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(54) TISSUE CONNECTOR APPARATUS AND METHODS

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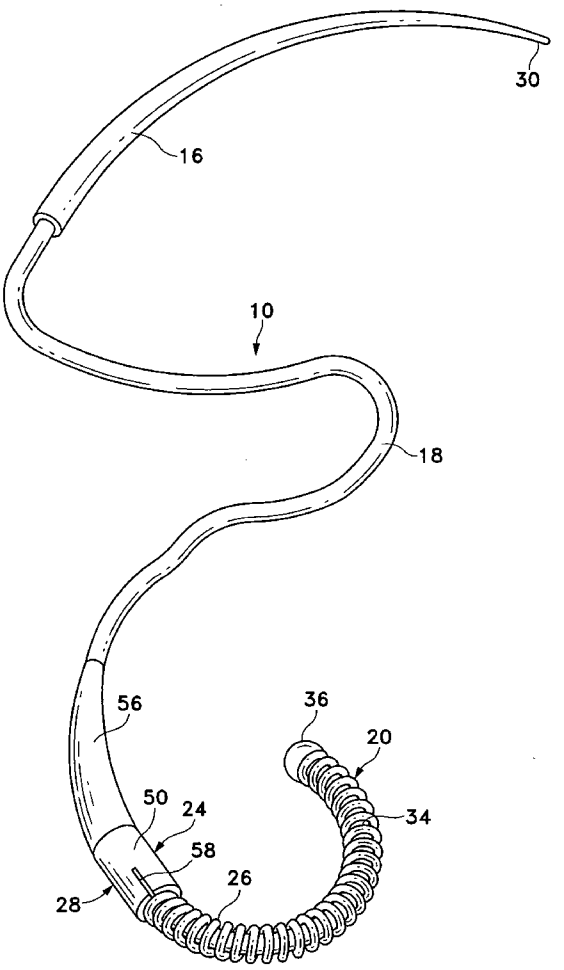
(57) **ABSTRACT**

A tissue connector assembly having a flexible member and a surgical clip releasably coupled to the flexible member. A needle may be secured to one end portion of the flexible member with the surgical clip coupled to the other end portion of the flexible member. A locking device may be used to couple the flexible member to the surgical clip. A method for connecting tissues is also disclosed. The method includes drawing tissue portions together with a clip assembly and securing the tissue portions together with the clip assembly.



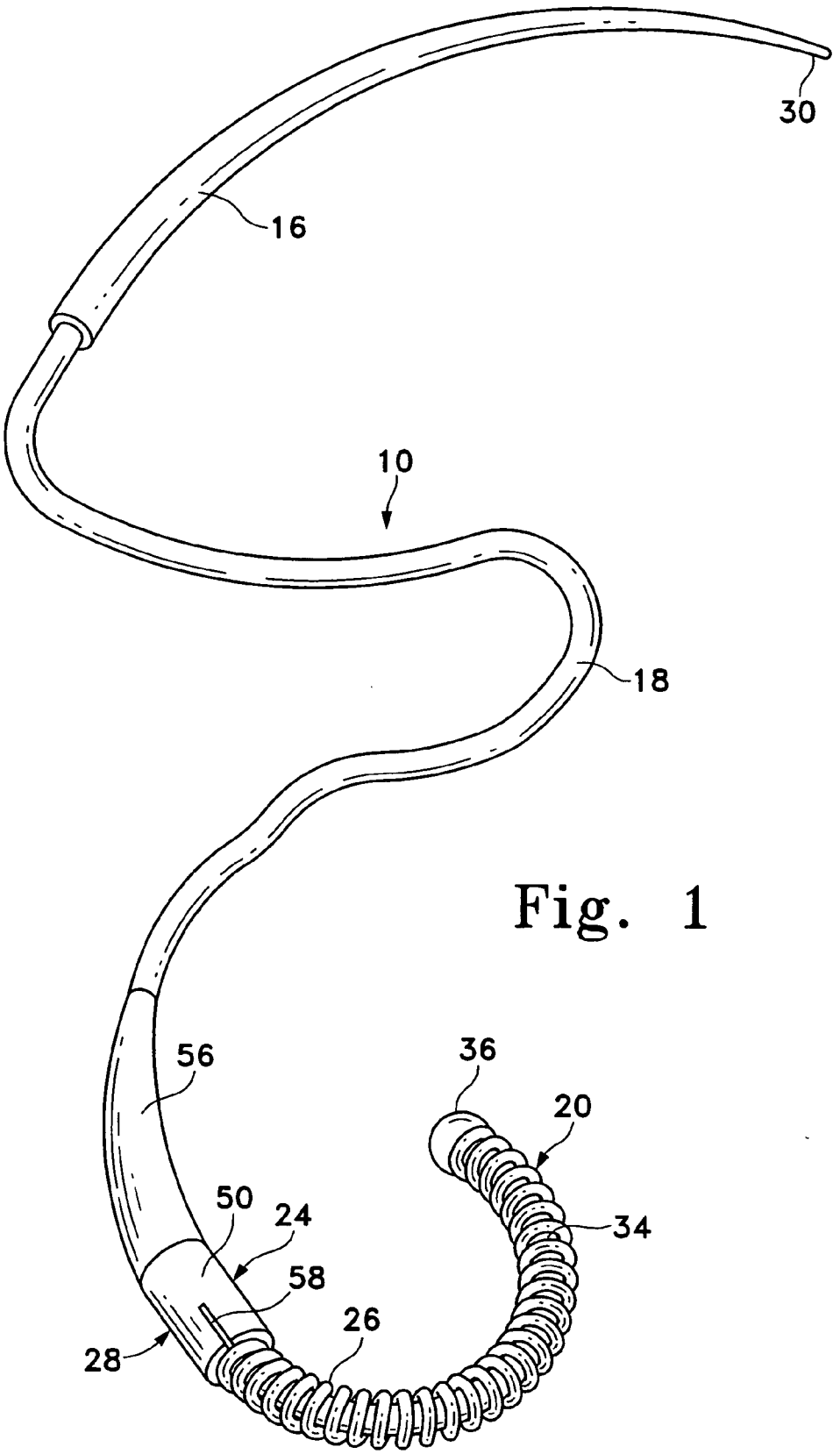


Fig. 1

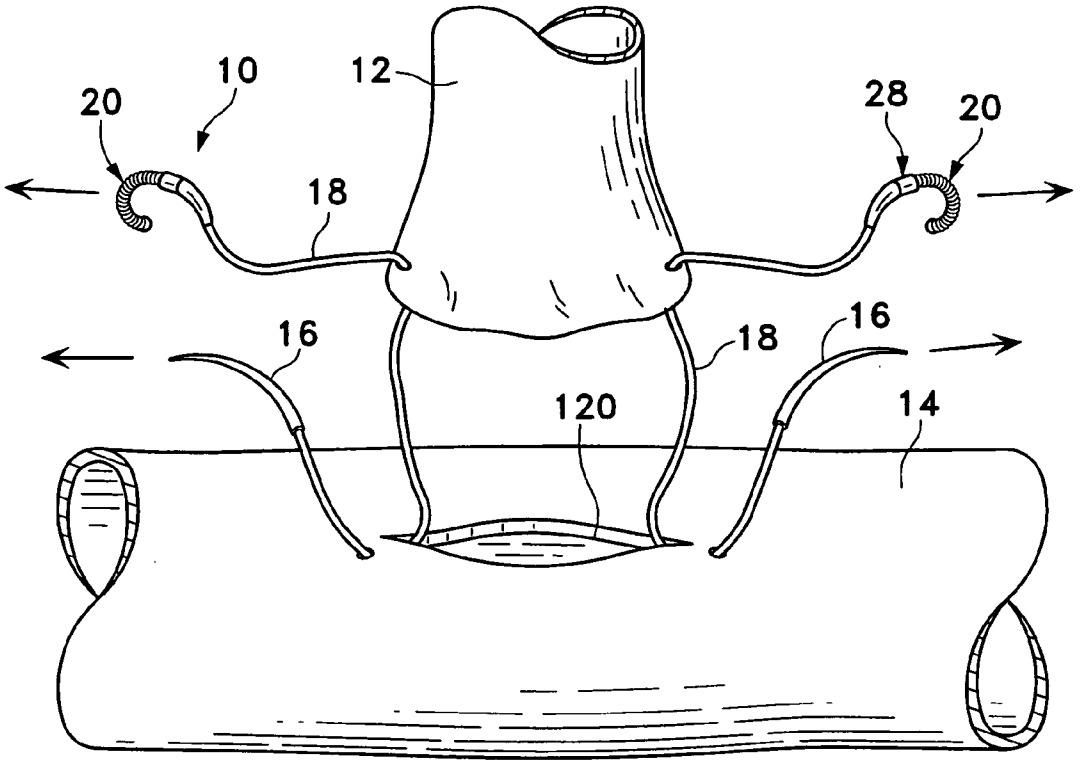


FIG. 2A

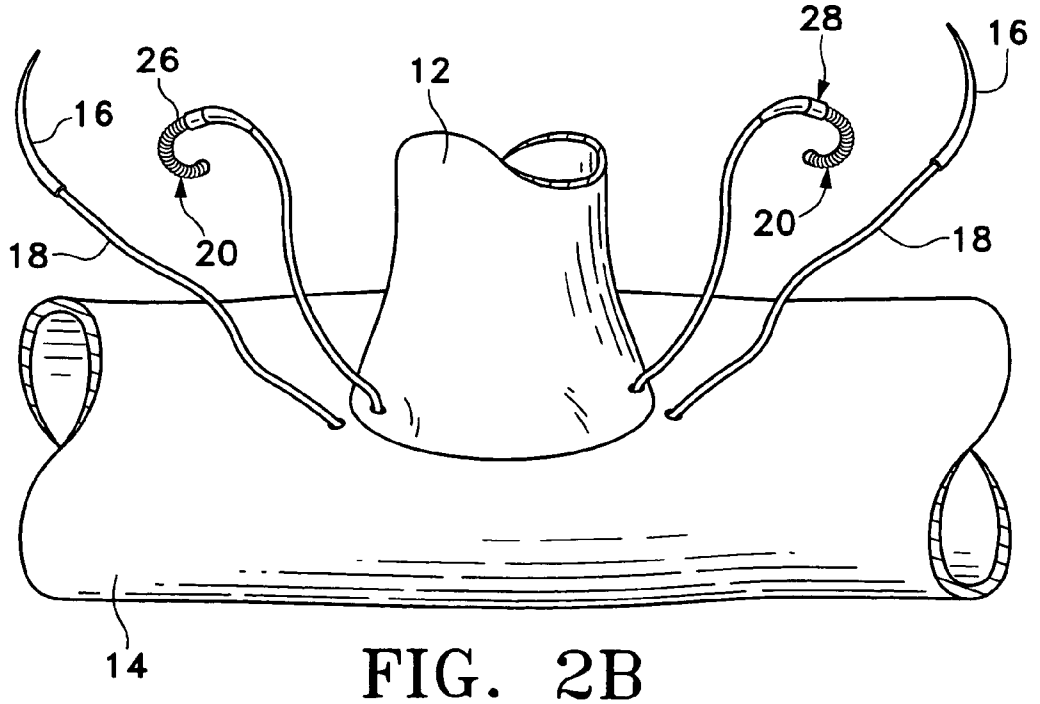


FIG. 2B

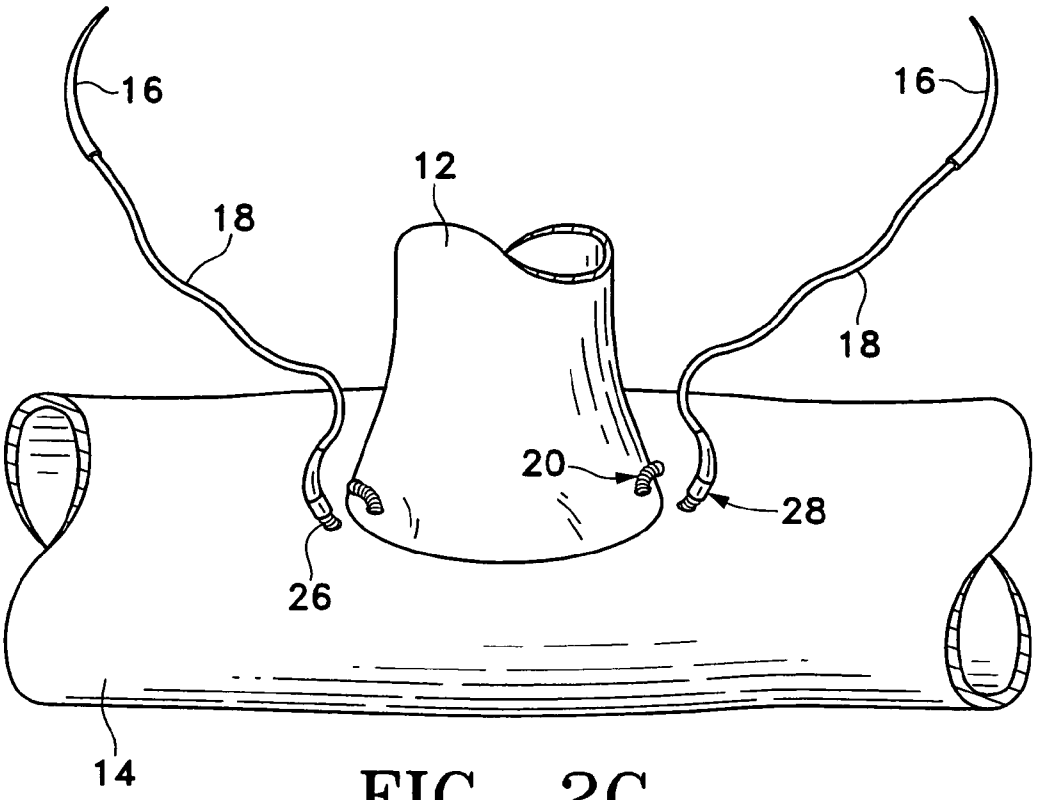


FIG. 2C

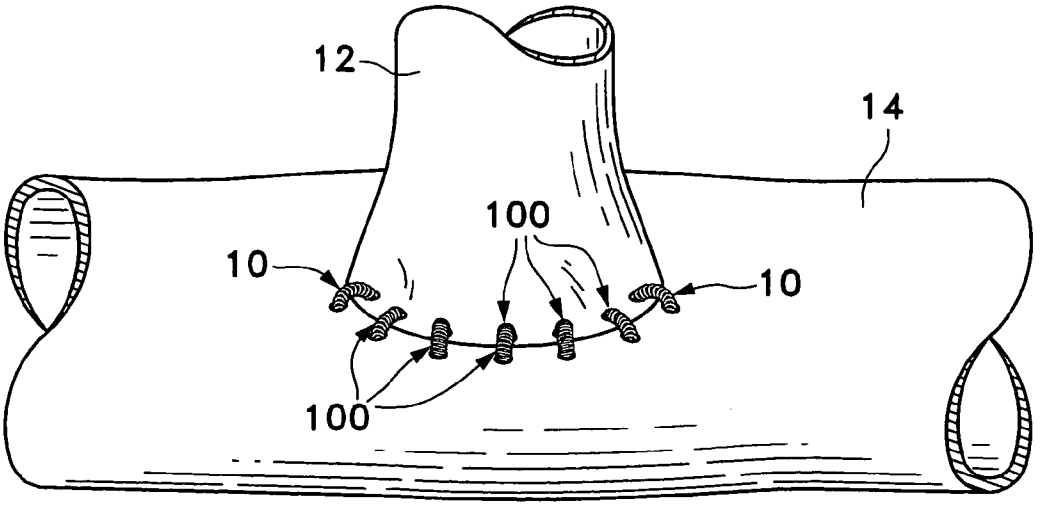


FIG. 2D

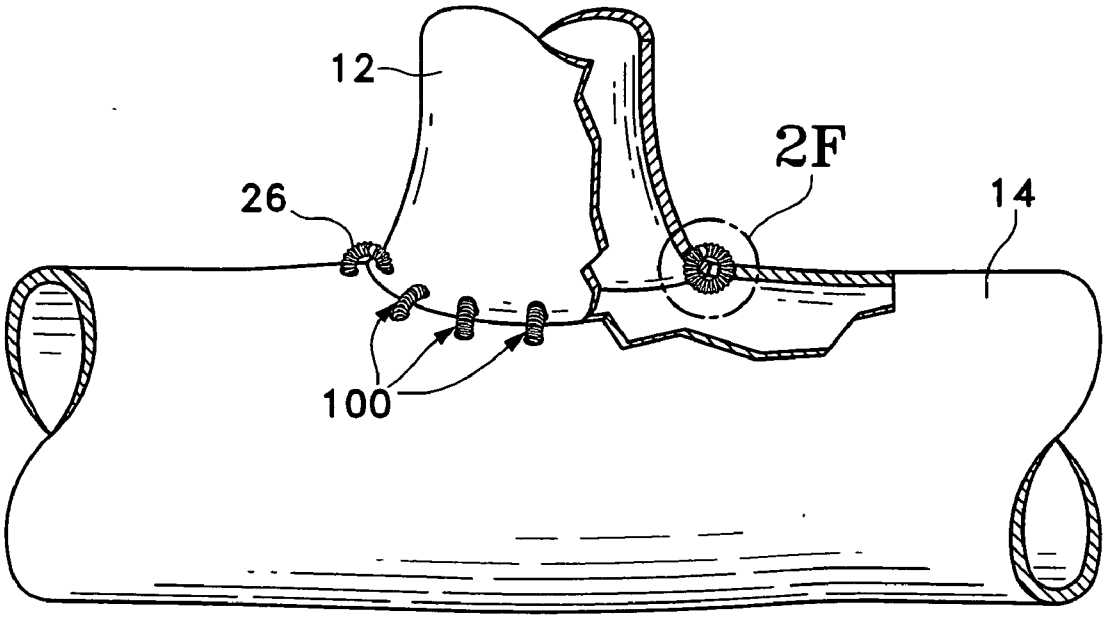


FIG. 2E

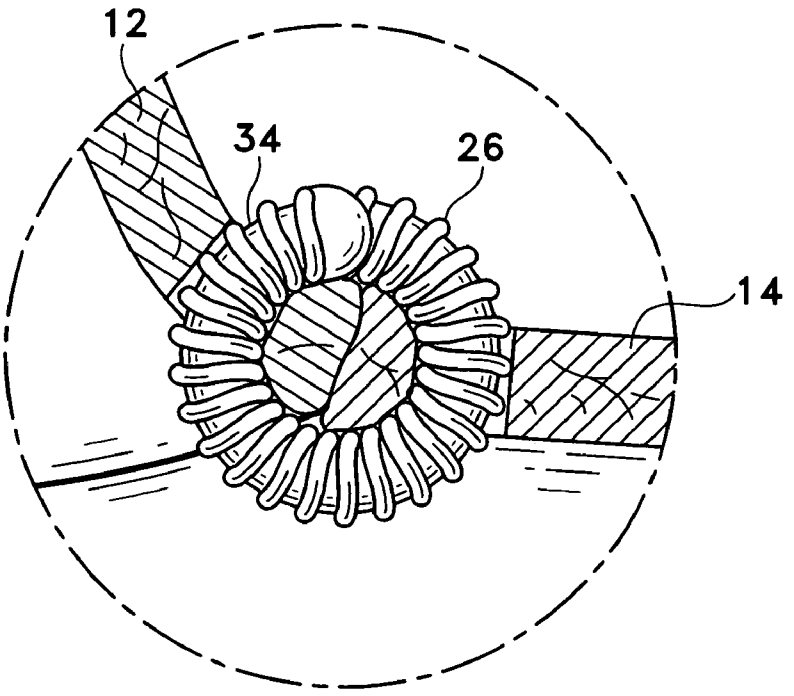


FIG. 2F

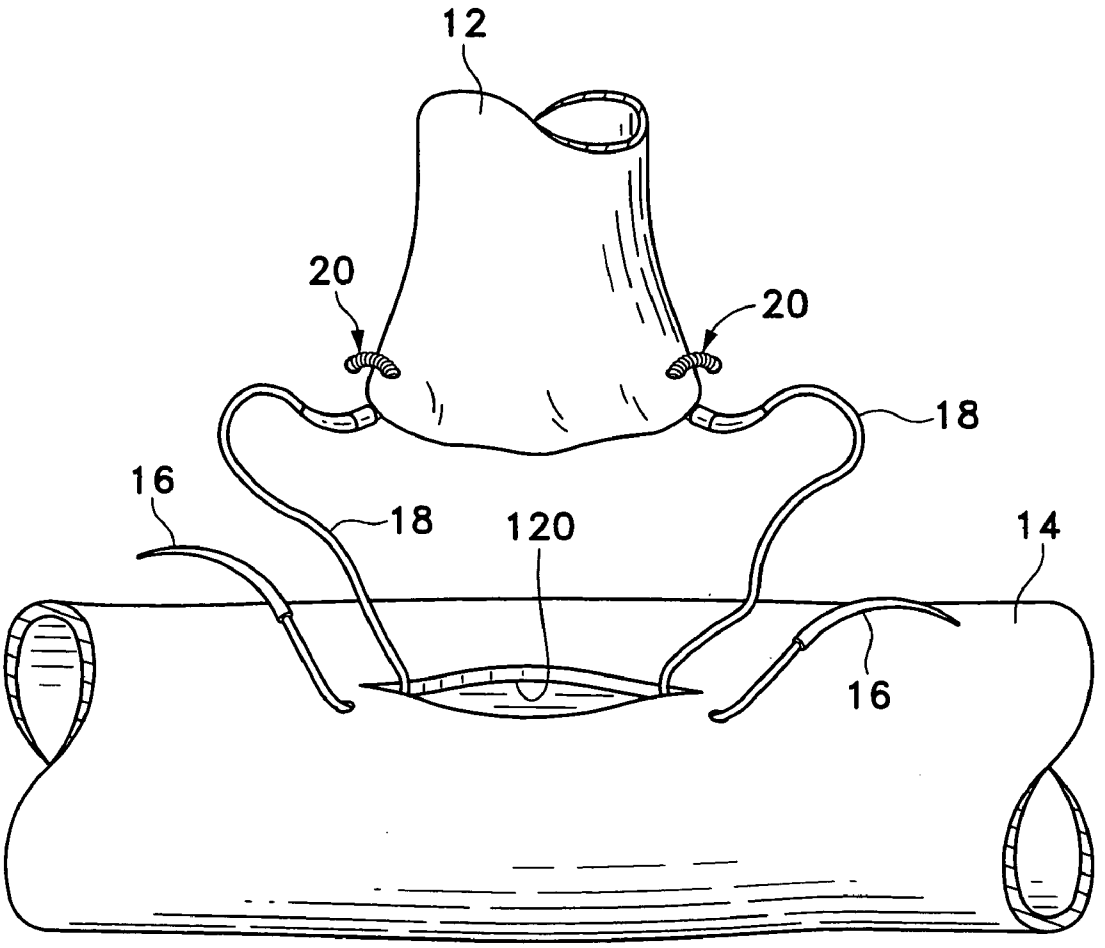


FIG. 2G

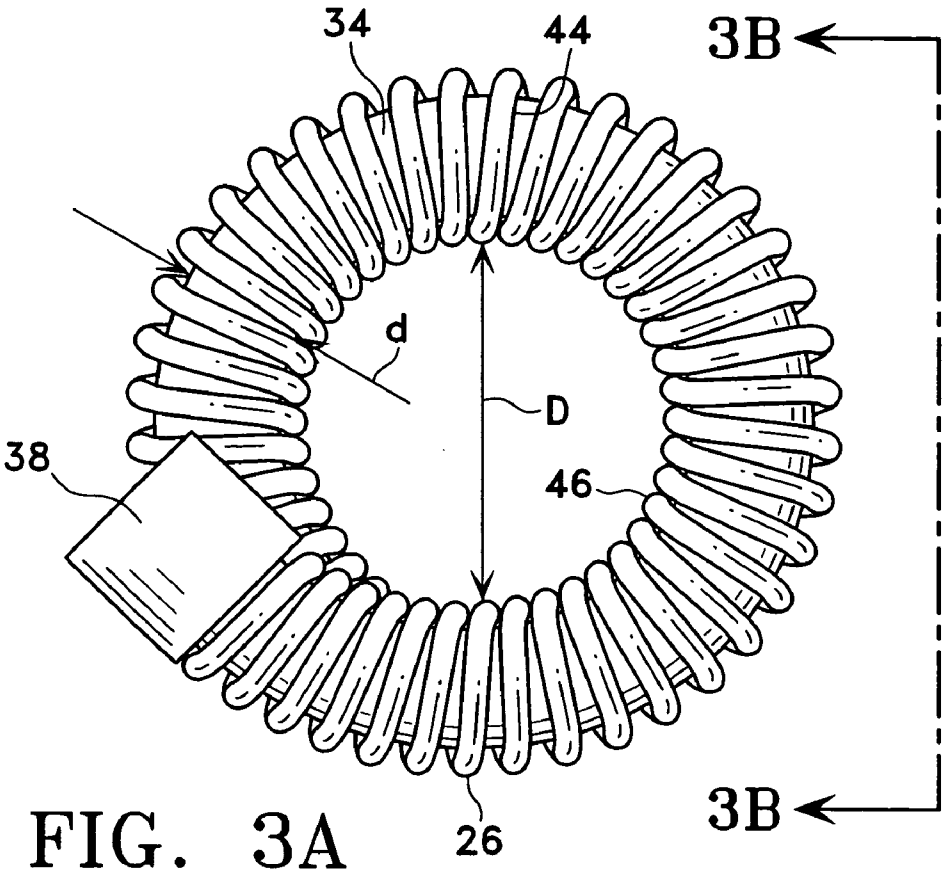


FIG. 3A

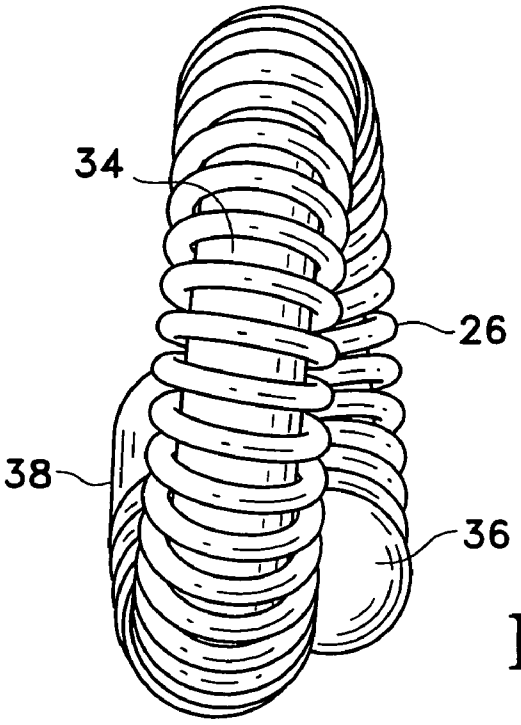


FIG. 3B

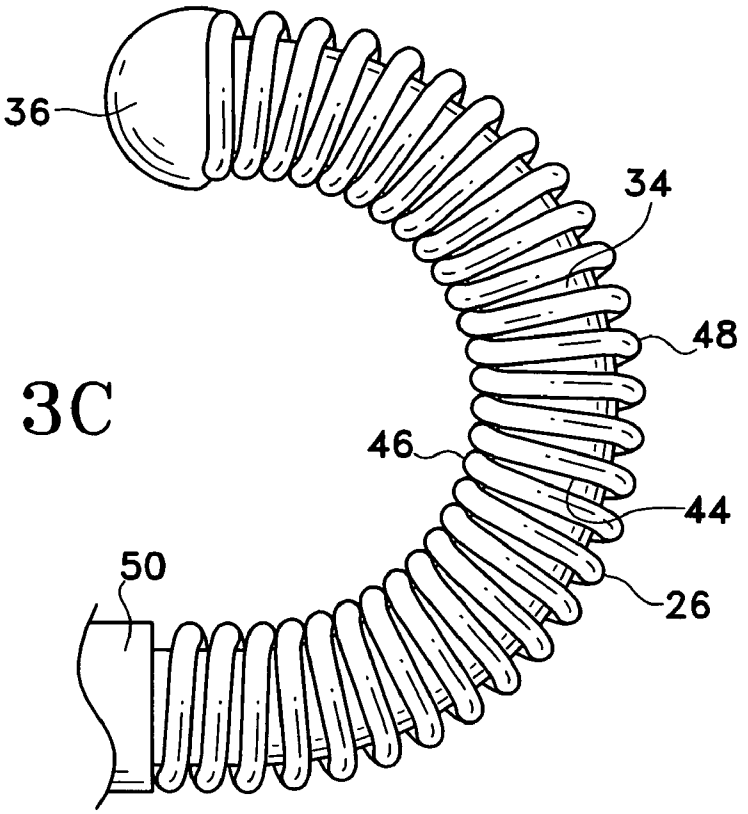


FIG. 3C

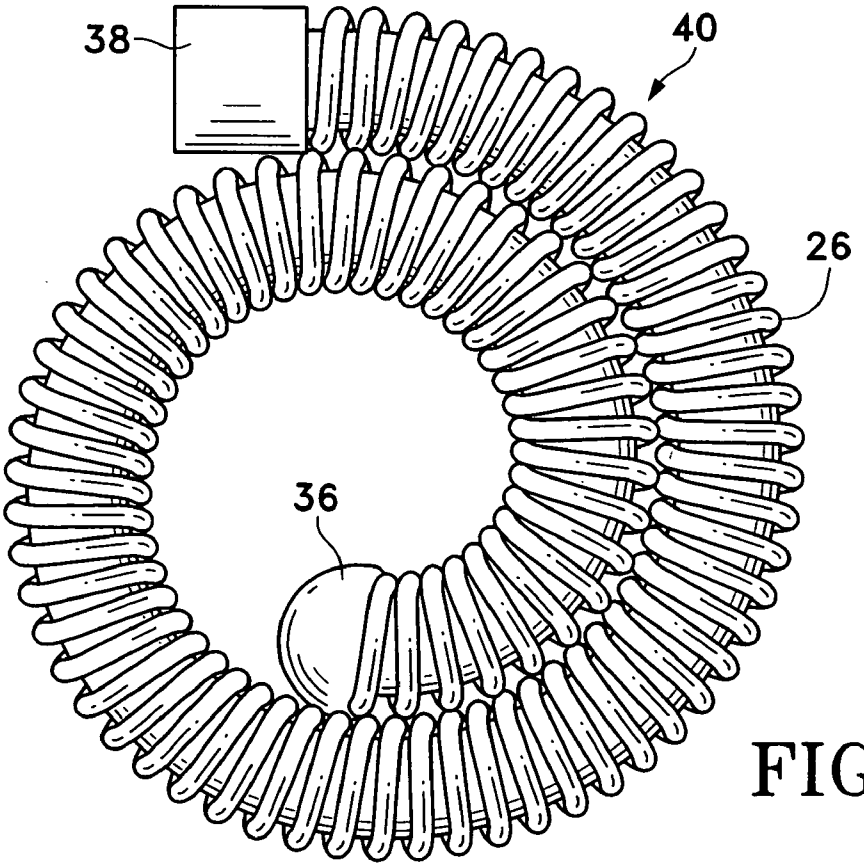


FIG. 3D

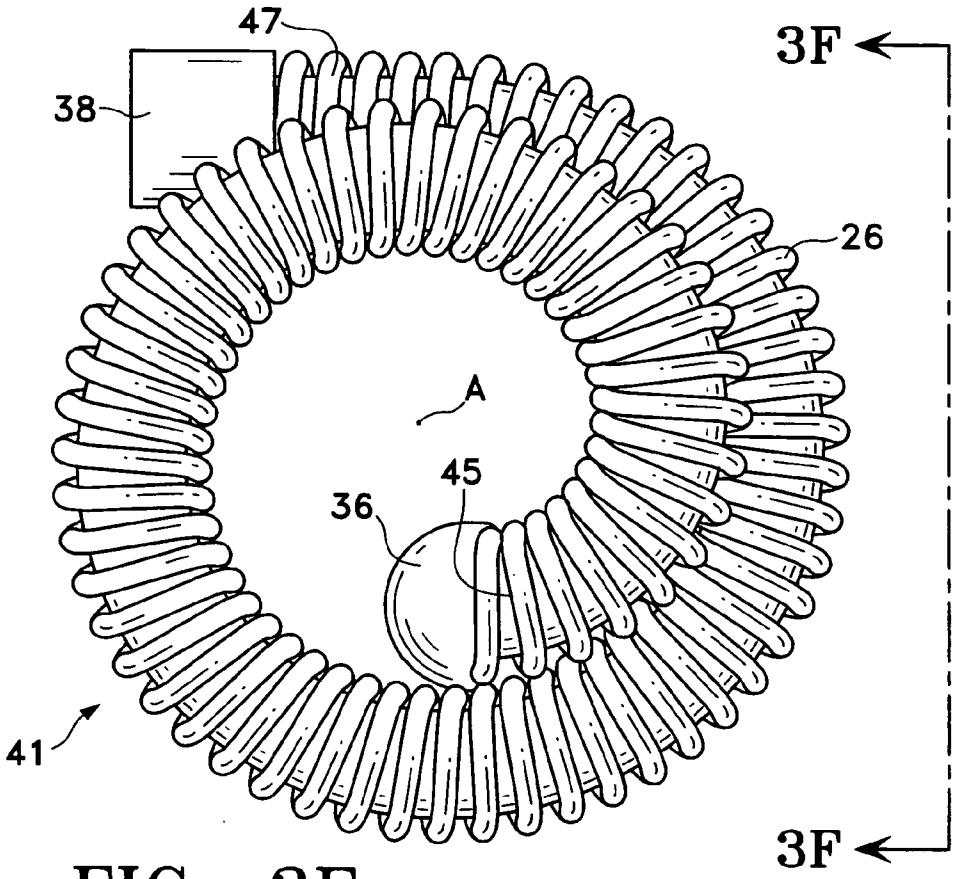


FIG. 3E

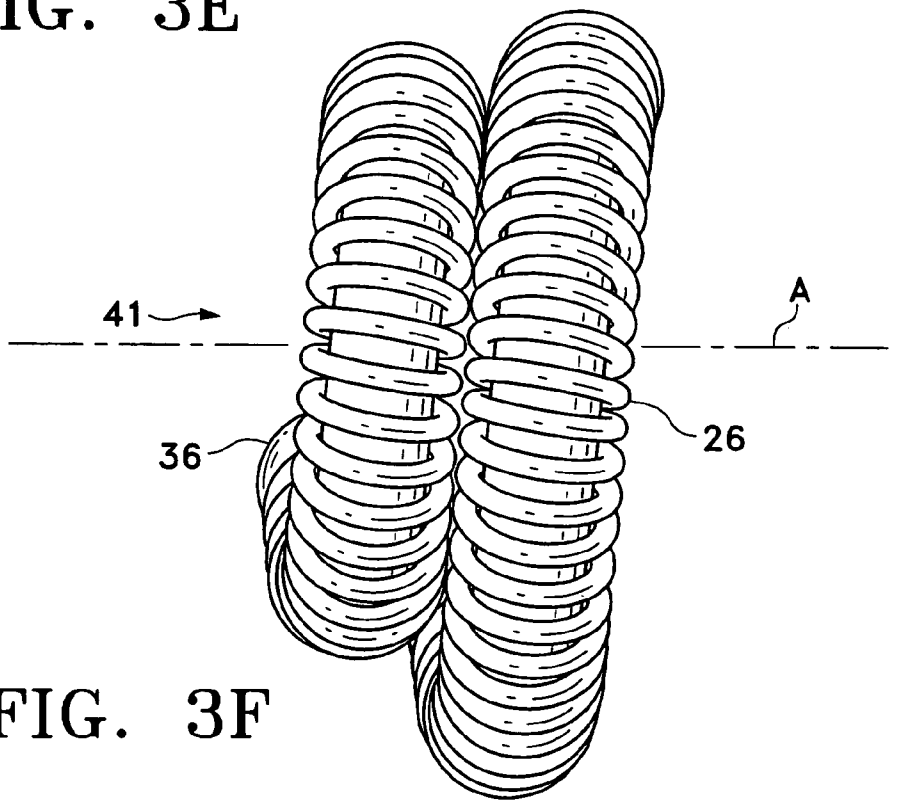


FIG. 3F

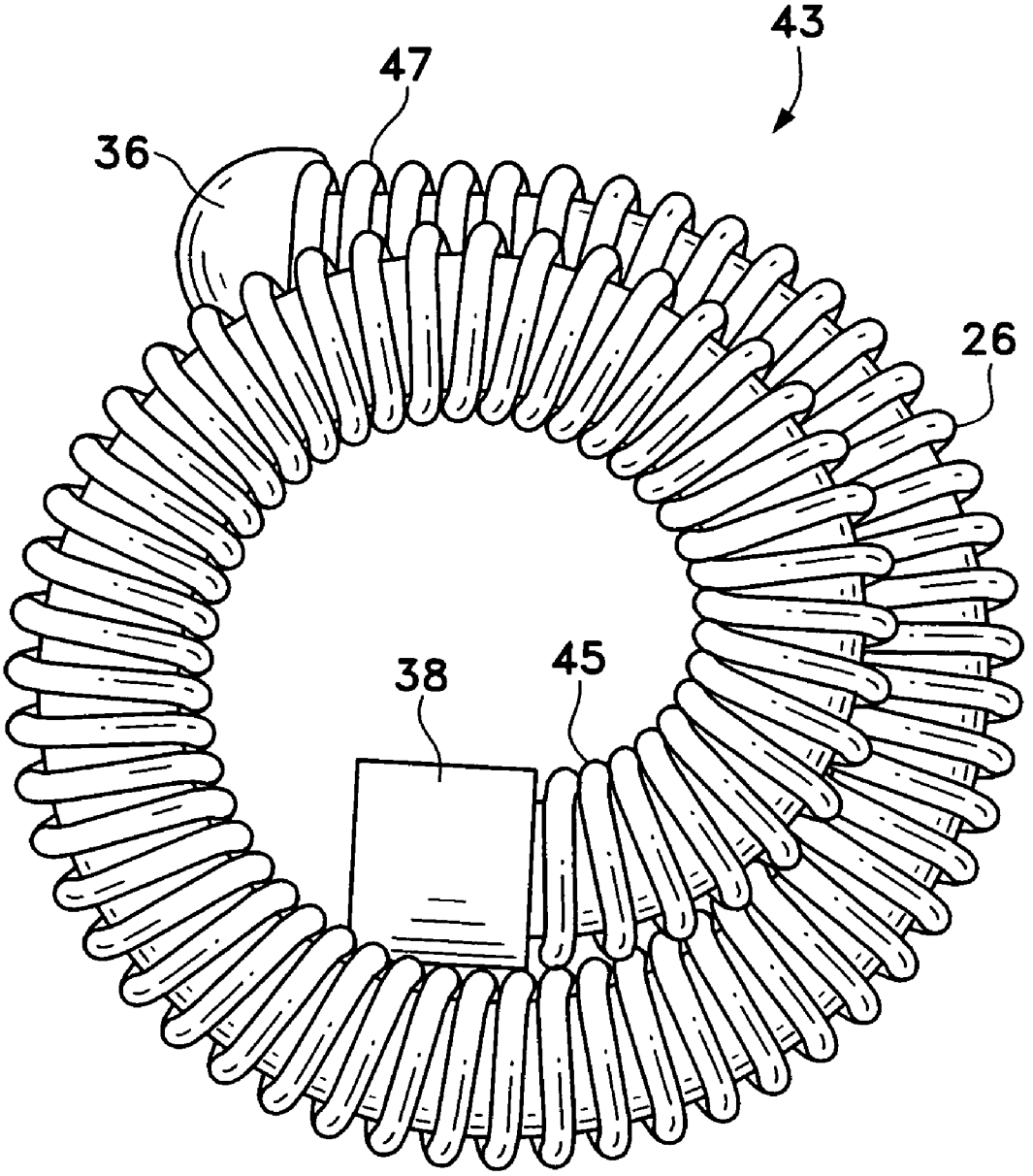


FIG. 3G

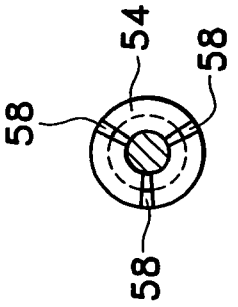


FIG. 4B

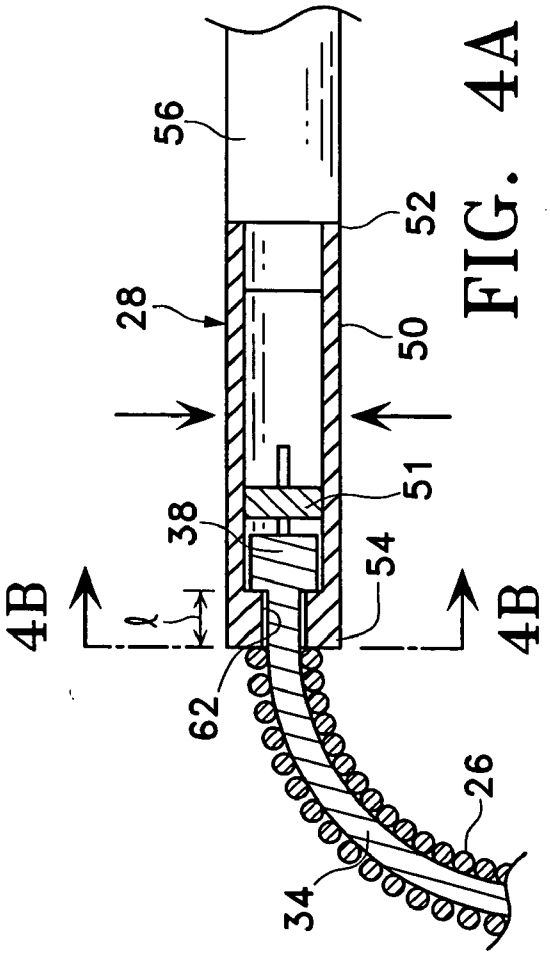


FIG. 4A

FIG. 4C

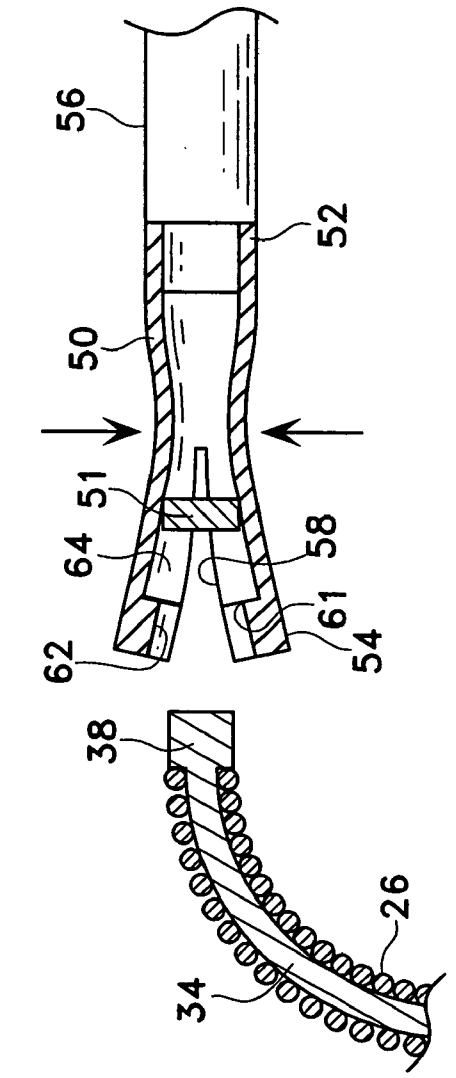


FIG. 5

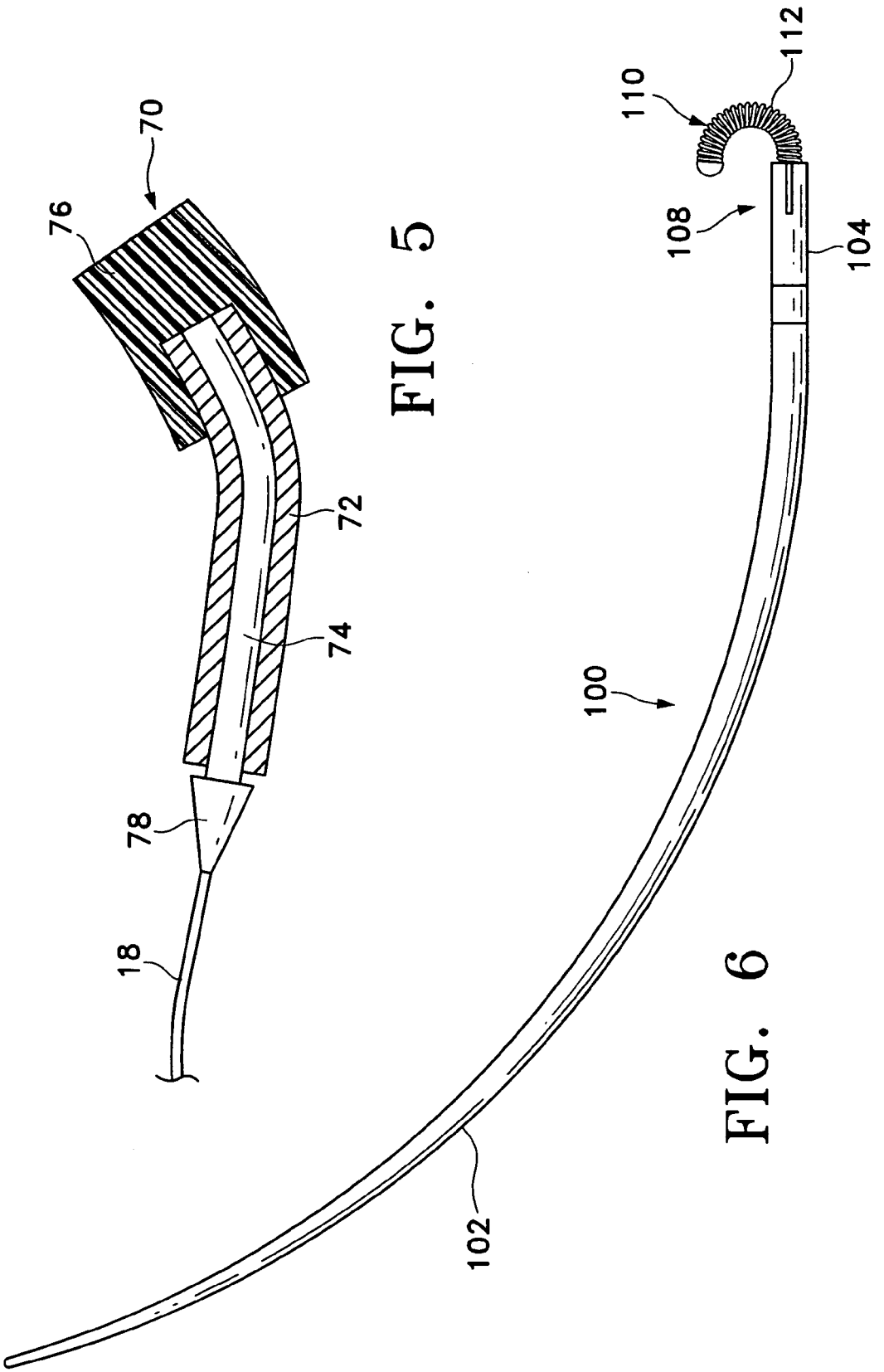


FIG. 6

TISSUE CONNECTOR APPARATUS AND METHODS

FIELD OF THE INVENTION

[0001] The present invention relates to instruments and methods for connecting body tissues, or body tissue to prostheses.

BACKGROUND OF THE INVENTION

[0002] Minimally invasive surgery has allowed physicians to carry out many surgical procedures with less pain and disability than conventional, open surgery. In performing minimally invasive surgery, the surgeon makes a number of small incisions through the body wall to obtain access to the tissues requiring treatment. Typically, a trocar, which is a pointed, piercing device, is delivered into the body with a cannula. After the trocar pierces the abdominal or thoracic wall, it is removed and the cannula is left with one end in the body cavity, where the operation is to take place, and the other end opening to the outside. A cannula has a small inside diameter, typically 5-10 millimeters, and sometimes up to as much as 20 millimeters. A number of such cannulas are inserted for any given operation.

[0003] A viewing instrument, typically including a miniature video camera or optical telescope, is inserted through one of these cannulas and a variety of surgical instruments and refractors are inserted through others. The image provided by the viewing device may be displayed on a video screen or television monitor, affording the surgeon enhanced visual control over the instruments. Because a commonly used viewing instrument is called an "endoscope," this type of surgery is often referred to as "endoscopic surgery." In the abdomen, endoscopic procedures are commonly referred to as laparoscopic surgery, and in the chest, as thoracoscopic surgery. Abdominal procedures may take place either inside the abdominal cavity (in the intraperitoneal space) or in a space created behind the abdominal cavity (in the retroperitoneal space). The retroperitoneal space is particularly useful for operations on the aorta and spine, or abdominal wall hernia.

[0004] Minimally invasive surgery has virtually replaced open surgical techniques for operations such as cholecystectomy and anti-reflux surgery of the esophagus and stomach. This has not occurred in either peripheral vascular surgery or cardiovascular surgery. An important type of vascular surgery is to replace or bypass a diseased, occluded or injured artery. Arterial replacement or bypass grafting has been performed for many years using open surgical techniques and a variety of prosthetic grafts. These grafts are manufactured as fabrics (often from DACRON® (polyester fibers) or TEFLON® (fluorocarbon fibers)) or are prepared as autografts (from the patient's own tissues) or heterografts (from the tissues of animals) or a combination of tissues, semi-synthetic tissues and or alloplastic materials. A graft can be joined to the involved artery in a number of different positions, including end-to-end, end-to-side, and side-to-side. This attachment between artery and graft is known as an anastomosis. Constructing an arterial anastomosis is technically challenging for a surgeon in open surgical procedures, and is almost a technical impossibility using minimally invasive techniques.

[0005] Many factors contribute to the difficulty of performing arterial replacement or bypass grafting. See generally, Wylie, Edwin J. et al., Manual of Vascular Surgery, (Springer-Verlag New York), 1980. One such factor is that the tissues to be joined must be precisely aligned with respect to each other to ensure the integrity and patency of the anastomosis. If one of the tissues is affixed too close to its edge, the suture can rip through the tissue and impair both the tissue and the anastomosis. Another factor is that, even after the tissues are properly aligned, it is difficult and time consuming to pass the needle through the tissues, form the knot in the suture material, and ensure that the suture material does not become tangled. These difficulties are exacerbated by the small size of the artery and graft. The arteries subject to peripheral vascular and cardiovascular surgery typically range in diameter from several millimeters to several centimeters. A graft is typically about the same size as the artery to which it is being attached. Another factor contributing to the difficulty of such procedures is the limited time available to complete the procedure. The time the surgeon has to complete an arterial replacement or bypass graft is limited because there is no blood flowing through the artery while the procedure is being done. If blood flow is not promptly restored, sometimes in as little as thirty minutes, the tissue the artery supplies may experience significant damage, or even death (tissue necrosis). In addition, arterial replacement or bypass grafting is made more difficult by the need to accurately place and space many sutures to achieve a permanent hemostatic seal. Precise placement and spacing of sutures is also required to achieve an anastomosis with long-term patency.

[0006] Highly trained and experienced surgeons are able to perform arterial replacement and bypass grafting in open surgery using conventional sutures and suturing techniques. A suture has a suture needle that is attached or "swedged on" to a long, trailing suture material. The needle must be precisely controlled and accurately placed through both the graft and artery. The trailing suture material must be held with proper tension to keep the graft and artery together, and must be carefully manipulated to prevent the suture material from tangling. In open surgery, these maneuvers can usually be accomplished within the necessary time frame, thus avoiding the subsequent tissue damage (or tissue death) that can result from prolonged occlusion of arterial blood flow.

[0007] A parachuting technique may be used to align the graft with the artery in an end-to-side anastomosis procedure. One or multiple sutures are attached to the graft and artery and are used to pull or "parachute" the graft vessel into alignment with an opening formed in a sidewall of the artery. A drawback to this procedure is the difficulty in preventing the suture from tangling and the time and surgical skill required to tie individual knots when using multiple sutures. Due to space requirements, this procedure is generally limited to open surgery techniques.

[0008] The difficulty of suturing a graft to an artery using minimally invasive surgical techniques has effectively prevented the safe use of this technology in both peripheral vascular and cardiovascular surgical procedures. When a minimally invasive procedure is done in the abdominal cavity, the retroperitoneal space, or chest, the space in which the operation is performed is more limited, and the exposure to the involved organs is more restricted, than with open surgery. Moreover, in a minimally invasive procedure, the instruments used to assist with the operation are passed into the surgical field through cannulas. When manipulating

instruments through cannulas, it is extremely difficult to position tissues in their proper alignment with respect to each other, pass a needle through the tissues, form a knot in the suture material once the tissues are aligned, and prevent the suture material from becoming tangled. Therefore, although there have been isolated reports of vascular anastomoses being formed by minimally invasive surgery, no system has been provided for wide-spread surgical use which would allow such procedures to be performed safely within the prescribed time limits.

[0009] As explained above, anastomoses are commonly formed in open surgery by suturing together the tissues to be joined. However, one known system for applying a clip around tissues to be joined in an anastomosis is disclosed in a brochure entitled, "VCS Clip Applier System", published in 1995 by Auto Suture Company, a Division of U.S. Surgical Corporation. A clip is applied by applying an instrument about the tissue in a nonpenetrating manner, i.e., the clip does not penetrate through the tissues, but rather is clamped down around the tissues. As previously explained, it is imperative in forming an anastomosis that tissues to be joined are properly aligned with respect to each other. The disclosed VCS clip applier has no means for positioning tissues. Before the clip can be applied, the tissues must first be properly positioned with respect to each other, for example by skewering the tissues with a needle as discussed above in common suturing techniques or with forceps to bring the tissues together. It is extremely difficult to perform such positioning techniques in minimally invasive procedures.

[0010] Therefore, there is currently a need for other tissue connecting systems.

SUMMARY OF THE INVENTION

[0011] The present invention involves apparatus and methods for connecting material, at least one of which is tissue. The invention may, for example, be used to secure one vessel to another, such as in a vascular anastomosis.

[0012] According to one aspect of the invention, a tissue connector assembly is provided and comprises a flexible member and a surgical clip which may be releasably coupled to the flexible member. With this construction, a needle may be coupled to the flexible member, which may be in the form of a suture, to facilitate, for example, parachuting suture tissue connecting procedures. The surgical clip may eliminate the need for tying sutures, which requires significant skill, space, and time.

[0013] According to another aspect of the invention a tissue connector assembly comprises a needle, a flexible member coupled to the needle, and a locking device coupled to the flexible member. The locking device is adapted for receiving a surgical fastener. Thus, a surgical fastener may be selected based on a desired procedure and coupled to the locking device to facilitate, for example, parachuting suture tissue connecting procedures as discussed above.

[0014] According to another aspect of the invention, a method for connecting tissues includes drawing portions of tissue together with a clip assembly and securing the tissue portions together with the clip assembly.

[0015] According to another aspect of the invention, multiple portions of material are drawn together with a tissue connector assembly having a clip in an open position. At least one of the portions of material is tissue. The clip is closed to secure the material portions therein. The materials may be drawn together by pulling the tissue connector assembly with at least a portion of the clip positioned in the materials. A needle may be used to insert the tissue connector assembly into the material. A portion of the tissue connector assembly may be manipulated to simultaneously actuate closure of the clip and release the needle from the clip.

[0016] According to another aspect of the invention, a tissue connector assembly is inserted through graft and target vessels with the graft vessel being spaced from the target vessel. The tissue connector assembly has a first end extending from an exterior surface of the graft vessel and a second end extending from an exterior surface of the target vessel. At least one end of the tissue connector assembly is pulled to draw the graft vessel into contact with the target vessel.

[0017] According to another aspect of the invention, a tissue connector assembly is inserted through the graft and target vessels with the graft vessel being spaced from the target vessel and the tissue connector assembly having a first end extending from an exterior surface of the graft vessel and a second end extending from an exterior surface of the target vessel. At least a portion of the tissue connector assembly is pulled to draw the graft vessel into contact with the target vessel.

[0018] The above is a brief description of some deficiencies in the prior art and advantages of the present invention. Other features, advantages, and embodiments of the invention will be apparent to those skilled in the art from the following description, accompanying drawings, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. **1** is a perspective of a tissue connector assembly of the present invention;

[0020] FIG. **2**A shows two tissue connector assemblies of FIG. **1** in a first step for connecting a graft vessel to a target vessel;

[0021] FIG. **2**B shows a second step for connecting the graft vessel to the target vessel;

[0022] FIG. **2**C shows a third step for connecting the graft vessel to the target vessel;

[0023] FIG. **2**D shows the graft vessel connected to the target vessel;

[0024] FIG. **2**E is a front view of the connected graft and target vessels of FIG. **2**D, with portions broken away to show detail;

[0025] FIG. **2**F is an enlarged view of the tissue connection shown in FIG. **2**E;

[0026] FIG. **2**G shows an alternate method for connecting the graft vessel to the target vessel with the tissue connector assembly of FIG. **1**;

[0027] FIG. **3**A is an enlarged view of a fastener of the tissue connector assembly of FIG. **1** shown in a closed position;

[0028] FIG. **3**B is a side view of the fastener of FIG. **3**A;

[0029] FIG. 3C is an enlarged view of the fastener in an open position;

[0030] FIG. 3D is an enlarged view of an alternate configuration of the fastener shown in a closed position;

[0031] FIG. 3E is an enlarged view of an alternate configuration of the fastener shown in a closed position;

[0032] FIG. 3F is a side view of the fastener of FIG. 3E;

[0033] FIG. 3G is an enlarged view of an alternate configuration of the fastener shown in a closed position;

[0034] FIG. 4A is a cross-sectional view of a restraining device of the tissue connector assembly of FIG. 1 in a locked position;

[0035] FIG. 4B is a cross-sectional view of the restraining device of FIG. 4A taken in the plane including line 4B-4B;

[0036] FIG. 4C is a cross-sectional view of the restraining device of FIG. 4A in an unlocked position;

[0037] FIG. 5 is an alternate embodiment of the restraining device of FIG. 4A; and

[0038] FIG. 6 is a front view of a second embodiment of a tissue connector assembly of the present invention shown in an open position.

[0039] Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

DESCRIPTION OF THE INVENTION

[0040] Referring now to the drawings, and first to FIG. 1, a tissue connector assembly constructed according to the principles of the present invention is shown and generally indicated with reference numeral 10. The tissue connector assembly 10 may be used to manipulate and align tissues, or tissue and prosthesis with respect to each other and thereafter connect the tissues or tissue and prosthesis together (FIGS. 2A-2G). As used herein, the term graft includes any of the following: homografts, xenografts, allografts, alloplastic materials, and combinations of the foregoing. The tissue connector assembly 10 may be used in vascular surgery to replace or bypass a diseased, occluded, or injured artery by connecting a graft vessel 12 to a coronary artery 14 or vein in an anastomosis, for example. The tissue connector assembly 10 may be used in open surgical procedures or in minimally invasive or endoscopic procedures for attaching tissue located in the chest, abdominal cavity, or retroperitoneal space. These examples, however, are provided for illustration and are not meant to be limiting.

[0041] In the embodiment shown in FIG. 1, the tissue connector assembly 10 generally comprises a penetrating member 16, flexible member 18, and fastener or surgical clip 20 (FIG. 1). A restraining device, generally indicated at 24 and comprising a spring (or coil) 26 and a locking device (coupling member) generally indicated at 28, is connected to the fastener 20 for holding the fastener in a deformed configuration as further described below. Although a particular fastener and accompanying restraining device is shown in FIG. 1, it should be understood that any suitable fastener can be used, including but not limited to the alternate fastener configurations described below. For example, the fastener or surgical clip may be a plastically deformable clip or may comprise two or more parts, at least one of which is movable relative to the other part, such as with a hinged clip.

[0042] The penetrating member or needle 16 has a sharp pointed tip 30 at its distal end for penetrating tissue. The needle 16 may be bent as shown in FIG. 1, for example. The diameter of at least a portion of the needle 16 is preferably greater than the diameter of the flexible member 18 so that the flexible member can easily be pulled through an opening formed in the tissue by the needle. The distal end of the needle 16 is preferably rigid to facilitate penetration of tissue. The remaining length of the needle 16 may be rigid or flexible to facilitate movement of the needle through the tissue as further described below. The tip 30 of the needle 16 may be conical, tapered, or grounded to attain a three or four facet tip, for example. The needle 16 may be made from stainless steel or any other suitable material, such as a polymeric material. It is to be understood that the needle 16 may have a shape or radius of curvature other than the one shown, without departing from the scope of the invention. The needle 16 may also be integrally formed with the flexible member 18 (e.g., both needle and flexible member formed of the same material.)

[0043] The flexible member 18 may be in the form of a suture formed from conventional filament material, metal alloy such as nitinol, polymeric material, or any other suitable material. The material may be non-stretchable or stretchable, solid or hollow, and have various cross-sectional diameters. The suture may have a cross-sectional diameter of 0.003 inch, for example. The diameter and length of the suture will vary depending on the specific application. The suture may be attached to the needle 16 by crimping or swaging the needle onto the suture, gluing the suture to the needle, or any other suitable attachment method. The flexible member 18 may have cross-sectional shapes other than the one shown herein.

[0044] One embodiment of a fastener comprises a deformable wire 34 made of a shape memory alloy. A nickel titanium (nitinol) based alloy may be used, for example. The nitinol may include additional elements which affect the yield strength of the material or the temperature at which particular pseudoelastic or shape transformation characteristics occur. The transformation temperature may be defined as the temperature at which a shape memory alloy finishes transforming from martensite to austenite upon heating (i.e., A_f temperature). The shape memory alloy preferably exhibits pseudoelastic (superelastic) behavior when deformed at a temperature slightly above its transformation temperature. At least a portion of the shape memory alloy is converted from its austenitic phase to its martensitic phase when the wire 34 is in its deformed configuration. As the stress is removed, the material undergoes a martensitic to austenitic conversion and springs back to its original undeformed configuration. When the wire 34 is positioned within the tissue in its undeformed configuration, a residual stress is present to maintain the tissue tightly together (FIG. 2E). In order for the pseudoelastic wire 34 to retain sufficient compression force in its undeformed configuration, the wire should not be stressed past its yield point in its deformed configuration to allow complete recovery of the wire to its undeformed configuration. The shape memory alloy is preferably selected with a transformation temperature suitable for use with a stopped heart condition where cold cardiople-

gia has been injected for temporary paralysis of the heart tissue (e.g., temperatures as low as 8-10 degrees Celsius).

[0045] It is to be understood that the shape memory alloy may also be heat activated, or a combination of heat activation and pseudoelastic properties may be used, as is well known by those skilled in the art.

[0046] The cross-sectional diameter of the wire **34** and length of the wire will vary depending on the specific application. The diameter d of the wire **34** may be, for example, between 0.001 and 0.015 inch. For coronary bypass applications, the diameter is preferably between 0.001 and 0.008 inch with a diameter D of the loop being between 0.0125 and 0.0875 inch (FIG. **3**A). As shown in FIG. **3**A, the wire **34** has a circular cross-sectional shape. The diameter D of the loop of the fastener **20** in its closed position is preferably sized to prevent movement between adjacent tissues. It is to be understood, however, that the wire may have other cross-sectional shapes such as rectangular, or may be formed from multiple strands without departing from the scope of the invention.

[0047] The proximal end of the wire **34** may include a stop **36** having a cross-sectional area greater than the cross-sectional area of the wire and coil **26** to prevent the wire and coil from passing through the tissue. The stop **36** may be attached to the end of the wire **34** by welding, gluing or other suitable attachment means or may be formed integrally with the wire by deforming the end of the wire. The stop **36** may also be eliminated to facilitate pulling the fastener completely through the tissue, if, for example, the entire fastener needs to be removed from the vessel during the insertion procedure. The distal end of the wire **34** includes an enlarged portion **38** for engagement with the restraining device **24** as further described below (FIG. **4**A). The enlarged portion **38** may be formed by deforming the end of the wire **34** by swaging or arc welding, or attaching by welding, swaging, or other suitable means an enlarged portion to the end of the wire.

[0048] The wire **34** has an undeformed or closed configuration (position, state) (FIG. **3**A) for keeping or connecting tissue together, and a deformed or open configuration (position, state) (FIG. **3**C) for insertion of the wire into tissue. As discussed above, the wire **34** is in its closed configuration when in a relaxed state. The wire **34** is preferably not deformed past its yield point in its open position. Accordingly, it may have a U-shaped configuration in its open position to facilitate insertion of the wire through the tissue. It is to be understood that U-shaped configuration may be alternatively substituted by an equivalent structure such as C-shaped, V-shaped, J-shaped, and other similarly shaped configurations. The wire **34** is moved from its closed position to its open position by a restraining device, as further described below. When in its closed position, the wire **34** forms a loop with the ends of the wire in a generally side-by-side or overlapping orientation (FIG. **3**B).

[0049] The wire **34** may be formed in the above described shape by first wrapping the wire onto a mandrel and heat treating the wire at approximately 400-500 degrees Celsius for approximately 5 to 30 minutes. The wire **34** is then air quenched at room temperature. The mandrel may have a constant diameter or may be conical in shape.

[0050] An alternate configuration of the surgical clip **20** in its closed position is shown in FIG. **3**D, and generally indicated at **40**. The fastener **40** forms a spiral configuration in its closed position for trapping the tissue within a loop formed by the spiral. In its open position, the fastener **40** is configured to form less than a full 360 degree turn.

[0051] Another alternate configuration of the surgical clip **20** is shown in FIGS. **3**E and **3**F in its closed position, and is generally indicated at **41**. The fastener **41** is formed in a spiral about a central longitudinal axis A. As shown in FIG. **3**F, the fastener **41** has a generally conical shape along the longitudinal axis A, with a decreasing diameter as the radius of curvature of the fastener **41** decreases. The fastener **41** has an inner end portion **45** and an outer end portion **47**, with the enlarged portion **38** of the wire being disposed at the outer end portion for engagement with the restraining device **24**.

[0052] A modification of the fastener **41** is shown in FIG. **3**G, and generally indicated at **43**. The fastener **43** is similar to the fastener **41** described above, except that the enlarged portion **38**, which is adapted for engaging a restraining device or releasable locking mechanism, is positioned at the inner end portion **45** of the fastener. Placement of the restraining device **24** at the inner end portion **45** of the fastener **43** increases the compression force of the wire in its undeformed position on the tissue and decreases the surface area of the fastener exposed to blood flow.

[0053] It is to be understood that the fastener **20**, **40**, **41**, **43** may have undeformed or deformed configurations different than those shown herein without departing from the scope of the invention. In addition, a locking clip (not shown) may also be attached to connect the ends of the fastener **20**, **40**, **41**, **43** when the fastener is in its closed position to prevent possible opening of the fastener over time. The locking clip may also be integrally formed with one end of the fastener.

[0054] As shown in FIG. **3**C, the wire **34** is surrounded by the spring or coil **26** which, along with the locking device **28**, restrains the wire in its deformed configuration. The coil **26** comprises a helical wire forming a plurality of loops which define a longitudinal opening **44** for receiving the shape memory alloy wire **34**. The coil **26** may be formed from a platinum alloy wire having a cross-sectional diameter of approximately 0.0005-0.005 inch, for example. The helical wire may have other cross-sectional shapes and be formed of different materials. The coil **26** is preferably sized so that when in its free (uncompressed state) it extends the length of the wire **34** with one end adjacent the stop **36** at the proximal end of the wire and the other end adjacent the enlarged portion **38** at the distal end of the wire. It is to be understood that the coil may not extend the full length of the wire. For example, a flange or similar device may be provided on an intermediate portion of the wire **34** to limit movement of the coil along the length of the wire.

[0055] When the coil **26** is in its free state (with the wire in its undeformed configuration), loops of the coil are generally spaced from one another and do not exert any significant force on the wire **34** (FIG. **3**A). When the coil **26** is compressed (with the wire **34** in its deformed configuration), loops of the coil on the inner portion **46** of the coil are squeezed together with a tight pitch so that the loops are contiguous with one another while loops on the outer portion **48** of the coil are spaced from one another (FIG. **3**C). This is due to the compressed inner arc length of the coil **26** and the expanded outer arc length of the coil. The compression

of the loops on the inner portion **46** of the coil **26** exerts a force on the inner side of the wire **34** which forces the wire to spread open (i.e., tends to straighten the wire from its closed configuration to its open configuration). The end of the coil **26** adjacent the stop **36** is held in a fixed position relative to the wire **34**. The opposite end of the coil **26** is free to move along the wire **34** and is held in place when the coil is in its compressed position by the locking device **28**.

[**0056**] The locking device **28** of the embodiment shown in FIGS. **1** and **4**A-**4**C comprises a flexible tubular member **50** having a distal end portion **52** coupled to the flexible member **18** and a proximal end portion **54** releasably attached to the wire. The locking device **28** couples the flexible member **18** and needle **16** to the clip **20**. In addition to releasably coupling the flexible member **18** and needle **16** to the clip **20**, the locking device compresses the coil **26** to bias the clip **20** in its open configuration. The distal end **52** of the tubular member **50** is attached to the flexible member **18** with a tapered portion or transition sleeve **56** extending from the tubular member to the suture to facilitate insertion of the locking device **28** through tissue. The tapered portion **56** is preferably sufficiently curved to facilitate movement of the tissue connector assembly **10** through connecting tissue in an anastomosis, for example. The tapered portion **56** may be formed from a metal alloy such as stainless steel or a suitable polymeric material and may be solid or in the form of a sleeve. Generally, portion **56** gradually diminishes in diameter to provide a smooth, non-stepped transition between the relatively small diameter of flexible member **18** to the larger diameter of locking device **28**. The flexible member **18** may be swaged into the tapered portion **56**, or a heat shrink plastic covering may hold the flexible member in place. The locking device **28** may also be curved.

[**0057**] The tubular member **50** is movable between a locked position (FIG. **4**A) for holding the coil **26** in its compressed position and the wire **34** in its deformed position, and an unlocked position (FIG. **4**C) for inserting or releasing the wire and coil. Three slots **58** are formed in the tubular member **50** extending from the proximal end **54** of the member and along at least a portion of the member (FIGS. **4**B and **4**C). The slots **58** are provided to allow the proximal end **54** of the tubular member **50** to open for insertion and removal of the wire **34** when the tubular member is in its unlocked position (FIG. **4**C). It is to be understood that the number of slots **58** and configuration of the slots may vary, or the tubular member **50** may be formed to allow expansion of the proximal end **54** without the use of slots.

[**0058**] The proximal end **54** of the tubular member **50** includes a bore **62** having a diameter slightly greater than the outer diameter d of the wire **34**, but smaller than the diameter of the enlarged portion **58** at the distal end of the wire and the outer diameter of the coil **26**. The bore **62** extends into a cavity **64** sized for receiving the enlarged portion **38** of the wire **34**. Member **50** may be described as having an annular flange **61** for releasably securing the enlarged portion **38**. As shown in FIG. **4**C, upon application of an inwardly directed radial squeezing force on the tubular member **50** the proximal end **54** of the tubular member is opened to allow for insertion or removal of the wire **34**. When the force is released (FIG. **4**A), the tubular member **50** moves back to its locked position and securely holds the wire **34** in place and compresses the coil **26**. A disc **51** may be inserted into the tubular member **50** to act as a fulcrum and cause the proximal end **54** of the tubular member to open. Alternatively, the disc **51** may be integrally formed with the tubular member **50**. As shown in FIG. **4**A, the length l of the bore **62** or flange **61** determines the amount of compression of the coil, which in turn determines the amount of deformation of the wire **34**. The greater the length l of the bore **62**, the greater the compression of the coil **26** and the more straightening the wire **34** will undergo. The compression of the coil **26** is preferably limited so that the wire **34** is not stressed beyond its yield point. This allows the wire **34** to revert back to its original undeformed configuration and apply sufficient pressure to hold the connected tissue together.

[**0059**] It is to be understood that locking devices other than those described above may be used without departing from the scope of the invention. For example, a locking device (not shown) may comprise a tubular member having an opening formed in a sidewall thereof for receiving an end portion of the wire. The end of the wire may be bent so that it is biased to fit within the opening in the sidewall of the tubular member. An instrument, such as a needle holder may then be used to push the wire away from the opening in the tubular member and release the wire from the tubular member. Various other types of locking devices including a spring detent or bayonet type of device may also be used.

[**0060**] An alternate embodiment of the restraining device is shown in FIG. **5**, and generally indicated with reference numeral **70**. The restraining device **70** is used with a tubular (hollow) shape memory alloy wire **72** and comprises an elongated member (or mandrel) **74** sized for insertion into the wire or tube. The mandrel **74** is preferably formed from a material which is stiffer than the material of the wire **72** so that upon insertion of the mandrel into the wire, the wire is deformed into its open position. The restraining device **70** includes a stop **76** located at the proximal end of the wire **72**. The stop operates to prevent the fastener from being pulled through the tissue, and limits axial movement of the mandrel **74** in the proximal direction (to the right as viewed in FIG. **5**). The distal end of the mandrel **74** is attached to the suture **18** and includes a tapered portion **78**. The tapered portion **78** may be a sleeve or may be solid and may be formed from any suitable metal or polymeric material, for example. It is to be understood that other types of restraining devices may be used without departing from the scope of the invention.

[**0061**] Another tissue connector assembly is shown in FIG. **6** and generally indicated with reference numeral **100**. The tissue connector assembly **100** is the same as the first embodiment **10** except that a needle **102** is attached directly to a locking device **104** with the suture **18** of the first embodiment being eliminated. The tissue connector assembly **100** includes the needle **102**, a restraining device **108**, and a fastener **110**. FIG. **6** shows the tissue connector assembly **100** with the fastener in its open (deformed) configuration. The fastener **110** may be the same as the fasteners **20**, **40**, **41**, **43** described above and shown in FIGS. **3**A-**3**G for the tissue connector assembly of the first embodiment, for example.

[**0062**] The restraining device **108** comprises a coil **112** and the locking device **104**. The locking device **104** is similar to the locking device **28** shown in FIGS. **4**A-**4**C, except that the distal end is configured for attachment directly to the needle **102**. The needle **102** may be integrally

formed with the locking device **104** or may be swaged, welded, threadably attached, or attached by any other suitable means to the locking device. The restraining device **70** shown in FIG. **5** may also be used with this embodiment **100** of the tissue connector assembly.

[**0063**] As noted above, the tissue connector assemblies **10**, **100** have many uses. They may be especially useful for minimally invasive surgical procedures including creating an anastomosis between a vascular graft **12** and an artery **14** (FIGS. **2**A-**2**G). The anastomosis may be used to replace or bypass a diseased, occluded or injured artery. A coronary bypass graft procedure requires that a source of arterial blood flow be prepared for subsequent bypass connection to a diseased artery. An arterial graft may be used to provide a source of blood flow, or a free graft may be used and connected at the proximal end to a source of blood flow. Preferably, the source of blood flow is one of any number of existing arteries which may be dissected in preparation for the bypass graft procedure. In many instances it is preferred to use the left internal mammary artery (LIMA) or the right internal mammary artery (RIMA), for example. Other vessels which may be used include the saphenous vein, gastroepiploic artery in the abdomen, radial artery, and other arteries harvested from the patient's body as well as synthetic graft materials, such as DACRON® (polyester fibers) or GORETEX® (expanded polytetrafluoroethylene). If a free graft vessel is used, the upstream end of the dissected vessel, which is the arterial blood source, will be secured to the aorta to provide the desired bypass blood flow, as is well known by those skilled in the art. The downstream end of the graft vessel is trimmed for attachment to an artery, such as the left anterior descending coronary (LAD). It is to be understood that the anastomosis may be formed in other vessels or tissue.

[**0064**] FIGS. **2**A-**2**F show an exemplary use of the tissue connector assemblies **10**, **100** for connecting a graft vessel **12** to an artery **14** (target vessel). In this example, two tissue connector assemblies **10** are used to make connections at generally opposite sides of the graft vessel and tissue connector assemblies **100** are used to make connections between those made with assemblies **10** (FIG. **6**). The procedure may be accomplished with a beating heart procedure with the use of a heart stabilizer to keep the heart stable, for example. The procedure may also be performed endoscopically.

[**0065**] The patient is first prepped for standard cardiac surgery. After exposure and control of the artery **14**, occlusion and reperfusion may be performed as required. After the arteriotomy of the snared graft vessel **12** has been made to the appropriate length, a tissue connector assembly **10** is attached to the free end of the graft vessel along an edge margin of the vessel. In order to attach the connector assembly **10**, the surgeon grasps the needle **16** with a needle holder (e.g., surgical pliers, forceps, or any other suitable instrument) and inserts the needle **16** into the tissue of the graft vessel **12** in a direction from the exterior of the vessel to the interior of the vessel. The surgeon then releases the needle **16** and grasps a forward end of the needle which is now located inside the graft vessel **12** and pulls the needle and a portion of the suture **18** through the vessel. The needle **16** is passed through an opening **120** formed in the sidewall of the artery **14** and inserted into the tissue of the artery in a direction from the interior of the artery to the exterior of the artery. The surgeon then grasps the needle **16** located outside the artery **14** and pulls the needle and a portion of the suture **18** through the arterial wall. A second tissue connector assembly **10** may be inserted at a location generally 180 degrees from the location of the first tissue connector in a conventional "heel and toe" arrangement.

[**0066**] Once the tissue connector assemblies **10** are inserted, the graft vessel **12** is positioned above and aligned with the opening **120** in the sidewall of the artery **14** (FIG. **2**A). A section of each suture **18** is located between the graft vessel **12** and artery **14**. The fasteners **20** and needles **16** are pulled generally away from the artery **14** to reduce the length of the suture **18** (eliminate slack of the suture) between the vessel **12** and artery and "parachute" the vessel onto the artery (FIG. **2**B). The needles **16** are then pulled away from the artery **14** until each fastener **20** is positioned within the graft vessel **12** and artery with one end of each fastener **20** extending from the vessel and the opposite end of each fastener extending from the artery (FIG. **2**C). The edges of the graft vessel **12** and artery **14** are positioned adjacent one another to form a continuous interior and exterior surface along the mating portions of the vessel and artery. As shown in FIG. **2**F, the tissue is compressed within the fastener **20**.

[**0067**] A surgical instrument (e.g., needle holder) is used to radially squeeze each locking device **28** to release the locking device from the fastener **20**. Upon removal of the locking device **28**, the coil **26** moves to its free uncompressed state which allows the wire **34** to return to its original undeformed closed position (FIG. **2**D). As the wires **34** move to their closed position the adjacent tissues of the graft vessel **12** and artery **14** which were previously pulled together during the parachuting of the graft vessel onto the artery, are squeezed together to securely engage the graft vessel and artery (FIGS. **2**E and **2**F). It should be noted that as the locking device **28** is squeezed two steps are accomplished. The fastener **20** is released from the locking device **28**, thus allowing the coil **26** to uncompress and the wire **34** to move to its closed configuration, and the needle **16** is released from the fastener. Thus, in this embodiment, the locking device **28** provides for simultaneous actuating closure of the fastener **20** and release of the needle **16** from the fastener.

[**0068**] The tissue connector assemblies **100** are subsequently inserted at circumferentially spaced locations around the periphery of the graft vessel to sealingly fasten the graft vessel **12** to the artery **14**. The needle **102** of the fastener **100** is inserted into the graft vessel **12** from the exterior surface of the graft vessel and pushed through the graft vessel and artery **14** tissue. The needle holder is then used to pull the needle **102** through the arterial wall. An instrument (same needle holder or other suitable instrument) is used to apply a squeezing force to the locking device **104** to release the wire and coil **112** from the needle **102**. This allows the coil **112** to move to its uncompressed configuration and the wire to move to its closed position. It should be noted that the tissue connector assemblies **10** may remain in their open position while the tissue connector assemblies **100** are inserted into the tissue and moved to their closed position. The locking devices **28** of the tissue connector assemblies **10** may subsequently be removed from the fasteners **20** to allow the fasteners to move to their closed position. The number and combination of tissue connectors assemblies **10**, **100** required to sealingly secure the connect-

ing tissues together may vary. For example, only tissue connector assemblies **10** may be used to complete the entire anastomosis.

[**0069**] Although the coil **26** is shown remaining on the wire (FIG. **2**D), it is to be understood that the coil **26** may also be removed from the wire **34**, leaving only the wire in the connected tissue.

[**0070**] As an alternative to inserting tissue connector assemblies **10** at "heel and toe" locations described above, a number of tissue connectors **10** may be inserted generally around the location of the heel. The graft vessel may then be pulled towards the artery to determine whether the opening formed in the sidewall of the artery is large enough before completing the anastomosis.

[**0071**] The graft vessel **12** may also be parachuted onto the artery **14** in the method shown in FIG. **2**G. The needle is inserted into the graft vessel **12** and artery **14** as described above and the suture **18** is pulled through the vessel so that the fastener **20** is positioned within the vessel and artery. The needles **16** are then pulled away from the artery **14** to "parachute" the graft vessel **12** onto the artery. The anastomosis may then be completed as described above.

[**0072**] Although the suturing procedure has been described for an end-to-side anastomosis, it should be appreciated that the procedure is applicable to an end-to-end and side-to-side anastomosis, connecting various tissue structures including single and multiple tissue structures, and puncture sites, and connecting tissue to a prosthetic graft or valve, for example.

[**0073**] It will be observed from the foregoing that the tissue connector assemblies of the present invention have numerous advantages. Importantly, the assemblies are easier and faster to apply than conventional sutures which require tying multiple knots. The assemblies also may be used in minimally invasive procedures including endoscopic procedures.

[**0074**] All references cited above are incorporated herein by reference.

[**0075**] The above is a detailed description of a particular embodiment of the invention. It is recognized that departures from the disclosed embodiment may be made within the scope of the invention and that obvious modifications will occur to a person skilled in the art. The full scope of the invention is set out in the claims that follow and their equivalents. Accordingly, the claims and specification should not be construed to unduly narrow the full scope of protection to which the invention is entitled.

1-38. (canceled)

39. A method for connecting a graft vessel to a target vessel in an anastomosis comprising:

inserting a tissue connector assembly through said graft and target vessels with said graft vessel being spaced from said target vessel and said tissue connector assembly having a first end extending from an exterior surface of said graft vessel and a second end extending from an exterior surface of said target vessel; and

pulling at least a portion of said tissue connector assembly to draw said graft vessel into contact with said target vessel.

40. The method of claim 39 further comprising inserting a second tissue connector assembly through said graft and target vessels prior to pulling at least a portion of said tissue connector assembly.

41. The method of claim 39 further comprising inserting a plurality of clips into said graft and target vessels after pulling at least a portion of said tissue connector assembly, to sealingly engage said vessels.

42. The method of claim 41 further comprising placing said clips into an open configuration prior to inserting said clips into said vessels.

43. The method of claim 42 wherein said deforming of said clips includes attaching a restraining device to each of said clips.

44. The method of claim 39 wherein said inserting a tissue connector assembly includes inserting said tissue connector assembly through an end margin of said graft vessel and a side of said target vessel.

45. The method of claim 39 wherein said inserting a tissue connector assembly includes inserting said tissue connector assembly through an end margin of said graft vessel and an end margin of said target vessel.

46. The method of claim 39 wherein said inserting a tissue connector assembly includes inserting said tissue connector assembly through said a side of said graft vessel and a side of said target vessel.

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