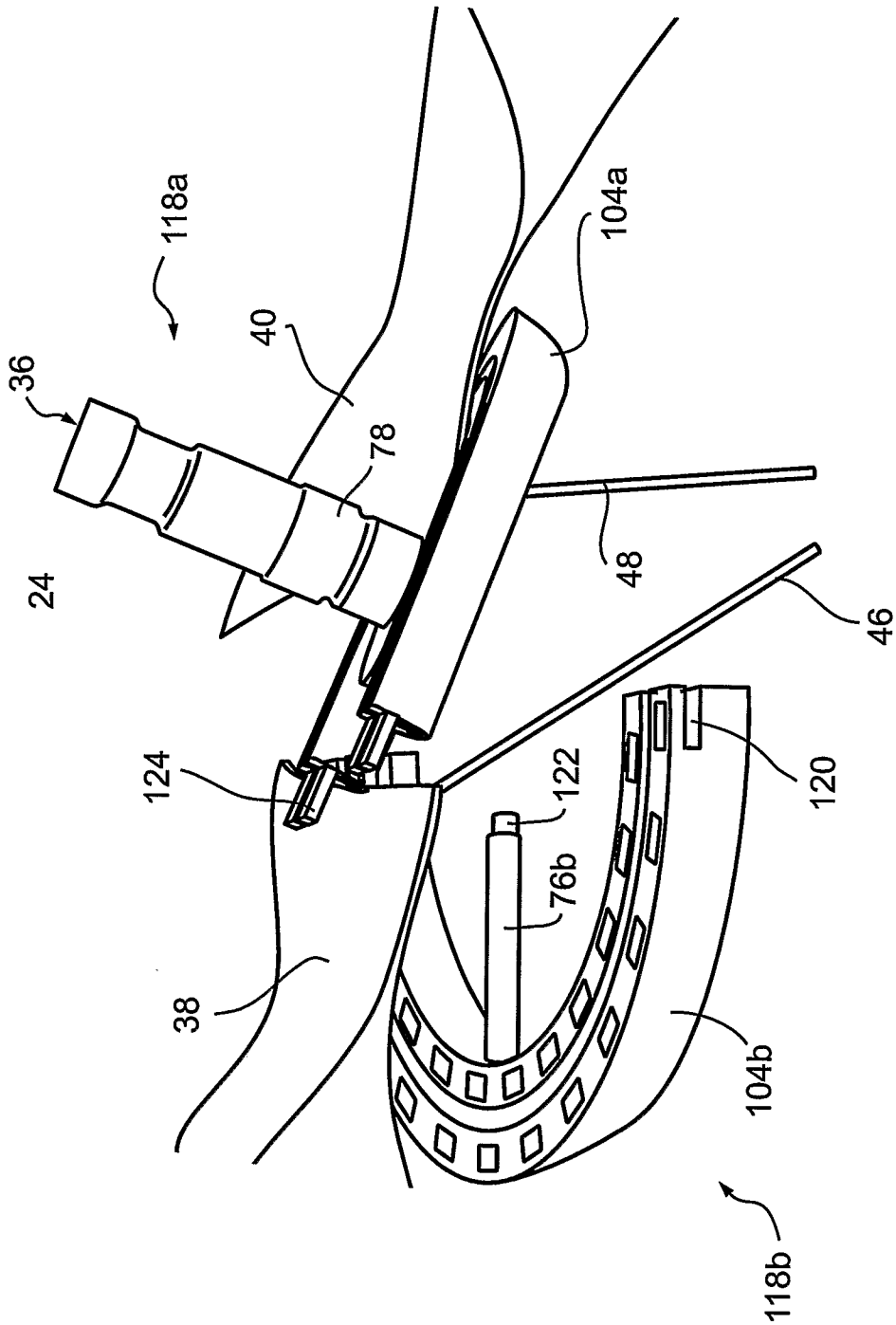


Fig. 8d

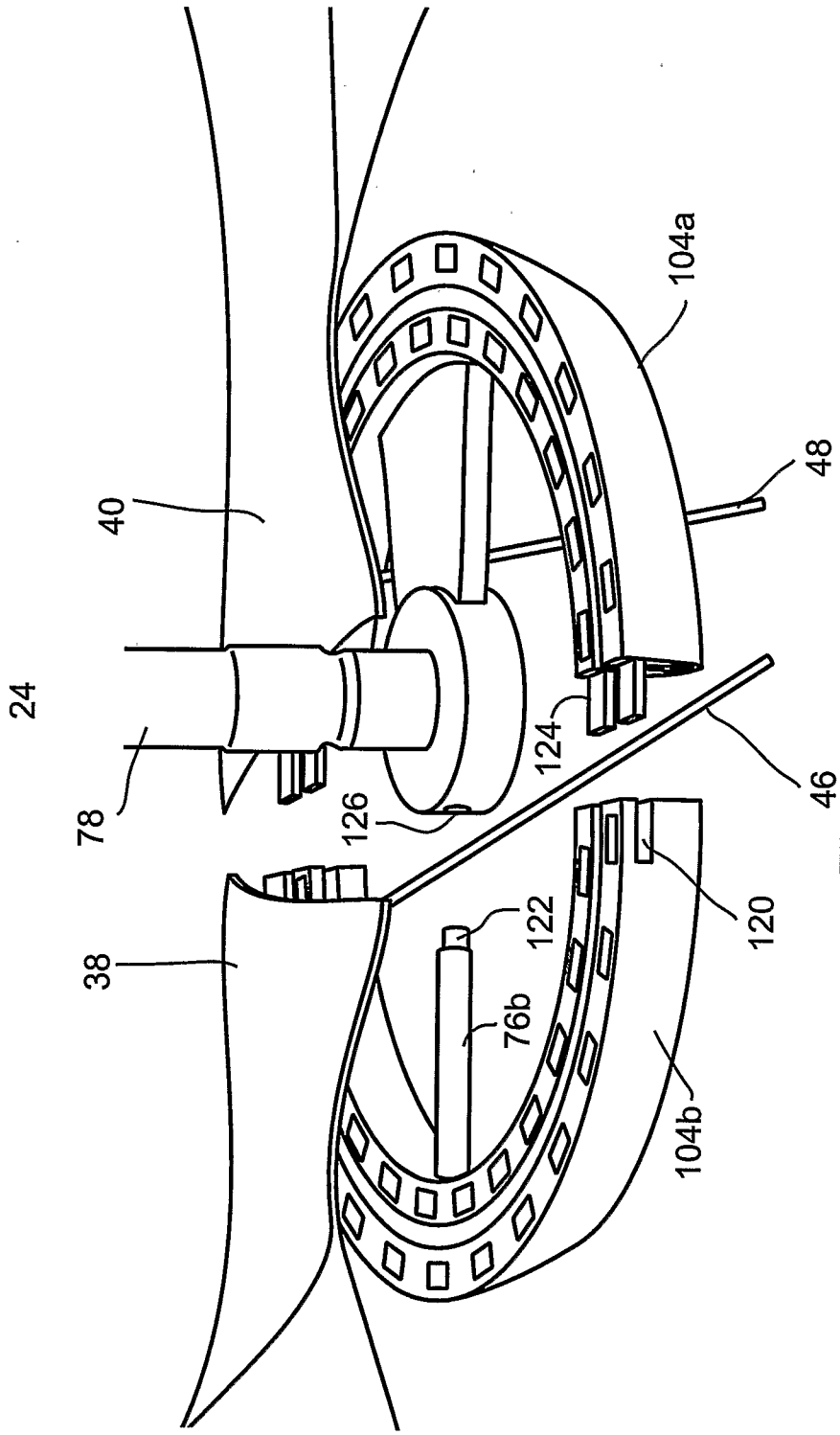


Fig. 8e

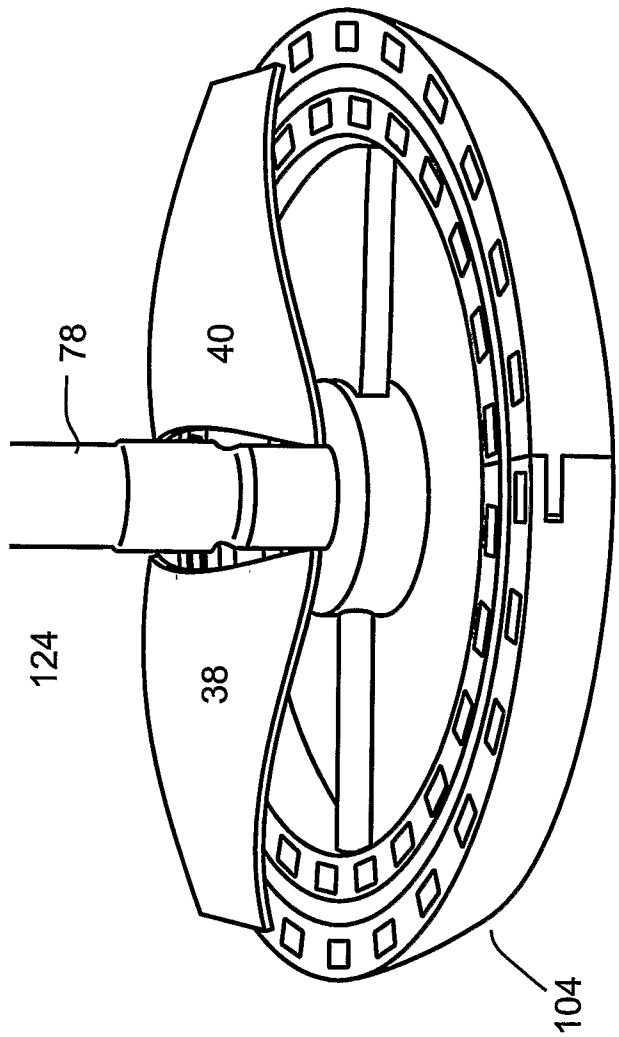
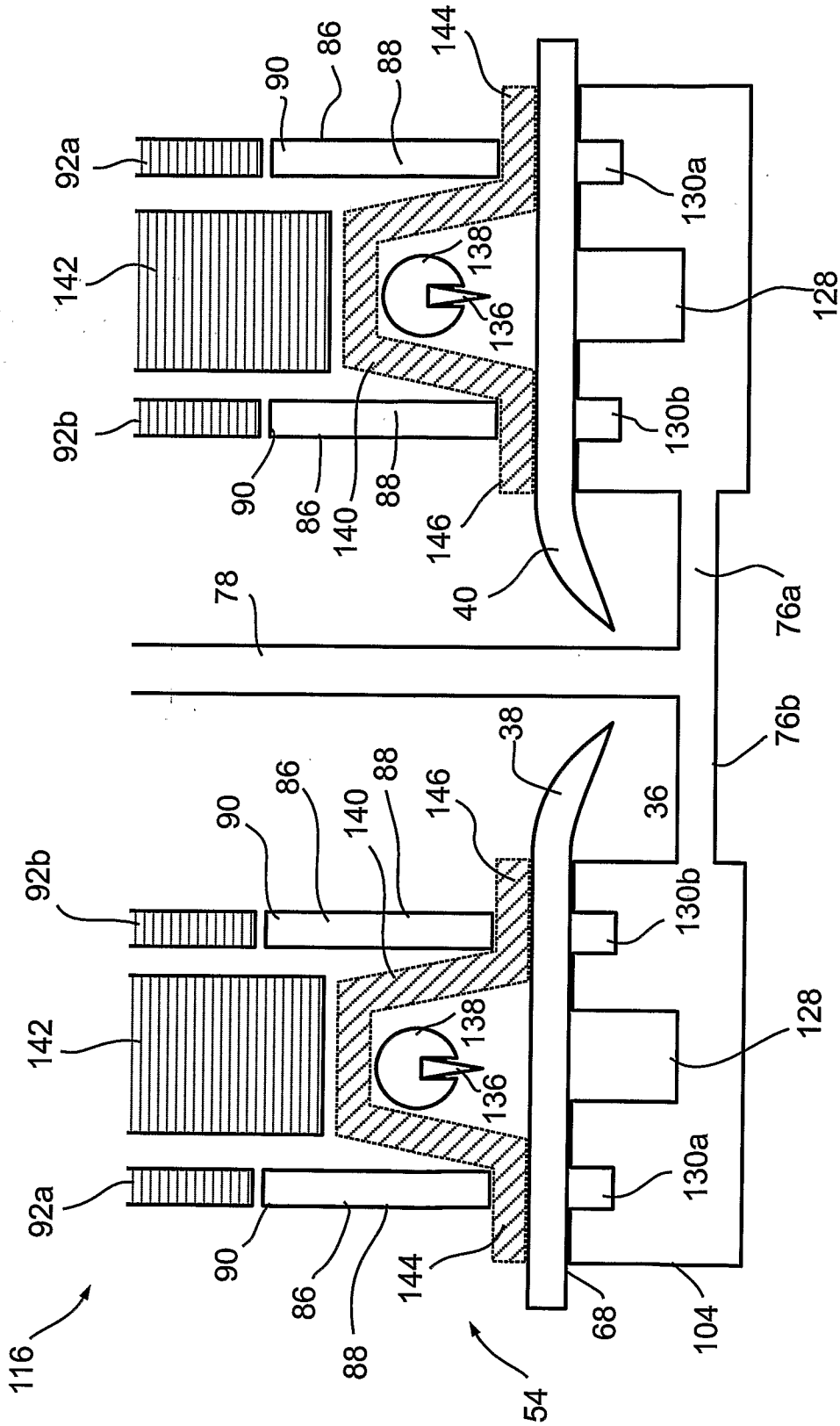


Fig. 8f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92b
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90
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88
144
138
136
140
146
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130b
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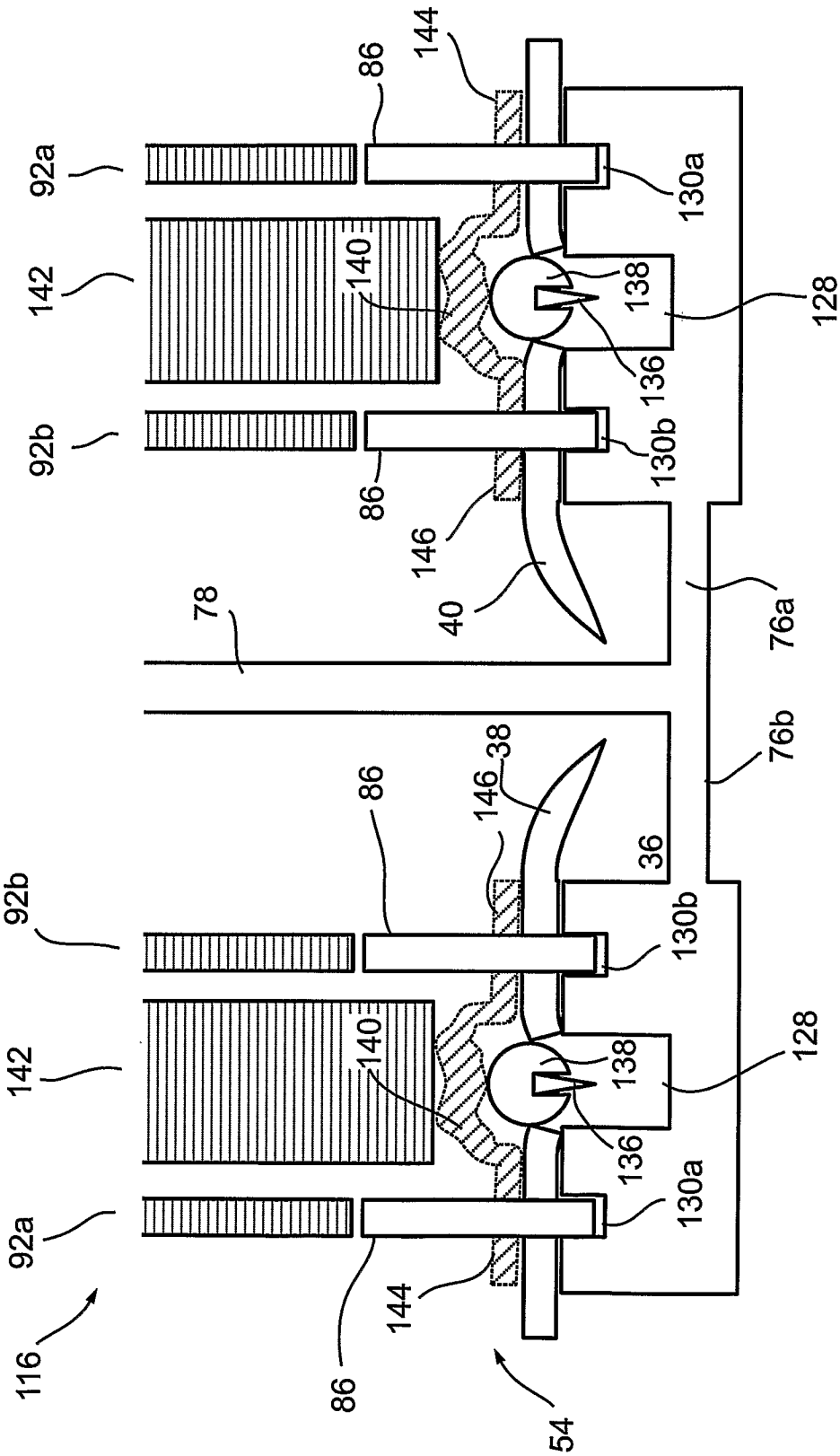
78
76a
76b
38
36
68
104
54
116

Fig. 8g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92b
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128
136
130b
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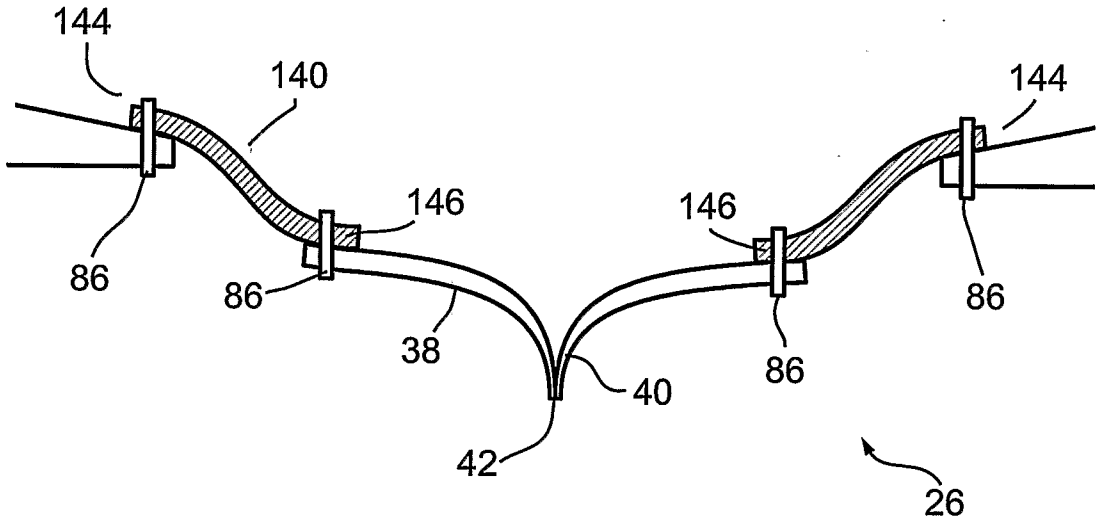
40
78
76a
76b
38
36
54

Fig. 8h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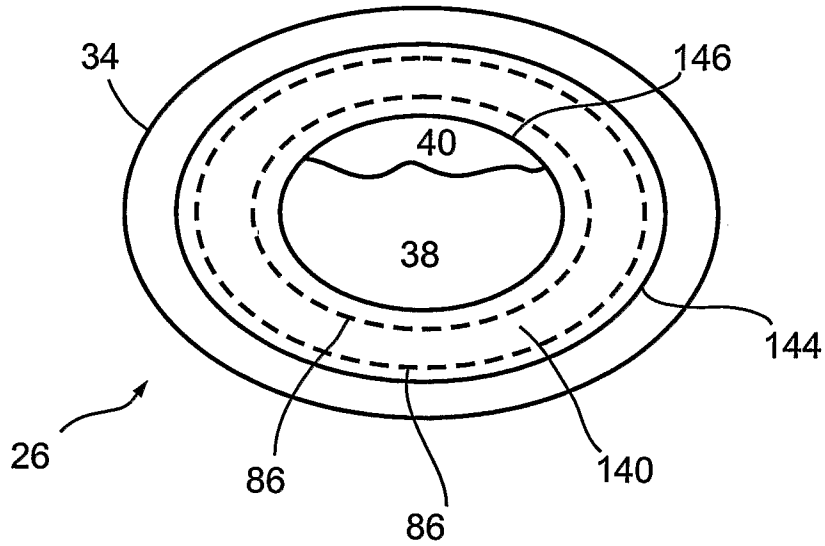
42
26

Fig. 8i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26
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86
140

Fig. 8j

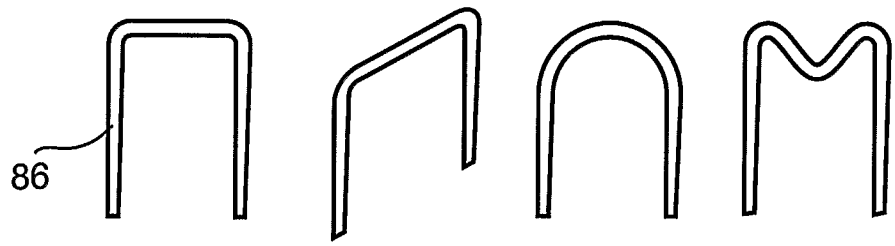

Fig. 9a

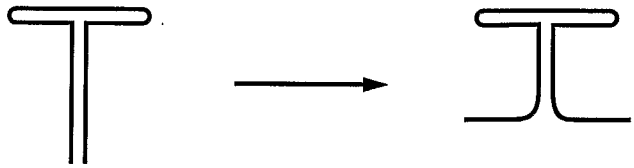

Fig. 9b

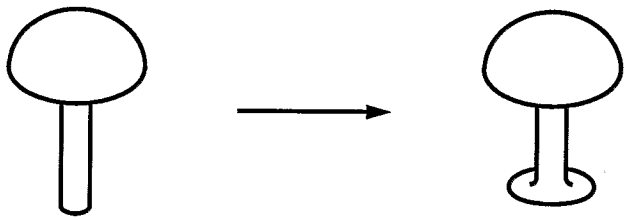

Fig. 9c

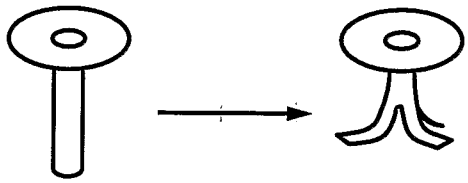

Fig. 9d

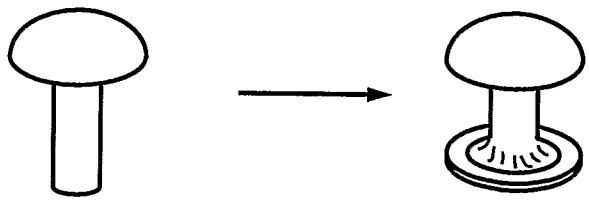

Fig. 9e

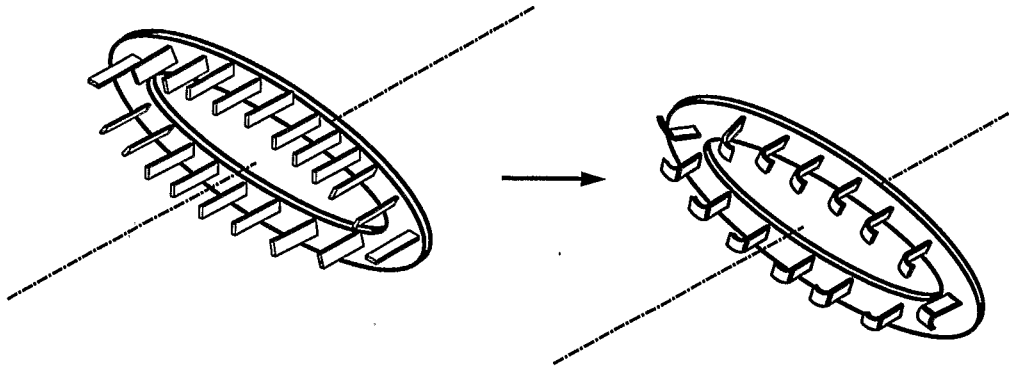

Fig. 9f

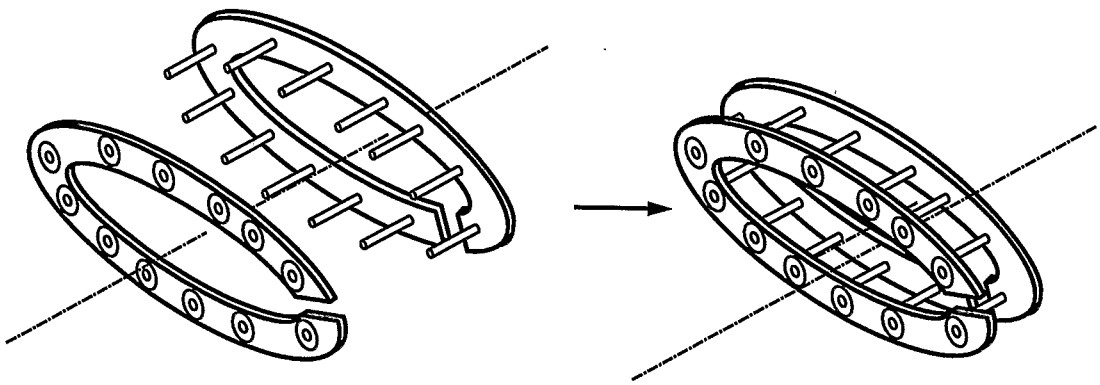

Fig. 9g