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(54) **MEDICAL ANASTOMOSIS APPARATUS**

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(60) Continuation of application No. 10/078,939, filed on Feb. 19, 2002, now Pat. No. 6,533,812, which is a continuation of application No. 09/955,231, filed on Sep. 17, 2001, now Pat. No. 6,440,163, which is a division of application No. 09/527,668, filed on Mar. 17, 2000, now Pat. No. 6,309,416, which is a division of application No. 09/186,774, filed on Nov. 6, 1998, now Pat. No. 6,113,612.

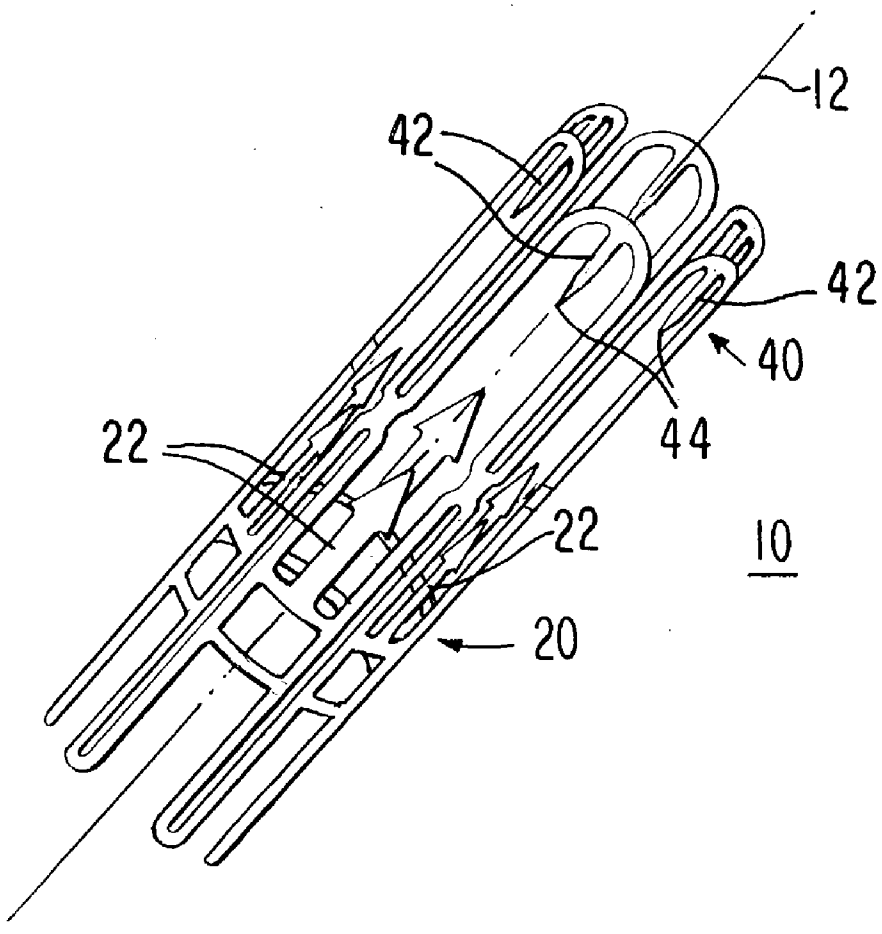
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(52) **U.S. Cl.** **623/1.23**

(57) **ABSTRACT**

A connector for use in providing an anastomotic connection between two tubular body fluid conduits in a patient. The connector is preferably a single, integral, plastically deformable structure that can be cut from a tube. The connector has axial spaced portions that include members that are radially outwardly deflectable from other portions of the connector. The connector is annularly enlargeable so that it can be initially delivered and installed in the patient in a relatively small annular size and then annularly enlarged to provide the completed anastomosis. The radially outwardly deflected members of the first and second portions respectively engage the two body fluid conduits connected at the anastomosis and hold those two conduits together in fluid-tight engagement. Apparatus for use in delivering and deploying a connector is also disclosed.



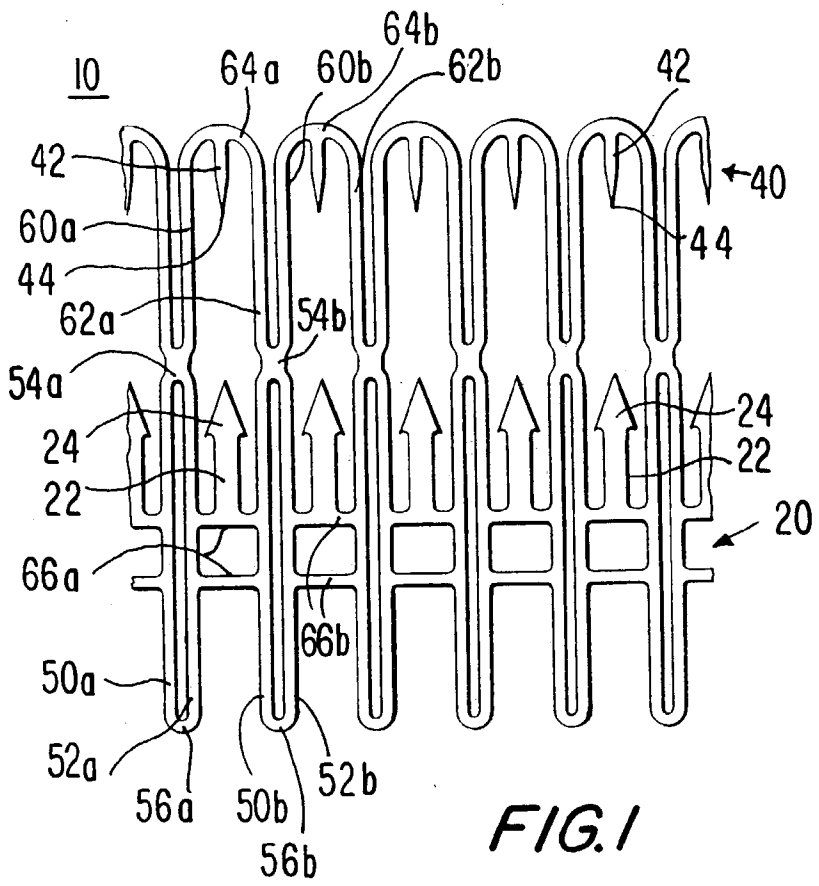

10
64a
60b
64b
62b
42
42
40
60a
44
44
62a
54b
54a
24
24
22
22
20
66a
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50a
52a
56a
50b
52b
56b

FIG.1

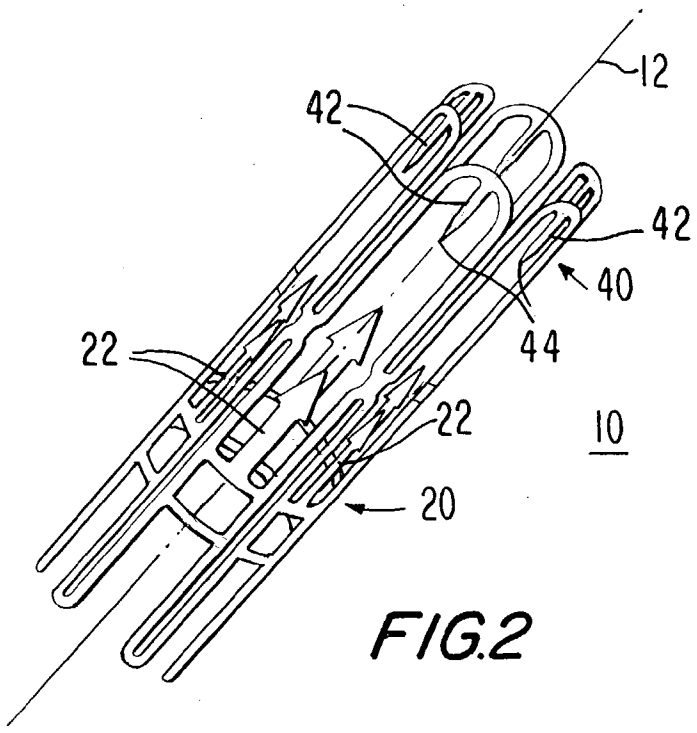

12
42
42
40
44
22
22
10
20

FIG.2

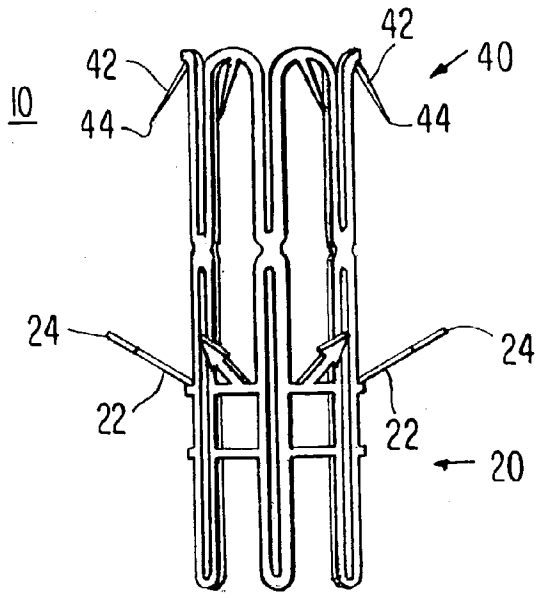

42
42
40
10
44
44
24
24
22
22
20

FIG. 3

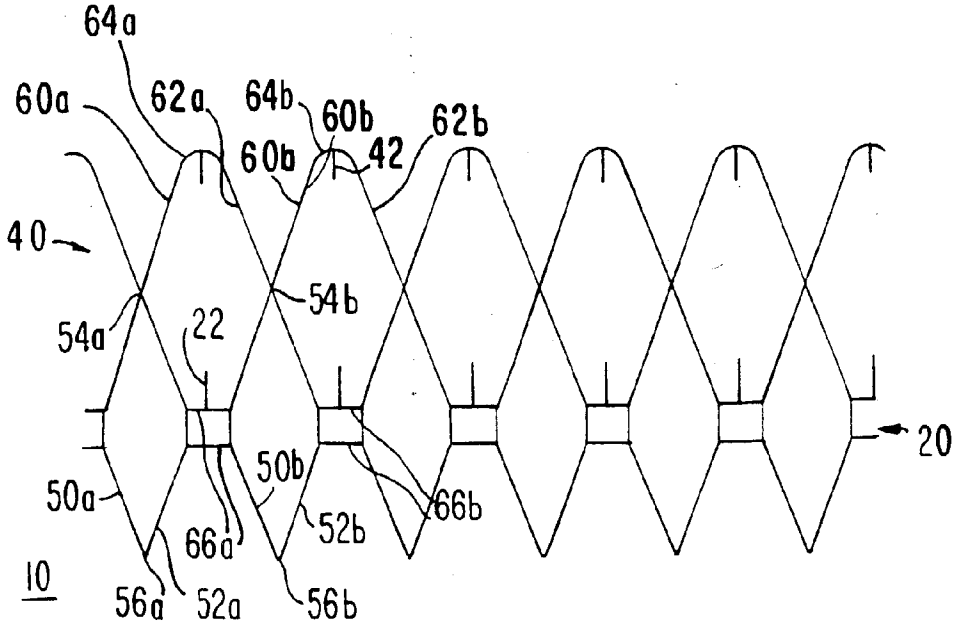

64a
60a
62a
64b
60b
62b
60b
42
40
54b
54a
22
20
50b
50a
66b
52b
66a
10
56a
52a
56b

FIG. 4

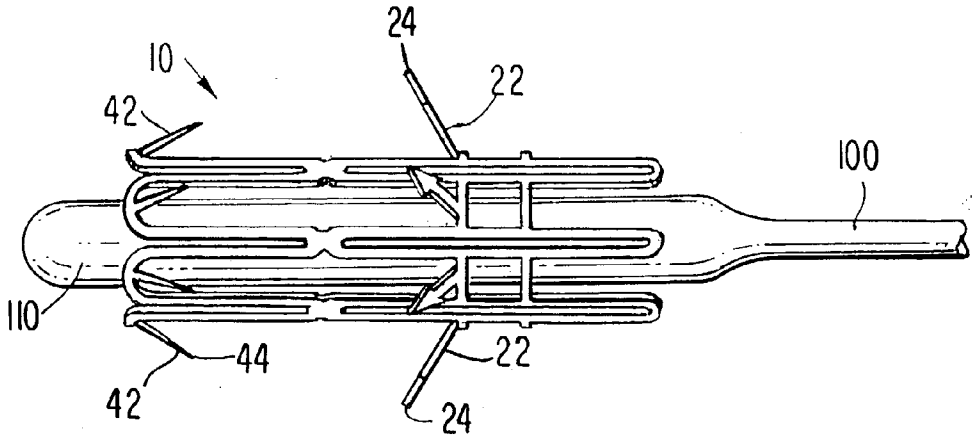


FIG. 5

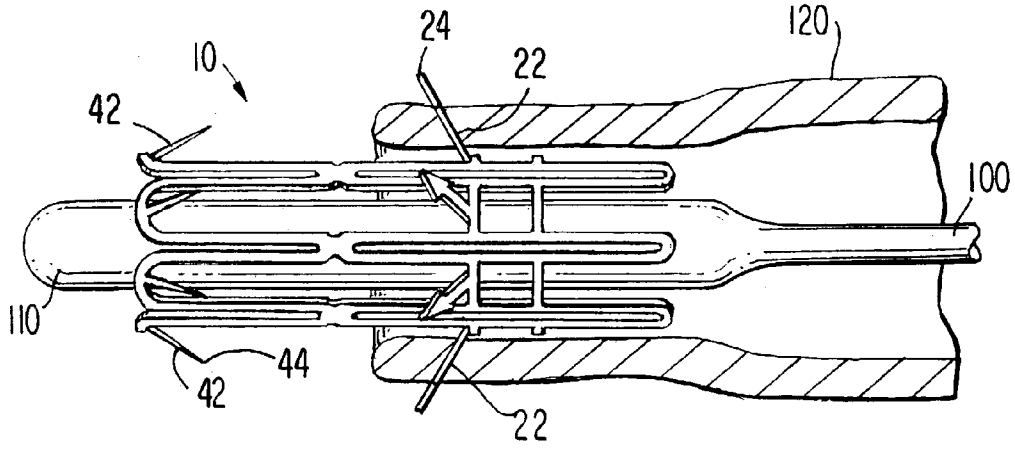


FIG. 6

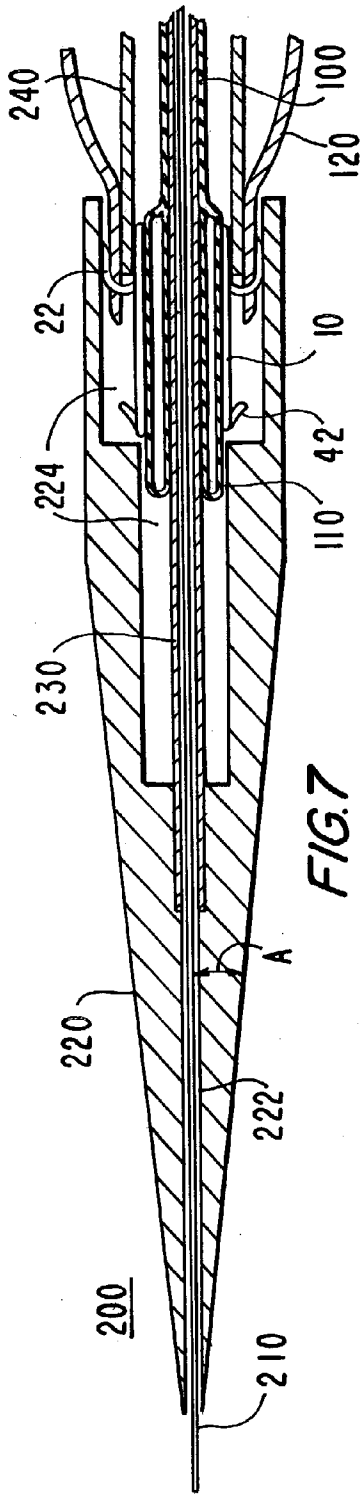

240
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120
22
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224
42
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230
220
222
A
200
210

FIG.7

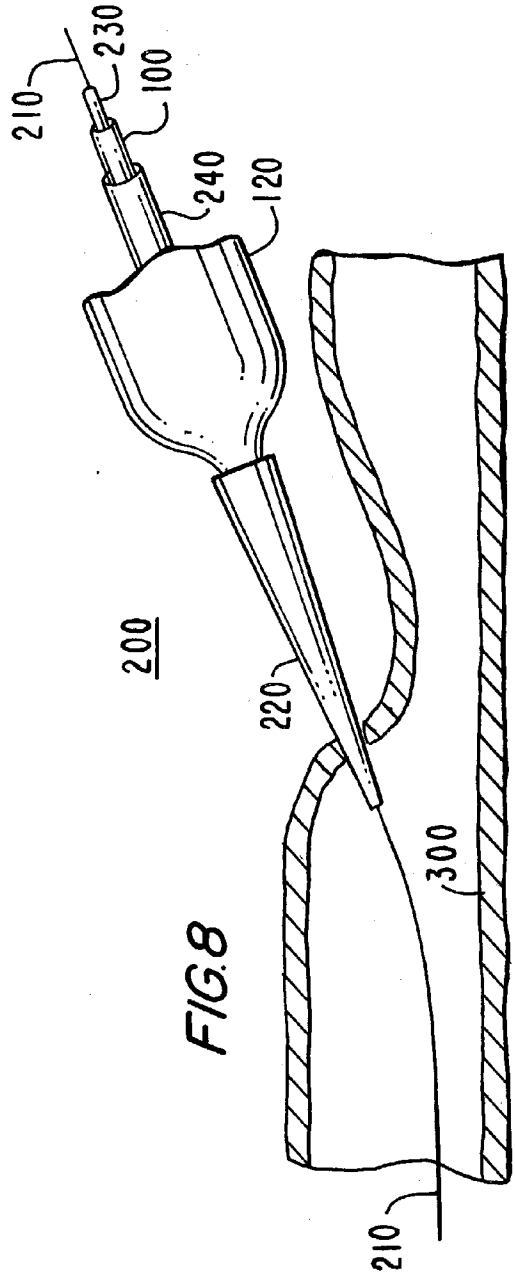

210
230
100
240
120
200
220
300
210

FIG.8

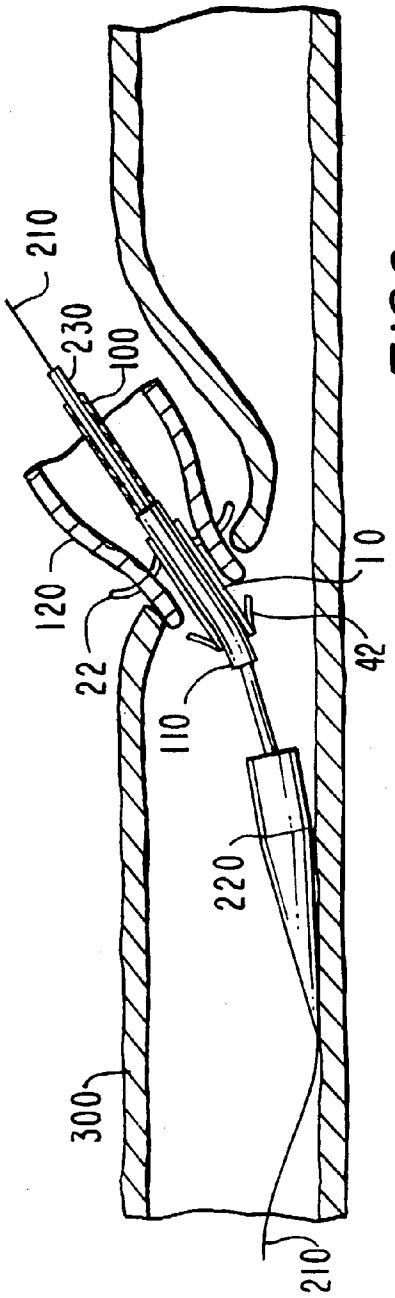

210
230
100
120
22
110
10
42
220
300
210

FIG.9

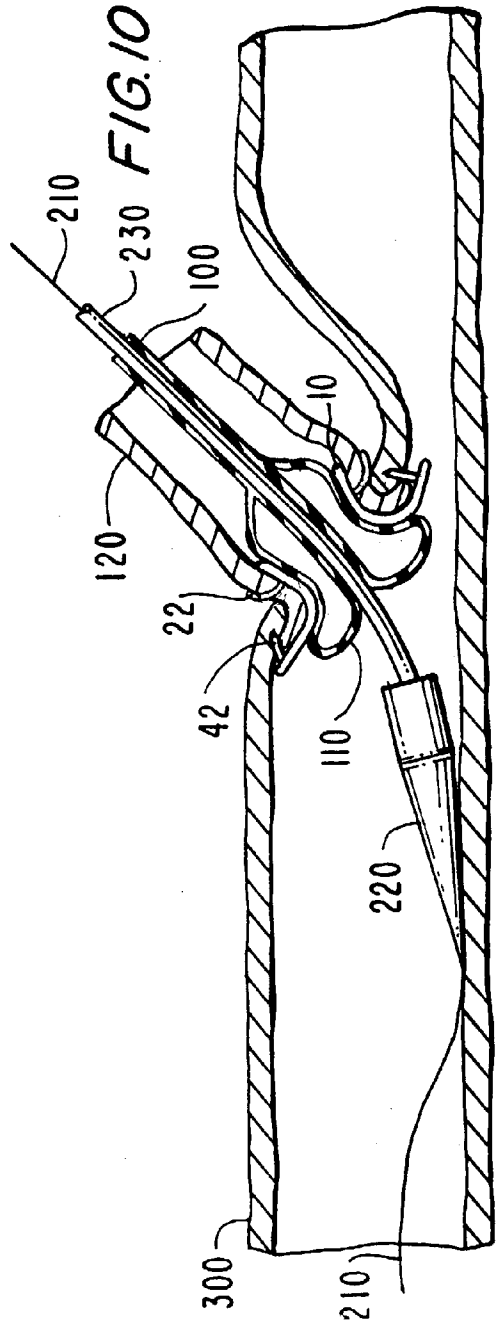

210
230
100
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120
22
42
110
220
300
210

FIG.10

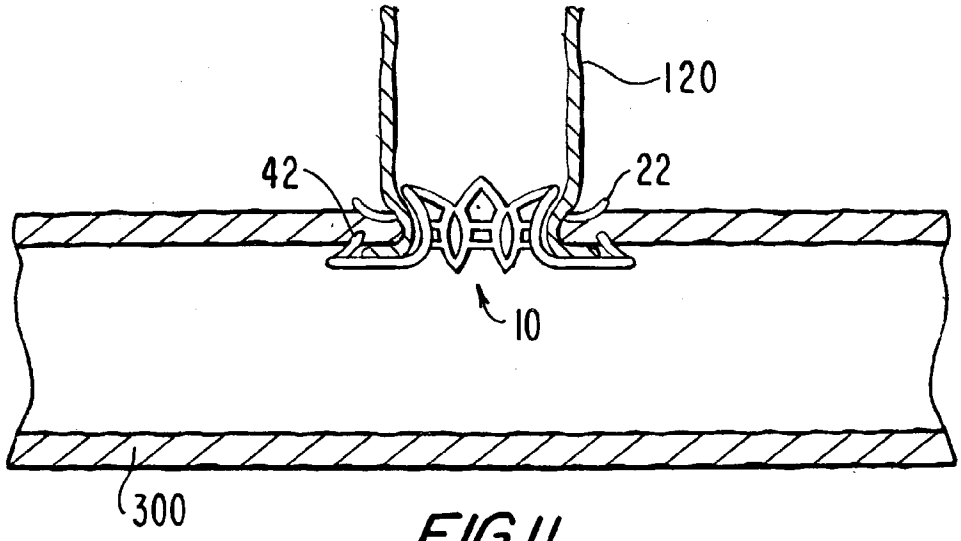

120
42
22
10
300

FIG.11

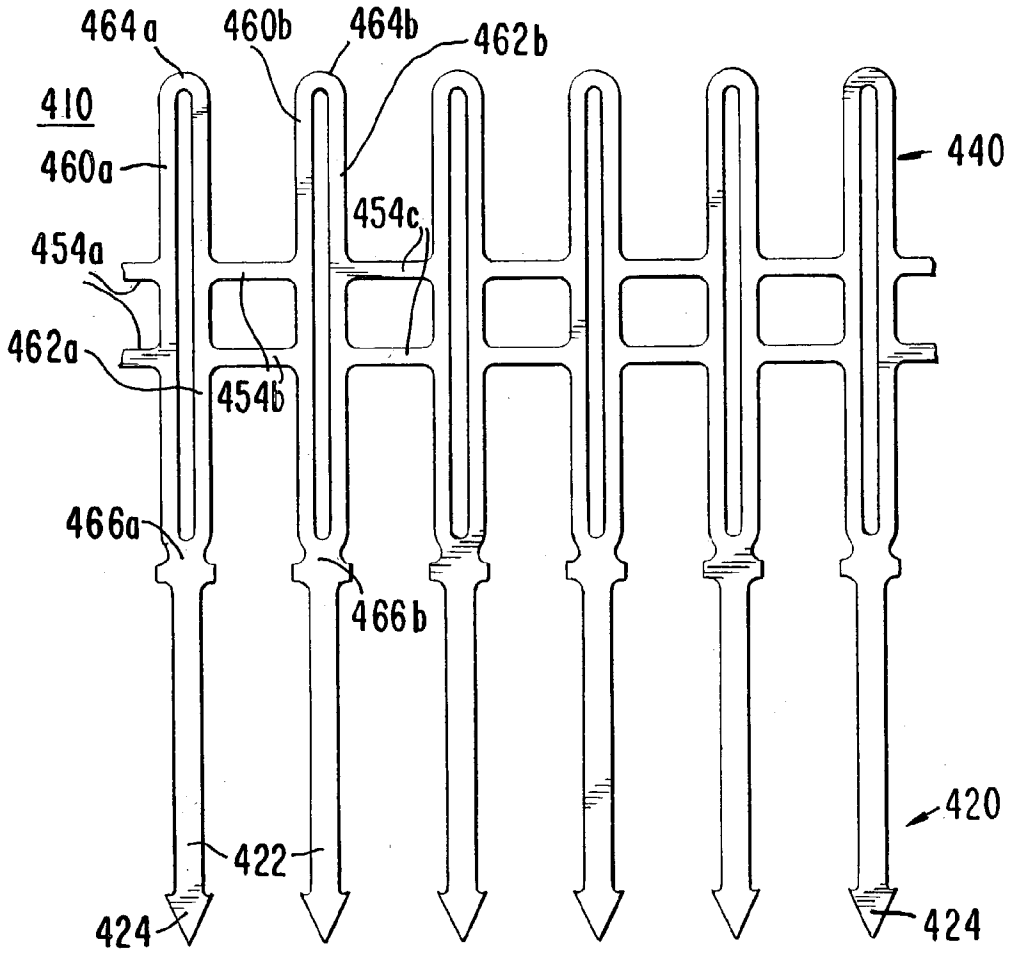

464a
460b
464b
462b
410
460a
440
454c
454a
462a
454b
466a
466b
420
422
424
424

FIG.12

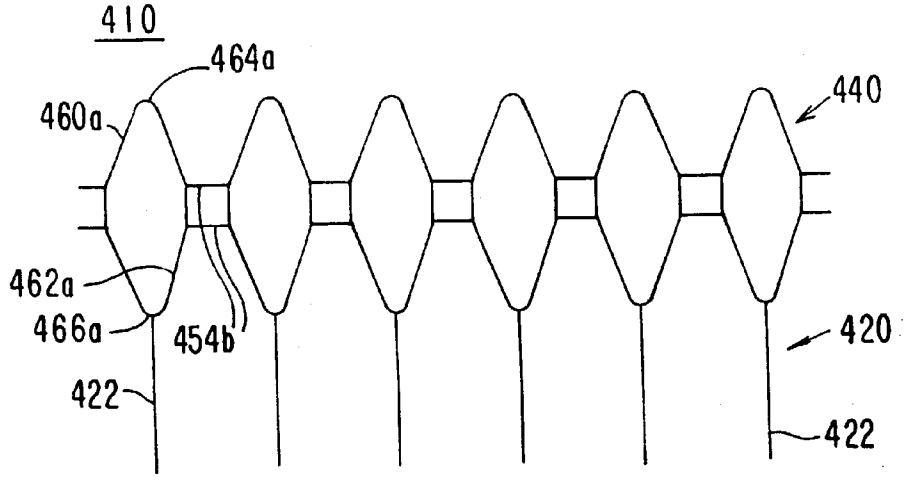

410
464a
460a
440
462a
466a
454b
420
422
422

FIG.13

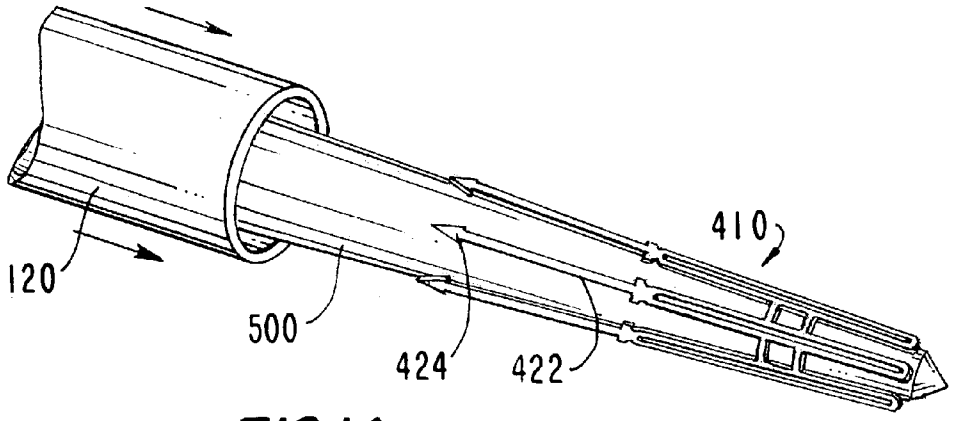

410
120
500
424
422

FIG.14

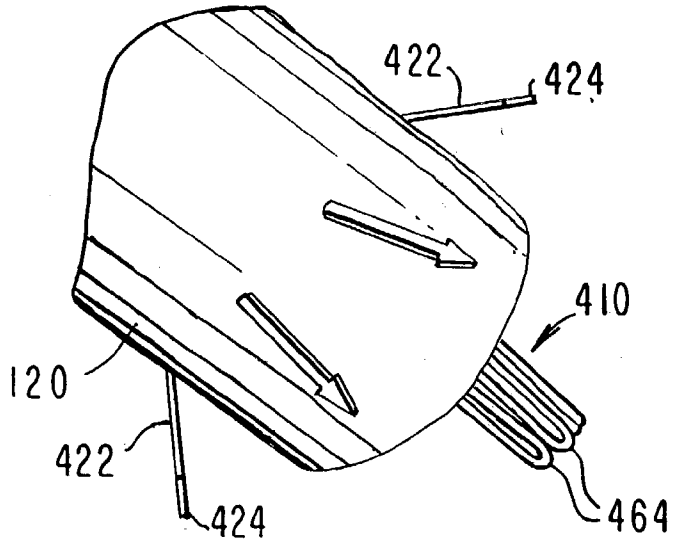


FIG.15

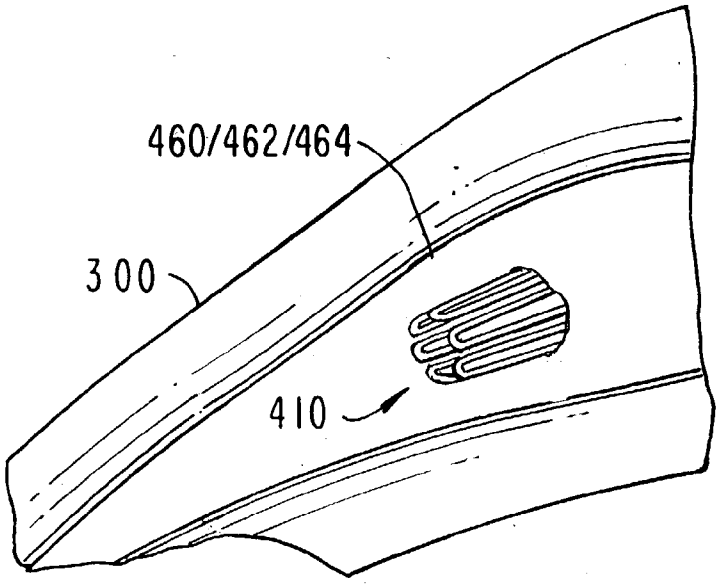


FIG.16

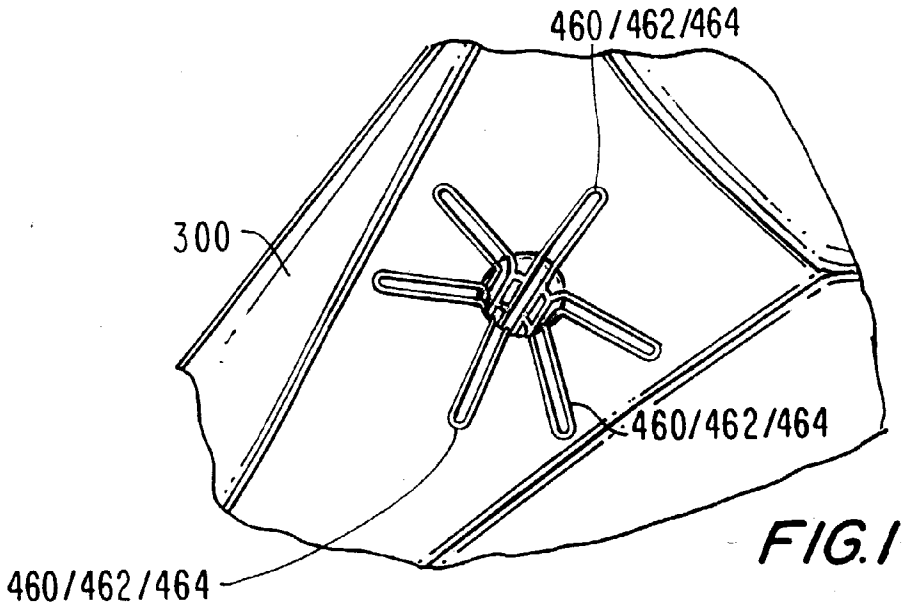


FIG.17

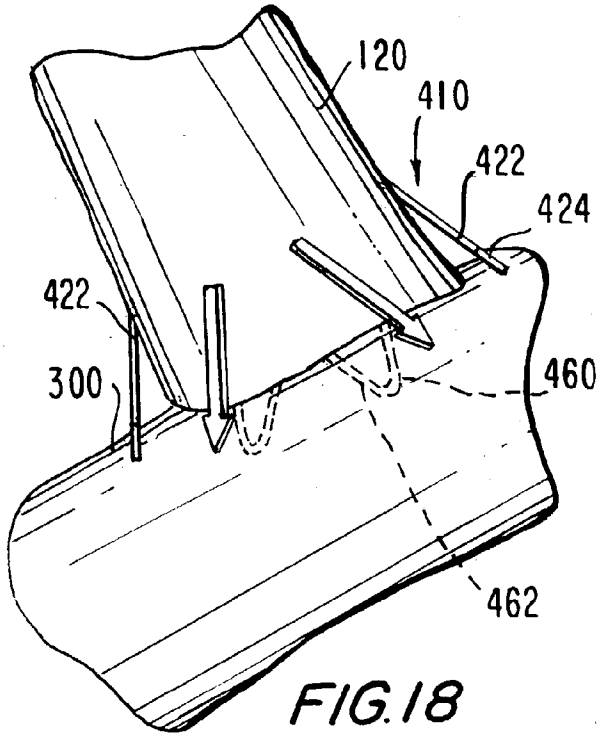


FIG.18

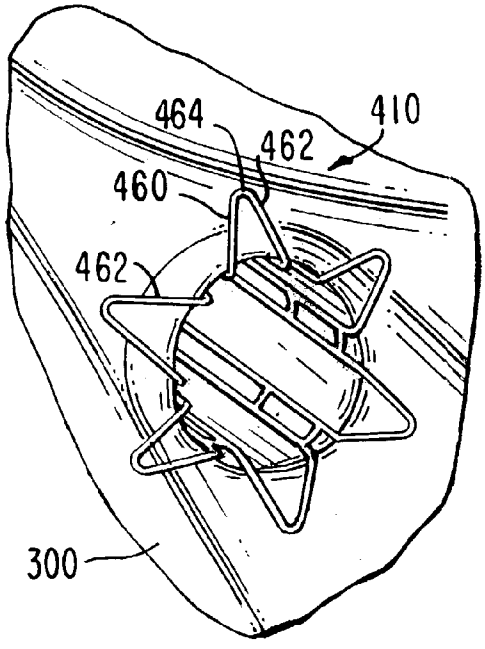


FIG.19

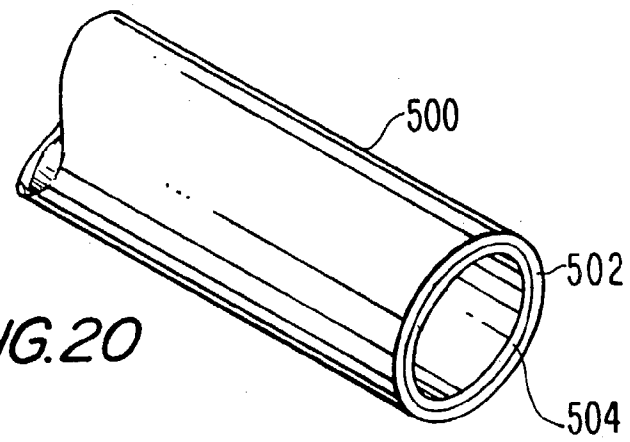


FIG. 20

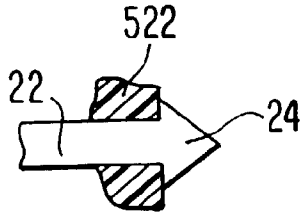


FIG. 21

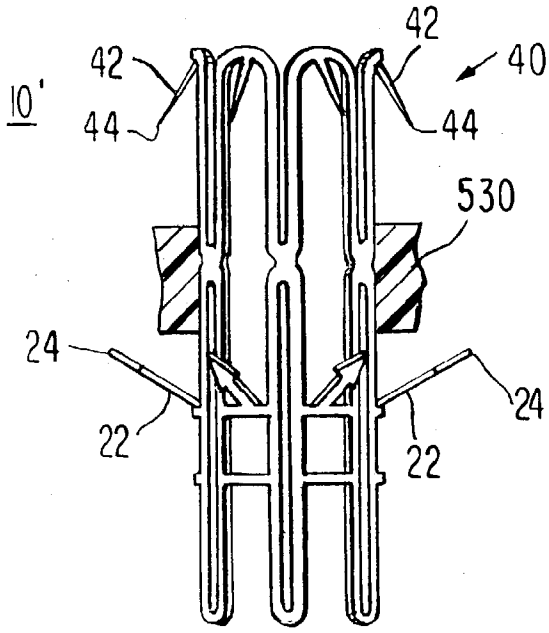


FIG. 22

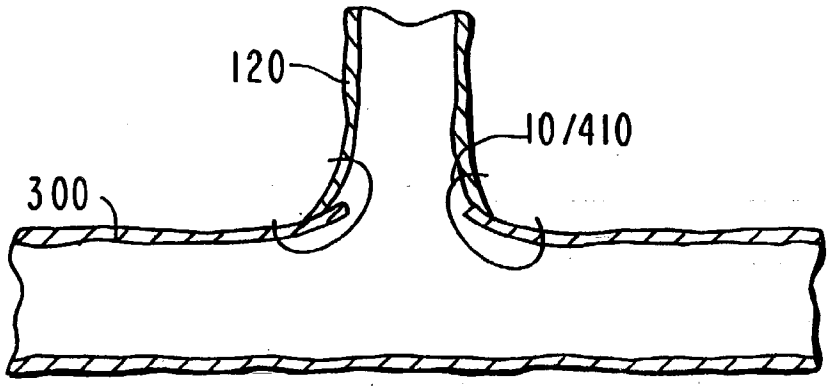


FIG. 23

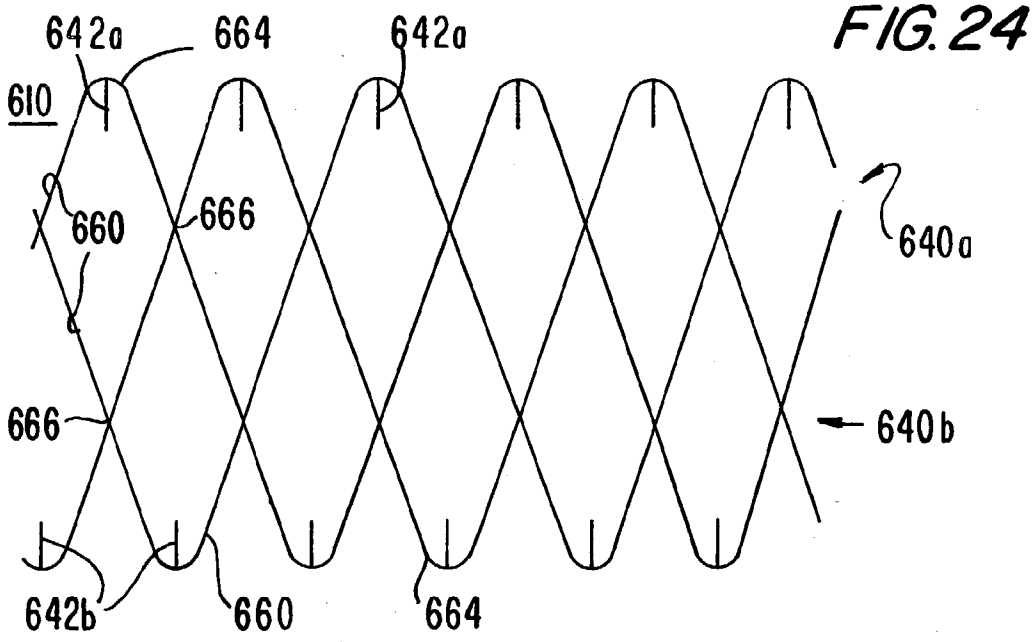


FIG. 24

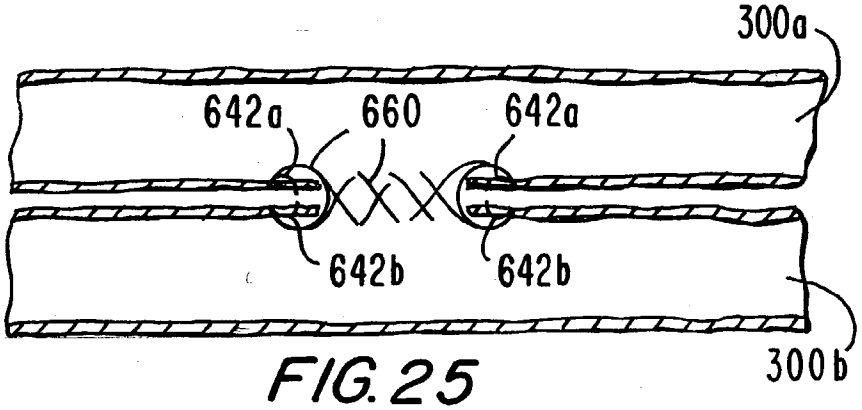


FIG. 25

MEDICAL ANASTOMOSIS APPARATUS

[0001] This application is a continuation of U.S. patent application Ser. No. 10/078,939, filed Feb. 19, 2002, which is a continuation of U.S. patent application Ser. No. 09/955,231, filed Sep. 17, 2001 (now U.S. Pat. No. 6,440,163), which is a division of U.S. patent application Ser. No. 09/527,668, filed Mar. 17, 2000 (now U.S. Pat. No. 6,309,416), which is a division of U.S. patent application Ser. No. 09/186,774, filed Nov. 6, 1998 (now U.S. Pat. No. 6,113,612). All of these prior applications are hereby incorporated by reference herein in their entireties.

BACKGROUND OF THE INVENTION

[0002] This invention relates to medical apparatus, and more particularly to apparatus for use in making anastomotic connections between tubular body fluid conduits in a patient.

[0003] There are many medical procedures in which it is necessary to make an anastomotic connection between two tubular body fluid conduits in a patient. An anastomotic connection (or anastomosis) is a connection which allows body fluid flow between the lumens of the two conduits that are connected, preferably without allowing body fluid to leak out of the conduits at the location of the connection. As just one example of a procedure in which an anastomosis is needed, in order to bypass an obstruction in a patient's coronary artery, a tubular graft supplied with aortic blood may be connected via an anastomosis to the contrary artery downstream from the obstruction. The anastomosis may be between the end of the graft and an aperture in the side wall of the coronary artery (a so-called end-to-side anastomosis), or the anastomosis may be between an aperture in the side wall of the graft and an aperture in the side wall of the coronary artery (a so-called side-to-side anastomosis (e.g., as in published Patent Cooperation Treaty ("PCT") patent application WO 98/16161, which is hereby incorporated by reference herein in its entirety)). The graft may be natural conduit, artificial conduit, or a combination of natural and artificial conduits. If natural conduit is used, it may be wholly or partly relocated from elsewhere in the patient (e.g., wholly relocated saphenous vein or partly relocated internal mammary artery). Alternatively, no relocation of the graft may be needed (e.g., as in above-mentioned application WO 98/16161 in which a length of vein on the heart becomes a "graft" around an obstruction in an immediately adjacent coronary artery). More than one anastomosis may be needed. For example, a second anastomosis may be needed between an upstream portion of the graft conduit and the aorta or the coronary artery upstream from the obstruction in that artery. Again, this second anastomosis may be either an end-to-side anastomosis or (as shown, for example, in above-mentioned application WO 98/16161) a side-to-side anastomosis. Alternatively, no second, upstream anastomosis may be required at all (e.g., if the graft is an only-partly-relocated internal mammary artery).

[0004] The currently most common technique for making an anastomosis is to manually suture the two tubular body fluid conduits together around an opening between them. Manual suturing is difficult and time-consuming, and the quality of the anastomosis that results is highly dependent on the skill of the person doing the suturing. In the case of coronary artery bypass procedures, one source of difficulty for suturing of an anastomosis may be motion of the heart. There is also increasing interest in procedures which are less invasive or even minimally invasive. Such procedures have potentially important advantages for patients, but they may increase the difficulty of performing manual suturing of an anastomosis by reducing or limiting access to the site within the patient at which the anastomosis must be made. Various examples of such less invasive or minimally invasive procedures are shown in above-mentioned application WO 98/16161, Goldsteen et al. U.S. Pat. No. 5,976,178, Sullivan et al. U.S. Pat. No. 6,120,432, published PCT patent application Wo 98/55027, and Berg et al. U.S. Pat. No. 6,475,222, all of which are hereby incorporated by reference herein in their entireties.

[0005] In view of the foregoing, it is an object of this invention to provide apparatus that can be used to make anastomotic connections in lieu of manual suturing.

[0006] It is another object of the invention to provide apparatus that can be used to make anastomotic connections even though access to the site of the anastomosis may be limited or even only indirect or remote.

[0007] It is still another object of the invention to provide apparatus that can be used to make anastomotic connections without the need for a high degree of manual suturing skill.

[0008] It is yet another object of the invention to provide apparatus for making anastomotic connections that is less adversely affected than manual suturing by adjacent or nearby body motion (e.g., motion of the patient's heart).

[0009] It is still another object of this invention to provide apparatus for facilitating the making of higher quality anastomotic connections more rapidly and with more consistent results than is possible with prior art methods and apparatus such as manual suturing.

SUMMARY OF THE INVENTION

[0010] These and other objects of the invention are accomplished in accordance with the principles of the invention by providing a connector for use in making an anastomotic connection between two tubular body fluid conduits in a patient, the connector being of substantially one-piece or unitary construction which extends annularly about a central longitudinal axis. The structure of the connector includes axially spaced first and second portions, at least one of which includes members that are deflectable radially out from a remainder of the connector structure. In some embodiments both of the axially spaced first and second portions include members that are deflectable radially out from a remainder of the structure. The connector structure is annularly enlargeable, preferably by inflation of a balloon placed temporarily inside the connector. The structure of the connector preferably lends itself to formation by removal of selected material from a single unitary tube. The connector is typically made of metal which is plastically deformable (e.g., in the above-mentioned radial outward deflections and annular enlargement).

[0011] The members that are deflectable radially out from the first portion of the connector structure are configured to engage the side wall of one of the two tubular body fluid conduits that are to be connected. The members that are deflectable radially out from the second portion of the connector structure are configured to engage the side wall of the other of the two body fluid conduits that are to be

connected. Alternatively, one of the two portions of the connector can be secured (preferably pre-secured) to the associated conduit by other means such as sutures. Annular expansion of the connector preferably causes the first and second portions of the connector structure to move toward one another along the central longitudinal axis of the connector, thereby causing the connector to draw the two tubular body fluid conduits together at the anastomosis between them. This helps produce an anastomosis which is fluid-tight (i.e., from which body fluid does not leak).

[0012] The connectors of this invention can be used to provide either end-to-side or side-to-side anastomoses. The connector may be first attached to one of the body fluid conduits to be connected (e.g., an end portion of a graft conduit), and then delivered along with the attached end of the first conduit to the connection point with the second conduit, where the connector is fully deployed to produce an anastomosis between the first and second conduits. Prior to full deployment the connector preferably has a relatively small circumference, which facilitates delivery and initial installation in the patient, even at relatively remote or inaccessible locations in the patient. For example, the connector can be delivered via lumens of body fluid conduits in the patient and/or relatively small-diameter instrumentation such as a cannula or laparascopic-type device. Final installation can be performed substantially solely by inflation of a balloon temporarily disposed in the connector. No direct manipulation of the connector may be needed. All of these attributes facilitate use of the connector at remote or inaccessible locations in the patient. The connector therefore lends itself to use in less invasive or minimally invasive procedures.

[0013] Instrumentation for facilitating installation of the connector through the side wall of a body fluid conduit is also disclosed. This instrumentation has a gradually tapered distal nose portion with an outer surface that is free of features that could snag on the side wall of the body fluid conduit to be penetrated by the nose portion. At least the portion of the connector that must pass through the body fluid conduit side wall is completely covered by the instrumentation until that portion of the connector is through the side wall. These features of the instrumentation help it penetrate the body fluid conduit side wall with no snagging and with minimal trauma. Thereafter the distal nose portion can be shifted distally relative to the connector to expose the connector in position through the side wall. Other parts of the instrumentation (e.g., an inflatable balloon) can then be operated to complete the deployment of the connector.

[0014] Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1** is a simplified planar development of the structure of an illustrative embodiment of a connector constructed in accordance with this invention.

[0016] **FIG. 2** is a simplified perspective view of the actual structure of the connector which is shown in planar development in **FIG. 1**.

[0017] **FIG. 3** is a simplified elevational view of the **FIG. 2** structure after some further processing in accordance with the invention.

[0018] **FIG. 4** is a simplified planar development of the structure of FIGS. **1-3** showing that structure's capacity for annular enlargement in accordance with the invention.

[0019] **FIG. 5** is a simplified elevational view of the structure of **FIG. 3** with some additional structure in accordance with the invention.

[0020] **FIG. 6** is a simplified elevational view, partly in section, of the structure of **FIG. 5** with still more additional structure in accordance with the invention.

[0021] **FIG. 7** is a simplified sectional view of the structure of **FIG. 6** with additional illustrative apparatus shown for use in delivering and deploying the **FIG. 6** structure in a patient in accordance with the invention.

[0022] **FIG. 8** is a simplified elevational view, partly in section, showing an early stage in use of the **FIG. 7** apparatus in accordance with the invention.

[0023] **FIG. 9** is a view similar to **FIG. 8**, but with more elements shown in section, and showing a later stage in use of the **FIG. 7** apparatus in accordance with the invention.

[0024] **FIG. 10** is a view similar to **FIG. 9** showing a still later stage in use of the **FIG. 7** apparatus in accordance with the invention.

[0025] **FIG. 11** is a view similar to **FIG. 10** showing the end result of using the **FIG. 7** apparatus in accordance with the invention.

[0026] **FIG. 12** is a view similar to **FIG. 1** for another illustrative embodiment of a connector constructed in accordance with the invention.

[0027] **FIG. 13** is a view similar to **FIG. 4**, but for the embodiment of **FIG. 12**.

[0028] **FIG. 14** is a simplified perspective view showing the connector of **FIG. 12** with other elements in accordance with the invention.

[0029] **FIG. 15** is another simplified perspective of a later stage in use of some of the elements shown in **FIG. 14**.

[0030] **FIG. 16** is another simplified perspective view, partly in section, of a still later stage in use of the elements shown in **FIG. 15**.

[0031] **FIG. 17** is another view, generally similar to **FIG. 16**, showing an even later stage in use of the elements shown in **FIG. 16**.

[0032] **FIG. 18** is a simplified perspective view of a completed anastomosis including the connector of **FIG. 12**.

[0033] **FIG. 19** is another view, partly in section, of the anastomosis of **FIG. 18**.

[0034] **FIG. 20** is a simplified perspective view of an illustrative embodiment of a starting structure for use in making connectors in accordance with the invention.

[0035] **FIG. 21** is a simplified elevational view, partly in section, illustrating a possible modification of connectors in accordance with the invention.

[0036] **FIG. 22** is a simplified elevational view, partly in section, illustrating another possible modification of connectors in accordance with the invention.

[0037] **FIG. 23** is a simplified sectional view of an alternative finished anastomosis in accordance with the invention.

[0038] **FIG. 24** is a view similar to **FIG. 4** for still another illustrative embodiment of a connector constructed in accordance with the invention.

[0039] **FIG. 25** is a view similar to **FIG. 11** for a completed anastomosis employing a connector of the type shown in **FIG. 24**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0040] **FIG. 1** shows a planar development of what is actually an integral, one-piece (unitary), annular structure **10**. In particular, the left and right edges of the structure shown in **FIG. 1** are actually joined to and integral with one another. Thus the actual structure is as shown in **FIG. 2**, although **FIG. 1** is useful to more clearly reveal the details of various features of the structure. A central longitudinal axis **12** about which structure **10** is annular is shown in **FIG. 2**.

[0041] An illustrative material for structure **10** is **304** stainless steel. Other examples of suitable materials include tantalum, tungsten, platinum, and nitinol. Structure **10** may be advantageously produced by starting with a single, unitary metal tube and removing selected material until only the structure shown in **FIG. 2** remains. For example, laser cutting may be used to remove material from the starting tube in order to produce structure **10**. Although connectors **10** can be made in various sizes for various uses, a typical connector has an initial outside diameter in the range from about 0.040 to about 0.065 inches, an initial length of about 4.0 mm, and a material thickness of about 0.004 inches.

[0042] Connector **10** may be described as including axially spaced first and second portions **20** and **40**, respectively. First portion **20** includes a plurality of annularly spaced members **22** that in this case have free end portions **24** that are sharply pointed and that point toward second portion **40**. Each of members **22** is deflectable radially out from the remainder of structure **10** as shown, for example, in **FIG. 3**. This outward deflection is preferably at least partly plastic.

[0043] Second portion **40** also includes a plurality of annularly spaced members **42** that in this case have free end portions **44** that are sharply pointed and that point toward first portion **20**. Each of members **42** is deflectable radially out from the remainder of structure **10** as shown, for example, in **FIG. 3**. Again, this outward deflection is preferably at least partly plastic.

[0044] The above-mentioned outward deflection of elements **22** and **42** can be produced by putting the connector on a mandrel and prying elements **22** and **42** radially outward.

[0045] Connector **10** is formed in such a way that it is annularly enlargeable (e.g., by inflation of a balloon that is temporarily disposed inside the connector). The annularly expanded condition of connector **10** is shown in **FIGS. 4, 10**, and **11**. The annular expandability of connector **10** is provided by making the connector with a plurality of annularly adjacent, annularly enlargeable cells. For example, a typical cell includes annularly spaced, but adjacent, longitudinal members **50***a* and **52***a*. The axially spaced ends of this pair of members are connected to one another at **54***a* and **56***a*. The next annularly adjacent similar cell includes elements **50***b*, **52***b*, **54***b*, and **56***b*. Annularly adjacent ones of these cells are connected to one another (e.g., as at **66***a*) at locations which are axially medial to their axial end connections **54** and **56**. In this way structure **10** is annularly enlargeable by annularly enlarging each of the above-mentioned cells (see **FIG. 4**).

[0046] In addition to the cells that are described above, structure **10** includes other, similarly annularly expandable cells that are axially and annularly offset from the first-described cells. A representative one of these other cells includes annularly adjacent longitudinal members **60***a* and **62***a*, the axially spaced ends of which are connected at **64***a* and **66***a*. (It should be noted that part of member **60***a* is common with part of member **52***a*, and part of member **62***a* is common with part of member **50***b*.) The next annularly adjacent cell of this kind includes components **60***b*, **62***b*, **64***b*, and **66***b*. Annularly adjacent cells of this kind are connected to one another at locations like **54***b*, which are axially medial the axial endpoints **64** and **66** of those cells. Thus again the structure is annularly enlargeable by annularly enlarging these cells as shown, for example in **FIG. 4**.

[0047] It will be appreciated that as structure **10** annularly enlarges, it generally axially shortens. In other words, as cells **50/52/54/56** and **60/62/64/66** widen in the annular direction, they shorten in the axial direction. Thus annular enlargement of structure **10** decreases the axial spacing between portions **20** and **40**, and more particularly decreases the axial spacing between member **22**, on the one hand, and members **42**, on the other hand.

[0048] A typical use of connector **10** is, in a coronary artery bypass procedure, to provide an anastomosis between an axial end portion of a tubular graft conduit and an aperture in a side wall of a coronary artery. For this kind of use connector **10** may be loaded on an uninflated balloon **110** near the distal end of a balloon catheter **100** as shown in **FIG. 5**. In other words, connector **10** and catheter **100** are assembled so that connector **10** extends annularly around uninflated balloon **110**.

[0049] Graft conduit **120** is then placed annularly around the first portion **20** of connector **10** and the adjacent portion of catheter **100** as shown in **FIG. 6**. Graft conduit may be natural body tissue (e.g., a length of the patient's saphenous vein harvested for use as a graft, a partly severed internal mammary artery, etc.), an artificial graft (e.g., as shown in Goldsteen et al. U.S. Pat. No. 5,976,178, or published PCT patent application WO 98/19632, both of which are hereby incorporated by reference herein in their entireties), or a combination of natural and artificial conduits (e.g., a length of natural conduit disposed substantially concentrically inside a length of artificial conduit). Graft conduit **120** is placed on assembly **10/100** so that radially outwardly deflected members **22** penetrate and pass through the side wall of the graft conduit (e.g., as a result of compressing the graft against the fingers, thereby forcing the fingers to pierce through the graft wall). The sharpened free ends of members **22** facilitate penetration of conduit **120** by members **22**. The blunt rear surfaces of enlarged free end portions **24** resist withdrawal of members **22** from conduit **120** after members **22** have penetrated the conduit. The graft may be addition-

ally or alternatively directly sutured to the connector body. If the alternative of suturing graft **120** to the connector is used, then the first portion **20** of the connector may not need radially outwardly deflectable members **22** for engagement of the graft conduit.

[**0050**] As an alternative to securing graft **120** to connector **10** after balloon **110** has been associated with the connector, balloon **110** may be installed in connector **10** after the graft has been secured to the connector.

[**0051**] Illustrative apparatus **200** for delivering connector **10** and graft **120** to a location in a patient requiring a graft and an anastomosis, and for then deploying the connector and graft, is shown in **FIG. 7**. Apparatus **200** includes an optional guide wire **210**, which may be first installed in the patient along the route that the remainder of the apparatus is later to follow to reach the desired location in the patient. The remainder of the apparatus is then slid into the patient along guide wire **210**. Alternatively, guide wire **210** may be omitted, or a leading guide member (e.g., a wire) may be fixedly mounted on the distal (leftward in **FIG. 2**) end of the remainder of the apparatus. The wire allows precise tracking of the nose cone **220** and delivery system **200** into a patient's body fluid conduit (e.g., a coronary artery **300** as shown in FIGS. **8-10** and described below).

[**0052**] Apparatus **200** includes a gradually tapered distal nose portion or dilator **220** which extends annularly around a central, longitudinally extending, guide wire lumen **222**. Distal nose portion **220** has a substantially conical outer surface with a cone angle A, which is preferably less than about 15° (e.g., in the range from about 5° to about 15°, more preferably in the range from about 5° to about 10°). Such gradual tapering of nose portion **220** is desirable to enable nose portion to gradually enlarge an aperture in a side wall of a body fluid conduit to which graft **120** is to be connected without snagging on that conduit side wall. This geometry allows optimal passage across a body conduit wall (e.g., a coronary artery wall as shown in **FIG. 8** and described below) with minimal wall damage, with minimal force being required, and with no catching or snagging on the wall. Distal nose portion **220** may have cutting edges to further facilitate entry through a body fluid conduit side wall.

[**0053**] Distal nose portion **220** is connected to tube **230**, which extends proximally from the nose portion annularly around guide wire **210**. Thus the lumen of tube **230** constitutes a proximal continuation of guide wire lumen **222**. Tube **230** may be made of stainless steel hypotube, which allows the depicted apparatus to be pushed or pulled axially along guide wire **210**.

[**0054**] A proximal portion of distal nose portion **220** is hollowed out as indicated at **224** to receive balloon **110**, connector **10**, and a distal portion of graft **120** substantially coaxially around a medial portion of tube **230**. For this arrangement balloon **110** is provided as a hollow annulus at or near the distal end of hollow tubular member **100**. The side wall of tube **100** may include a separate lumen (not shown but conventional for balloon catheters) through which pressurized inflation fluid may be supplied from a proximal region of the apparatus to balloon **110**. Elements **100** and **110** are slidable axially along the outer surface of tube **230**. Insertion of elements **10**, **110**, and **120** (**FIG. 6**) into the annular recess **224** in distal nose portion **220** deflects the radially outermost portions of members **22** back over graft **120** as shown in **FIG. 7**. Tube **240**, disposed substantially coaxially around element **100** inside graft **120** so that its distal end bears against members **22**, may be used to help load elements **10**, **110**, and **120** into recess **224**, and also to hold connector **10** in place in recess **224** during delivery of the connector to the anastomosis site in the patient.

[**0055**] **FIG. 8** shows a typical use of apparatus **200** to deliver graft **120** for connection to an aperture in a side wall of a patient's tubular body conduit **300** (e.g., a coronary artery requiring a bypass graft). Guide wire **210** is first installed through a small aperture in the side wall of the conduit. The natural elastic recoil of the conduit **300** side wall seals the aperture around the guide wire so that there is little or no body fluid (e.g., blood) leakage out of the conduit via the aperture. The tapered distal nose portion **220** of apparatus **200** is then gradually forced into the aperture (e.g., by using tube **230** to push portion **220** distally into the aperture) to dilate the aperture. The natural elastic recoil of the conduit **300** side wall tissue continues to keep the aperture sealed or substantially sealed around portion **220**.

[**0056**] When distal nose portion **220** has been pushed far enough into the aperture in the side wall of conduit **300** so that connector **10** is part way through the aperture, further distal motion of elements **10**, **100**, **110**, and **120** can be stopped (e.g., by holding a proximal portion of element **100** stationary). Tube **240** is then pulled proximally out of the patient. Thereafter, distal nose portion **220** is pushed farther into conduit **300** (e.g., by continuing to push distally on a proximal portion of element **230**). This causes distal nose portion **220** to separate from connector **10**, thereby exposing the connector and leaving it in the aperture through the conduit **300** side wall as shown in **FIG. 9**.

[**0057**] The next step in use of apparatus **200** is to inflate balloon **110** as shown in **FIG. 10**. The balloon is typically sized to a specific anastomosis size (e.g., 3 millimeters diameter, 4 millimeters diameter, etc.). Inflation of the balloon forces connector **10** to annularly enlarge by enlarging cells **50/52/54/56** and **60/62/64/66** in the annular direction. In addition, the portions of members **60** and **62** that are adjacent to elements **64** (as well as elements **64** and **42**) are deflected radially out beyond other portions of the connector inside the side wall of conduit **300**, thereby causing the extreme distal end of graft **120** to similarly flare out inside that side wall. This outward flaring of portions of connector **10** and graft **120** helps secure the connector and graft to the side wall of conduit **300**, and also helps seal the graft to the conduit. The axial shortening of connector **10** that accompanies annular enlargement ensures that graft **120** is drawn into secure and fluid-tight engagement with conduit **300**. The free ends of members **42** preferably penetrate the side wall of conduit **300** to further secure connector **10** and graft **120** in the aperture in the side wall. Members **50**, **52**, **56**, and **24** may also flare out somewhat outside the side wall of graft **300** to help ensure that graft **120** remains open where it connects to conduit **300**. Assuming that the connector is approximately properly positioned relative to the side wall of conduit **300** prior to inflation of balloon **110**, the connector is effectively self-centering on the conduit **300** side wall as the balloon is inflated.

[**0058**] The next step in use of apparatus **200** is to deflate balloon **110** and withdraw all of elements **100**, **110**, **210**, **220**,

and **230** (e.g., by pulling them proximally out of graft **120**). This leaves the axial end portion of graft **120** connected to the side wall of conduit **300** by annularly enlarged connector **10** as shown in **FIG. 11**. In particular, in this example connector **10** provides an end-to-side anastomosis between graft **120** and conduit **300**. Body fluid from graft **120** is able to flow into conduit **300** via this connection. Connector **10** presses graft **120** radially outward against the aperture through the side wall of conduit **300** all the way around that aperture, thereby preventing body fluid from leaking out of conduits **120** and **300**. Connector **10** also prevents the end of conduit **120** from pulling out of the side wall of conduit **300**.

[**0059**] Another illustrative embodiment of a connector **410** in accordance with this invention is shown (in simplified planar development) in **FIG. 12**. Again, although connector **410** can be made in various sizes for various uses, a typical initial length of connector **410** is about 4.0 mm, and a typical initial outside diameter is in the range from about 0.040 to about 0.065 inches. A typical shaft length for members **422** is about 0.0539 inches, and a typical shaft width for those members is about 0.0050 inches. As in the case of connector **10**, connector **410** may be cut from a single integral tube. A typical thickness for the material of connector **410** is about 0.004 inches. Suitable materials for connector **410** include stainless steel, tantalum, tungsten, platinum, and nitinol.

[**0060**] Connector **410** may be described as including axially spaced first and second portions **420** and **440**, respectively. First portion **420** includes a plurality of annularly spaced first members **422** having free end portions **424** that initially point axially away from second portion **440**. However, members **422** are deflectable radially out from other parts of the connector, and, if desired, free end portions **424** can be curved back so that they point toward second portion **440** (see **FIG. 15**).

[**0061**] The first portion **420** of connector **410** may also be said to include the lower portions (below members **454**) of cells, each of which includes one member **460**, one member **462**, one member **464**, and one member **466**. For example, the left-most cell shown in **FIG. 12** includes substantially parallel members **460***a* and **462***a* joined at their axially spaced ends by members **464***a* and **466***a*. Annularly adjacent cells are joined by members **454** at points that are axially medial their axial ends. For example, the cell that includes member **462***a* is joined to the cell that includes member **460***b* by members **454***b*. The portions of members **460** and **462** below members **454** are also deflectable radially out from other portions of the connector.

[**0062**] The second portion **440** of connector **410** may be said to include the portions of members **460** and **462** above members **454**. These portions of members **460** and **462** are also deflectable radially out (as loops **460/462/464**) from other portions of the connector. If desired, loops **460/462/464** could also have fingers or barbs on them like members **42** in the embodiment of FIGS. **1-11**.

[**0063**] Connector **410** is annularly enlargeable by deforming members **460** and **462** to enlarge each of the above-described cells in the annular direction as shown in greatly simplified form in **FIG. 13**.

[**0064**] **FIG. 14** shows an illustrative embodiment of tooling **500** that can be used to facilitate attachment of a graft conduit **120** to connector **410**. Tooling **500** includes a mandrel with a conical end portion, the pointed free end of which is small enough to fit axially into connector **410** in its initial relatively small annular size. As connector **410** is forced farther onto the conical end portion of mandrel **500**, the cone of the mandrel begins to deflect members **422** radially out from other portions of the connector. Graft conduit **120** can be placed around mandrel **500** and shifted axially toward connector **410** until an axial end portion of conduit **120** axially overlaps outwardly deflected members **422**. The free end portions of members **422** can then be pried out through the side wall of conduit **120** as shown in **FIG. 15** to secure connector **410** to conduit **120**. Mandrel **500** can be pulled proximally out of graft **120** and connector **410** at any suitable time. Use of mandrel **500** in this way helps ensure that members **422** penetrate the side wall of conduit **120** substantially equidistantly in the annular direction around the conduit. This helps avoid excessive stretching of any angular segment of graft **120** when connector **410** is subsequently expanded by balloon **110**.

[**0065**] After connector **410** has been attached to graft **120** as shown in **FIG. 15**, an inflatable balloon like balloon **110** (with tube **100**) can be inserted into the connector in a manner similar to what is shown in **FIG. 6**. Elements **100**, **110**, **120**, and **410** can then be loaded into apparatus like **200** in a manner similar to what is shown in **FIG. 7** (except that in this case the free ends **424** of members **422** will typically point in the distal direction rather than in the proximal direction as is true for the free ends **24** of members **22** in **FIG. 7**). Apparatus **200** can then be used to install connector **410** and graft **120** in a patient in a manner similar to the installation shown in FIGS. **8-11**. **FIG. 16** shows the second portion **440** after it has been conveyed through the side wall of conduit **300** by apparatus **200** and apparatus **200** has been shifted distally farther into conduit **300** to expose the connector. **FIG. 17** shows second portion loops **460/462/464** deployed (radially outwardly deflected), but the remainder of the connector not yet annularly expanded. A shaped balloon or dual balloon system may be utilized to achieve this. For example, one of two axially adjacent balloons may be used to help form distal retention fingers **460/462/464** as shown in **FIG. 17**. The second of the two balloons is thereafter used to annularly expand the remainder of the connector and the anastomosis opening. Alternatively, a single "bulbous" shaped balloon may be used to produce a temporary intermediate condition like that shown in **FIG. 17**, and to then annularly enlarge the remainder of the connector and the anastomosis opening. As still another possibility the distal retention fingers **460/462/464** may be self-actuating (i.e., spring-biased) and not require balloon assist to spring out to the condition shown in **FIG. 17**. For example, distal retention fingers **460/462/464** may be preformed to deflect radially outward in a manner similar to the radially outward preform that is given to elements **22** and **42** in **FIG. 3**.

[**0066**] The final anastomosis employing connector **410** is shown in **FIGS. 18 and 19**. In particular, as shown in **FIGS. 18 and 19** connector **410** has been annularly expanded by enlargement of the cells **460/462/464/466** in the annular direction. The portions of members **460** and **462** that comprise portion **440** of the connector have been deflected radially out from other portions of the connector inside conduit **300**, thereby functioning to secure connector **410** and graft **120** to conduit **300**. Members **422** are deflected radially out from other portions of the connector and pass

through the axial end portion of graft **120**. The free end portions of members **422** point toward the second portion **440** of the connector, thereby ensuring that the end of graft **120** cannot slip away from its body-fluid-sealing abutment with the side wall of conduit **300**. The annularly expanded medial portion of connector **410** holds open the aperture in the side wall of conduit **300**, as well as the attached end of graft **120**, thereby ensuring unobstructed body fluid flow through the anastomosis between conduits **120** and **300**.

[**0067**] Still another illustrative embodiment of a connector **610** in accordance with this invention is shown in greatly simplified, annularly expanded, planar development in **FIG. 24**. Connector **610** is configured for use in performing a side-to-side anastomosis between two body fluid conduits **300***a* and **300***b* as shown in **FIG. 25**. Connector **610** has a construction like two portions **40** of connector **10** connected together. Thus members **642***a* and **642***b* are constructed and operate like members **42** in connector **10**. Similarly, members **660** are constructed and operate generally like members **60** and **62** in connector **10**, and elements **664** and **666** are constructed and operate generally like elements **64** and **66**, respectively, in connector **10**.

[**0068**] Connector **610**, in an initially relatively small annular size and mounted on a balloon, is insertable through adjacent apertures in the side walls of body fluid conduits **300***a* and **300***b*. For example, apparatus like **200** can be used to deliver connector **610** to such a site via the lumen of one of conduits **300** and to then position the connector so that it spans both conduits. Apparatus **200** is then shifted relative to connector **610** in a manner generally similar to **FIG. 9** to expose the connector. The balloon **110** associated with the connector is then inflated to annularly enlarge the connector to the condition shown in **FIG. 25**. In particular, this annular expansion causes members **642***a* to penetrate the side wall of conduit **300***a* annularly around the anastomotic opening, and also causes members **642***b* to penetrate the side wall of conduit **300***b* annularly around the anastomotic opening. As with the other connectors of this invention, annular enlargement of connector **610** is accompanied by axial shortening, which helps to draw the side walls of conduits **300***a* and **300***b* together annularly around the connector, thereby providing the desired fluid-tight anastomosis between the conduits. When the anastomosis is thus complete, the balloon inside the connector is deflated and all the apparatus is withdrawn through the anastomosis.

[**0069**] It will be understood that the foregoing is only illustrative of the principles of this invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the number and shape of the annularly enlargeable connector cells can be different from what is shown in the drawings herein. The number of axially adjacent rows of annularly enlargeable cells can be different from the numbers of such rows that are shown herein (i.e., two rows of cells in the case of connectors **10** and **610** or one row of cells in the case of connector **410**). For example, a connector may have three, four, or more rows of cells. The cells may have any of many forms, depending on the desired degree of expansion and final radial strength. The number of cells, the number of rows of cells, the size of the cells, and the geometry of the cells can all be selected to control the expansion, strength, and sizing of the finished connector. The number and shape of the radially outwardly deflectable connector members can also differ from what is shown herein. Techniques and apparatus different from what is shown and described herein can be used for attaching a connector of this invention to a graft conduit and/or installing the connector in a patient. Instead of the extreme end of graft **120** being inside conduit **300**, the connector of this invention may be configured to secure the end of the graft **120** against the outside of the side wall of conduit **300** in an end-to-side anastomosis as shown in **FIG. 23**. The nose cone **220** of apparatus **200** may not need to cover the proximal fingers **22** or **422** of the connector. Instead, the proximal fingers can extend to an outer circumference which is larger than the outer circumference of nose cone **220**. This allows the proximal fingers to be used as a stop which prevents the connector from going too far through the aperture in the side wall of conduit **300**. In other words, the radially outer ends of proximal fingers **22** or **422** come into contact with the outer surface of the side wall of conduit **300** and thereby stop the connector from going any farther into that conduit.

[**0070**] Although considerable variation in the connectors of this invention is thus possible and contemplated, in general such connectors comprise a unitary structure disposed annularly about a longitudinal axis (e.g., axis **12** in **FIG. 2**). The connector structure generally has axially spaced first and second portions (e.g., **20** and **40**, **420** and **440**, or **640***a* and **640***b* in the depicted illustrative embodiments). The first portion generally has a plurality of annularly spaced first members that are deflectable radially out from a remainder or other generally axially medial portion of the structure. For example, in the illustrative embodiment shown in FIGS. **1-11** these first members include elements **22**. In the illustrative embodiment shown in FIGS. **12-19** these first members include elements **422**. In the illustrative embodiment shown in **FIGS. 24 and 25** these first members include elements **642***a*. The second portion may also have a plurality of annularly spaced second members that are deflectable radially out from a remainder or other generally axially medial portion of the structure. For example, in the illustrative embodiment shown in FIGS. **1-11** these second members include elements **44** and (later in use of the connector) the portions of elements **60** and **62** that are above elements **54** in **FIG. 1**. In the illustrative embodiment shown in FIGS. **12-19** the second members include U-shaped structures that are the portions of elements **460**, **462**, and **464** above elements **454** in **FIG. 12**. In the illustrative embodiment shown in **FIGS. 24 and 25** these second members include members **642***b*. Also, in general, the connector structures of this invention are annularly enlargeable. For example, in the illustrative embodiment shown in FIGS. **1-11** the connector is annularly enlargeable by enlarging cells **50/52/54/56** and **60/62/64/66** in the annular direction as shown, e.g., in **FIG. 4**. Similarly, in the illustrative embodiment shown in FIGS. **12-19** the connector is annularly enlargeable by enlarging cells **460/462/464/466** in the annular direction as shown, e.g., in **FIG. 13**. And in the embodiment shown in **FIGS. 24 and 25** the connector is annularly enlargeable by enlarging cells **660/664/666** in the annular direction.

[**0071**] It will be appreciated that, in general, the structure of the connectors of this invention is such that radial enlargement of the connector reduces the axial spacing between the above-mentioned first and second members. This helps the connector draw together in a fluid-tight way the two body fluid conduits that are to be connected by the

connector. In the embodiment shown in FIGS. **1-11**, for example, annular enlargement of cells **60/62/64/66** causes a decrease in the axial spacing between members **22**, on the one hand, and members **42**, on the other hand. Similarly, in the embodiment shown in FIGS. **12-19** annular enlargement of cells **460/462/464/466** causes a decrease in the axial spacing between members **422**, on the one hand, and the portions of elements **460** and **462** above elements **454** in **FIG. 12**, on the other hand. And in the embodiment shown in **FIGS. 24 and 25** annular enlargement of the connector decreases the axial spacing between members **642***a*, on the one hand, and members **642***b*, on the other hand. The above-described axial shortening of the connector advantageously applies compressive forces (for sealing) to the body fluid conduits being connected.

[**0072**] In general, most of the deformation of the connectors of this invention is preferably plastic strain and therefore permanent. The deformation thus referred to includes both the above-described radially outward deflection of members like **22**, **42**, **422**, **642**, etc., and the above-described radial enlargement of the connector.

[**0073**] The radially outwardly deflectable members or portions of the connector may be barbs, hooks, spikes, loops, or suture rings.

[**0074**] The connectors of this invention may be constructed so that different portions of the connector annularly enlarge in response to different amounts of applied annular enlargement force. For example, in the embodiment shown in FIGS. **1-11**, the portions of the structure above elements **54** in **FIG. 1** may be made so that they are less resistant to inflation of a balloon **110** inside the connector than portions of the structure below elements **54** in **FIG. 1**. In an application of the type shown in FIGS. **1-11** this causes these less resistant portions to annularly enlarge by deflecting radially out inside conduit **300** before the remainder of the connector begins to significantly annularly enlarge. This early response of the less resistant portions inside conduit **300** may help to ensure that the connector does not slip out of engagement with conduit **300** during annular enlargement of the connector. This technique of making different portions of the connector with different strengths can be used to provide any sequence or phasing of annular enlargement of various portions of the connector. Alternatively or additionally, the connector can be shaped, molded, or phased in any desired way by providing a balloon structure **110** which is shaped, molded, or phased in that way. For example, balloon structure **110** may comprise two or more separately inflatable balloons of the same or different inflated circumferential size. Two such balloons may be axially displaced from one another inside the connector so that axially different portions of the connector can be annularly enlarged at different times and/or by different amounts.

[**0075**] Radiologically (e.g., x-ray) viewable markers can be used anywhere on the connectors and/or delivery apparatus (e.g., **200**) of this invention to facilitate radiologic observation of the proper placement and deployment of a connector in a patient if the connector-utilizing procedure is such that more direct visual observation is not possible or sufficient. One way to enhance the radiologic viewability of connectors in accordance with this invention is to make them from clad tubing. Clad tubing has two (or more) substantially concentric layers of metal, each with a desired property. As shown in **FIG. 20**, for example, clad tubing **500** has a tantalum layer **502** over a stainless steel layer **504**. The tantalum layer **502** provides radiodensity, thereby making a connector **10**, **410**, or **610** that is cut from tube **500** radiologically viewable. The stainless steel layer **504** provides rigidity to the connector. The medial section can be ground to reduce the thickness ratio to favor the tantalum. This improves the ability for balloon expansion. Although tube **500** (and the resulting connector **10**, **410**, or **610**) may thus be made of two or more layers of different materials, the tube and the connector are still accurately described as unitary, one-piece, or integral. As an alternative to using clad tubing, the connector may be plated with a radiologic material to give it a desired radiodensity. Another example of a material suitable for radiologic layer **502** is platinum.

[**0076**] Small polyester or other polymer patches or bands may be used on or in association with a connector of this invention to help seal and coagulate blood. Such patches may be inserted over individual fingers as shown, for example, at **522** in **FIG. 21**. Alternatively, such a band or web may be provided around the medial portion of connector **10**, **410**, or **610** as shown, for example, at **530** in **FIG. 22**. A band or web like **530** may also be used to constrain the size of the connector or a graft (such as a vein graft) relative to the connector. Vein grafts may dilate significantly under arterial blood pressure. A band or web can be used to fix its size relative to the connector. Alternatively or additionally a band or web like **530** can be provided to help seal the completed anastomosis For purposes of these various kinds, a band or web like **530** may preferably be elastic (e.g., of a rubber or rubber-like material such as silicone or polyurethane). The band or web like **530** can be porous, if desired, and may be impregnated with drugs to facilitate healing and/or sealing. Similarly, polymer patches like **522** in **FIG. 21** can include and release coagulant and/or other medication to help prevent bleeding and promote healing. Patches like **522** in **FIG. 21** can help prevent members like **22** from pulling back through tissue that the member has penetrated.

[**0077**] An important attribute of the connectors of this invention is the characteristic that the medial section is soft enough to allow balloon expansion and strong enough to secure the two body fluid conduits via such elements as **22** and **42**, **422** and **460/462/464**, or **642**. To achieve this with a single material and wall thickness, which may be preferable from a manufacturing perspective, the center section may be annealed selectively to soften it without compromising the rigidity of the retention elements (e.g., **22**, **42**, **422**, **642**, etc.). This can be done, for example, by laser heat treating the medial section only. The results of this process are relatively low hardness in the medial section and relatively high hardness in the end sections, all within an overall length of about 0.2 inches.

[**0078**] The connectors of this invention may also be made of a super-elastic material such as nickel-titanium ("nitinol"), which would allow a similar geometry as stainless steel to self-deploy or actuate in-vivo.

[**0079**] It will be appreciated that the fact that the connectors of this invention can be initially relatively small in circumference, and that they can be remotely controlled to position them in the patient and to then annularly expand them for final deployment, facilitates use of these connectors and associated apparatus (e.g., apparatus **200**) at remote

and/or inaccessible locations in a patient. For example, a connector of this invention may be delivered into and installed in a patient (using apparatus such as apparatus **200**) through relatively small instrumentation such as laparascopic apparatus, a cannula, or an intraluminal catheter. Thus a connector and associated apparatus (e.g., apparatus **200**) of this invention can be used in any of the procedures mentioned earlier in this specification, and in particular in procedures and with other elements shown in any of abovementioned references WO 98/16161, U.S. Pat. No. 5,976,178, U.S. Pat. No. 6,120,432, WO 98/55027, and U.S. Pat. No. 6,475,222. Alternatively, the connector and/or apparatus (e.g., apparatus **200**) of this invention can be used in more traditional or conventional surgical procedures or in other, known, less invasive or minimally invasive procedures. As just some examples of possible uses of the connectors and apparatus of this invention, they can be used to perform an anastomosis to a beating or still heart without the use of sutures or direct access.

[**0080**] Again, although the connectors of this invention can be made in various sizes for various uses, a typical connector is initially less than about 1 millimeter in diameter and in the range from about 2 to about 4 millimeters in length. After annular enlargement, a typical connector is more than about 2.5 millimeters in diameter. The pre-yield geometry of these connectors is ideal for delivery and positioning; the post-yield geometry is ideal for vessel securement, seal, and patency. The geometry of the connectors is ideal for annular enlargement. Radial outward deflection of certain connector members such as **22**, **42**, **422**, **642**, etc., is ideal for interfacing the expanding medial section of the connector to each of the two body fluid conduits to be connected (e.g., a graft vessel and an artery vessel).

[**0081**] As has been explained, certain connector cells may be configured to open before other cells as desired to optimize deployment positioning. Integral connector fingers such as **22**, **42**, **422**, **642**, etc., can be deflected radially out from the remainder of a connector for the purpose of attachment to body fluid conduits (e.g., a graft and an artery). These fingers are part of the connector body and can be hooks, barbs, loops, or spikes. The geometry of the fingers can also change, as desired, in response to balloon expansion. A balloon catheter can be used to actuate the connector and provide an anastomosis opening and attachment. The nose cone portion **220** of apparatus **200** covers the connector and graft interface, allowing dilation of the other body fluid conduit wall and passage of the connector through that wall. The connector provides the actual anastomotic opening and the connection simultaneously. The device is actuated via a balloon and catheter delivery system.

[**0082**] Among the advantages of the invention are that it eliminates suturing and reduces the time required to produce an anastomosis. In major circulatory system repair procedures such as cardiac bypass procedures, this can reduce cardiopulmonary pump time, which is of great benefit to the patient. The invention provides optimal flow dynamics, e.g., from a graft to the coronary artery. The blood entrance angle can be engineered into the connector geometry rather than relying on suture skill or technique. The invention eliminates possible suture injury to vessels. At the high stress site of an anastomosis sutures are eliminated. The connector and a graft can be delivered percutaneously, e.g., as in several of the references that are mentioned above. Direct access required for suturing is eliminated. An anastomotic connection can be made to a beating heart.

The invention claimed is:

1. Apparatus for inserting an annular anastomotic connector into a side wall of a tubular body tissue conduit comprising:

substantially conical tip structure having a cone angle less than about 15° and configured for passage through the side wall starting with an apex of the cone;

a shaft structure extending from the tip structure in a direction away from the apex and configured to receive the connector annularly around the shaft structure;

an inflatable annular balloon having a first cross-sectional radius at the distal end, and a second cross-sectional radius at the proximal end, wherein the second cross-sectional radius is greater than the first cross-sectional radius, wherein the inflatable annular balloon is configured for disposition annularly around the shaft structure and inside the connector around the shaft structure, wherein expansion of the balloon first causes deformation of distal fingers of the connector and subsequently causes radial expansion of the connector.

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