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(54) **PROSTHETIC CHORDAE ASSEMBLY AND METHOD OF USE**

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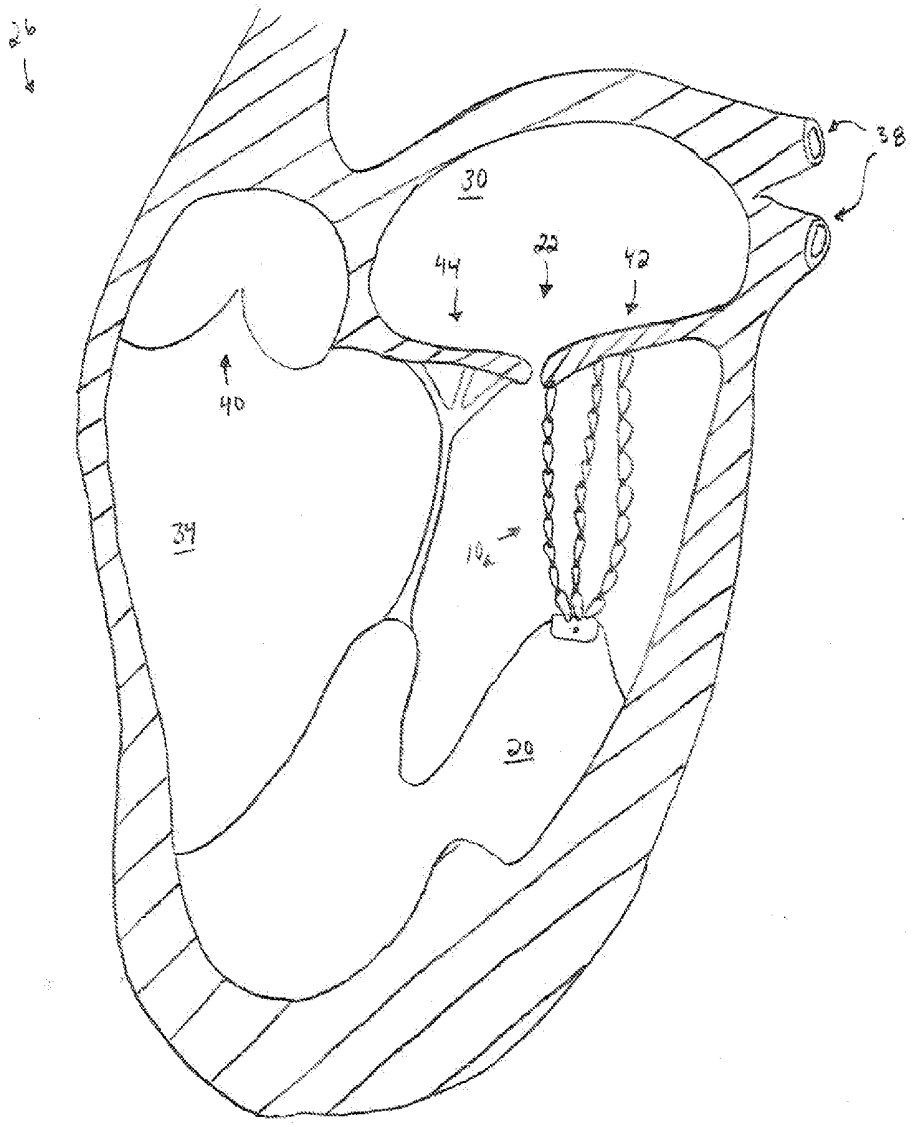
(57) **ABSTRACT**

A prosthetic chordae assembly includes a plurality of equally-sized, interconnected loop members formed from a single strand of a biocompatible material. Each of the loop members includes first and second ends respectively defining a first arcuate junction and a second arcuate junction. The prosthetic chordae assembly is adjustable to a pre-determined length by removing one of the loop members.



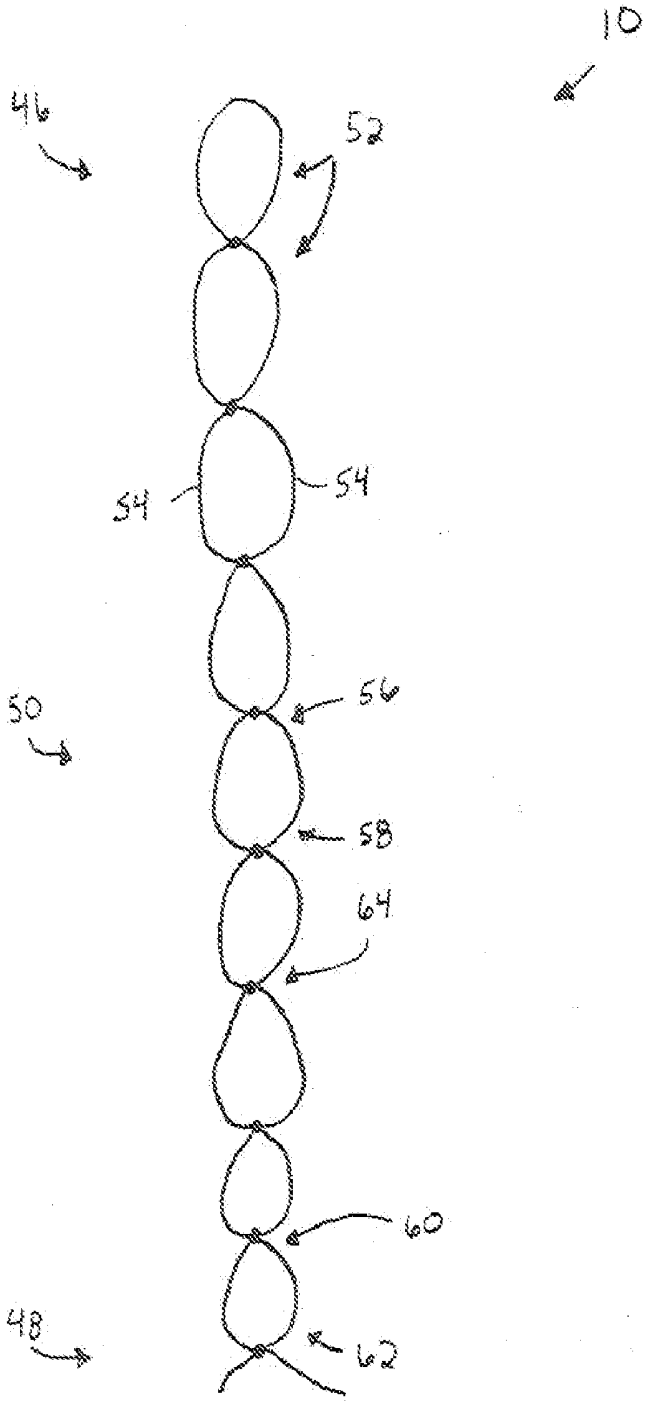


Fig. 1

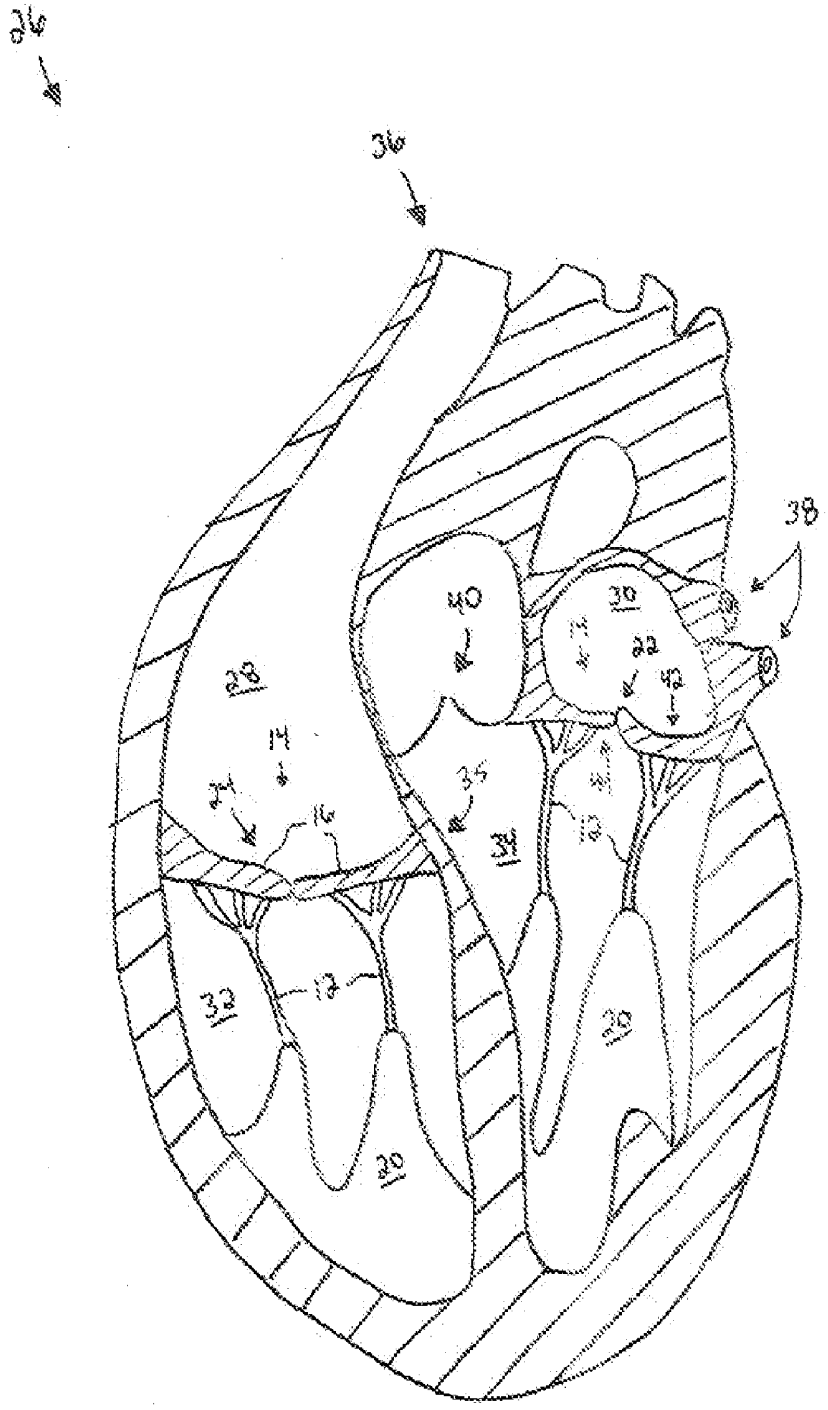


Fig. 2

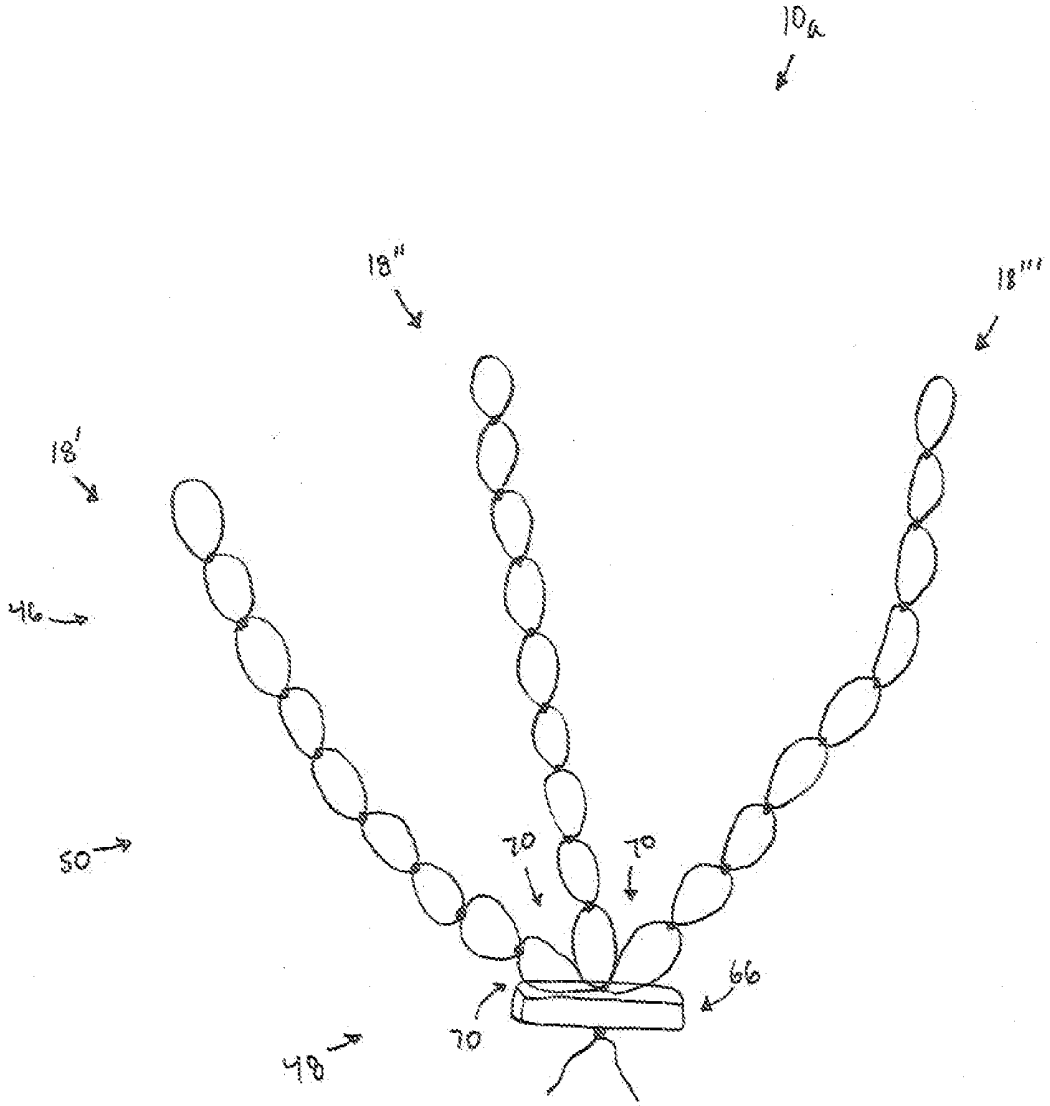


Fig. 3

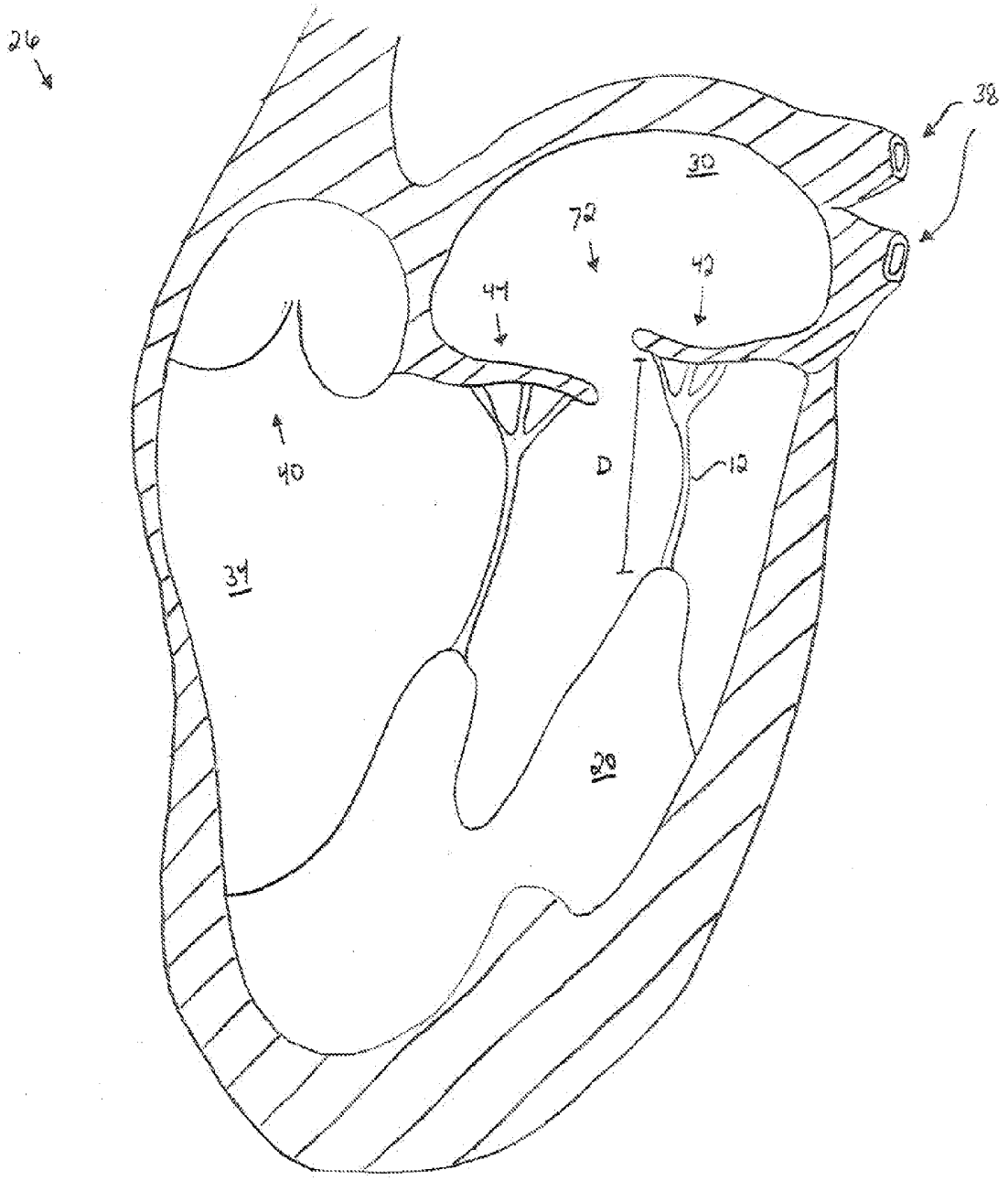


Fig. 4

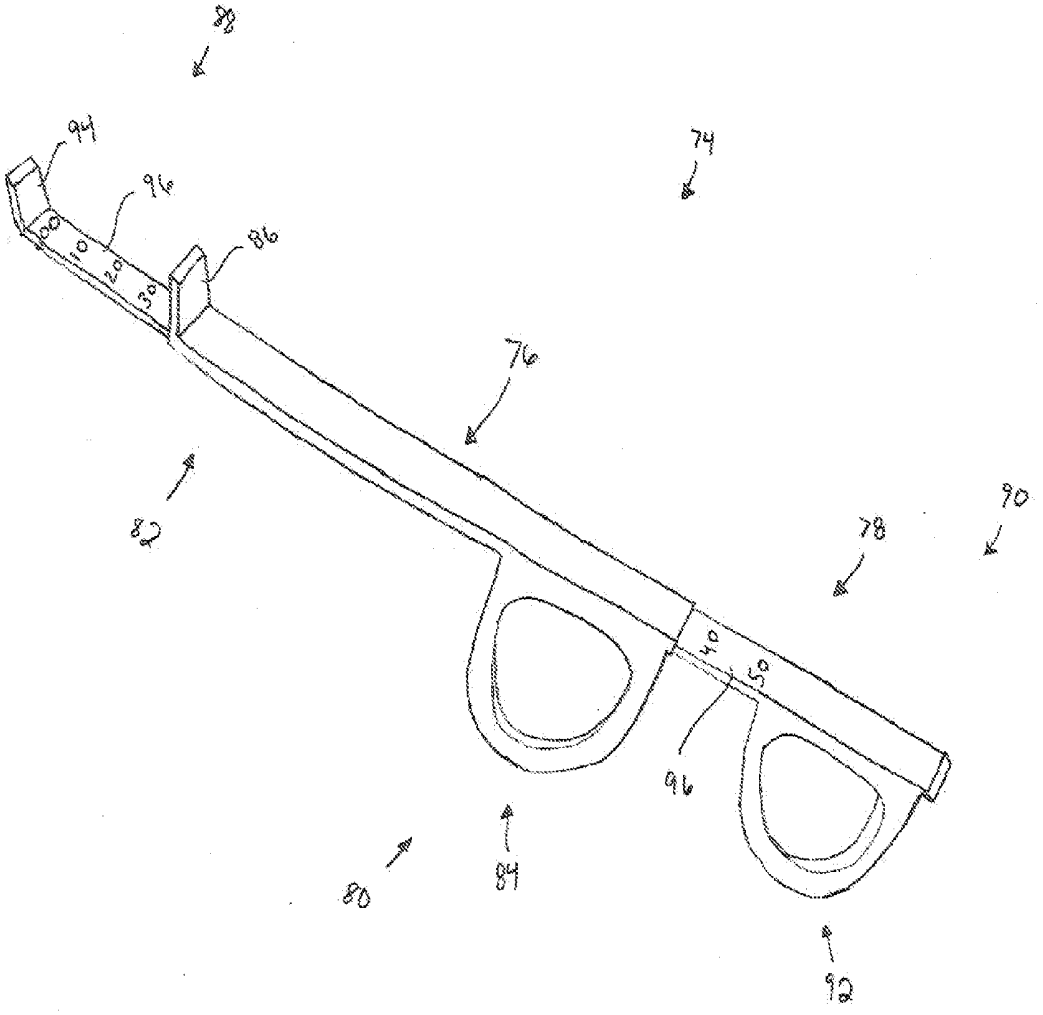


Fig. 5A

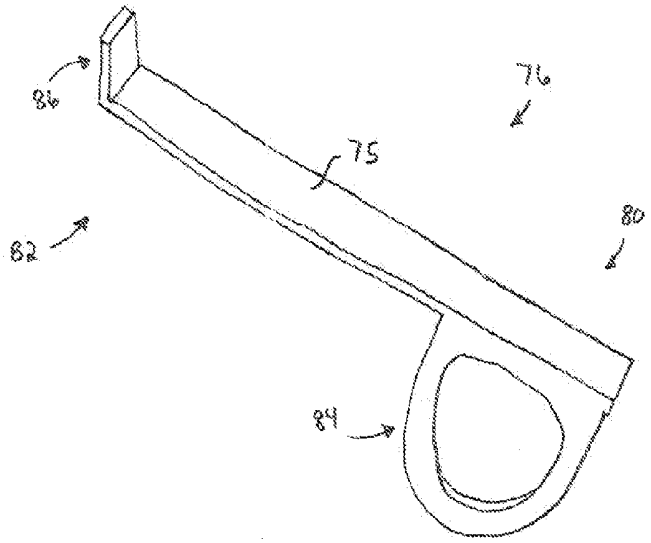


Fig. 5B

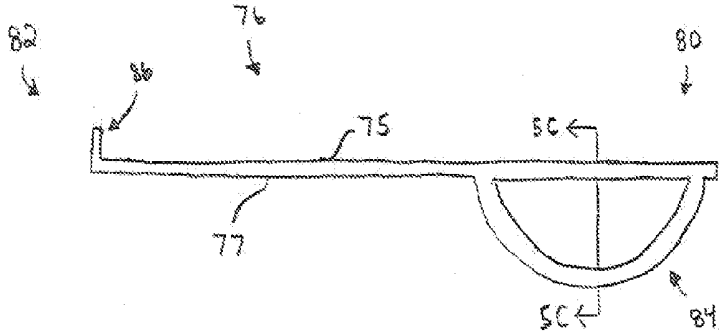


Fig. 5C

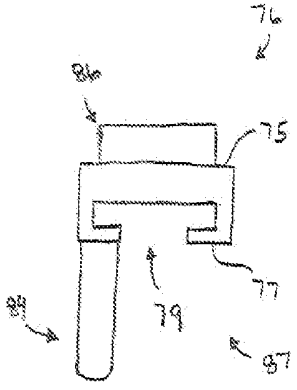


Fig. 5D

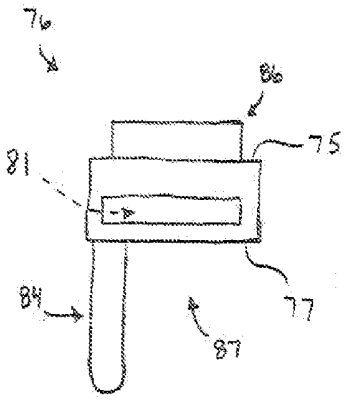


Fig. 5E

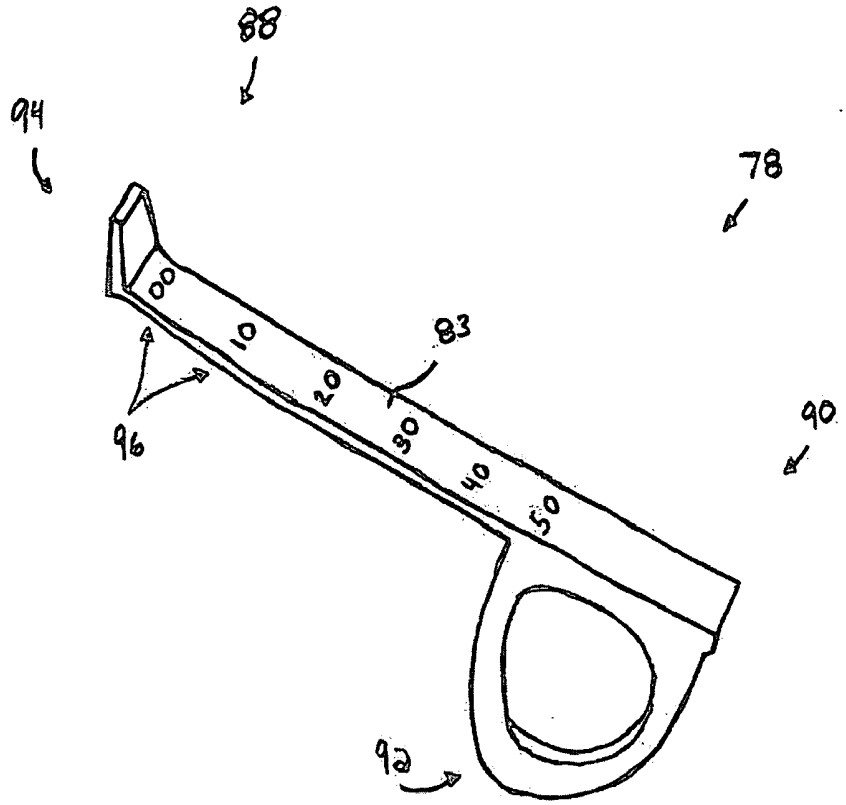


Fig. 5F

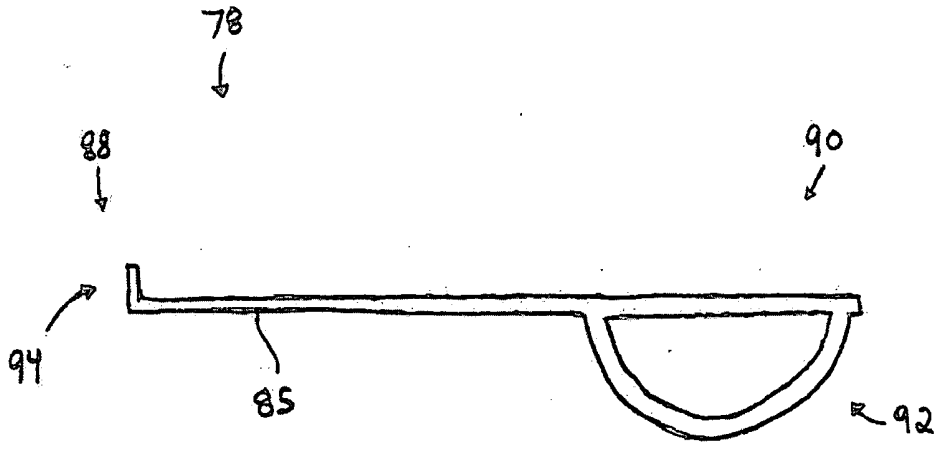


Fig. 5G

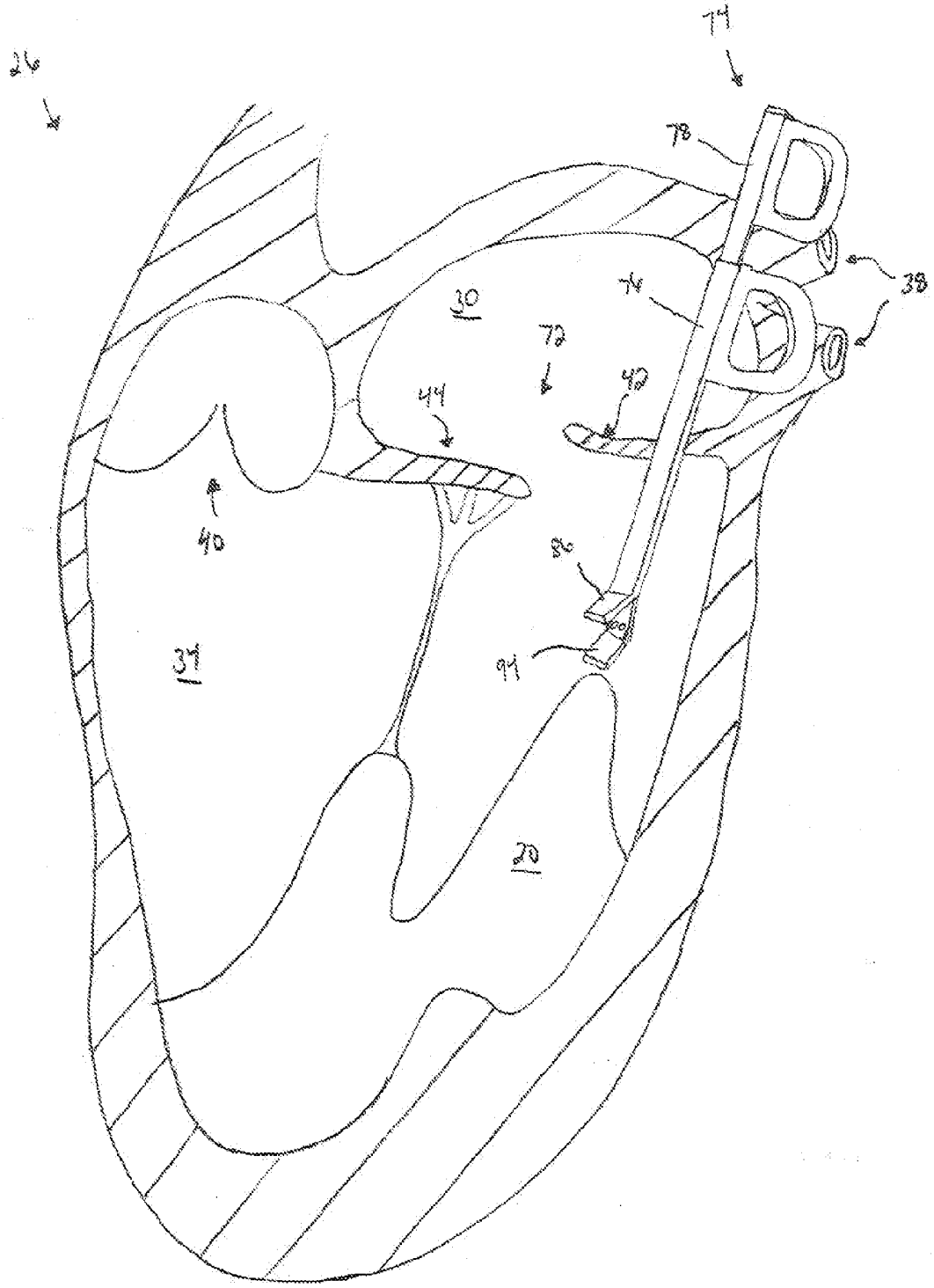


Fig. 6

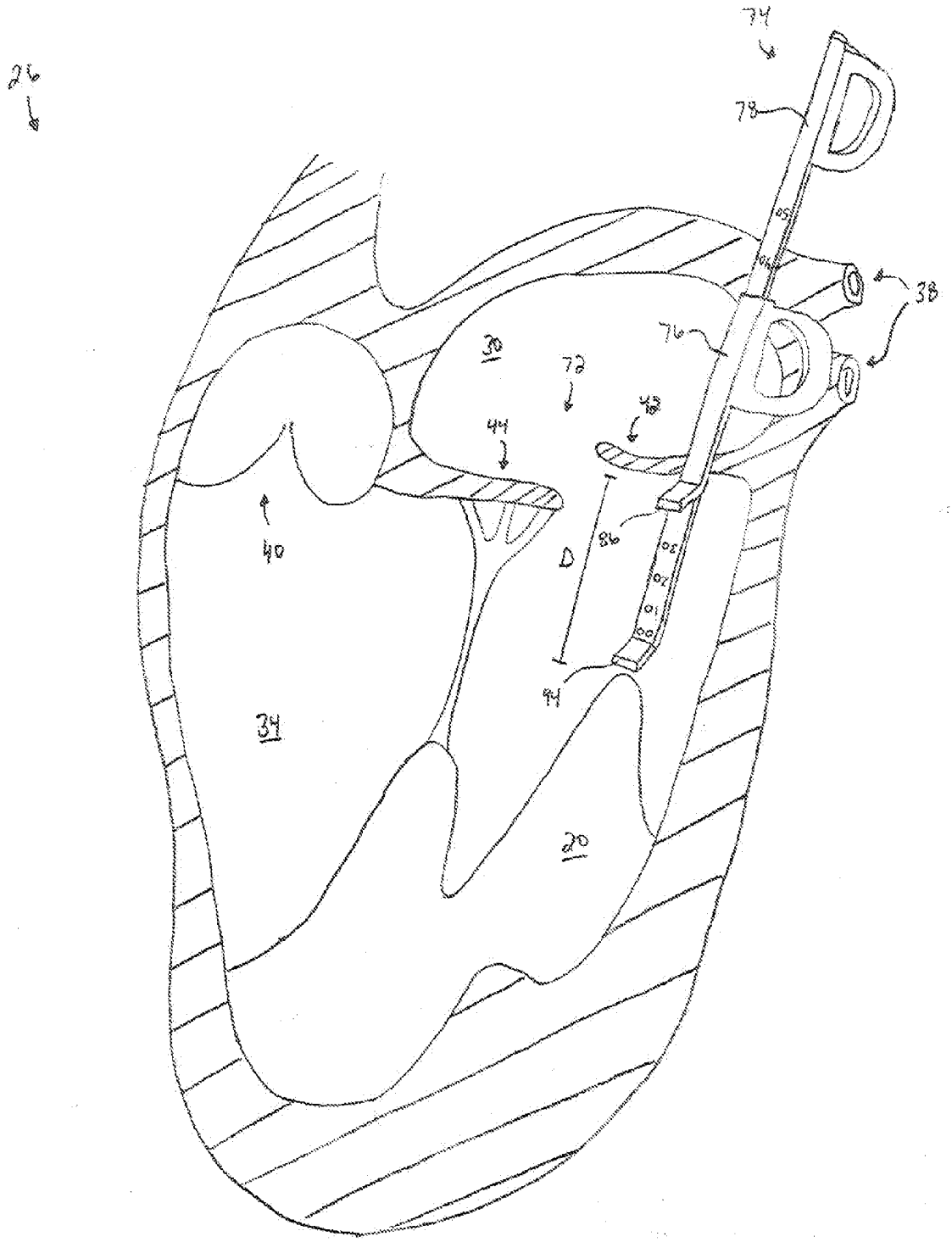


Fig. 7

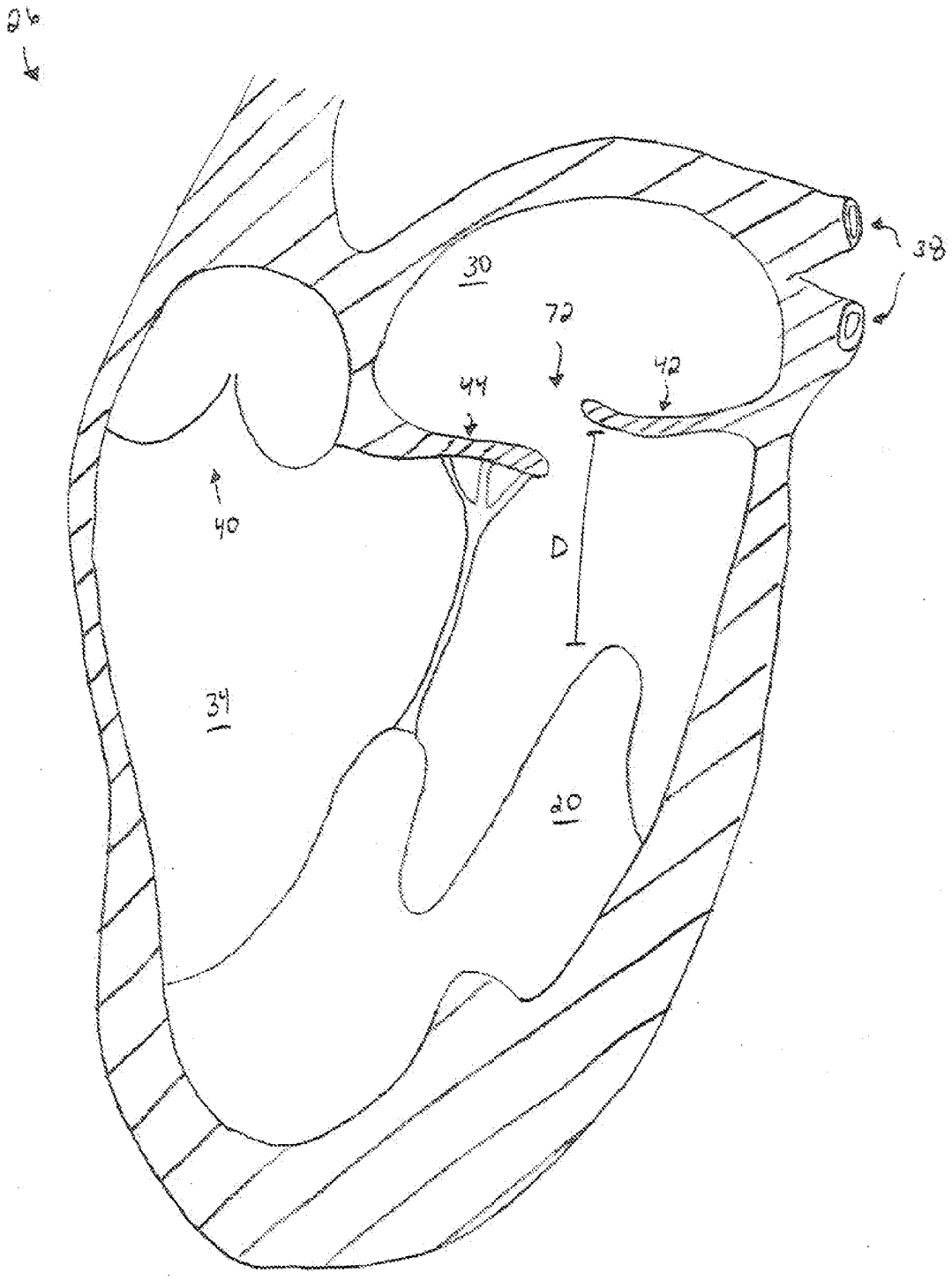


Fig. 8

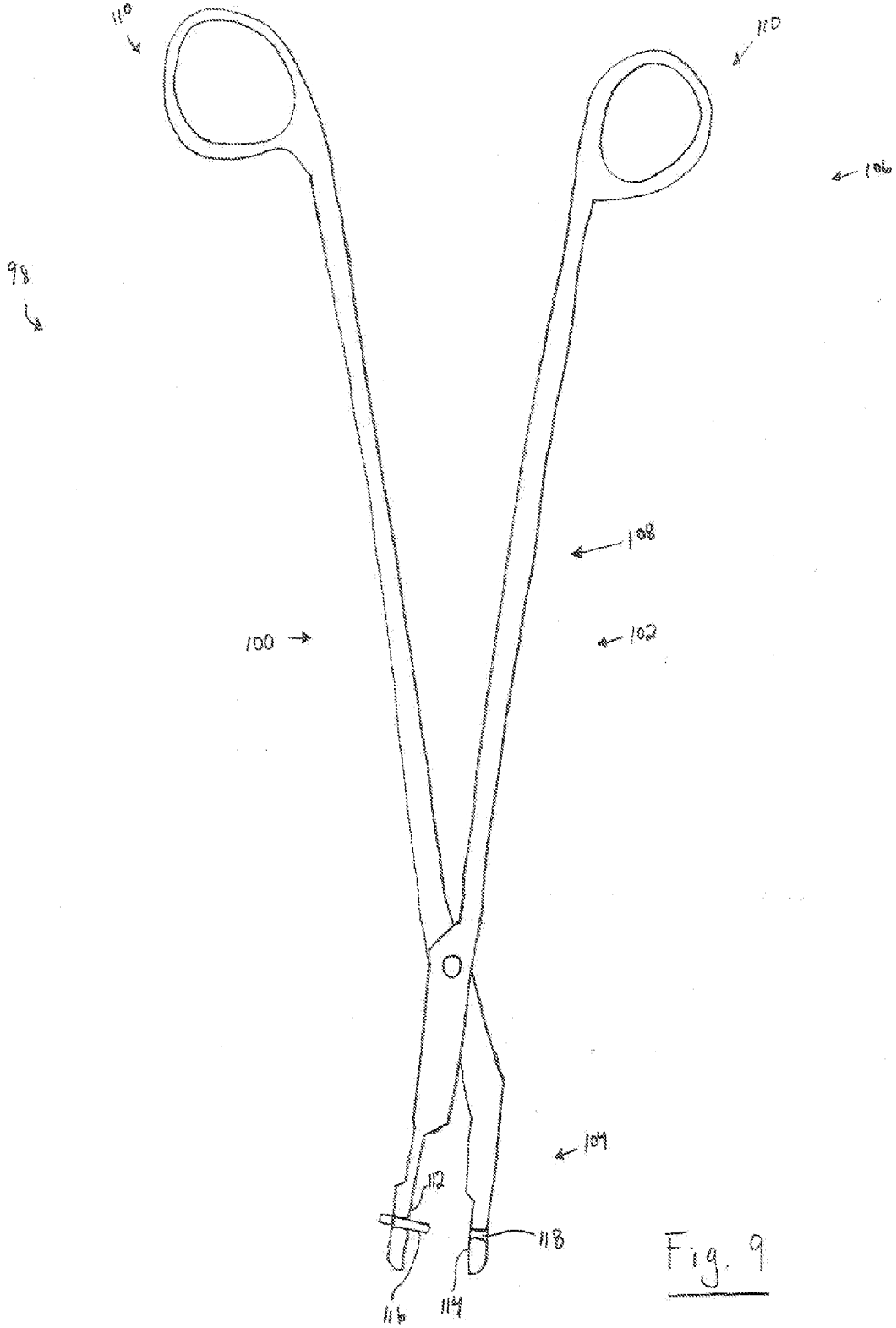


Fig. 9

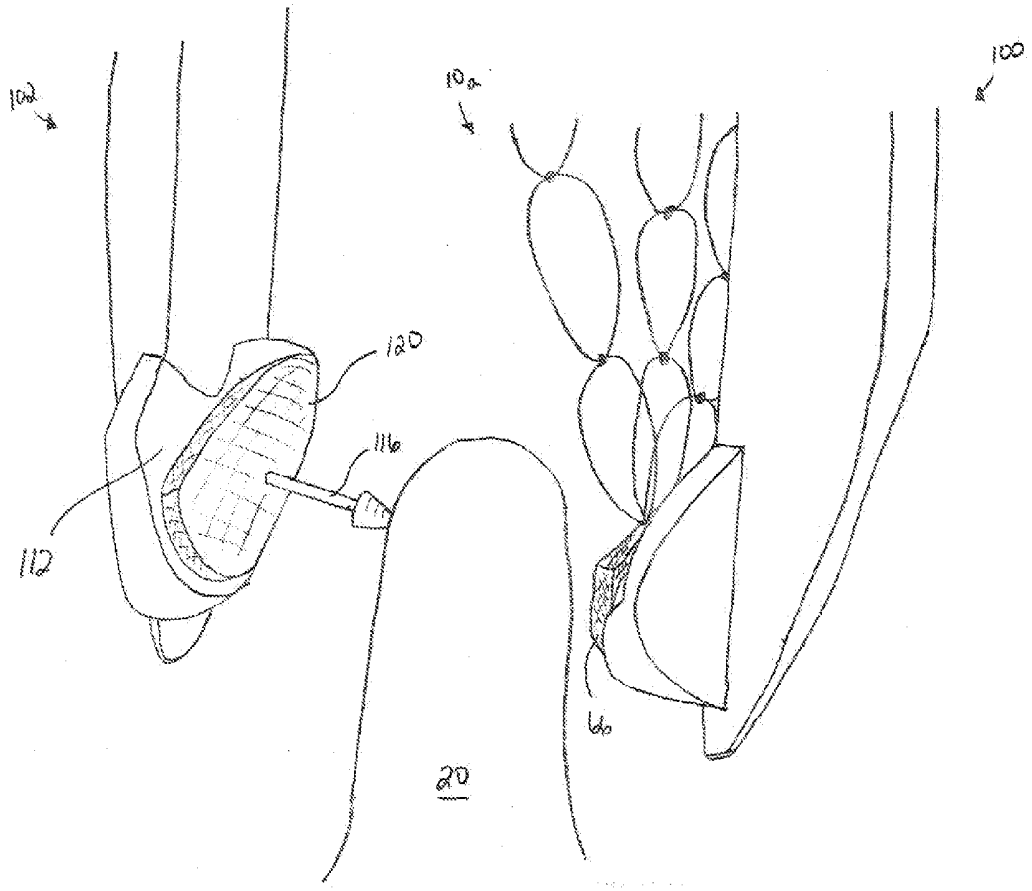


Fig. 10

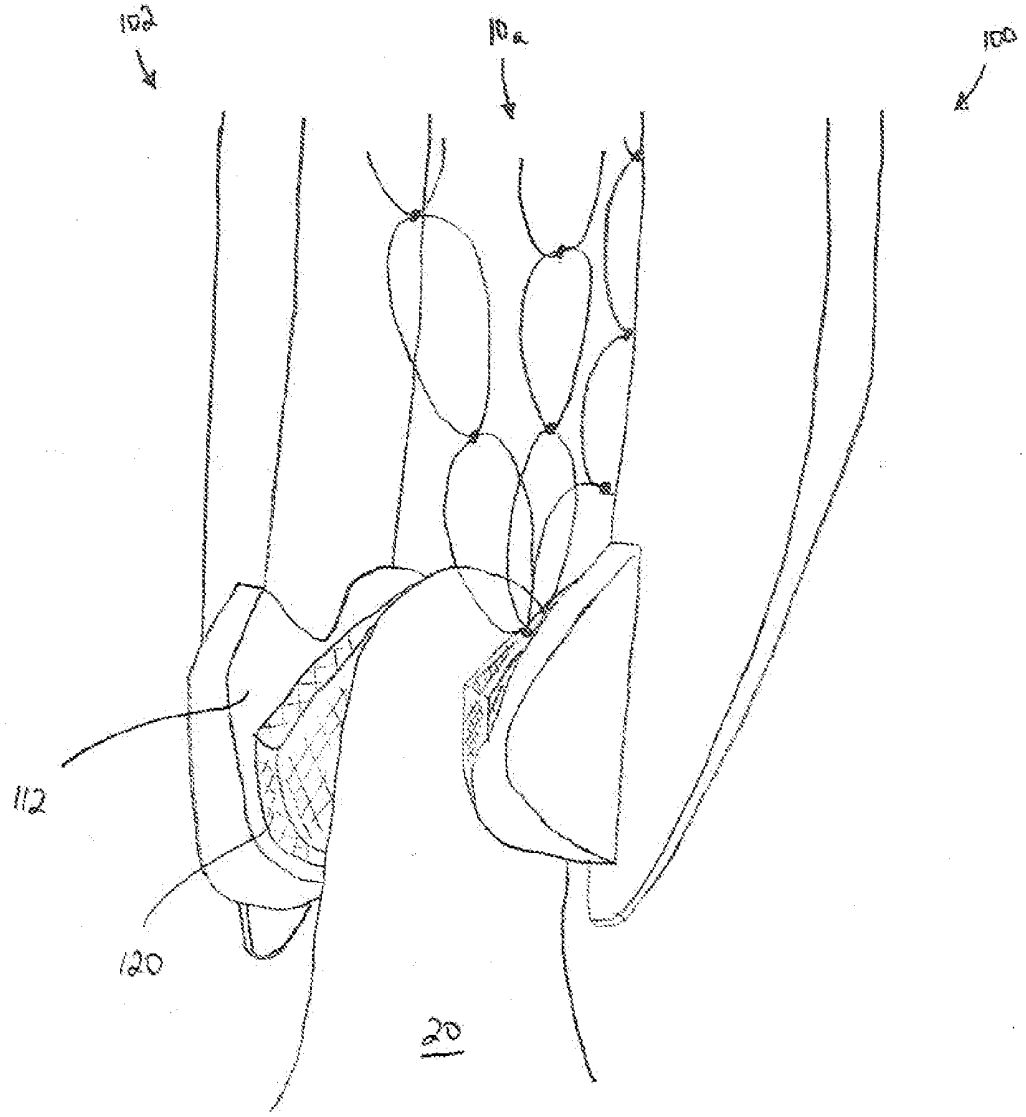


Fig. 11

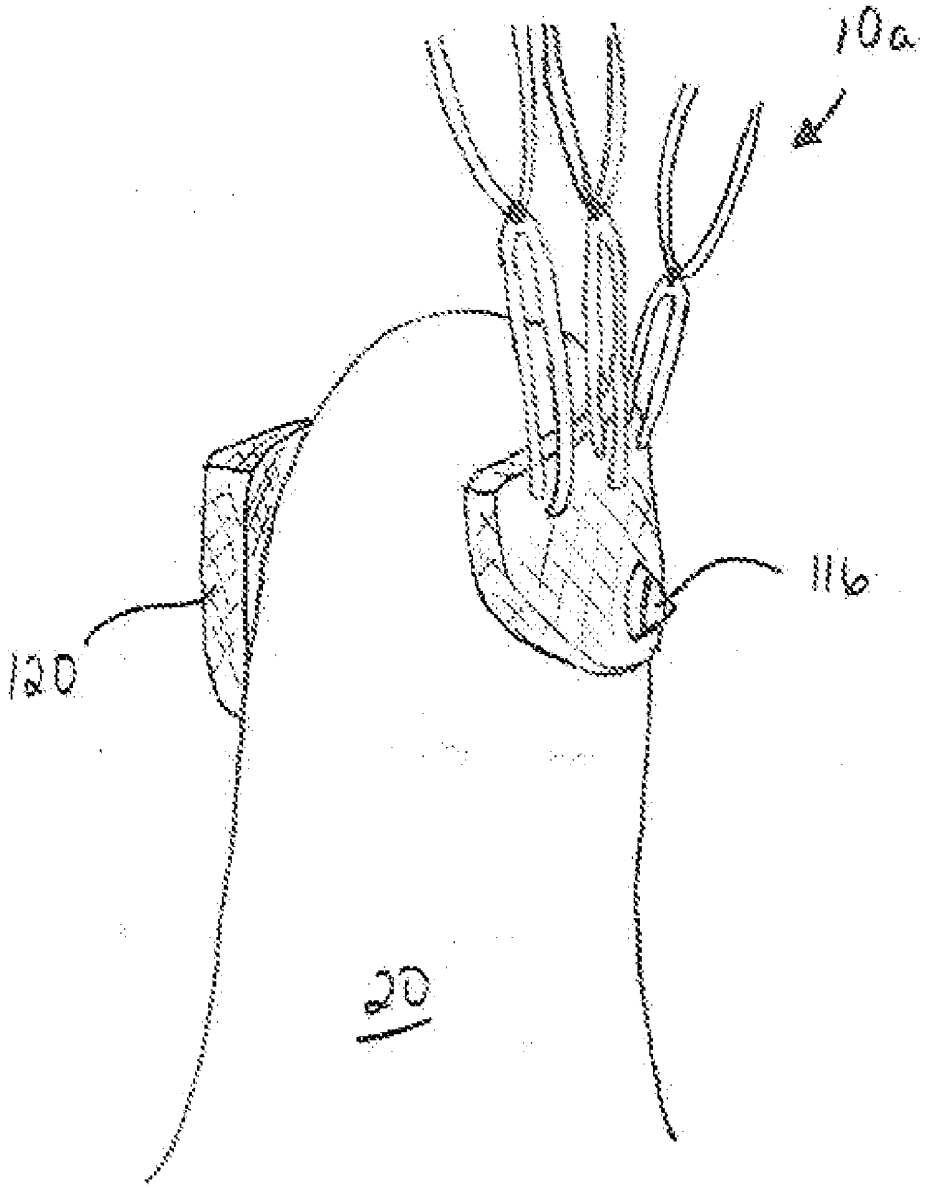


Fig. 12

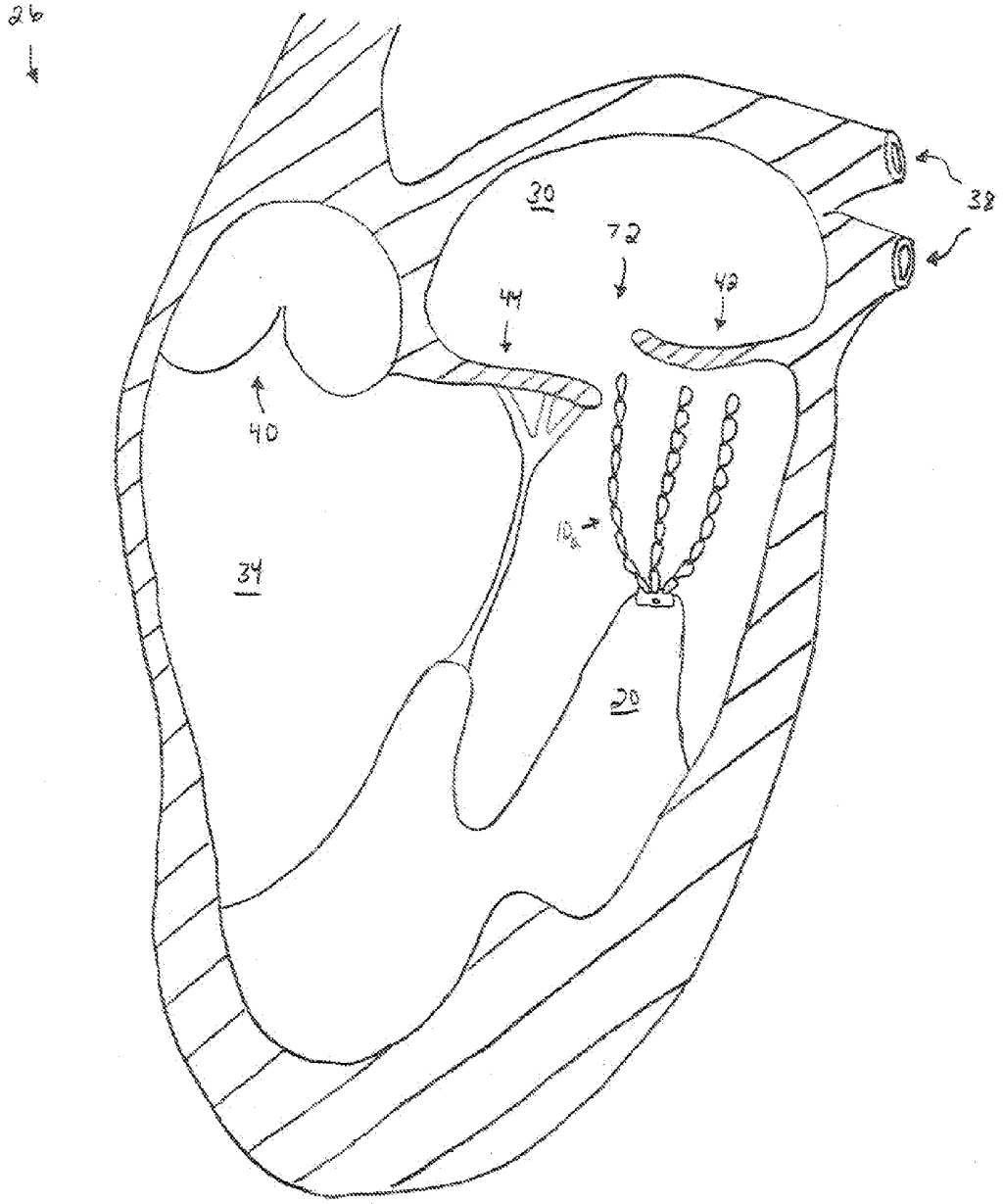


Fig. 13

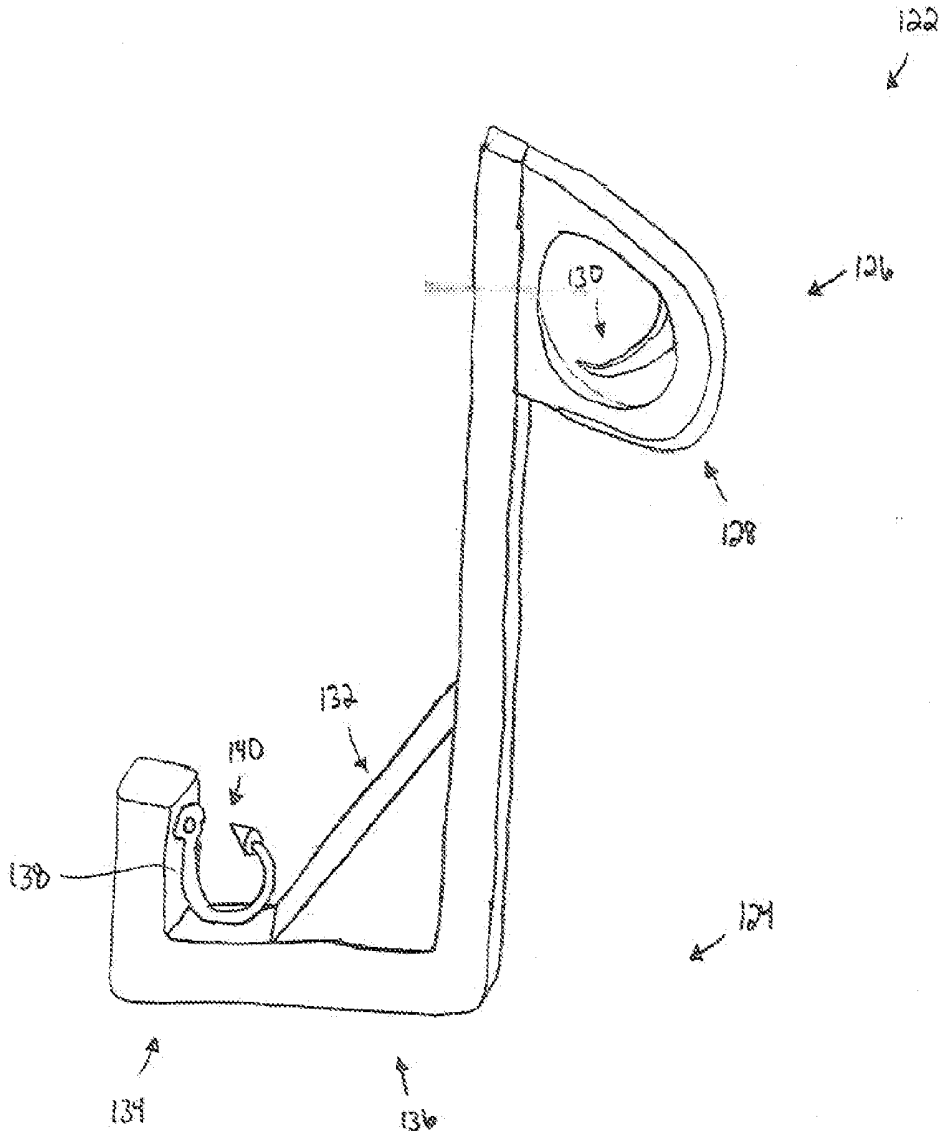


Fig. 14

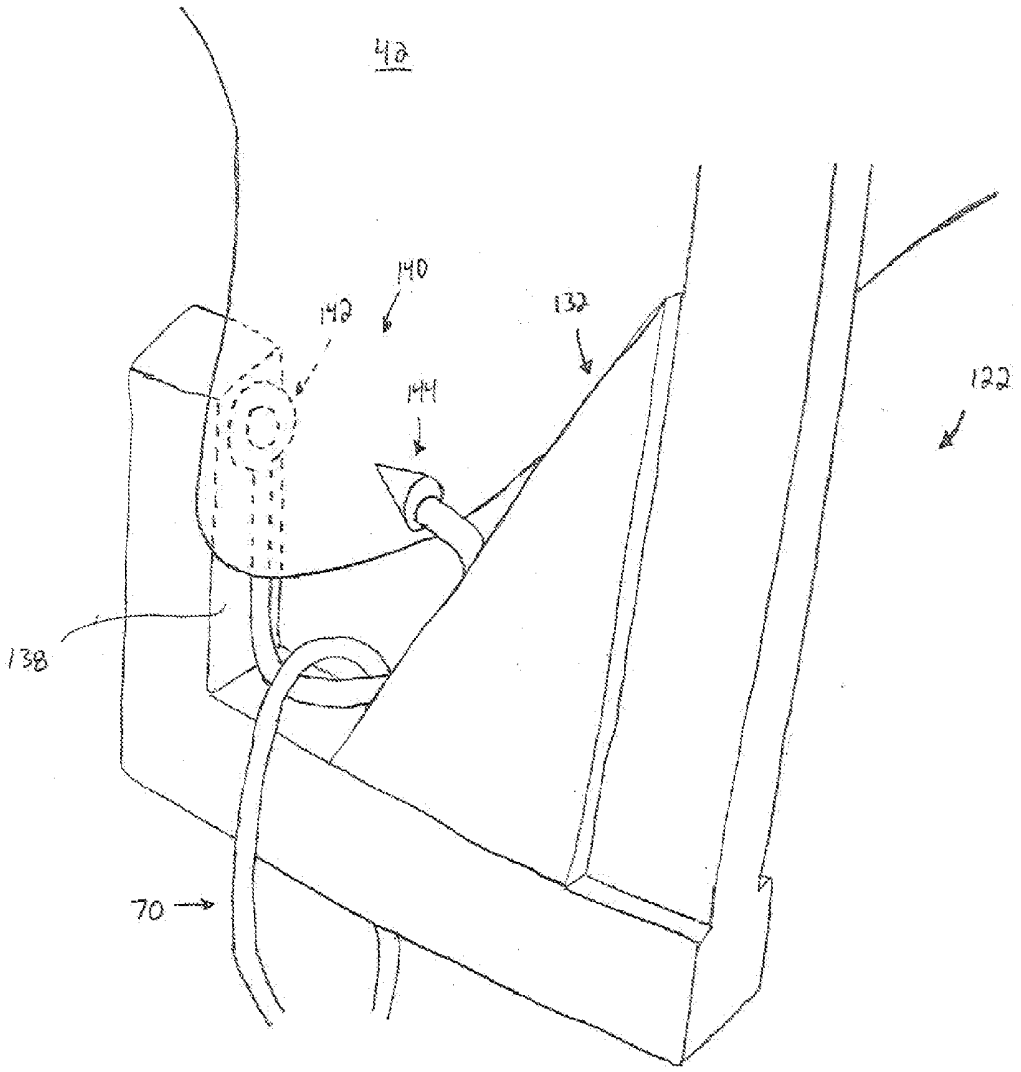


Fig. 15

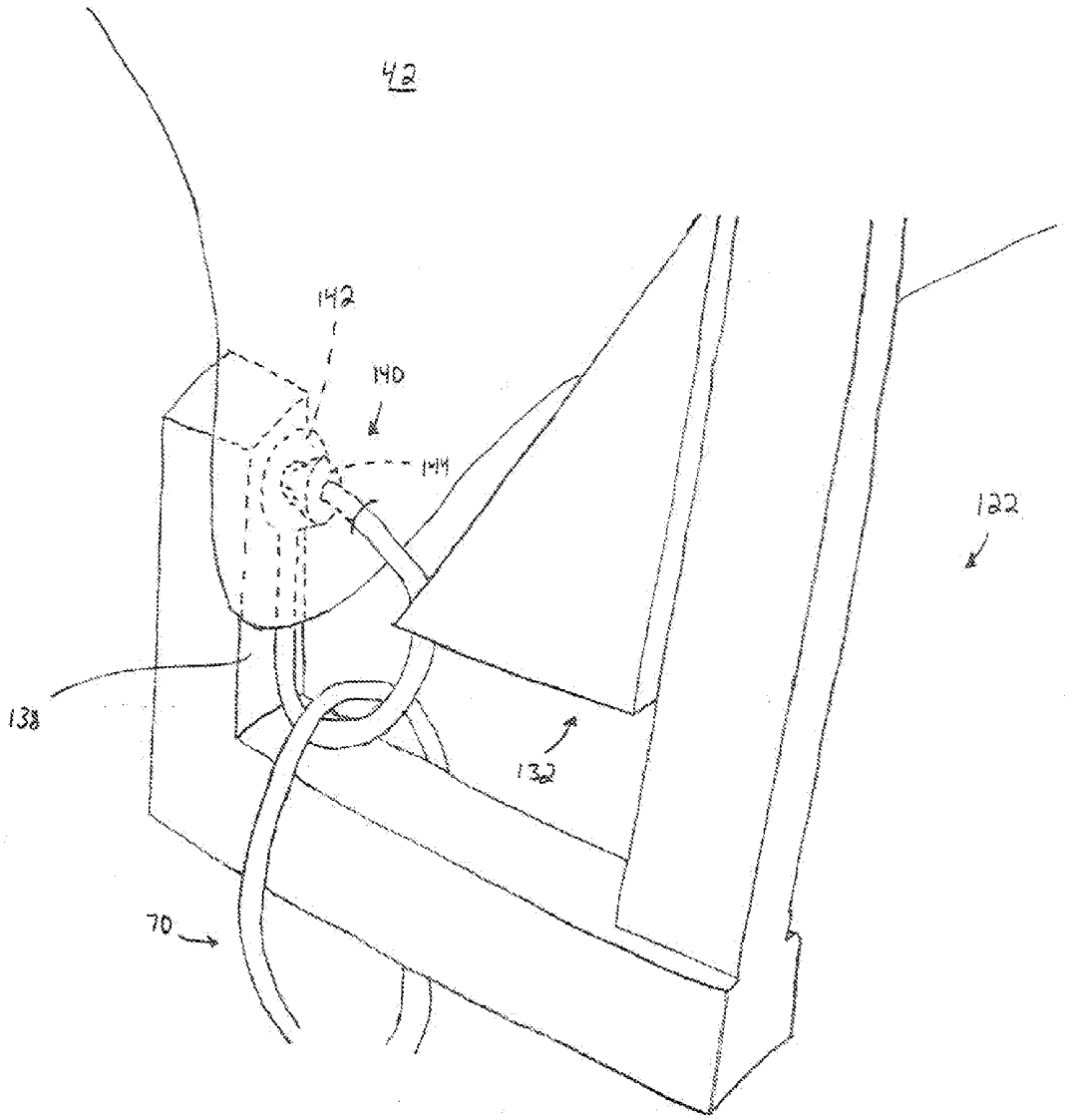


Fig. 16

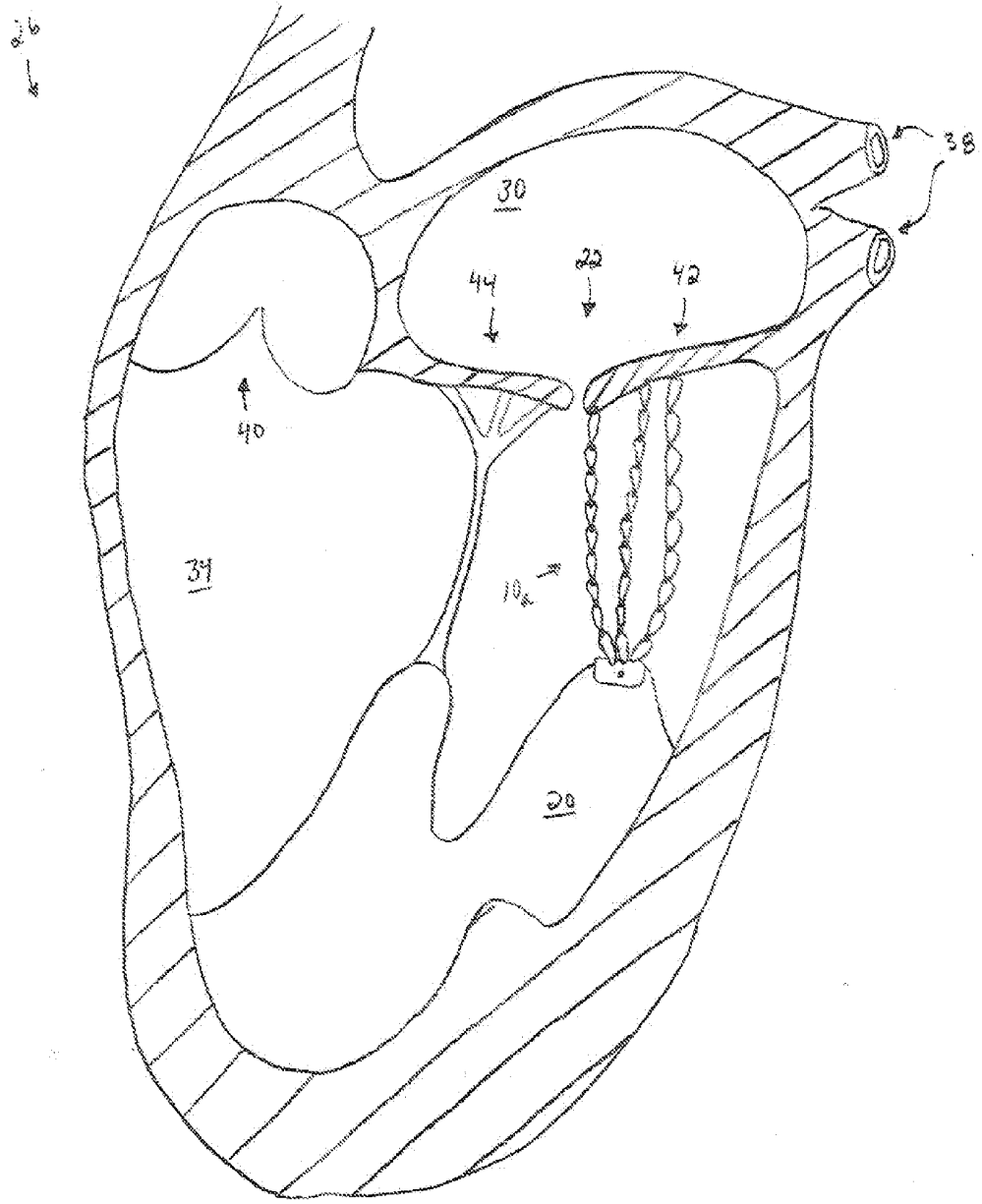


Fig. 17

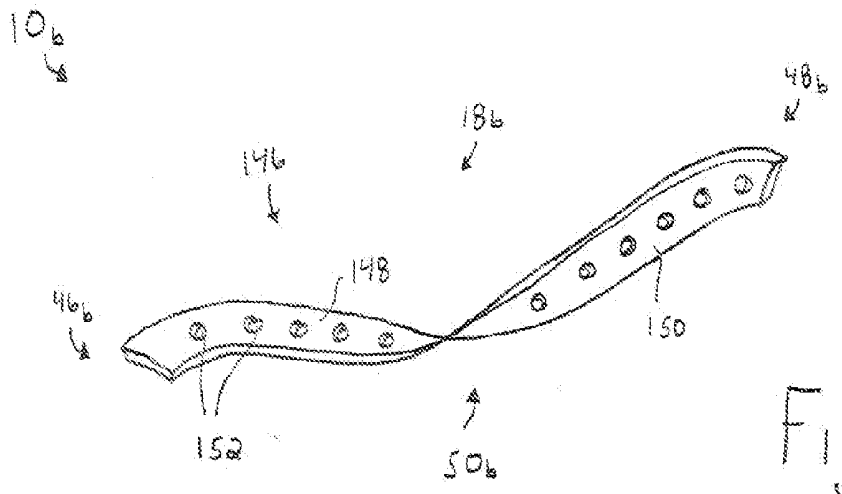


Fig. 18A

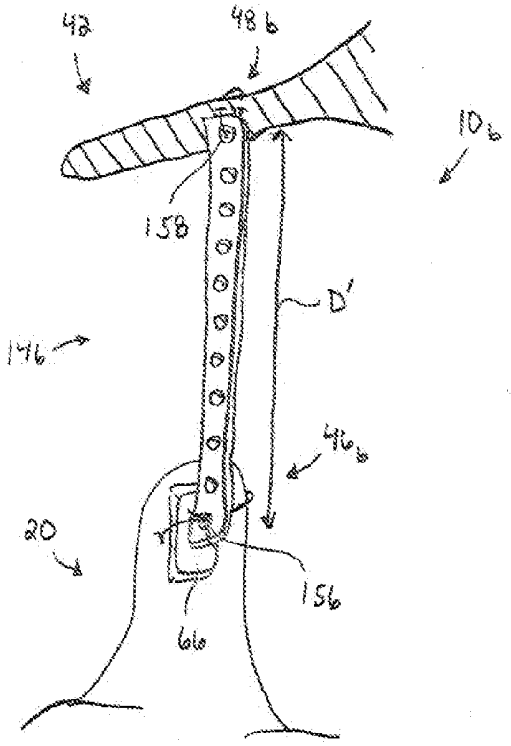


Fig. 18B

PROSTHETIC CHORDAE ASSEMBLY AND METHOD OF USE

RELATED APPLICATION

[0001] This application claims priority from U.S. provisional patent application Ser. No. 60/975,886, filed Sep. 28, 2007, the entirety of which is hereby incorporated by reference.

TECHNICAL FIELD

[0002] The present invention generally relates to artificial chordae, and more particularly to a prosthetic chordae assembly for mitral or tricuspid valve repair.

BACKGROUND OF THE INVENTION

[0003] Heart valve replacement is a well known procedure in which an artificial heart valve prosthesis is implanted in place of a diseased or malfunctioning heart valve. Heart valve prostheses may be mechanical or bioprosthetic. Use of mechanical valves typically requires extensive anticoagulation therapy. The need for anticoagulation therapy can be avoided in general by the use of artificial biological heart valves, such as bovine xenografts. Nevertheless, dystrophic calcification with subsequent degeneration is the major cause of failure of such bioprostheses in the long term.

[0004] When mitral or tricuspid valve replacement is performed, the chordae tendineae are cut, thus leaving the geometry and function of the ventricle impaired and in need of reconstruction. As an alternative to conventional heart valve replacement operations, diseased and malfunctioning chordae can be repaired by surgically replacing diseased heart chordae with artificial chordae. One known way of replacing a malfunctioning chordae uses a simple suture with a needle on each end of the suture. The suture is stitched through the papillary muscle and secured thereto with a knot. The two ends of the suture are then similarly stitched through the free ends of the valve leaflets.

[0005] Operations to repair heart valve chordae are technically demanding. For exam pie, when a second knot is needed to secure the suture to the valve leaflets, the length of the suture spanning the distance between the papillary muscle and the valve leaflet is likely to change since there is nothing holding the suture in place. This complication increases the skill and time required to perform the procedure. Moreover, the valve will not function properly if the length of the artificial chordae between the papillary muscle and valve leaflet is overly long or overly short.

SUMMARY OF THE INVENTION

[0006] According to one aspect of the present invention, a prosthetic chordae assembly comprises a plurality of equally-sized, interconnected loop members formed from a single strand of a biocompatible material. Each of the loop members includes first and second ends respectively defining a first arcuate junction and a second arcuate junction. The prosthetic chordae assembly is adjustable to a pre-determined length by removing one of the loop members.

[0007] According to another aspect of the present invention, a method is provided for replacing the native chordae of a heart valve having at least two leaflets. One step of the method includes measuring the distance between a papillary muscle and a location on at least one of the at least two leaflets of the heart valve. Next, a prosthetic chordae assembly is provided. The prosthetic chordae assembly comprises a plurality of equally-sized, interconnected loop members formed from a single strand of a biocompatible material. Each of the loop members includes first and second ends respectively defining a first arcuate junction and a second arcuate junction. The length of the prosthetic chordae assembly is then adjusted to the measured distance by removing at least one of the loop members. Next, the second arcuate junction of a loop member is attached to the papillary muscle, and the first arcuate junction of another loop member is attached at the location on one of the at least two leaflets of the heart valve.

[0008] According to another aspect of the present invention, a measuring device for determining a distance between a papillary muscle and a location on a heart valve leaflet comprises a first handle member slidably connected to a second handle member. The first handle member includes a first proximal end portion and a first distal end portion. The first proximal end portion includes a first reference tab, and the first distal end portion includes a first handle. The second handle member includes a second proximal end portion and a second distal end portion. The second proximal end portion includes a second reference tab, and the second distal end portion includes a second handle. The second handle member includes a first major surface having a plurality of distance markers for indicating the distance between the papillary muscle and the location on the heart valve leaflet.

[0009] According to another aspect of the present invention, a method is provided for measuring a distance between a papillary muscle and a location on a heart valve leaflet. One step of the method includes providing a measuring device comprising a first handle member slidably connected to a second handle member. The first handle member includes a first proximal end portion with a reference tab and a first distal end portion with a first handle. The second handle member includes a second proximal end portion with a second reference tab and a second distal end portion with a second handle. The second handle member also includes a first major surface having a plurality of distance markers. The measuring device is inserted into a cardiac ventricle. The second proximal end portion of the second handle member is then positioned substantially adjacent the papillary muscle. Next, the first handle member is manipulated so that the first proximal end portion of the first handle member is substantially adjacent the location on the heart valve leaflet. The distance between the first and second reference tabs is then determined.

[0010] According to another aspect of the present invention, a prosthetic chordae assembly comprises an elongated, belt-like strap member having a first major surface oppositely disposed from a second major surface. The strap member includes a plurality of apertures extending between the first and second major surfaces.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The foregoing and other features of the present invention will become apparent to those skied in the art to which the present invention relates upon reading the following description with reference to the accompanying drawings, in which:

[0012] FIG. **1** is a plan view of an apparatus for replacing the native chordae of a heart valve having at least two leaflets constructed in accordance with the present invention;

[0013] FIG. **2** is a cross-sectional view of a human heart;

[0014] FIG. **3** is a plan view showing an alternative embodiment of the apparatus in FIG. **1**;

[0015] FIG. **4** is an exploded cross-sectional view of the human heart in FIG. **2** showing a regurgitant mitral valve;

[0016] FIG. **5**A is a perspective view showing a measuring device comprising first and second handle members for determining the distance between a papillary muscle and a location on a heart valve leaflet;

[0017] FIG. **5**B is a perspective view of the first handle member;

[0018] FIG. **5**C is a side view of the first handle member in FIG. **5**B;

[0019] FIG. **5**D is a cross-sectional view taken along Line **5**C-**5**C in FIG. **5**C;

[0020] FIG. **5**E is a cross-sectional view showing an alternative embodiment of the first handle member in FIG. **5**D;

[0021] FIG. **5**F is a perspective view of the second handle member;

[0022] FIG. **5**G is a side view of the second handle member in FIG. **5**F;

[0023] FIG. **6** is a perspective view showing the measuring device in FIG. **5** being positioned between a papillary muscle and a heart valve leaflet;

[0024] FIG. **7** is a perspective view showing the measuring device in FIG. **6** being used to measure the distance between the papillary muscle and the heart valve leaflet;

[0025] FIG. **8** is a cross-sectional view showing the native chordae resected from the human heart in FIG. **4**;

[0026] FIG. **9** is a top plan view showing a papillary implantation device for securing the apparatus of the present invention to a papillary muscle;

[0027] FIG. **10** is a magnified perspective view showing the papillary implantation device in FIG. **9** being used to position the apparatus in FIG. **3** about a papillary muscle;

[0028] FIG. **11** is a magnified perspective view showing the implantation device of FIG. **10** securing the apparatus in FIG. **3** to the papillary muscle;

[0029] FIG. **12** is a magnified perspective view showing the apparatus in FIG. **11** secured to the papillary muscle;

[0030] FIG. **13** is a cross-sectional view showing the apparatus in FIG. **12** secured to the papillary muscle;

[0031] FIG. **14** is a perspective view showing a leaflet implantation device for securing the apparatus of the present invention to a heart valve leaflet;

[0032] FIG. **15** is a magnified perspective view showing the leaflet implantation device in FIG. **14** being positioned about a heart valve leaflet;

[0033] FIG. **16** is a magnified perspective view showing the leaflet implantation device of FIG. **15** securing the apparatus in FIG. **3** to the heart valve leaflet;

[0034] FIG. **17** is a cross-sectional view showing the apparatus in FIG. **3** implanted in a human heart;

[0035] FIG. **18**A is a perspective view showing an alternative embodiment of the apparatus in FIG. **1**; and

[0036] FIG. **18**B is a perspective view of the apparatus in FIG. **18**A attached to a mitral leaflet and a papillary muscle.

DETAILED DESCRIPTION

[0037] The present invention relates to artificial chordae, and more particularly to a prosthetic chordae assembly for mitral or tricuspid valve repair. As representative of the present invention, FIG. **1** illustrates an apparatus **10** for replacing the native chordae **12** (FIG. **2**) of a heart valve **14** having at least two leaflets **16**. The apparatus **10** (FIG. **1**) comprises a prosthetic chordae assembly **18** configured to extend from a papillary muscle **20** (FIG. **2**) to a location on one of the at least two heart valve leaflets **16**. Although the present invention is described herein as being useful for treating a dysfunctional mitral valve **22**, it should be appreciated that other cardiac valves, such as the tricuspid valve **24** are also treatable using the present invention.

[0038] FIG. **2** shows a human heart **26**. The human heart **28** contains four chambers: the right and left atria **28** and **30** and the right and left ventricles **32** and **34**. The thin-walled right atrium **28** receives deoxygenated blood from the superior vena cava **36**, the inferior vena cava (not shown), and from the coronary sinus (not shown). The thin-wailed left atrium **30** receives oxygenated blood from pulmonary veins **38**. The right and left ventricles **32** and **34** pump oxygenated and deoxygenated blood, respectively, throughout the body, and the pocket-like pulmonary (not shown) and aortic **40** semilunar valves prevent reflux into the ventricles.

[0039] Atrial blood is pumped through the atrioventricular orifices, guarded by the 3-cusp tricuspid valve **24** on the right and the 2-cusp mitral valve **22** on the left. The mitral valve **22** is formed by two leaflets; namely, the anterior leaflet **42** and the posterior leaflet **44**. The anterior leaflet **42** extends along a generally planar base of a D-shaped annulus (hot shown in detail), while the posterior leaflet **44** extends arcuately around the curved portion of the annulus. The mitral and tricuspid valves **22** and **24** are secured to the papillary muscles **20** in the right and let ventricles **32** and **34** by tendinous chordae tendineae **12** and by the mitral annulus and the tricuspid annulus (not shown in detail).

[0040] Referring to FIG. **1**, the prosthetic chordae assembly **18** includes a first end portion **46**, a second end portion **48**, and a middle portion **50** extending between the first and second end portions. The prosthetic chordae assembly **18** is comprised of a plurality of loop members **52** arranged in a daisy chain or ladder-like configuration. Each of the loop members **52** comprises two generally parallel strands **54** and includes first and second ends **56** and **58** which respectively define first and second arcuate junctions **60** and **62**. The distance between the first and second arcuate junctions **60** and **62** can be about 1 cm; however, it should be appreciated that the distance between the first and second arcuate junctions will depend upon variations in subject anatomy. The two generally parallel strands **54** are fluidly connected to the first and second arcuate junctions **60** and **62** of each loop member **52**. Each loop member **52** has a size and length that is substantially equal to the size and length of the other loop members. It should be appreciated, however, that each loop member **52** can have a length and size different from each of the other loop members. For example, the apparatus **10** can be configured so that prosthetic chordae assemblies **18** of different lengths can be easily constructed from a plurality of loop members **52**.

[0041] Each loop member **52** is made from a biocompatible material that is relatively elastic and flexible to allow movement of the heart valve leaflets **16** during opening and closing of the valve **14**. Examples of suitable biocompatible materials include Teflon and expanded polytetrafluoroethylene (ePTFE). The ePTFE may be suture material or fabric material. Besides Teflon and ePTFE, it should be apparent to one skilled in the art that there are other suitable biocompatible materials, including those which are frequently used to form sutures.

[0042] The prosthetic chordae assembly **18** shown in FIG. **1** comprises an elongated, unitary unit of nine interconnected loop members **52**. The prosthetic chordae assembly **18** is

comprised of a single strand or fiber, such as a suture; however, it should be appreciated that the prosthetic chordae assembly may be comprised of multiple units, e.g., multiple sutures. Where the prosthetic chordae assembly **18** is comprised of multiple sutures, for example, each of the sutures can be fixedly joined to form each of the loop members **52**. It should also be appreciated that any number of loop members **52** can be used to form the prosthetic chordae assembly **18**. Accordingly, the prosthetic chordae assembly **18** is adjustable to a pre-determined length by removing any desired number of loop members **52**. It should be appreciated, however, that any desired number of loop members **52** may also be added to the prosthetic chordae assembly **18**.

[0043] Where the prosthetic chordae assembly **18** comprises a unitary unit, each loop member **52** is interconnected at a common junction **64**. The common junction **64** is formed by grouping each loop member **52** and then tying a knot to secure each loop member at the common junction. The knot may be formed by tying a portion of the prosthetic chordae assembly **18** (e.g., using an end of the suture) around the common junction **64**. Alternatively, the knot may be tied by using a separate material, e.g., a separate suture. Other methods may also be used to secure each loop member **52** at the common junction **64**. For instance, each loop member **52** may be secured at the common Junction **64** by gluing, stapling, pinning, or any other suitable method.

[0044] Although not shown in FIG. **1**, the prosthetic chordae assembly **18** can additionally comprise a pledget **66** (FIG. **3**) to facilitate attachment of the prosthetic chordae assembly to a papillary muscle **20** (FIG. **2**). As shown in FIG. **3**, the pledget **66** may be fixedly or slidably attached to the second end portion **48** of the prosthetic chordae assembly **18**. The pledget **66** may be comprised of a non-absorbable material, such as polyurethane, silicon, polyvinyl acetate, neoprene, Teflon foam, or polyester. Alternatively, the pledget **66** may be comprised of an absorbable material, such as gelatin or collagen.

[0045] Another aspect of the present invention is illustrated in FIG. **3**. The apparatus $\mathbf{10}_a$ shown in FIG. **3** is identically constructed as the apparatus **10** shown in FIG. **1**, except as described below, in FIG. **3**, structures that are identical as structures in FIG. **1** use the same reference numbers, whereas structures that are similar but not identical carry the suffix "a". The apparatus $\mathbf{10}_a$ can be implanted during open heart surgery or, alternatively, via a catheter-based procedure.

[0046] As shown in FIG. **3**, the apparatus $\mathbf{10}_a$ can comprise a series of prosthetic chordae assemblies **18** securely attached to an attachment mechanism **68**, such as a pledget **66**. More particularly, the apparatus $\mathbf{10}_a$ can include a first prosthetic chordae assembly **18'**, a second prosthetic chordae assembly **18"**, and a third prosthetic chordae assembly **18'"** securely attached to the pledget **66**. Each of the first, second, and third prosthetic chordae assemblies **18'**, **18"**, and **18'"** can include an elongated, unitary unit having a first end portion **46**, a second end portion **48**, and a middle end portion **50** extending between the end portions. Each of the first, second, and third prosthetic chordae assemblies **18'**, **18"**, and **18'"** can be comprised of nine interconnected loop members **52**. Each of the loop members **52** can include first and second ends **58** and **58** respectively defining first and second arcuate Junctions **60** and **62**. Each loop member **52** can have a size and length that is equal to the size and length of the other loop members.

[0047] As shown in FIG. **3**, the terminal loop member **70** at the second end portion **48** of each of the first, second, and third prosthetic chordae assemblies **18'**, **18"**, and **18'"** can be securely attached to the pledget **88**. For example, the strands **54** of each terminal loop member **70** can be threaded through the pledget **66** so that each of the first, second and third prosthetic chordae assemblies **18'**, **18"**, and **18'"** are securely attached to the pledget. The presence of the first, second, and third prosthetic chordae assemblies **18'**, **18"**, and **18'"** provides multiple attachment points for securing the first arcuate junction **60** of each of the terminal loop members **70** to the location on the at least one heart valve leaflet **16**. It should be appreciated that the apparatus $\mathbf{10}_a$ can include two, four, five or even more prosthetic chordae assemblies **18** depending upon, for example, the anatomy of the heart **26** and the medical condition being treated.

[0048] The replacement of native chordae **12** of a human heart **26** with the present invention is illustrated in FIGS. **4-17**. As shown in FIGS. **4-17**, the apparatus $\mathbf{10}_a$ of FIG. **3** is used to replace the native chordae **12** of a regurgitant mitral valve **72**. It should be appreciated that more than one apparatus $\mathbf{10}_a$ may be used, i.e., to replace the other set of native chordae **12**. Additionally, it should be appreciated that the apparatus $\mathbf{10}_a$ can be fixed to a portion of the left ventricular wail, the right ventricular wall, or the septum **35** (FIG. **2**).

[0049] To replace the native chordae **12**, the distance D (FIG. **4**) between a papillary muscle **20** and a location on the anterior mitral valve leaflet **42** is first measured. Access to the native chordae **12** may be obtained by open-heart surgery, for example. During the surgery, the native chordae **12** are inspected to determine the size of the apparatus $\mathbf{10}_a$ needed to replace the native chordae. Generally, the size of the apparatus $\mathbf{10}_a$ needed will depend on the size of the heart **26** as well as the appropriate implantation site.

[0050] A measuring device **74**, such as the one shown in FIGS. **5**A-G is then used to measure a distance D between the papillary muscle **20** and the location on the anterior mitral valve leaflet **42**. As shown in FIG. **5**A, the measuring device **74** comprises a first handle member **76** slidably attached to a second handle member **78**. The first handle member **76** (FIGS. **5**B-C) includes a first distal end portion **80** and first proximal end portion **82**. Additionally, the first handle member **76** includes oppositely disposed first and second major surfaces **75** and **77**. The first and second handle members **76** and **78** can be made from one or a combination of known medical grade materials, such as a hardened plastic and/or metal alloy.

[0051] The first distal end portion **80** of the first handle member **76** includes a handle **84** to manipulate the measuring device **74** and facilitate longitudinal movement of the first handle member relative to the second handle member **78**. The first proximal end portion **82** of the first handle member **76** includes a first reference tab **88** that extends in a substantially radial direction from the first major surface **75**. The first reference tab **86** can have a rigid, semi-rigid, or flexible configuration.

[0052] The first handle member **76** also includes a sliding mechanism **87**, such as a channel **79** (FIG. **5**D) or a lumen **81** (FIG. **5**E) for slidably receiving the second handle member **78**. The channel **79** or lumen **81** can extend between the first proximal end portion **82** and the first distal end portion **80** of the first handle member **78**. As shown in FIGS. **5**D-E, the cross-sectional shape of the channel **79** or lumen **81** corresponds to the cross-sectional shape of the second handle member **78**. Depending upon the configuration of the sliding

mechanism **87**, the position of the first handle **84** about the second major surface **77** can be varied as needed.

[0053] The second handle member **78** (FIGS. **5**F-G) includes a second proximal end portion **88** and a second distal end portion **90**. Additionally, the second handle member **78** includes a first major surface **83** oppositely disposed from a second major surface **85**. The second distal end portion **90** includes a second handle **92** for holding the measuring device **74** and manipulating the second handle member **78** relative to the first handle member **78**. The second proximal end portion **88** includes a second reference tab **94** that extends in a substantially radial direction from the first major surface **83**. The second reference tab **94** can have a rigid, semi-rigid, or flexible configuration.

[0054] The first major surface **83** of the second handle member **78** also includes a plurality of distance markers **96**. The distance markers **96** include a series of spaced apart indicia that may be used to determine the distance D between a papillary muscle **20** and a location on the anterior mitral valve leaflet **42**. As shown in FIGS. **5**A and **5**G, for example, the distance markers **96** include a series of numerical values ranging from 0 mm to 50 mm. It will be appreciated that any range of values may be used for the distance markers **96**. Additionally, it should be appreciated that other devices for measuring the distance D between the papillary muscle **20** and a location on at least one heart valve leaflet **16**, such as the devices disclosed in U.S. Patent App. No. 2003/0105519A1 are known in the art and may alternatively be used for measuring the distance D between the papillary muscle and a location on at least one heart valve leaflet.

[0055] As shown in FIG. **6**, the measuring device **74** is positioned in the left ventricle **34** of the heart **26**. More particularly, the measuring device **74** is inserted into the left ventricle **34** so that the first and second proximal end portions **82** and **88** of each of the first and second handle members **76** and **78** are substantially adjacent the papillary muscle **20** (e.g., the apical surface of the papillary muscle), and the first reference tab **86** is positioned at the distance marker **96** corresponding to 0 mm. The first handle member **76** is then moved distally relative to the second handle member **78** until the first reference tab **86** is positioned substantially adjacent the location on the anterior mitral valve leaflet **42**. The measuring device **74** is held in place so that the numerical value corresponding to the position of the first reference tab **86** can be determined. As shown in FIG. **7**, the numerical value corresponding to the first reference tab **86** is approximately 40 mm. After determining the distance D between the papillary muscle **20** and the location on the anterior mitral valve leaflet **42** (i.e., 40 mm), the native chordae **12** are then resected as shown in FIG. **8**.

[0056] After measuring the distance D between the papillary muscle **20** and the location on the anterior mitral valve leaflet **42**, an appropriately-sized apparatus $\mathbf{10}_a$ is selected. The size of the loop members **52** comprising each of the first, second, and third prosthetic chordae assemblies **18'**, **18"**, and **18"'** defines the size and length of the implanted apparatus $\mathbf{10}_a$. Accordingly, an apparatus $\mathbf{10}_a$ having first, second, and third prosthetic chordae assemblies **18'**, **18"**, and **18"'**, each of which has a pre-determined size equal to the measured distance D between the papillary muscle **20** and the location on the anterior mitral valve leaflet **42**, is selected for implantation. Failure to accurately determine the correct size of the apparatus $\mathbf{10}_a$ may result in an ineffective repair and, in turn, cause prolapse of the anterior mitral valve leaflet **42**.

[0057] Once an appropriately-sized apparatus $\mathbf{10}_a$ has been selected, the apparatus is attached to the papillary muscle **20** using a papillary implantation device **98** (FIG. **9**). As shown in FIG. **9**, the papillary implantation device **98** has a scissor-like configuration and includes first and second opposing arm members **100** and **102**. Each of the arm members **100** and **102** includes a proximal end portion **104**, a distal end portion **106**, and a middle portion **108** extending between the end portions. Each of the distal end portions **106** includes a handle **110** for operating the papillary implantation device **98**. The proximal end portion **104** of the second arm member **102** has a flattened surface **112** for mating to a receiving surface **114** of the first arm member **100**, and includes a holding pin **116** for securing the apparatus $\mathbf{10}_a$ during implantation. The proximal end portion **104** of the first arm member **100** includes a channel **118** for receiving the holding pin **116**.

[0058] FIGS. **10-12** illustrate attachment of the apparatus $\mathbf{10}_a$ to the papillary muscle **20** using the papillary implantation device **98**. The papillary implantation device **98** and the apparatus $\mathbf{10}_a$ can be introduced via the outer wall of the left ventricle **34** with or without the use of a heart-lung machine (not shown). A second pledget **120** is first operably attached to the proximal end portion **104** of the second arm member **102**, and the apparatus $\mathbf{10}_a$ is then operably attached to the proximal end portion of the first arm member **100**. As shown in FIG. **10**, the papillary implantation device **98** is then operated so that the proximal end portion **104** of the first arm member **100** and the proximal end portion of the second arm member **102** are radially disposed about the papillary muscle **20**.

[0059] After appropriately positioning the papillary implantation device **98**, the papillary implantation device is operated so that the proximal end portion **104** of the first arm member **100** and the proximal end portion of the second arm member **102** engage the papillary muscle **20** as shown in FIG. **11**. As the first arm member **100** is contacted with the papillary muscle **20**, the holding pin **116** penetrates the papillary muscle. The papillary implantation device **98** is then continually operated until the holding pin **116** extends through the pledget **66** of the apparatus $\mathbf{10}_a$ and thereby securely attaches the apparatus to the papillary muscle **20** (FIG. **12**). The papillary implantation device **98** is then removed from the left ventricle **34**, in turn leaving the apparatus $\mathbf{10}_a$ securely attached to the papillary muscle **20** as shown in FIG. **13**.

[0060] During attachment of the apparatus $\mathbf{10}_a$ to the papillary muscle **20**, it is important that undue pressure is not exerted on the papillary muscle. Excess pressure on the papillary muscle **20** may crush or deform the papillary muscle, in turn rendering the papillary muscle dysfunctional. Therefore, the papillary implantation device **98** may be operated using tactile feedback to avoid delivery of undue pressure to the papillary muscle **20**. Alternatively, the papillary implantation device **98** may be used with assistance from a device (not shown) capable of preventing deformation or crushing of the papillary muscle **20**.

[0061] After securing the apparatus $\mathbf{10}_a$ to the papillary muscle **20**, the terminal loop members **70** of each of the first, second, and third prosthetic chordae assemblies **18'**, **18"**, and **18"'** are securely attached to the location on the anterior mitral valve leaflet **42** using a leaflet implantation device **122** (FIG. **14**). As shown in FIG. **14**, the leaflet implantation device **122** has J-shaped configuration and includes a proximal end portion and a distal end portion **124** and **126**. The distal end portion **126** includes a handle **128** with a mechanism **130** for operating the leaflet implantation device **122**. As described in

more detail below, the mechanism **130** can include a trigger operably linked to a crimping member **132**. The proximal end portion **124** of the leaflet implantation device **122** includes a first end portion **134** and a second end portion **136**. The first end portion **134** includes a receiving surface **138** for receiving a securing member **140**, such as a barb or hook, and the second end portion **136** includes the crimping member **132** for attaching the securing member to the anterior mitral valve leaflet **42**.

[0062] FIGS. **15-17** illustrate attachment of the terminal loop member **70** at the first end portion **46** of the first prosthetic chordae assembly **18'** to the location on the anterior mitral valve leaflet **42**. As shown in FIG. **15**, the first arcuate junction **60** of the terminal loop member **70** is threaded around both the securing member **140** and the first end portion **134** of the leaflet implantation device **122**. The leaflet implantation device **122** is then positioned so that the location on the anterior mitral valve leaflet **42** is positioned between a receptacle portion **142** and a barb portion **144** of the securing member **140**. Next, the mechanism **130** of the leaflet implantation device **122** is manipulated so that the crimping member **132** advances toward the distal end portion **126** of the leaflet implantation device. As the crimping member **132** is advanced, the crimping member engages the securing member **140** and forces the barb portion **144** through the location on the anterior mitral valve leaflet **42** and into the receptacle portion **142** (FIG. **16**). The barb portion **144** then extends through the receptacle portion **142** so that the securing member **140**, and thus the terminal loop member **70** of the first prosthetic chordae assembly **18'** is securely attached to the location on the anterior mitral valve leaflet **42**.

[0063] After securely attaching the first prosthetic chordae assembly **18'**, the same steps are repeated to securely attach the second and third prosthetic chordae assemblies **18"** and **18'"** to the anterior mitral valve leaflet **42** (FIG. **17**). By including multiple prosthetic chordae assemblies **18'**, **18"**, and **18'"** to secure the apparatus $\mathbf{10}_a$ at the location on the anterior mitral valve leaflet **42**, the tension at any one location on the anterior mitral valve leaflet is reduced. By reducing the tension at each location, tearing or ripping of the anterior mitral valve leaflet **42** can be avoided. With the apparatus $\mathbf{10}_a$ implanted in the left ventricle **34**, the anterior mitral valve leaflet **42** is pulled back into proper alignment so that the mitral valve **22** can function properly and regurgitation through the valve is substantially reduced or prevented. Upon successful placement of the apparatus $\mathbf{10}_a$, effective valve **22** function is verified (i.e., proper leaflet coaptation) and the open-heart surgery is completed.

[0064] Another aspect of the present invention is shown in FIGS. **18**A-B. The apparatus $\mathbf{10}_b$ shown in FIGS. **18**A-B is identically constructed as the apparatus **10** shown in FIG. **1**, except as described below. In FIGS. **18**A-B, structures that are identical as structures in FIG. **1** use the same reference numbers, whereas structures that are similar but not identical carry the suffix "b".

[0065] As shown in FIGS. **18**A-B, the apparatus $\mathbf{10}_b$ can comprise a prosthetic chordae assembly $\mathbf{18}_b$ including a first end portion $\mathbf{46}_b$, a second end portion $\mathbf{48}_b$, and a middle portion $\mathbf{50}_b$ extending between the first and second end portions. The prosthetic chordae assembly $\mathbf{18}_b$ can be comprised of a single, belt-like strap member **146**. The strap member **146** can be made of a biocompatible material that is relatively elastic and flexible to allow movement of the heart valve leaflets **16** during opening and closing of the valve **14**. Non-limiting examples of biocompatible materials that can be used to form the strap member **146** include Teflon, PTFE and ePTFE.

[0066] The strap member **146** has an elongated configuration and can include a first major surface **148** oppositely disposed from a second major surface **150**. The strap member **146** can also include a plurality of apertures **152** extending between the first and second major surfaces **148** and **150**. As shown in FIG. **18**A, the apertures **152** can have a circular shape; however, it should be appreciated that the apertures can have any one or combination of shape's (e.g., square, rectangular, ovoid, etc.).

[0067] To implant the prosthetic chordae assembly $\mathbf{18}_b$ in a left ventricle **34**, for example, the first and second end portions $\mathbf{46}_b$ and $\mathbf{48}_b$ can be respectively positioned adjacent a papillary muscle **20** and a location on an anterior mitral valve leaflet **42** (FIG. **18**B; entire method not shown) using the papillary implantation device **98** (as described above). It will be appreciated that the proper size of the prosthetic chordae assembly $\mathbf{18}_b$ can be determined prior to implantation by measuring the distance D between the papillary muscle **20** and the location on the anterior mitral valve leaflet **42** (as described above). After determining the distance D, a corresponding distance D' between a first aperture **156** and a second aperture **158** can be identified.

[0068] Next, the first end portion $\mathbf{46}_b$ can be secured to the papillary muscle **20** by passing a suture (or other similar means) through the first aperture **156**, into the pledget **66**, and through the papillary muscle. The suture can then be tied into a knot to secure the first end portion $\mathbf{46}_b$. Additionally or optionally, it should be appreciated that a suture can be passed through the strap member **146** to secure the first end portion $\mathbf{46}_b$ to the papillary muscle **20**.

[0069] After securing the first end portion $\mathbf{46}_b$ of the strap member **146** to the papillary muscle **20**, the second end portion $\mathbf{48}_b$ can be secured to the location on the anterior mitral valve leaflet **42** by passing a suture (or other similar means) through the second aperture **158** and into the mitral leaflet. The suture can then be tied into a knot to secure the second end portion $\mathbf{48}_b$. Additionally or optionally, it should be appreciated that a suture can be passed through the strap member **146** to secure the second end portion $\mathbf{48}_b$ to the location on the anterior mitral valve leaflet **42**. Upon successful placement of the prosthetic chordae assembly $\mathbf{18}_b$, effective valve **22** function can be verified (i.e., proper leaflet coaptation) and the surgery completed.

[0070] From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications, if should be appreciated that the method of the present invention is not restricted to the order of steps presented herein. For example, the apparatus **10** may be attached to the location on at least one of the two heart valve leaflets **16** of the heart valve **14** instead of first attaching the apparatus to a papillary muscle **20**. As another example, all or only a portion of the apparatus **10** may be implanted prior to excising the native chordae **12**. Such improvements, changes, and modifications are within the skill of the art and are intended to be covered by the appended claims.

Having described the invention, we claim:

1. A prosthetic chordae assembly comprising:

a plurality of equally-sized, interconnected loop members formed from a single strand of a biocompatible material,

each of said loop members including first and second ends respectively defining a first arcuate junction and a second arcuate junction;

wherein said prosthetic chordae assembly is adjustable to a pre-determined length by removing one of said loop members.

2. A method for replacing the native chordae of a heart valve having at least two leaflets, said method comprising the steps of:

measuring the distance between a papillary muscle and a location on at least one of the at least two leaflets of the heart valve;

providing a prosthetic chordae assembly comprising a plurality of equally-sized, interconnected loop members formed from a single strand of a biocompatible material, each of the loop members including first and second ends respectively defining a first arcuate junction and a second arcuate junction;

adjusting the length of the prosthetic chordae assembly to the measured distance by removing at least one of the loop members;

attaching the second arcuate junction of a loop member to the papillary muscle; and

attaching the first arcuate junction of another loop member at the location on one of the at least two leaflets of the heart valve.

3. A measuring device for determining a distance between a papillary muscle and a location on a heart valve leaflet, said measuring device comprising:

a first handle member including a first proximal end portion and a first distal end portion, said first proximal end portion including a first reference tab and said first distal end portion including a first handle; and

a second handle member slidably connected to said first handle member, said second handle member including a second proximal end portion and a second distal end portion, said second proximal end portion including a second reference tab and said second distal end portion including a second handle, said second handle member including a first major surface having a plurality of distance markers for indicating the distance between the papillary muscle and the location on the heart valve leaflet.

4. The measuring device of claim **3**, wherein said first handle member includes a sliding mechanism for slidably receiving said second handle member and facilitating movement of said first handle member relative to said second handle member.

5. The measuring device of claim **4**, wherein said sliding mechanism comprises a lumen extending between said first proximal end portion and said first distal end portion.

6. The measuring device of claim **4**, wherein said sliding mechanism comprises a channel extending between said first proximal end portion and said first distal end portion.

7. The measuring device of claim **3**, wherein said first and second reference tabs extend in a substantially radial direction from said first and second proximal end portions, respectively.

8. A method for measuring a distance between a papillary muscle and a location on a heart valve leaflet, said method comprising the steps of:

providing a measuring device comprising a first handle member slidably connected to a second handle member, the first handle member including a first proximal end portion with a reference tab and a first distal end portion with a first handle, the second handle member including a second proximal end portion with a second reference tab and a second distal end portion with a second handle, the second handle member also including a first major surface having a plurality of distance markers;

inserting the measuring device into a cardiac ventricle;

positioning the second proximal end portion of the second handle member substantially adjacent the papillary muscle;

manipulating the first handle member so that the first proximal end portion of the first handle member is substantially adjacent the location on the heart valve leaflet; and

determining the distance between the first and second reference tabs.

9. The method of claim **8**, wherein said step of positioning the second proximal end portion of the second handle member substantially adjacent the papillary muscle further comprises positioning the second reference tab substantially adjacent an apical surface of the papillary muscle.

10. The method of claim **8**, wherein said step of manipulating the first handle member further comprises positioning the first reference tab substantially adjacent the location on the heart valve leaflet.

11. The method of claim **8**, wherein said step of determining the distance between the first and second reference tabs further comprises determining the position of the first reference tab with respect to at least one of the distance markers;

wherein the at least one distance marker indicates the distance between the papillary muscle and the location on the heart valve leaflet.

12. A prosthetic chordae assembly comprising:

an elongated, belt-like strap member having a first major surface oppositely disposed from a second major surface, said strap member including a plurality of apertures extending between said first and second major surfaces.

* * * * *

专利名称(译)	假肢腱索组件和使用方法		
公开(公告)号	US20090088837A1	公开(公告)日	2009-04-02
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[标]申请(专利权)人(译)	克里夫兰诊所基金会		
申请(专利权)人(译)	克利夫兰诊所基金会		
当前申请(专利权)人(译)	克利夫兰诊所基金会		
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摘要(译)

假体腱索组件包括由单股生物相容性材料形成的多个相同尺寸的互连环构件。每个环构件包括分别限定第一弧形结和第二弧形结的第一和第二端。通过移除一个环构件，可将假肢腱索组件调节到预定长度。