US 20030195535A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2003/0195535 A1**

(43) **Pub. Date: Oct. 16, 2003**

**Swanson et al.**

(54) **MEDICAL GRAFTING METHODS & APPARATUS**

(75) Inventors: **William J. Swanson**, St. Paul, MN (US); **Jason A. Galdonik**, St. Louis Park, MN (US); **Paul J. Hindrichs**, Plymouth, MN (US); **Gregory A. Boldenow**, St. Michaels, MN (US); **Todd A. Berg**, Stillwater, MN (US); **Rick Cornelius**, Wayzata, MN (US); **Luis Bonilla**, Eden Prairie, MN (US)

Correspondence Address:
**FISH & NEAVE**
**1251 AVENUE OF THE AMERICAS**
**50TH FLOOR**
**NEW YORK, NY 10020-1105 (US)**

(73) Assignee: **St. Jude Medical ATG, Inc.**

(21) Appl. No.: **10/411,550**

(22) Filed: **Apr. 9, 2003**

**Related U.S. Application Data**

(62) Division of application No. 09/693,578, filed on Oct. 20, 2000, now Pat. No. 6,602,263.

(60) Provisional application No. 60/168,200, filed on Nov. 30, 1999.

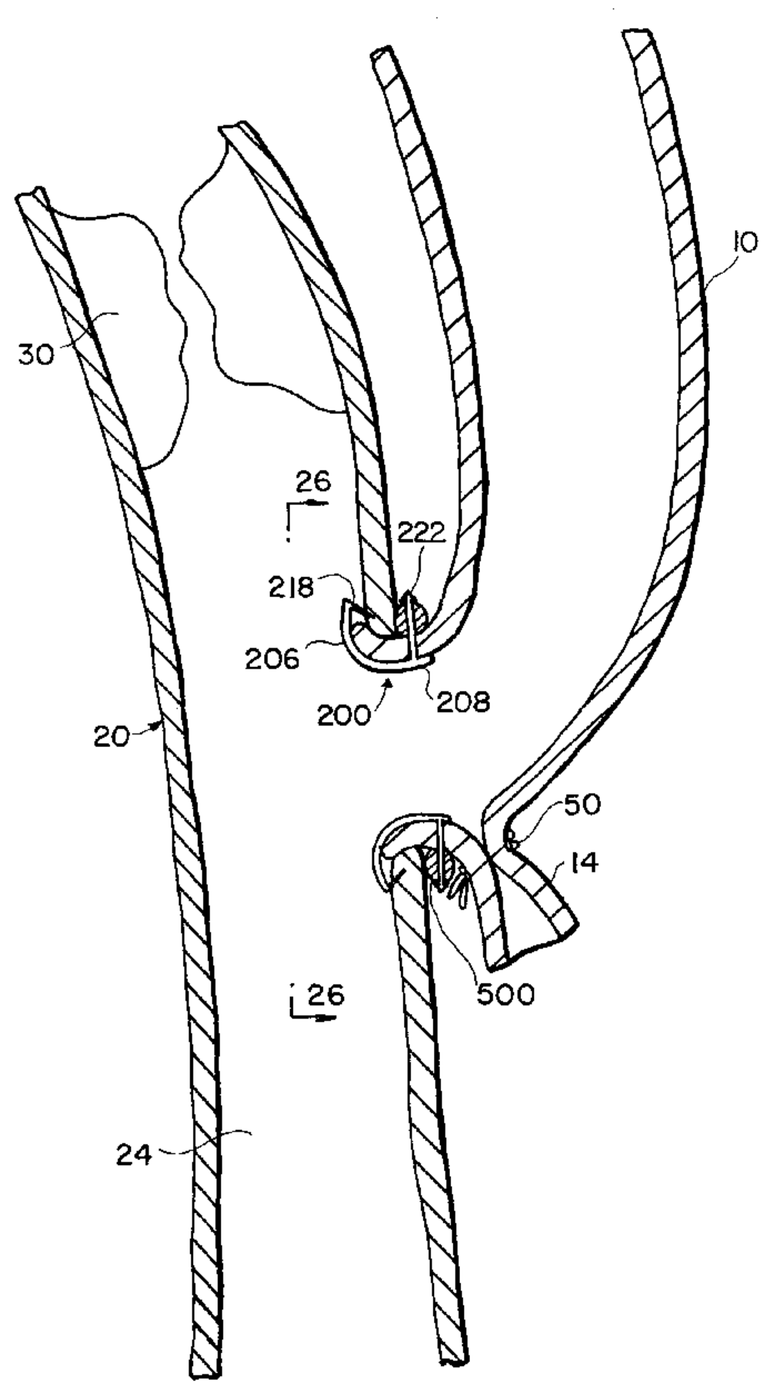
**Publication Classification**

(51) **Int. Cl.**[7] ..... **A61B 17/08**

(52) **U.S. Cl.** ..... **606/153**

(57) **ABSTRACT**

Methods and apparatus for making an anastomotic connection between a first conduit and a second conduit. A connector structure having a first end portion and a second end portion is positioned about a balloon catheter, which when pressurized, expands to a significant extent at the distal end thereof. The balloon enlarges the connector structure when positioned at the distal end portion of the balloon to create the anastomosis, and at the same time reduces the axial length of the connector, thereby compressing the first conduit to the second conduit, creating a hemodynamic seal and a firm attachment of the two conduits. After enlargement, the connector structure remains in place and adds structure to the anastomosis. During introduction, the second end portion of the connector is covered by a nosecone assembly to prevent trauma to the second conduit while the apparatus is being introduced. The nosecone assembly has a flexible structure which may change configuration to expose the second set of members after insertion into the second conduit and to allow removal of the nosecone after deployment.



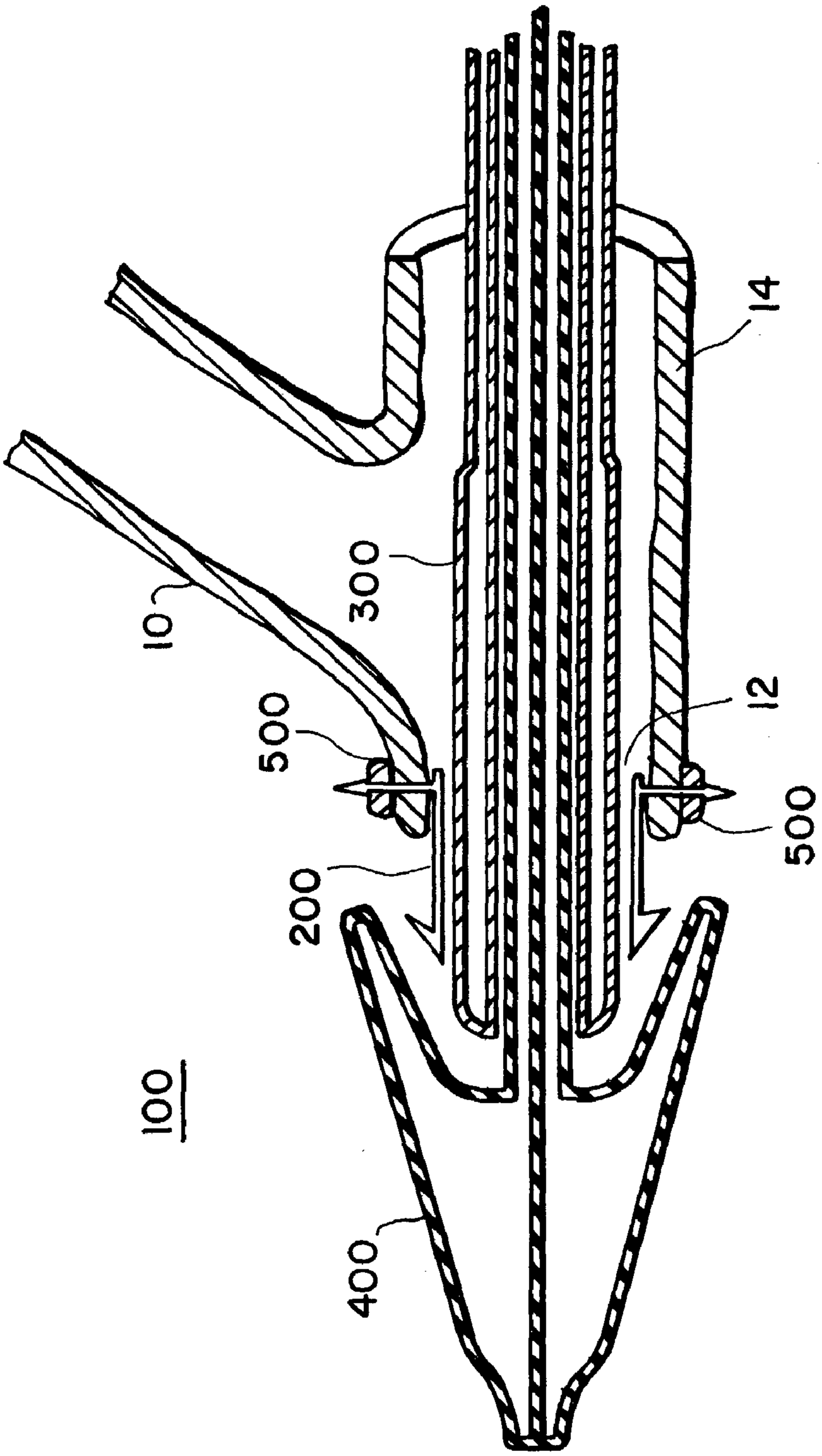



FIG. 1

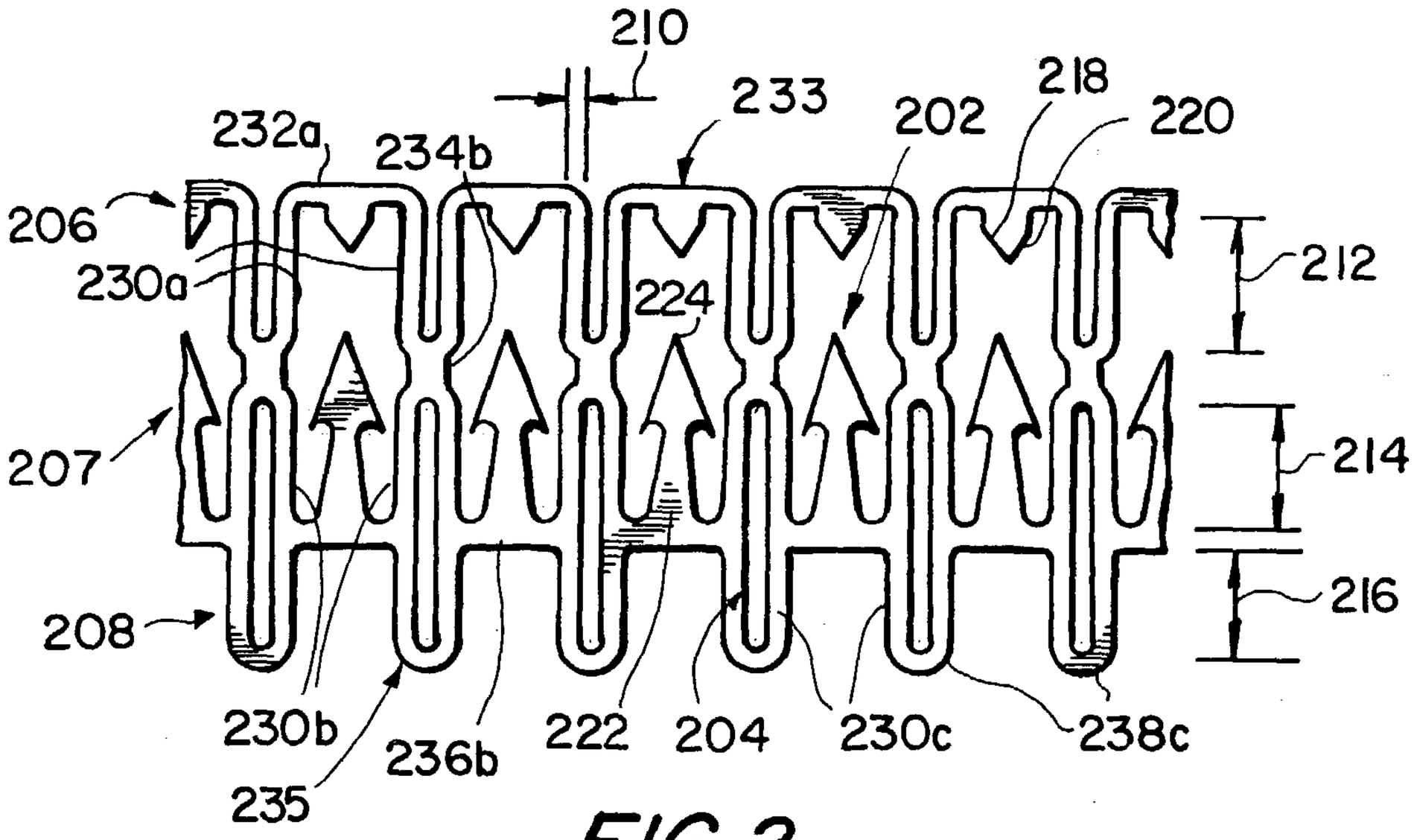

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FIG. 2

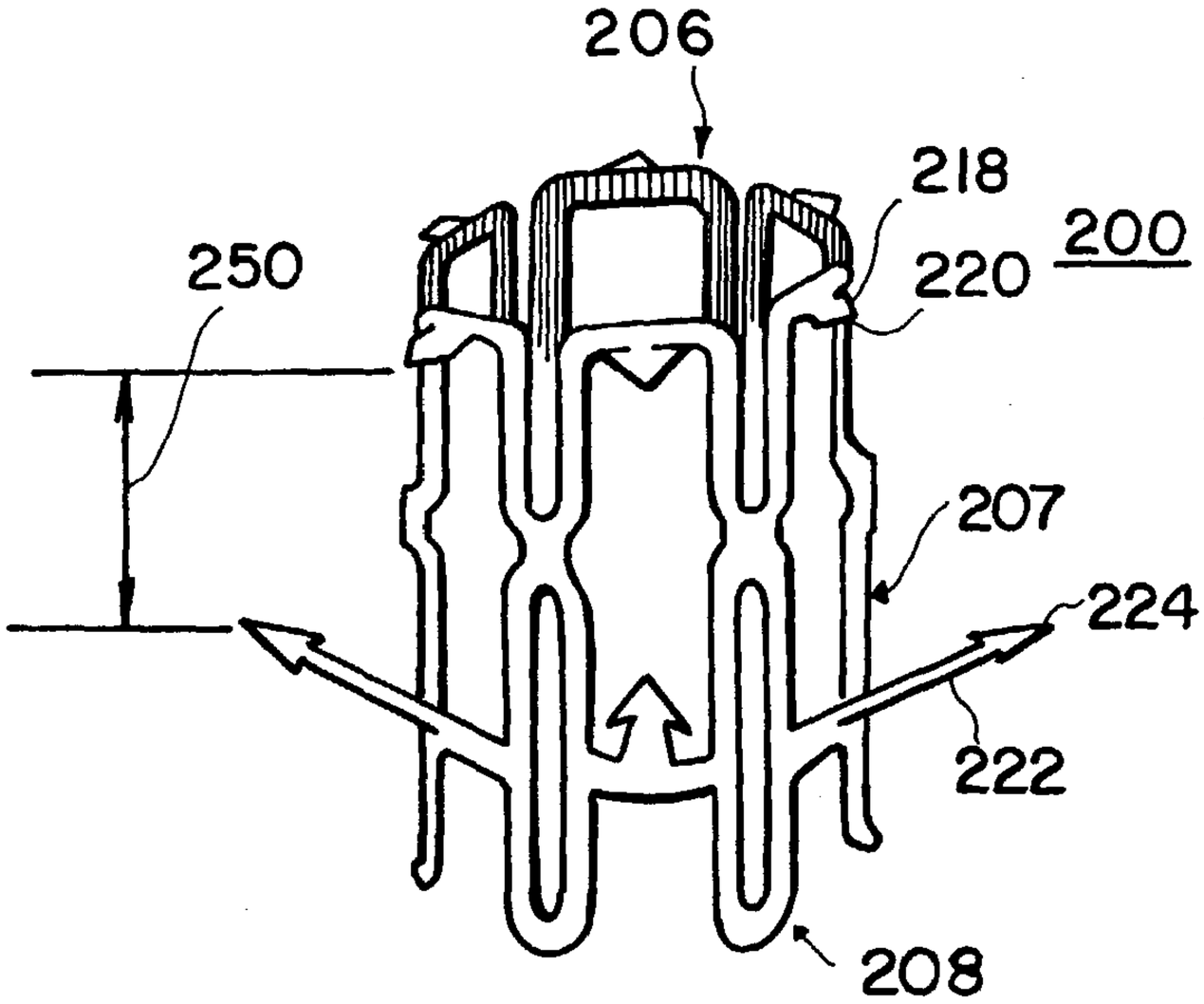

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FIG. 3

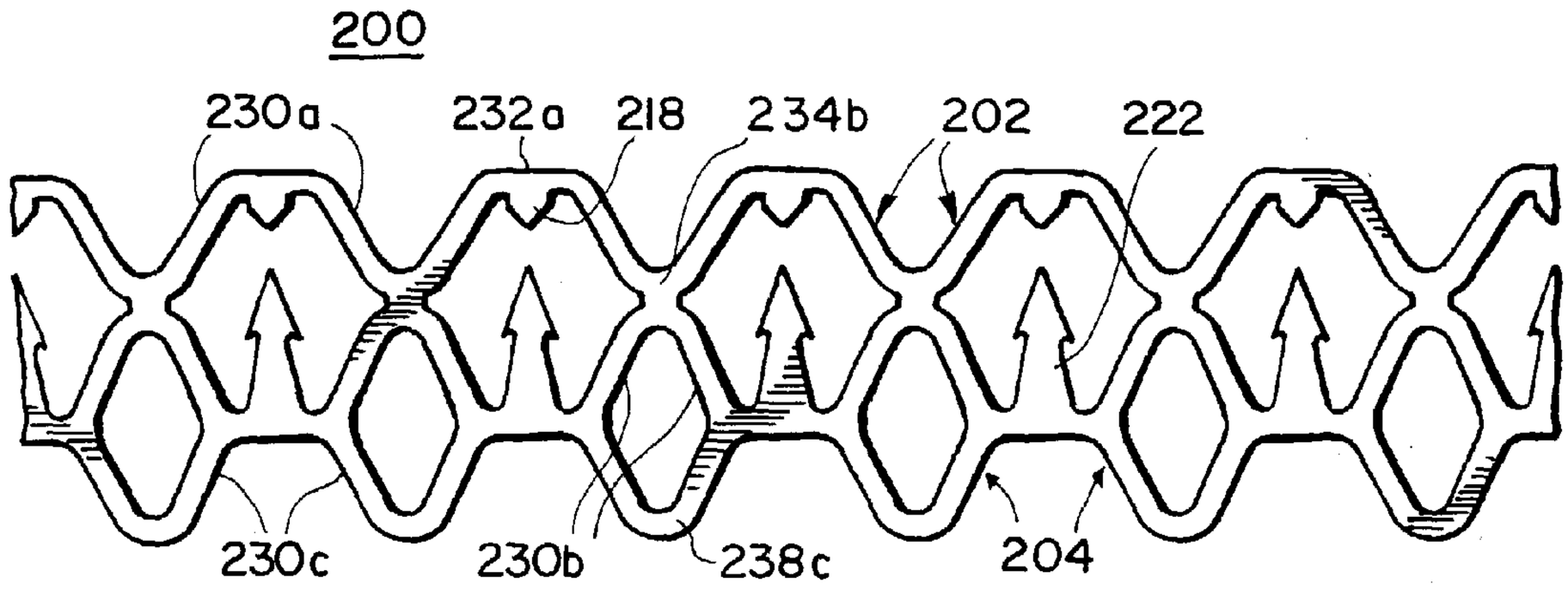

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FIG. 4

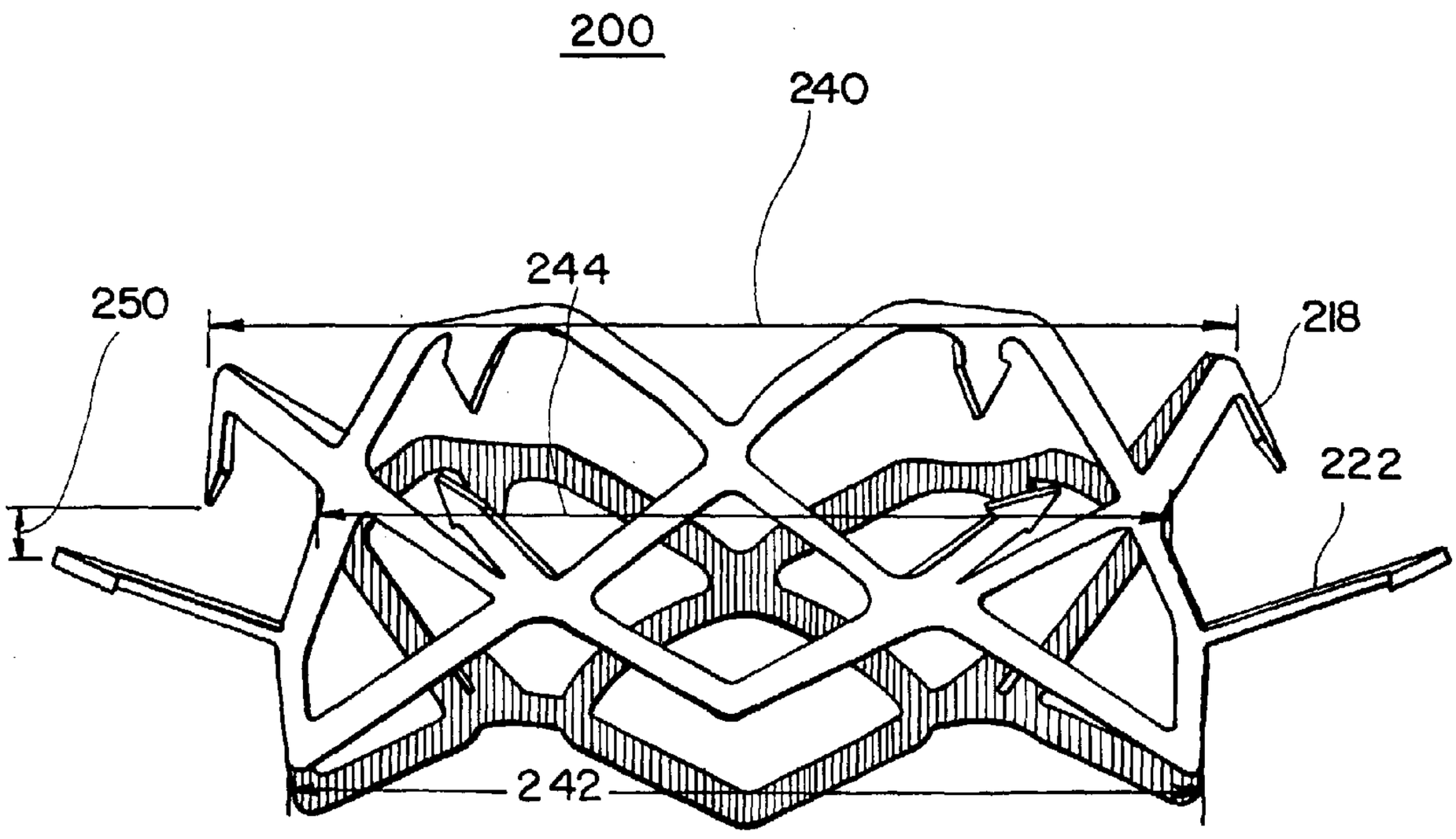

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FIG. 5

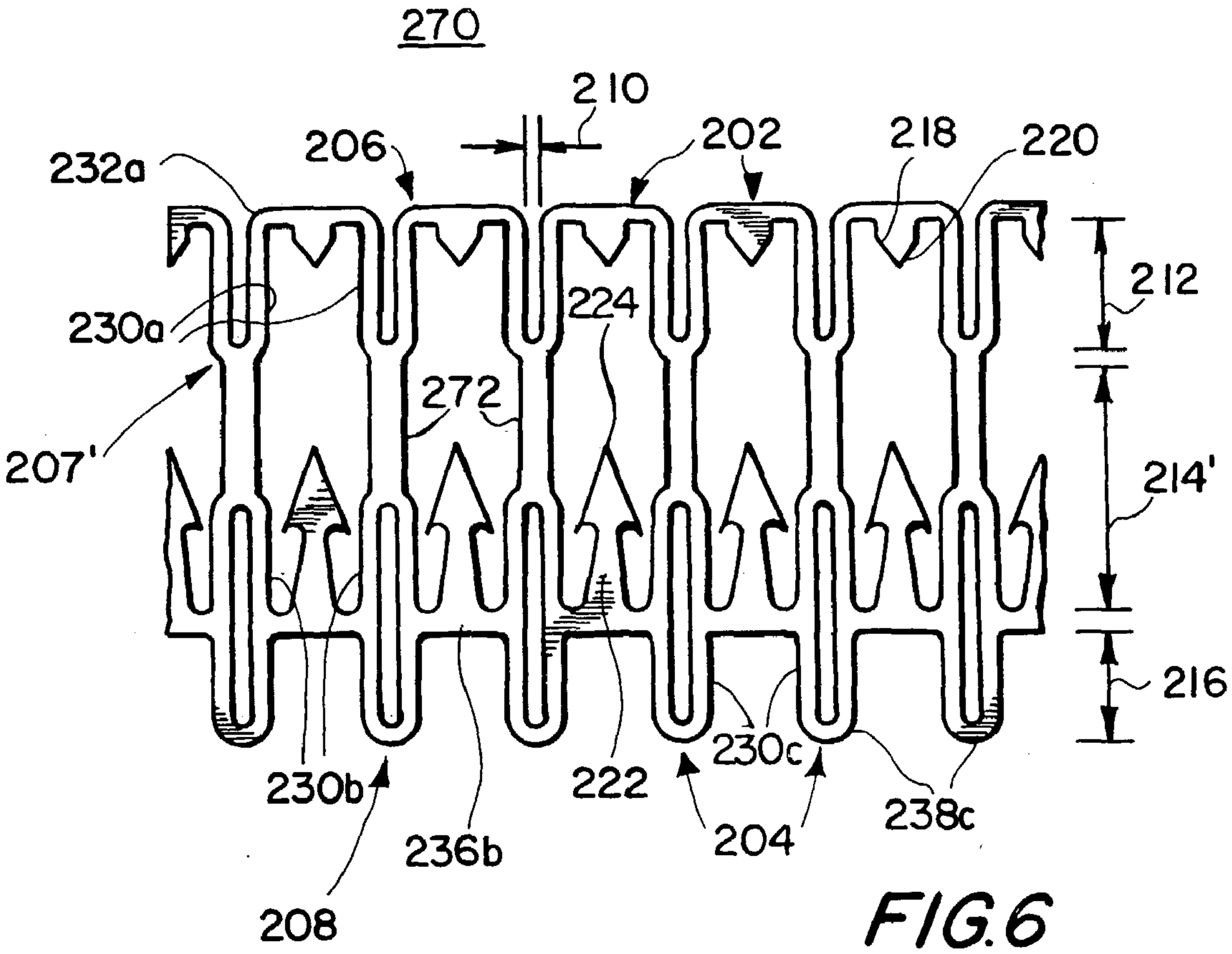

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FIG. 6

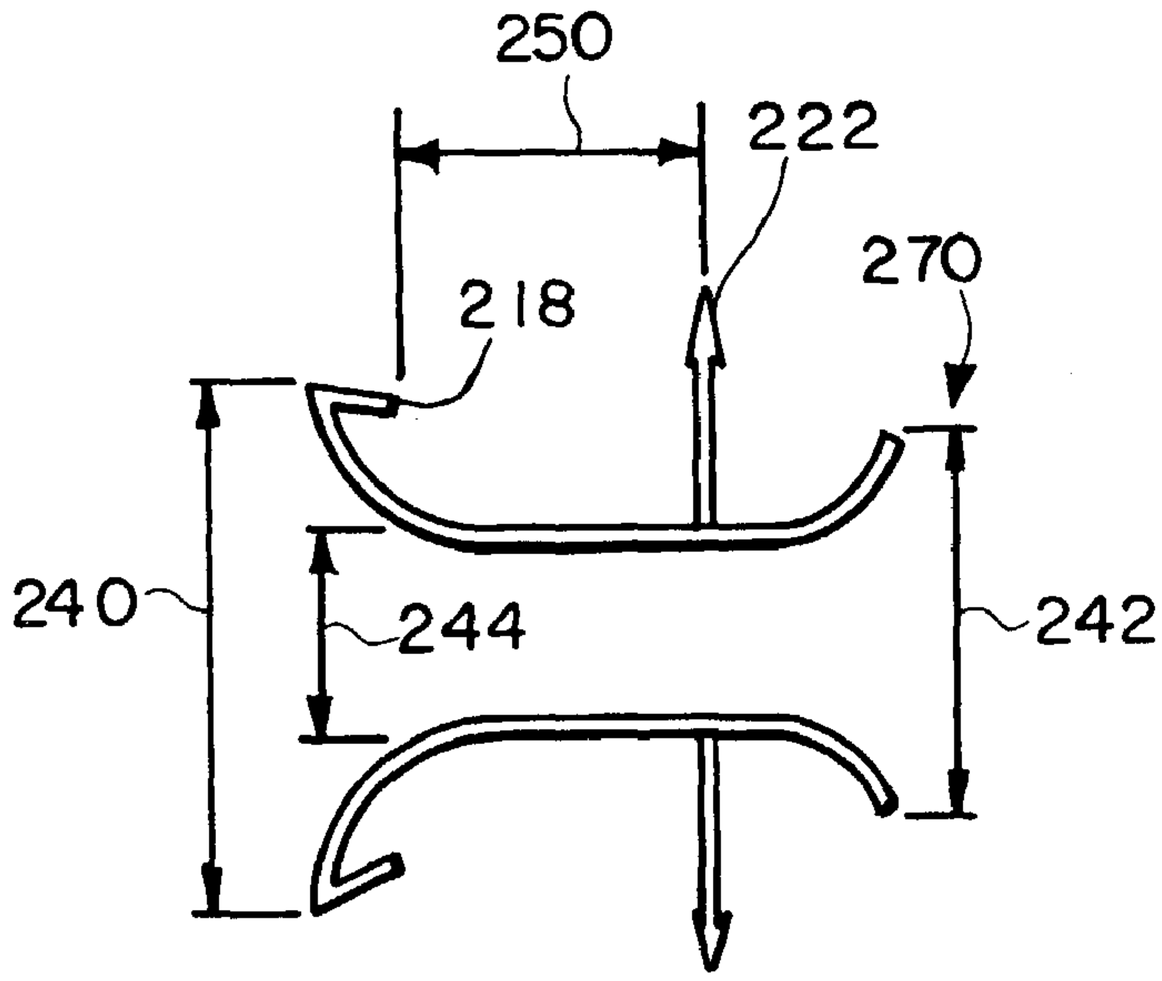

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FIG. 7

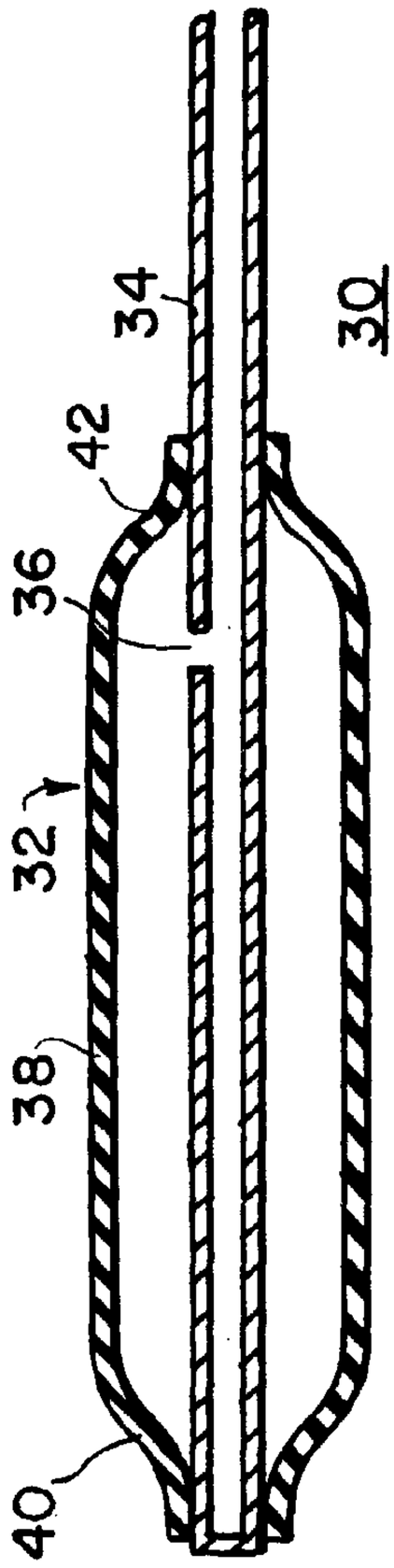
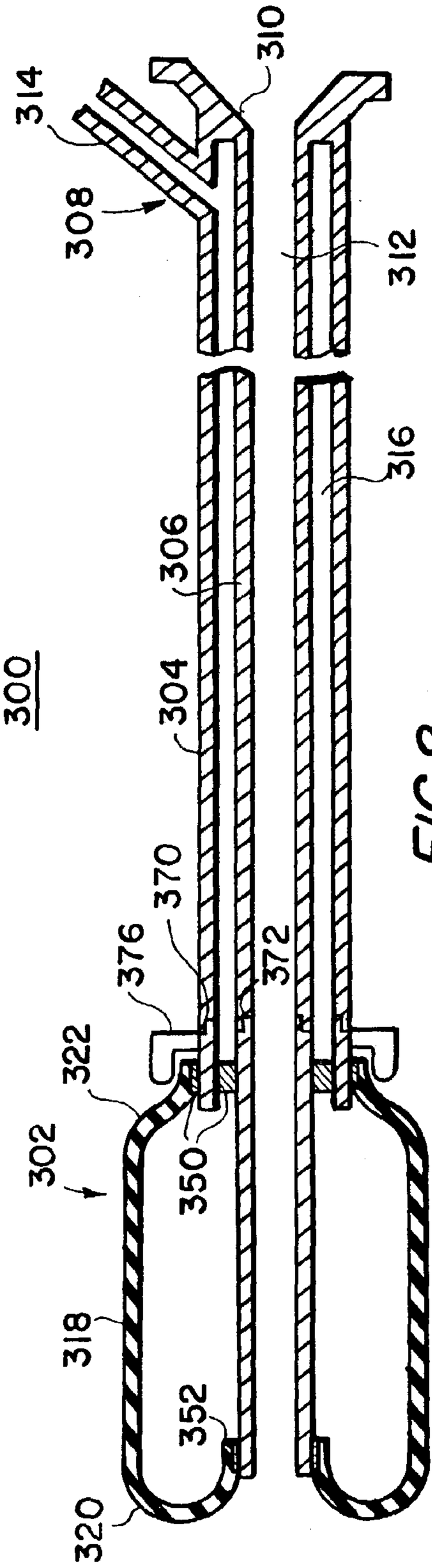



FIG. 9
PRIOR ART




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FIG. 8

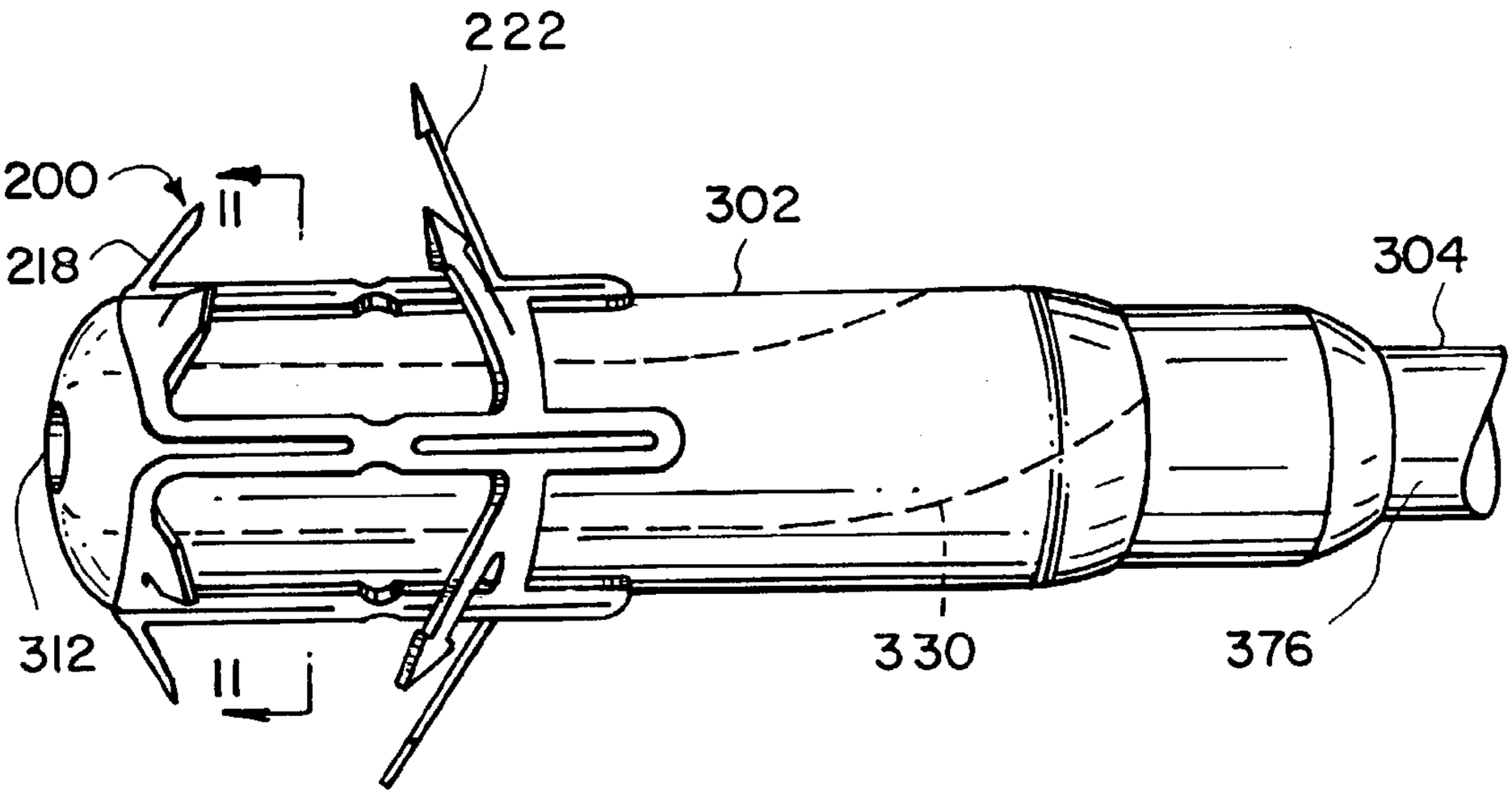



FIG.10

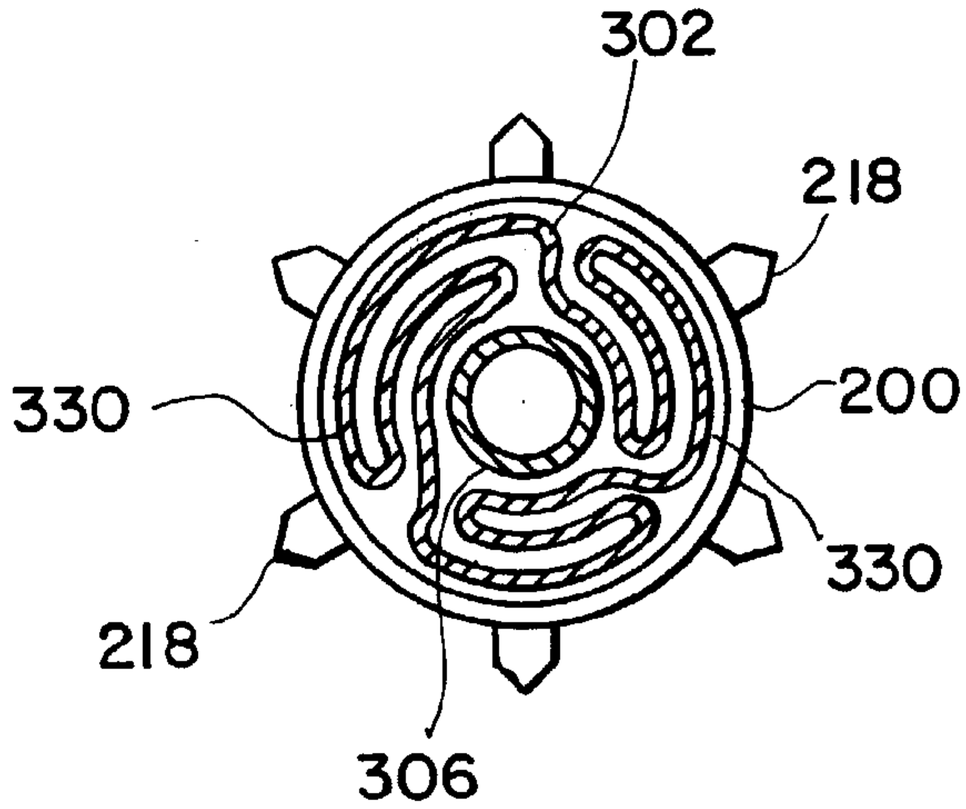



FIG.11

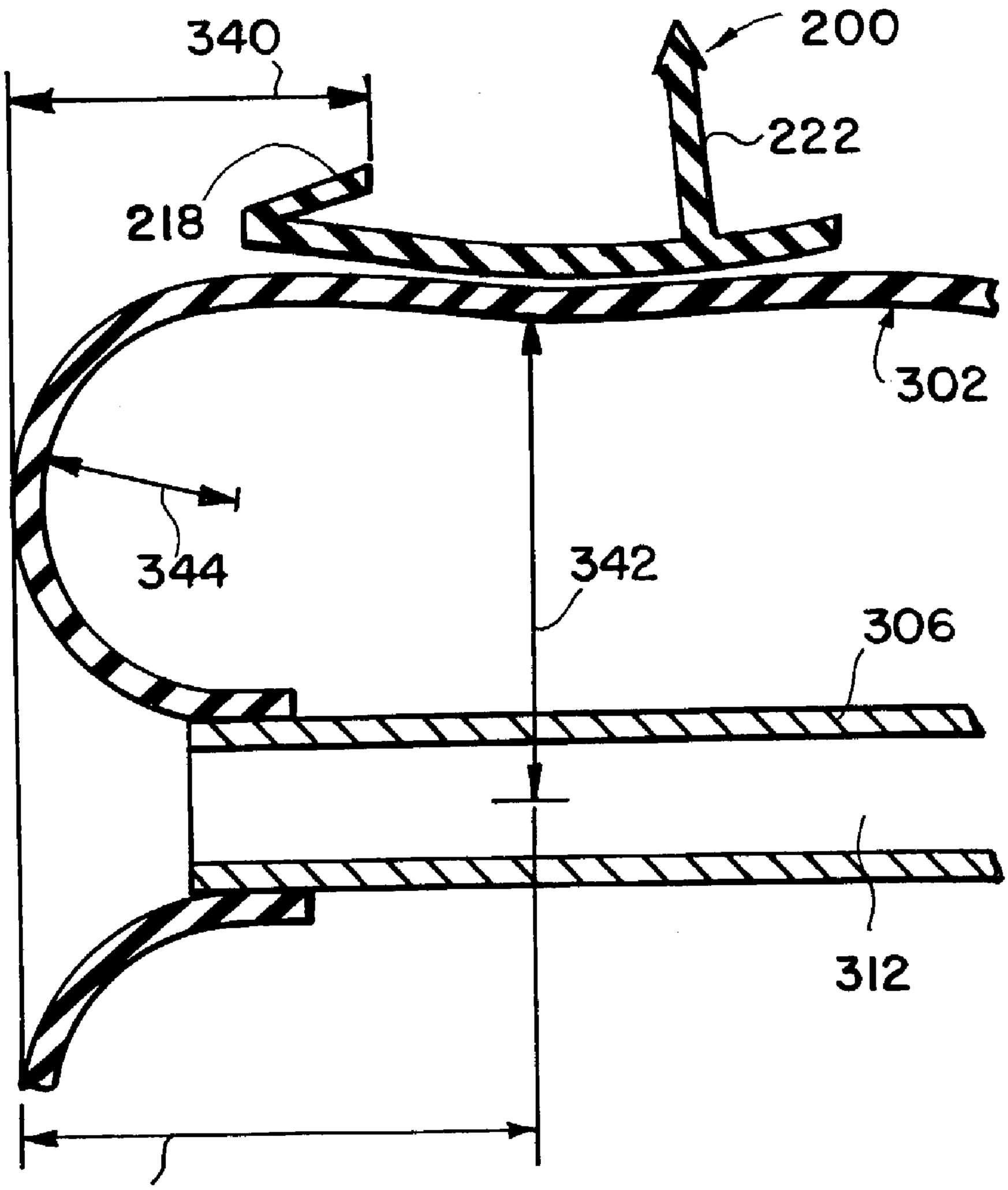



FIG. 12

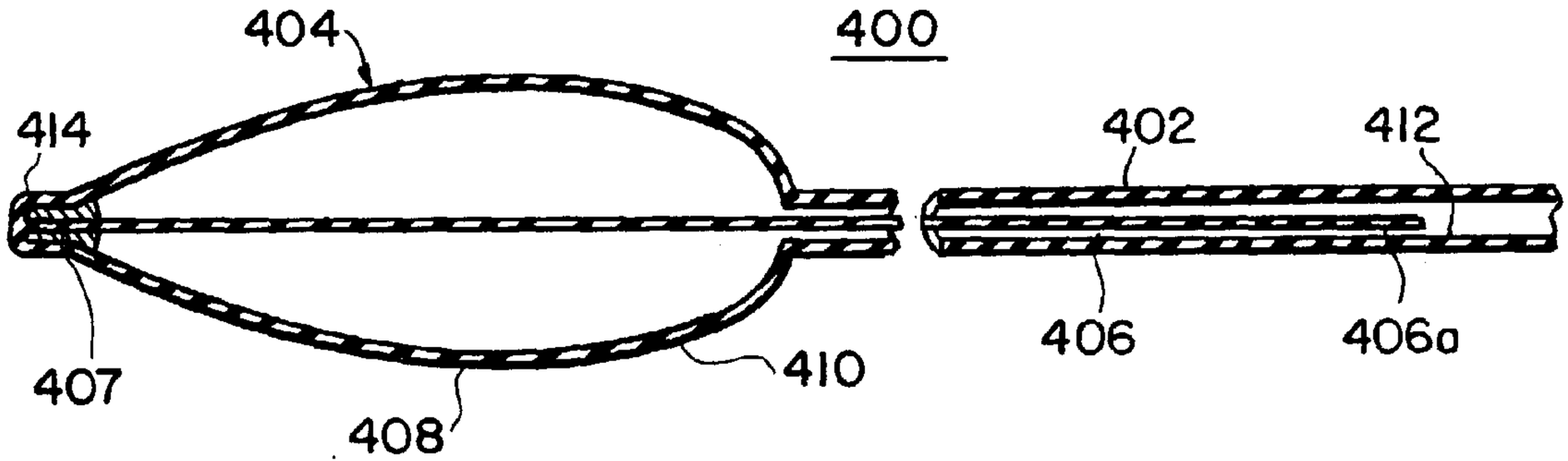

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FIG. 13

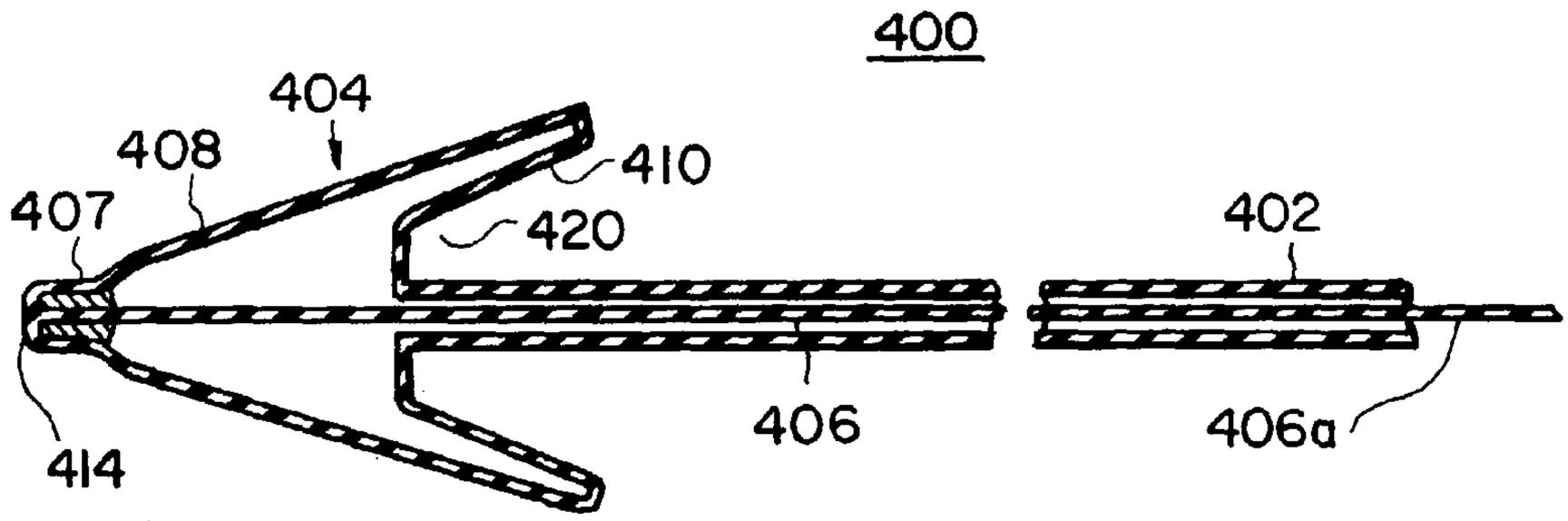

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FIG. 14

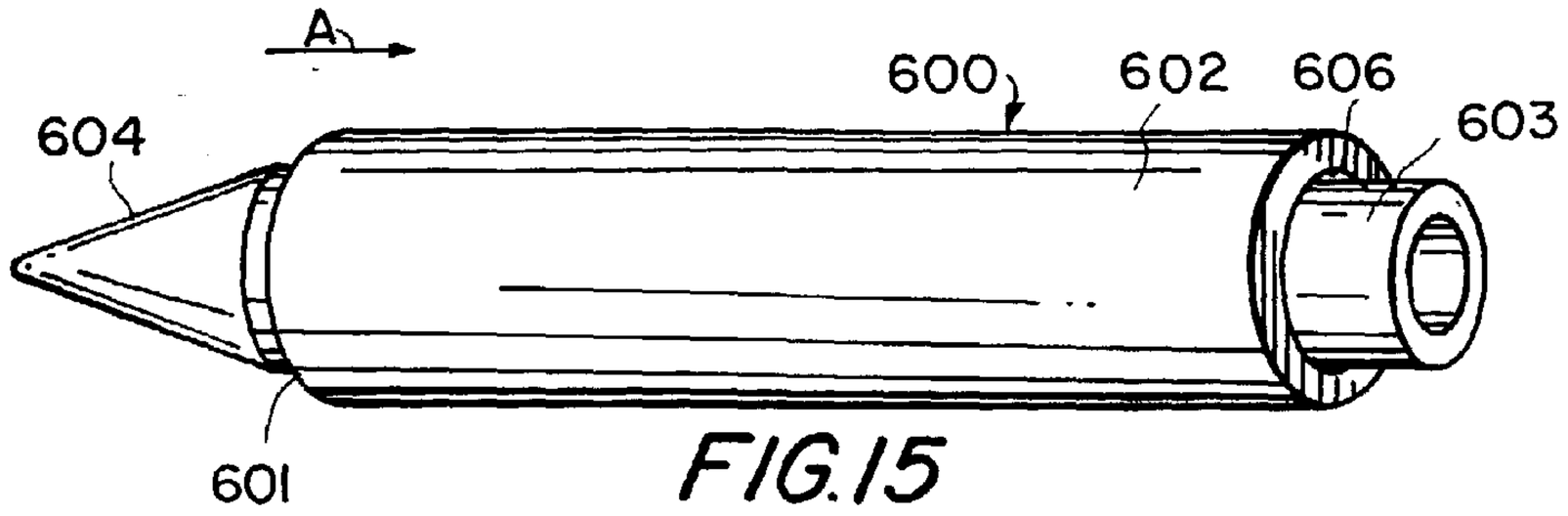



FIG. 15

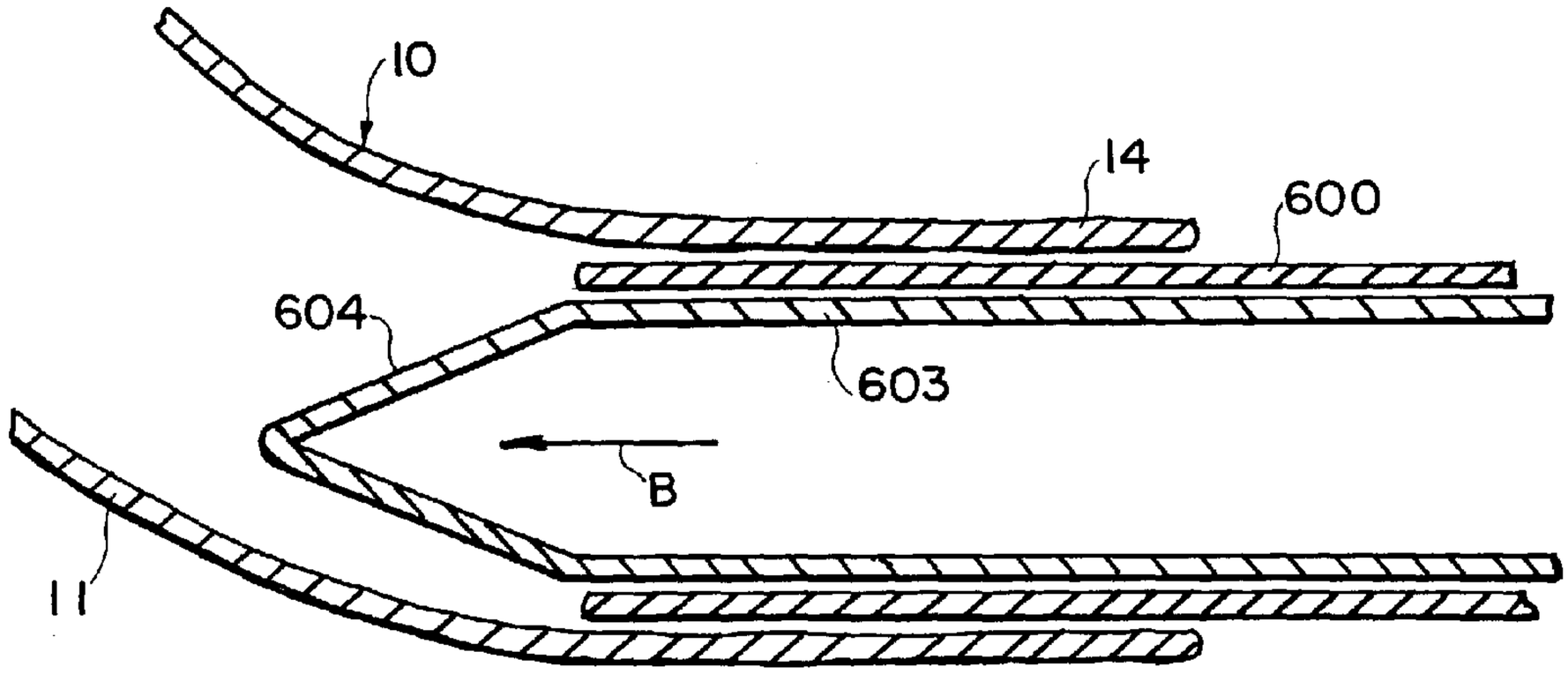



FIG. 16

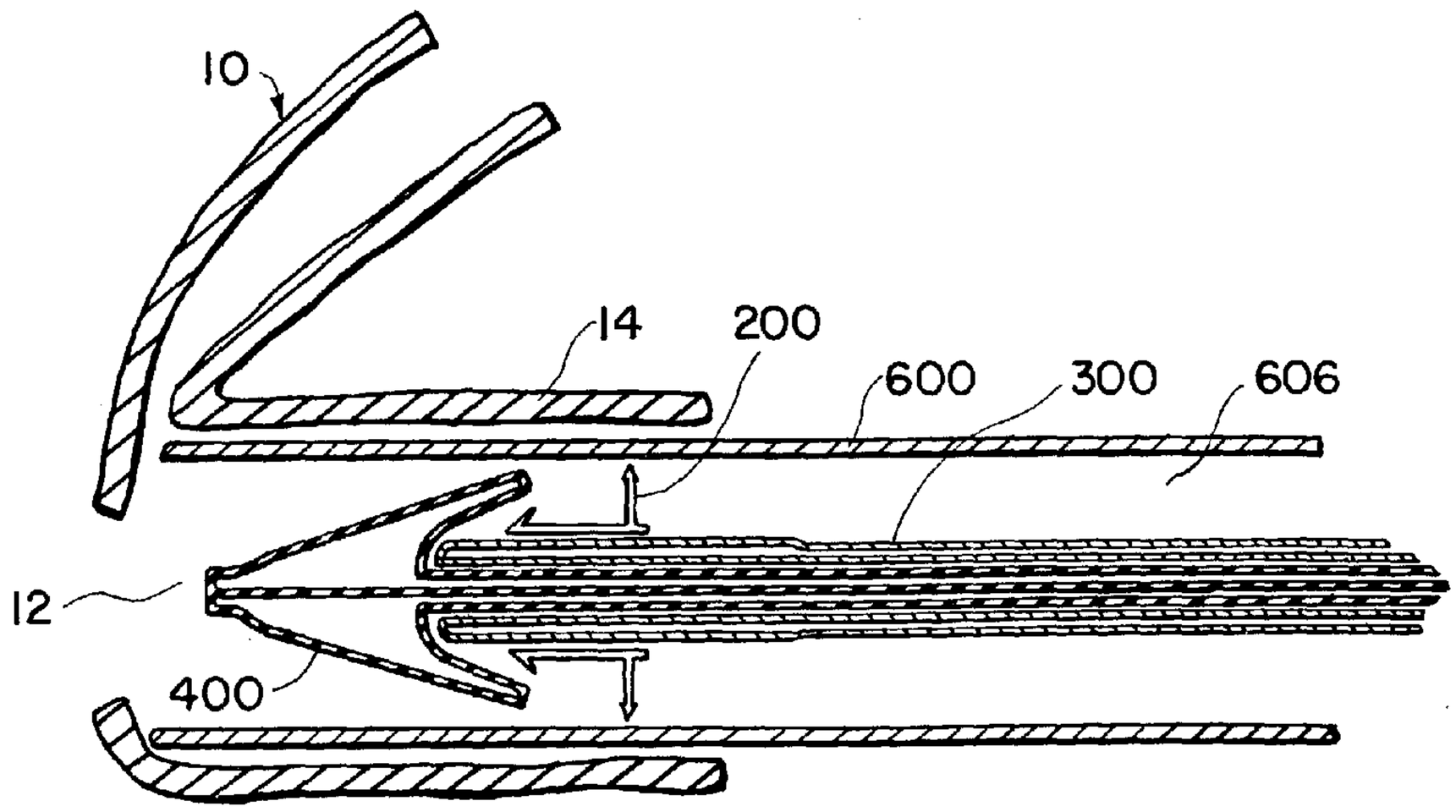



FIG. 17

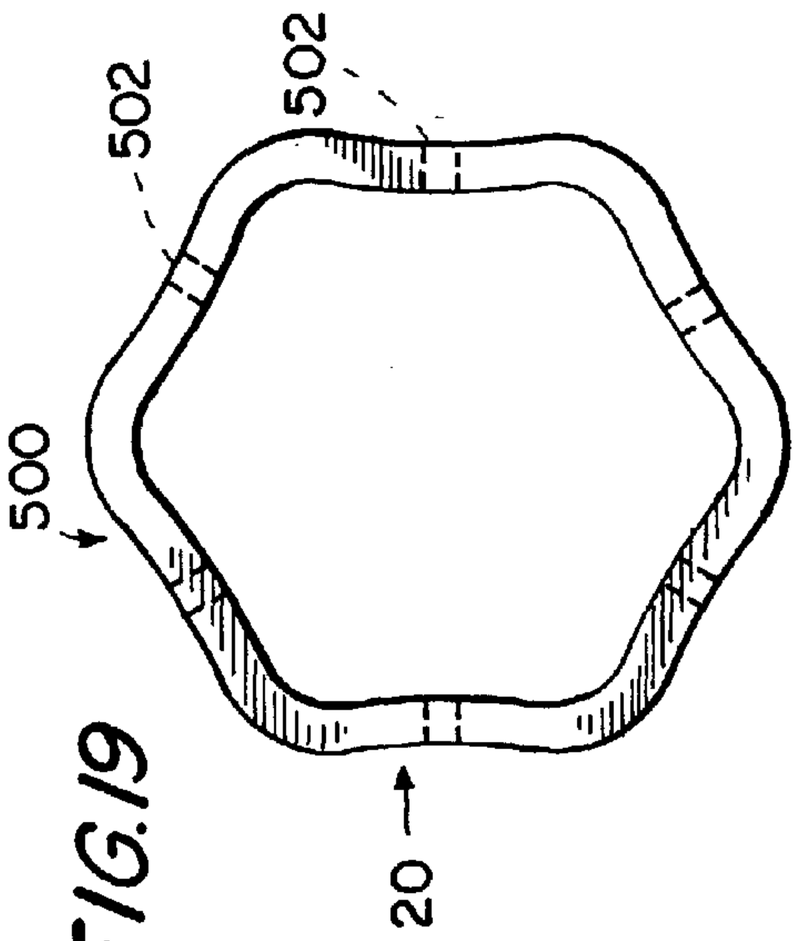



FIG.19

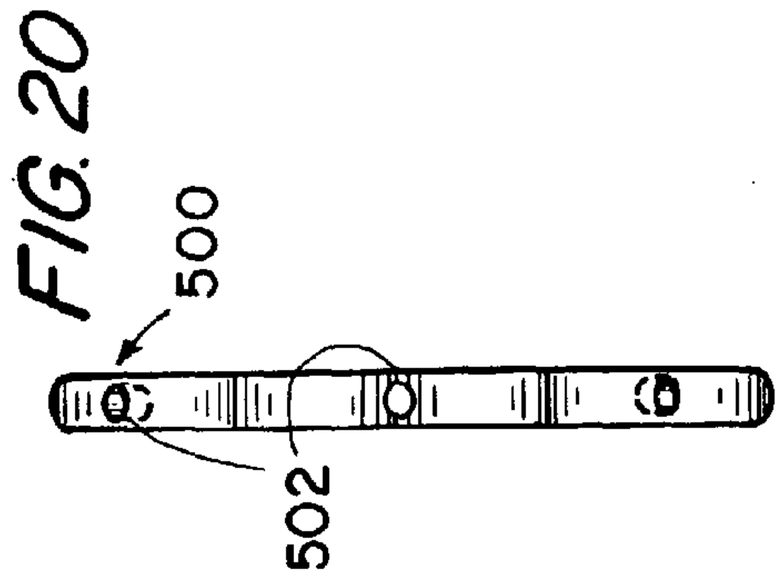



FIG. 20

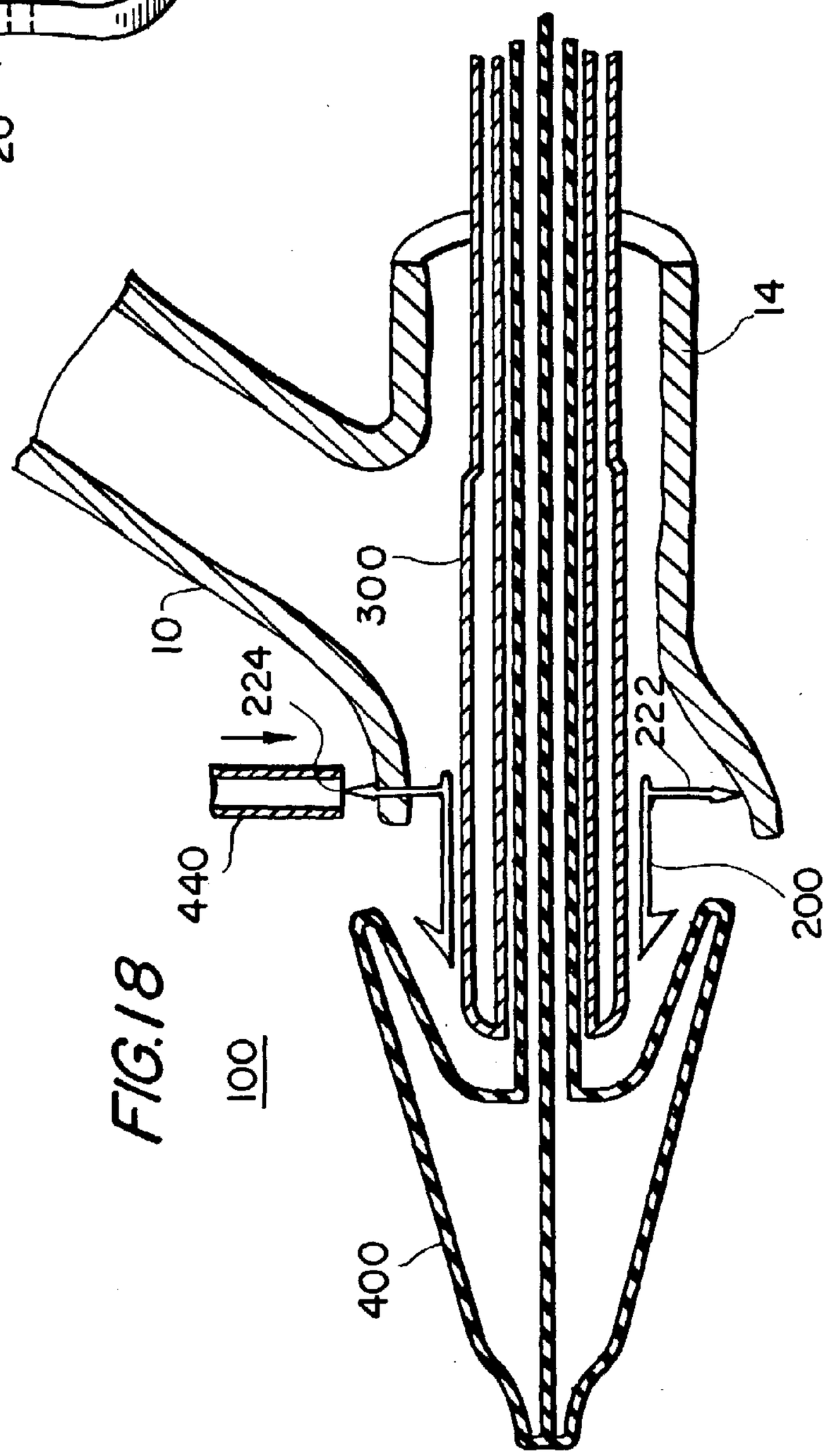



FIG.18

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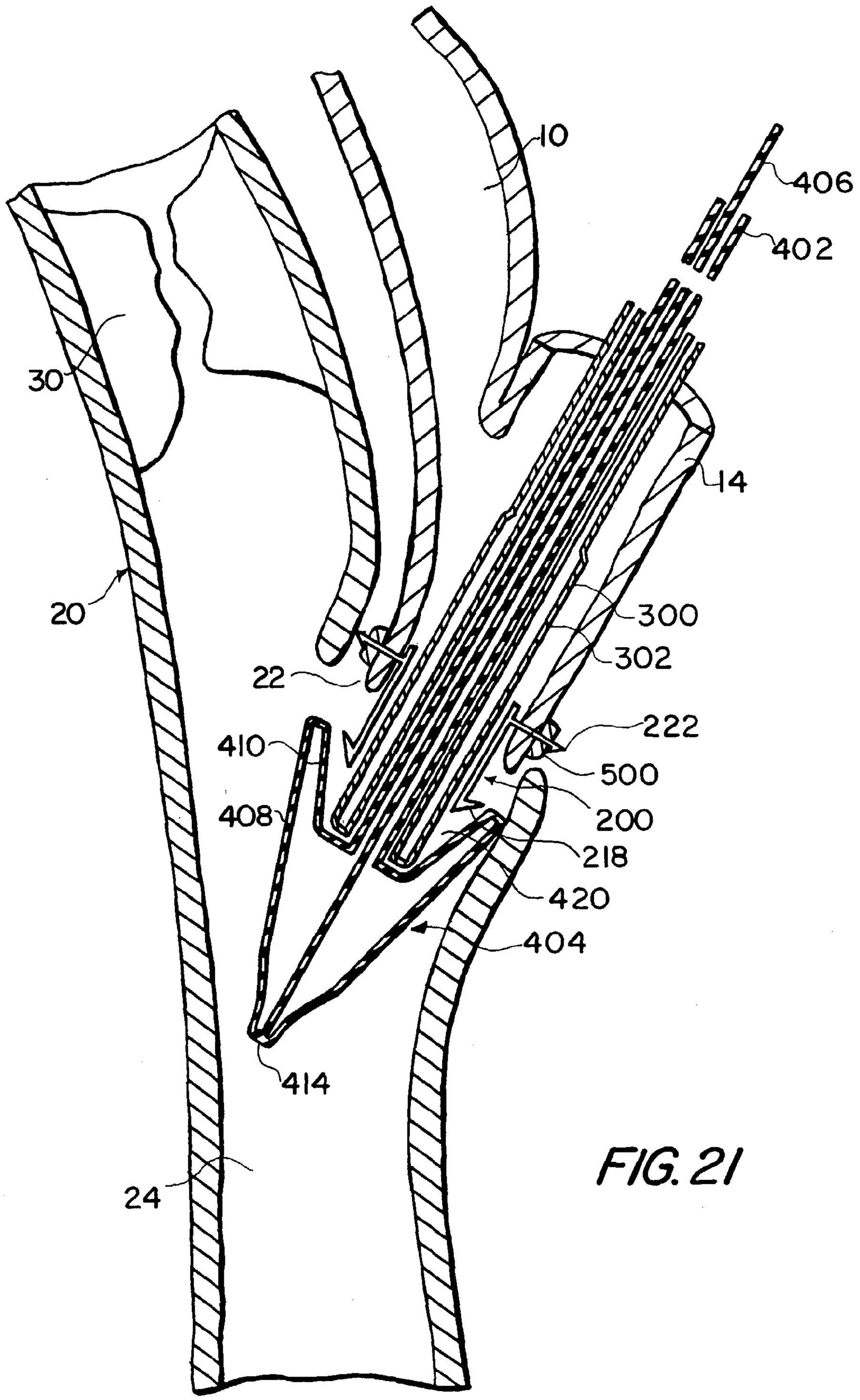

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FIG. 21

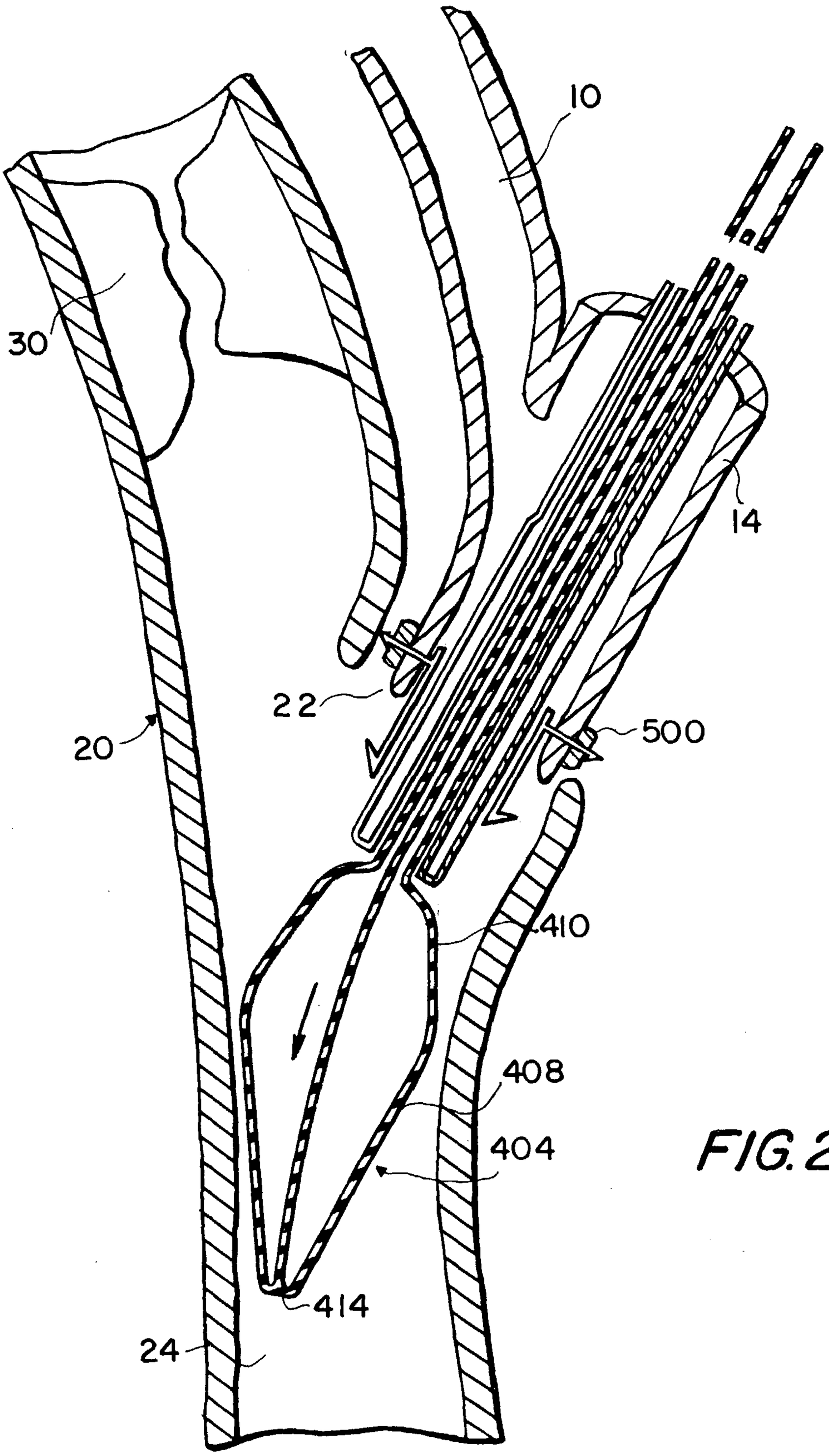



FIG. 22

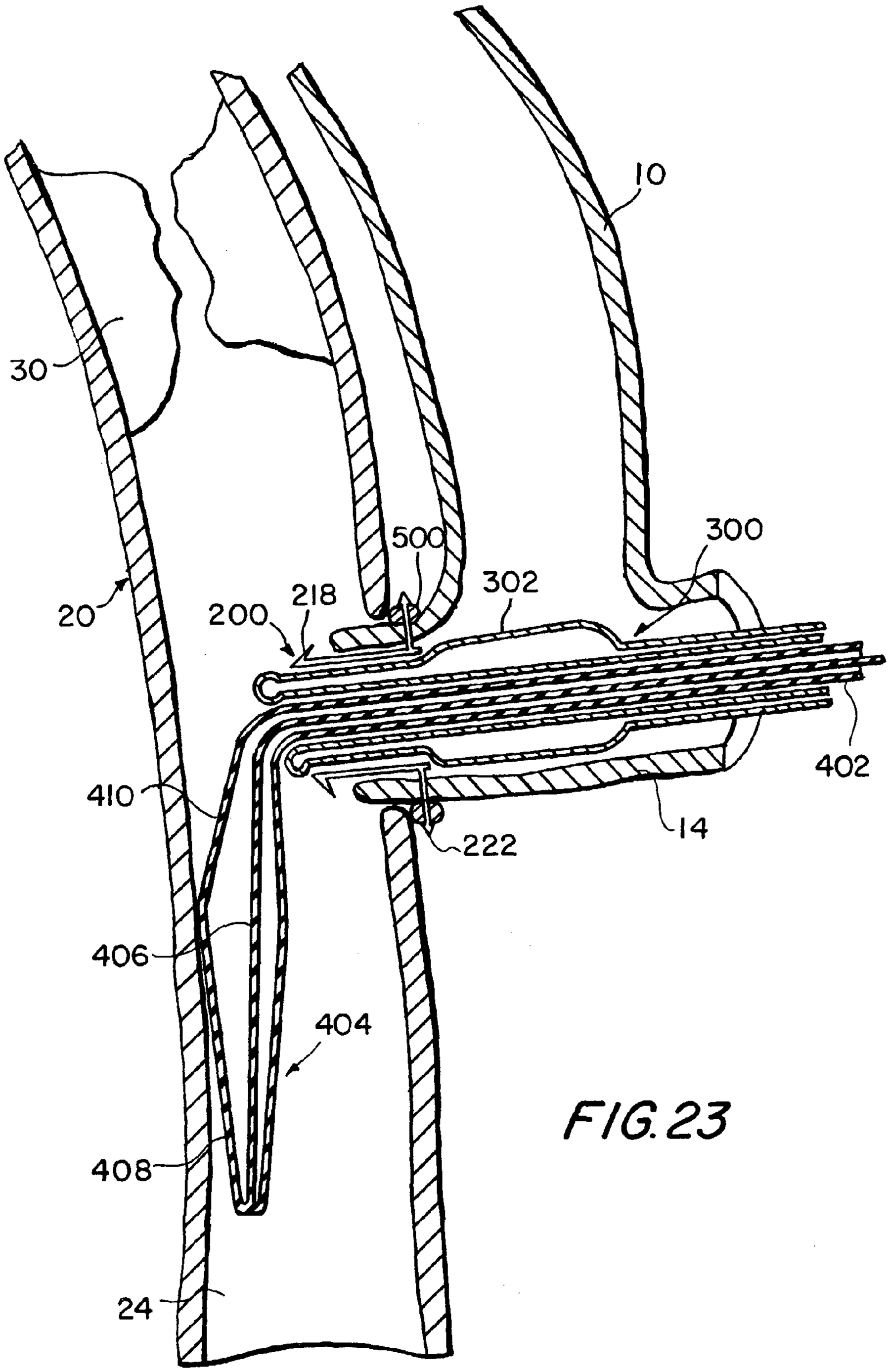



FIG. 23

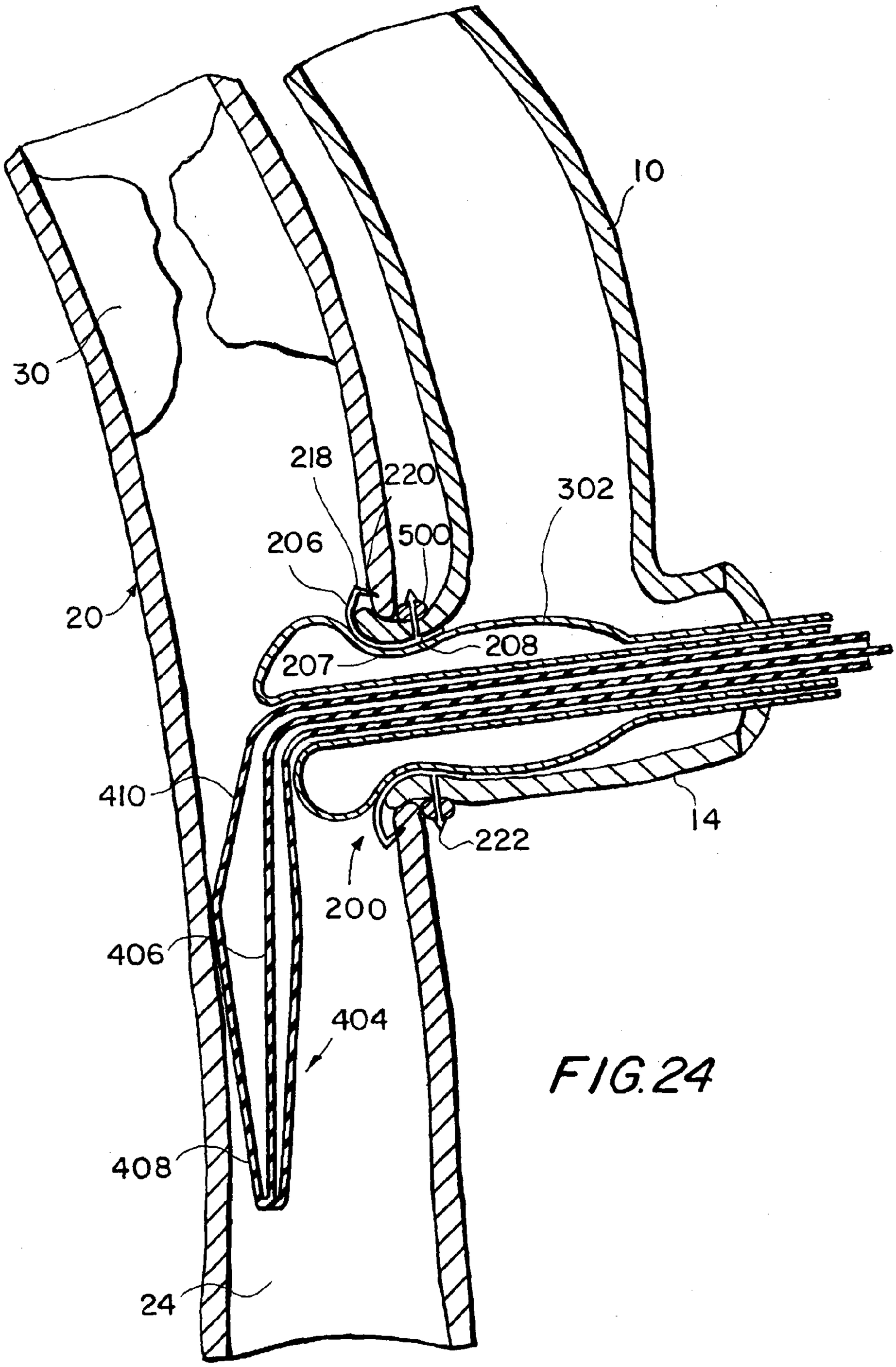



FIG. 24

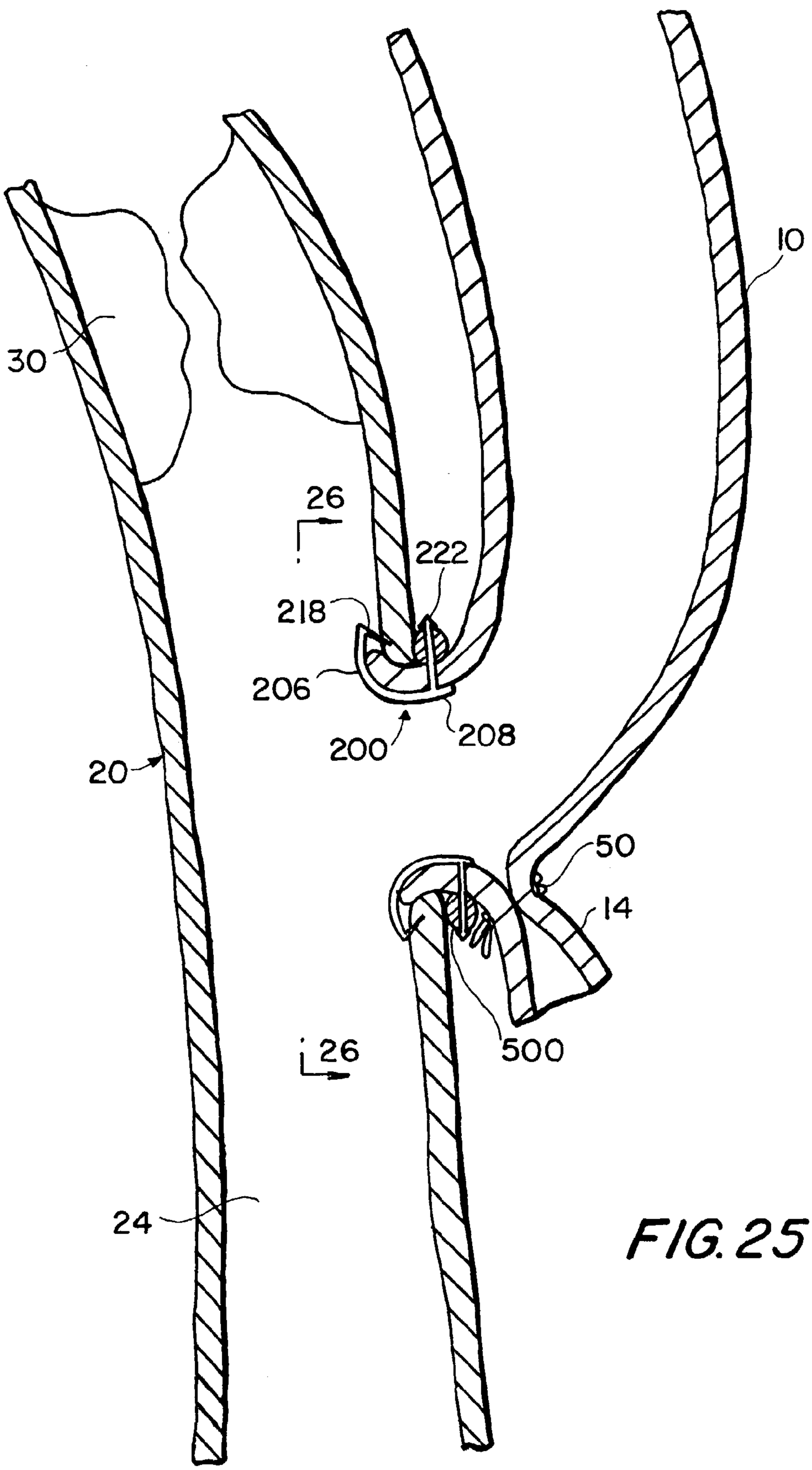



FIG. 25

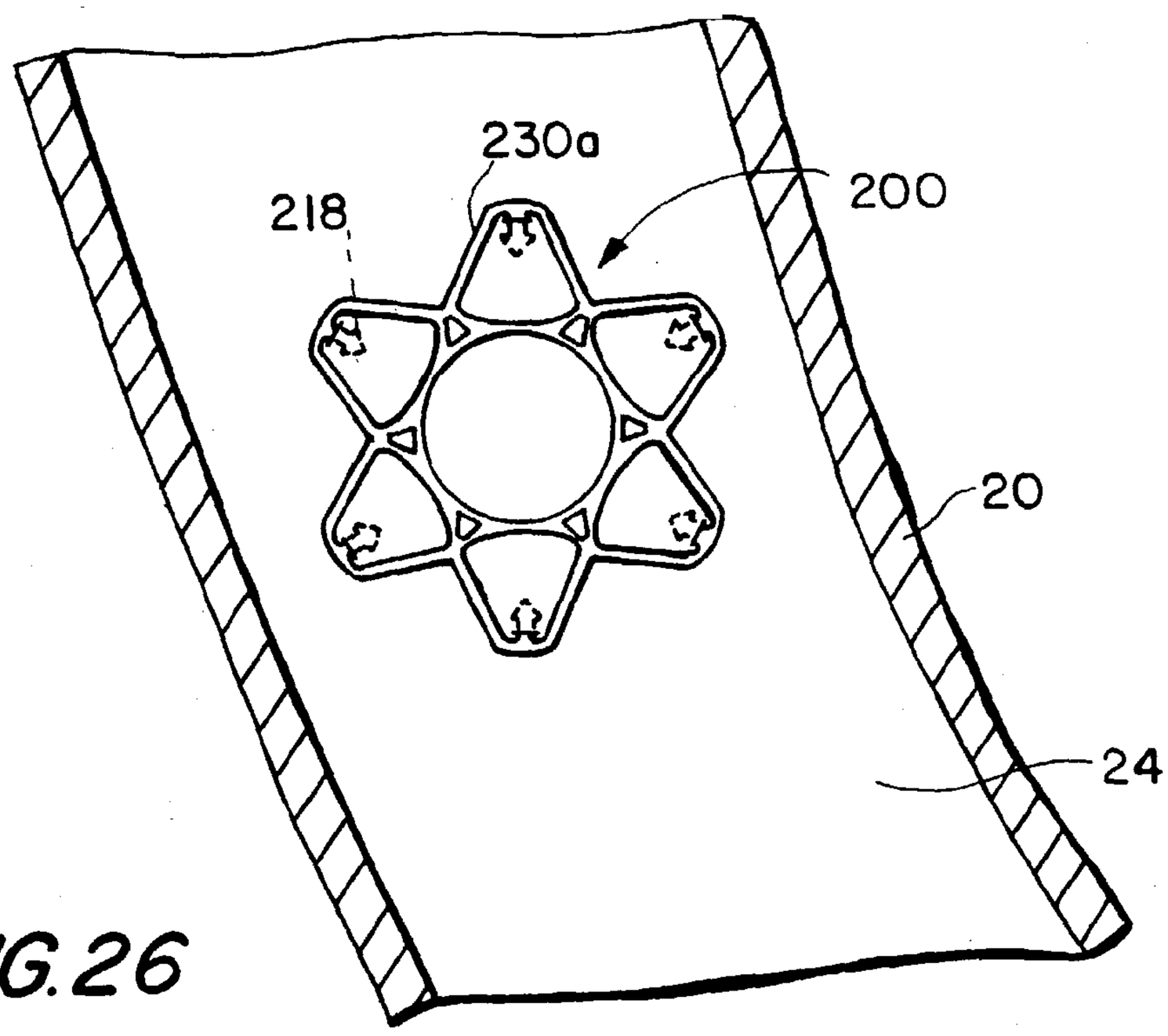



FIG. 26

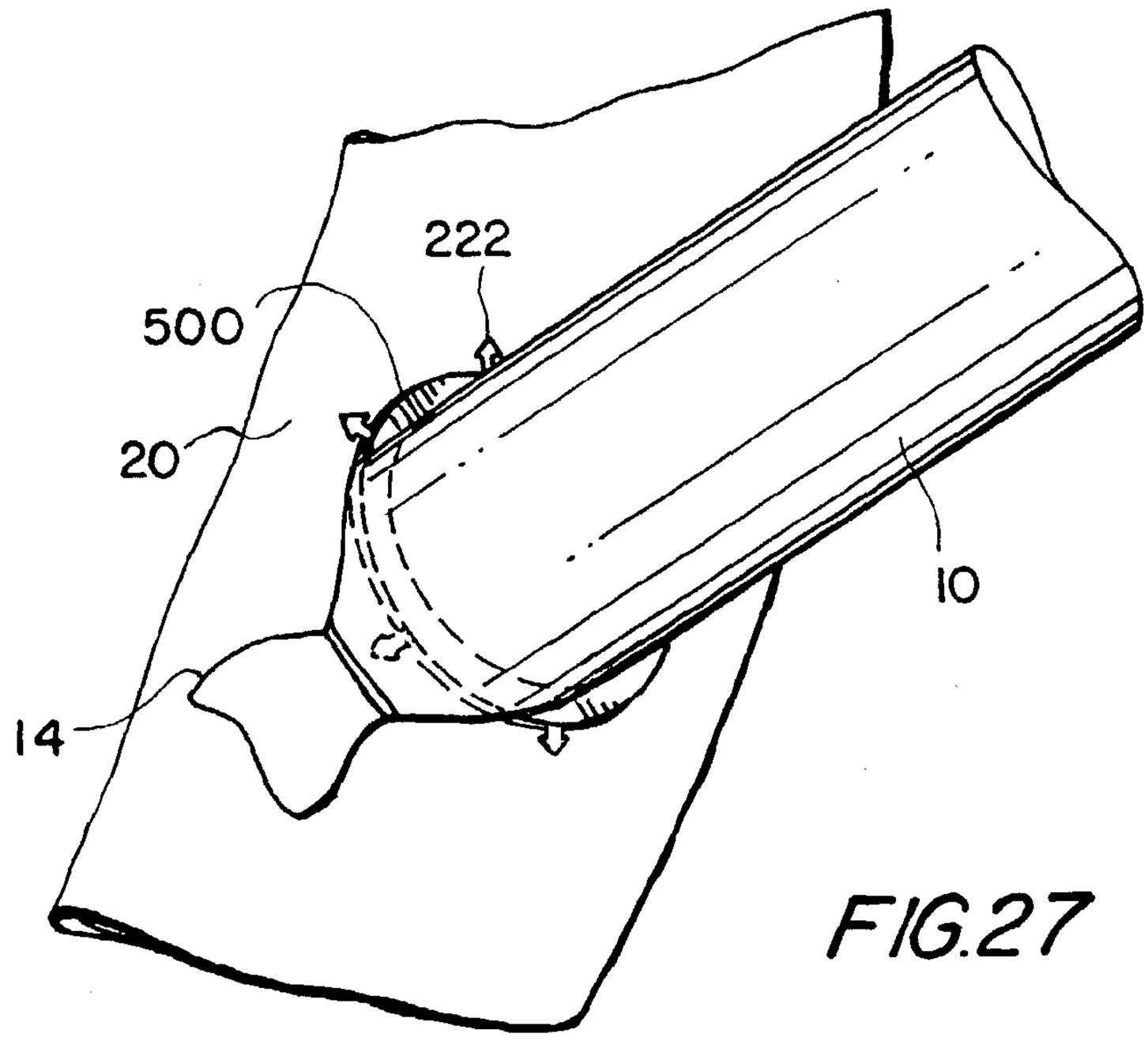



FIG. 27

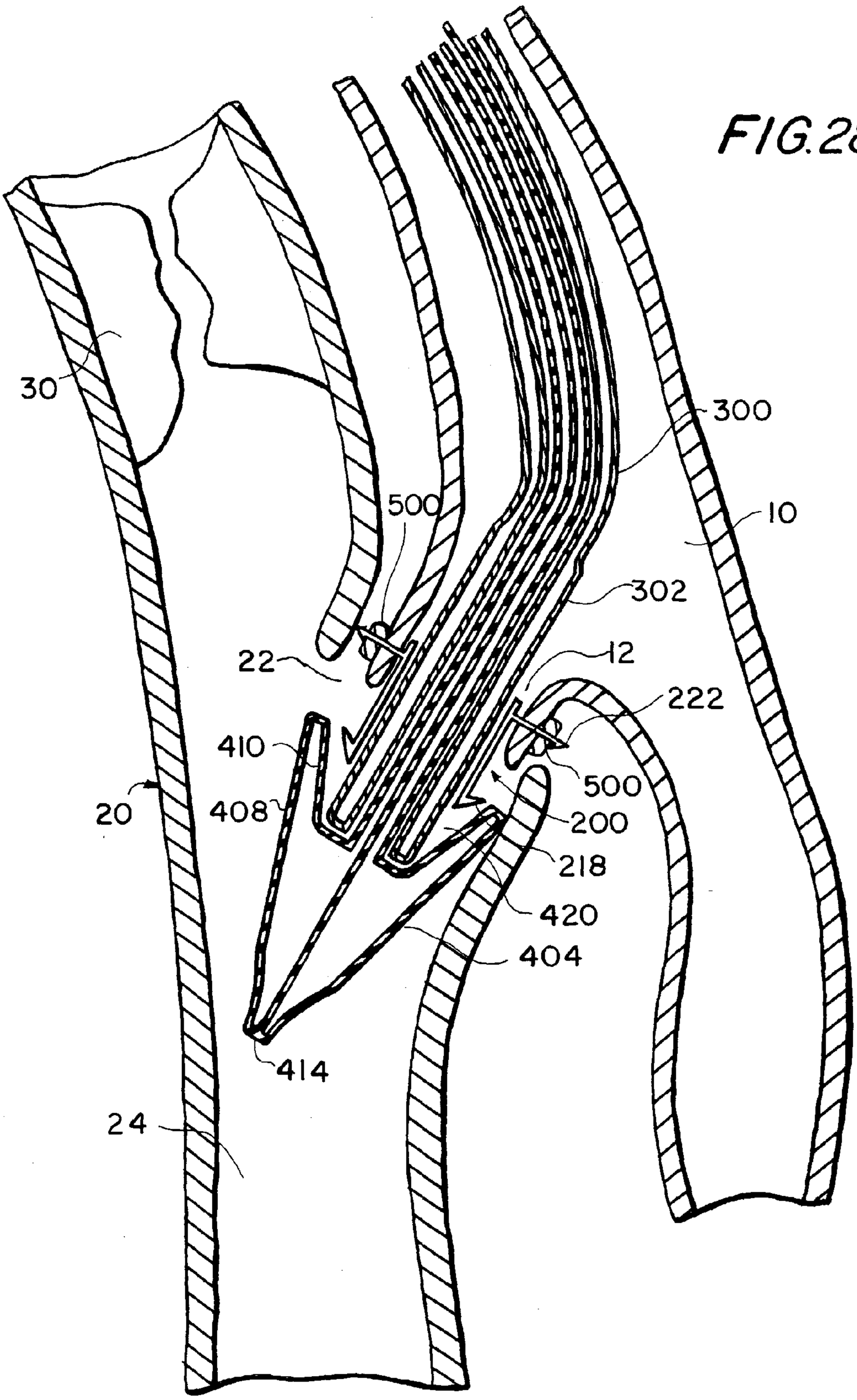



FIG. 28

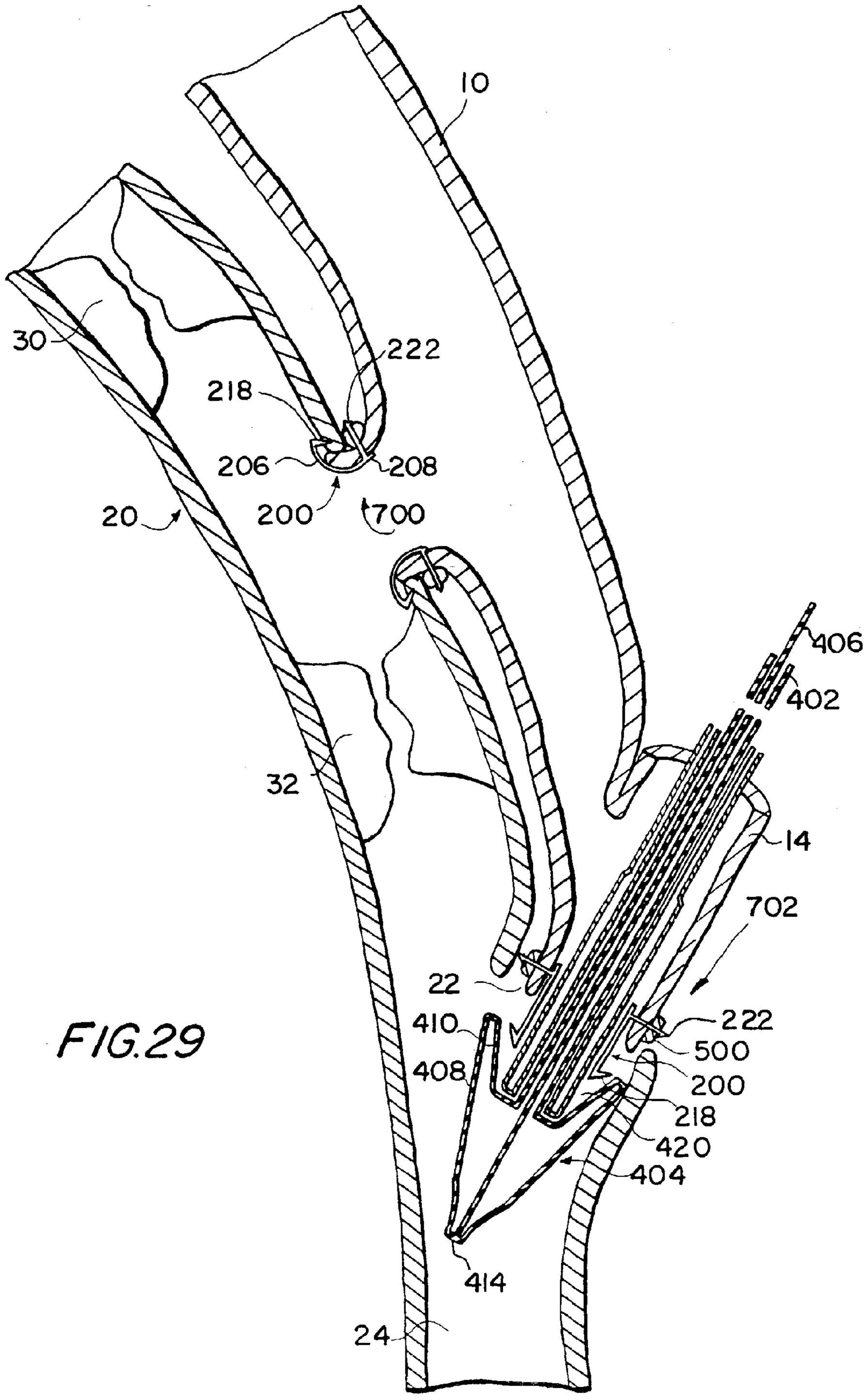

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FIG. 29

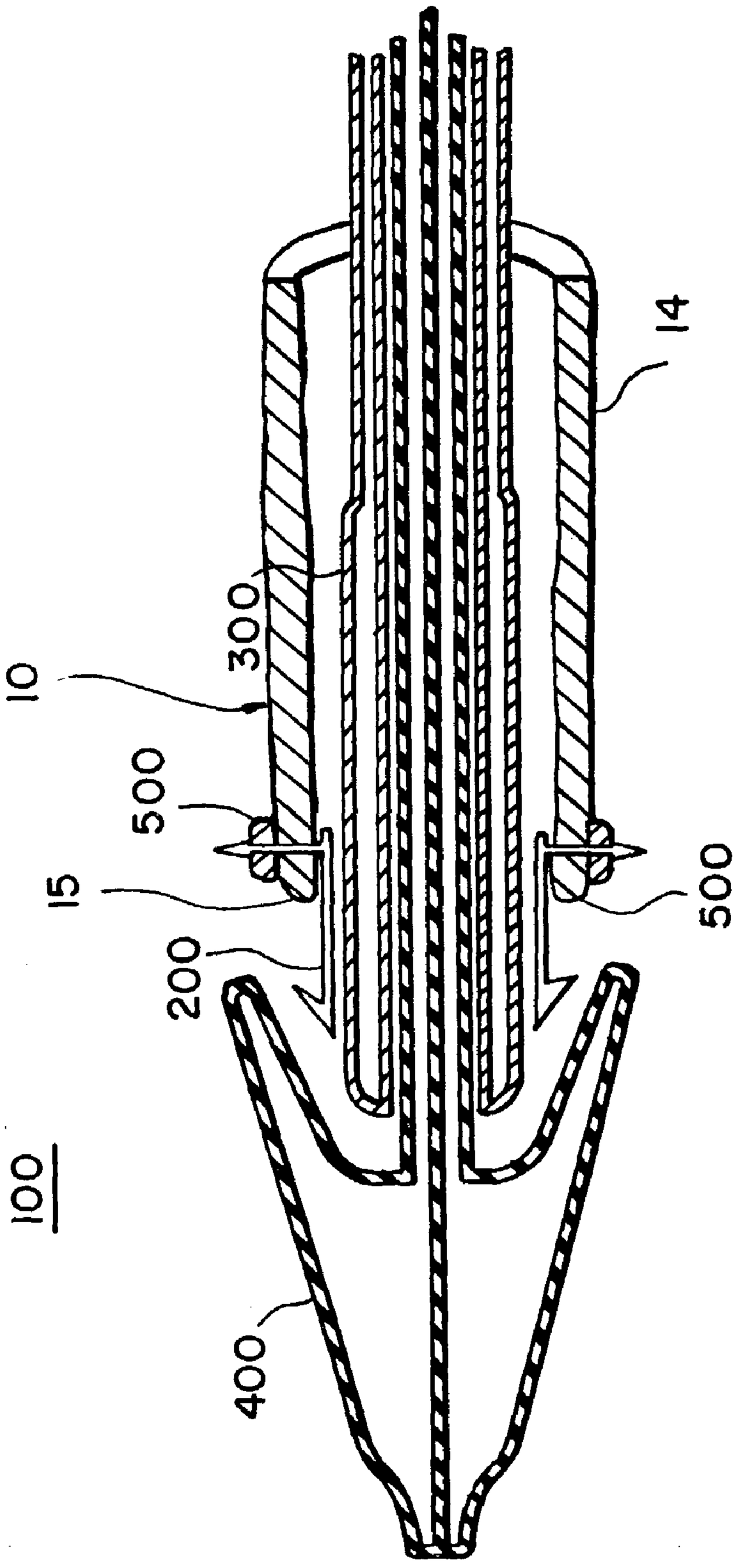



FIG.30

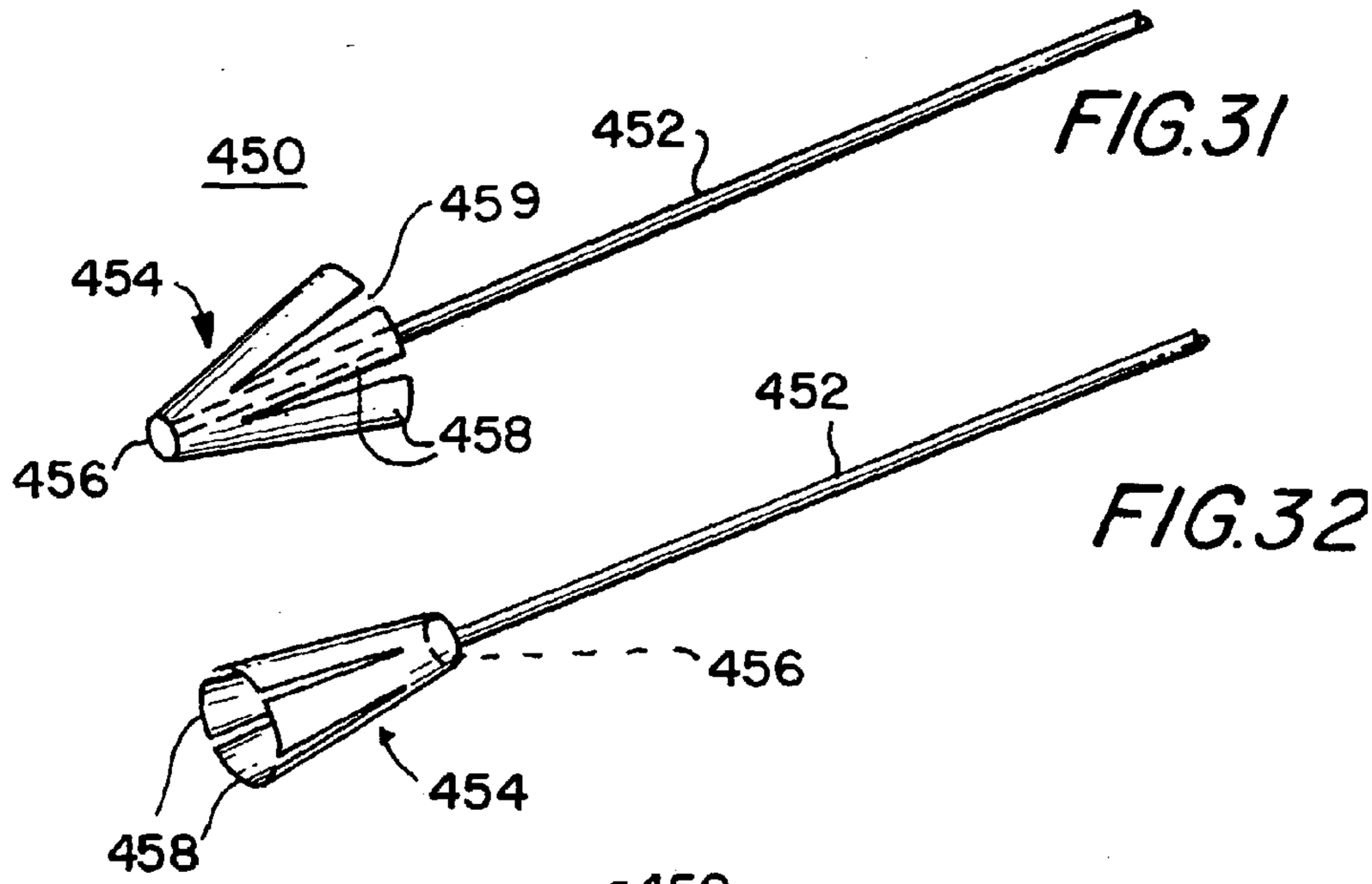



FIG.31




FIG.32

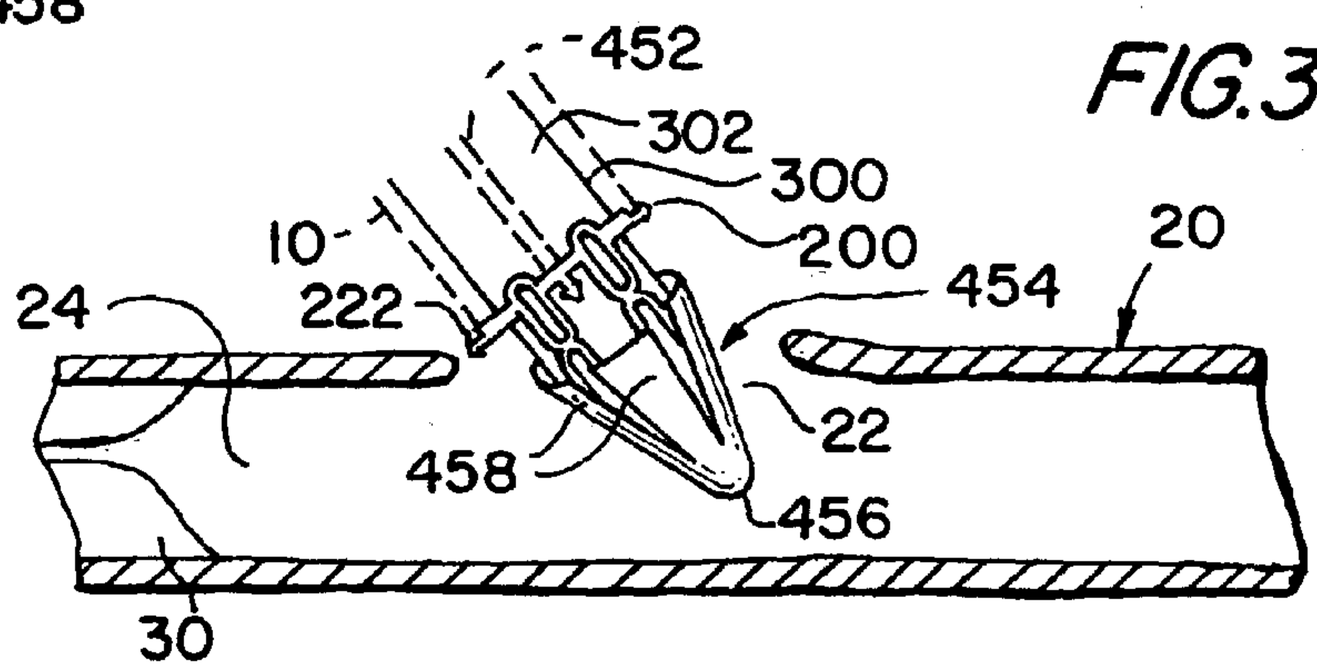



FIG.33

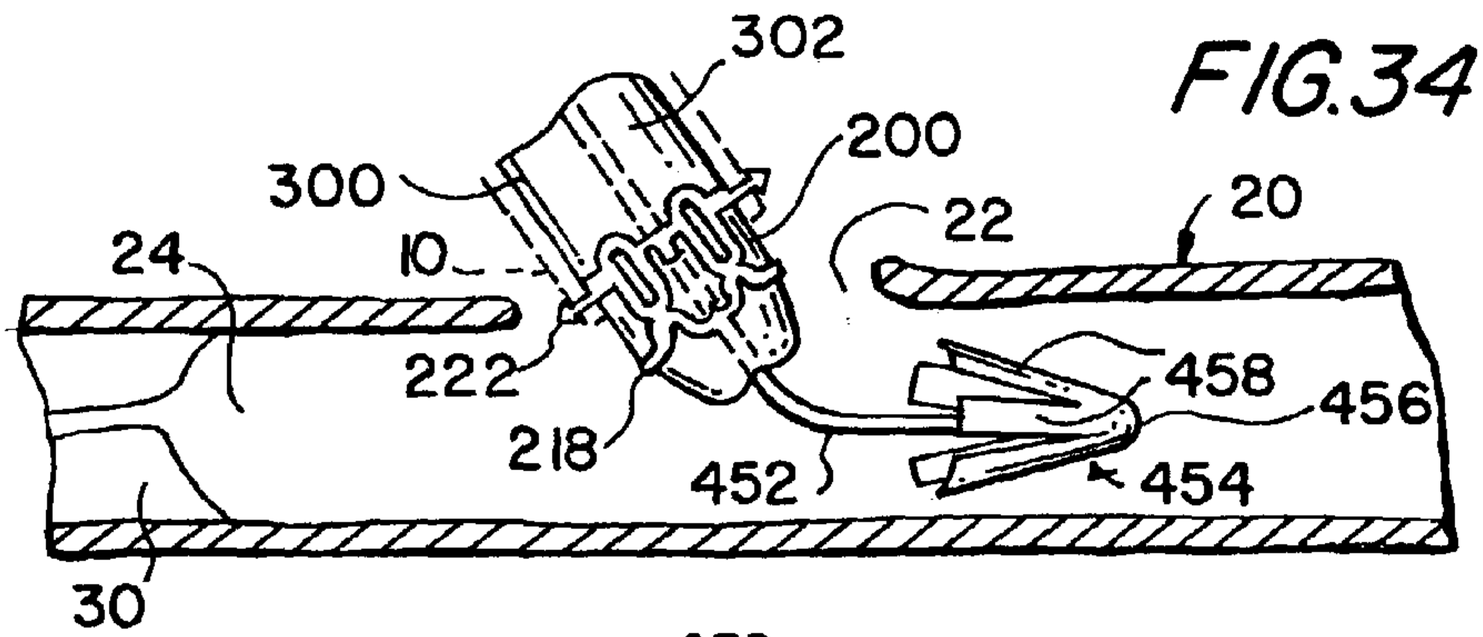



FIG.34

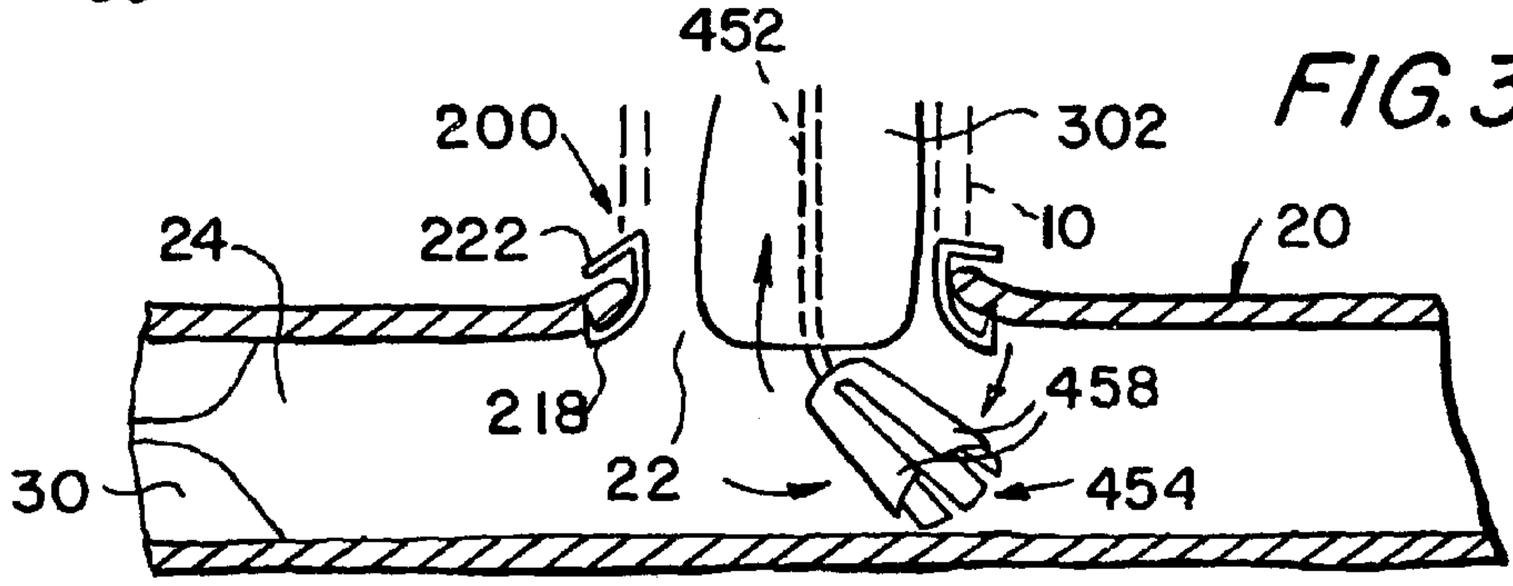



FIG.35

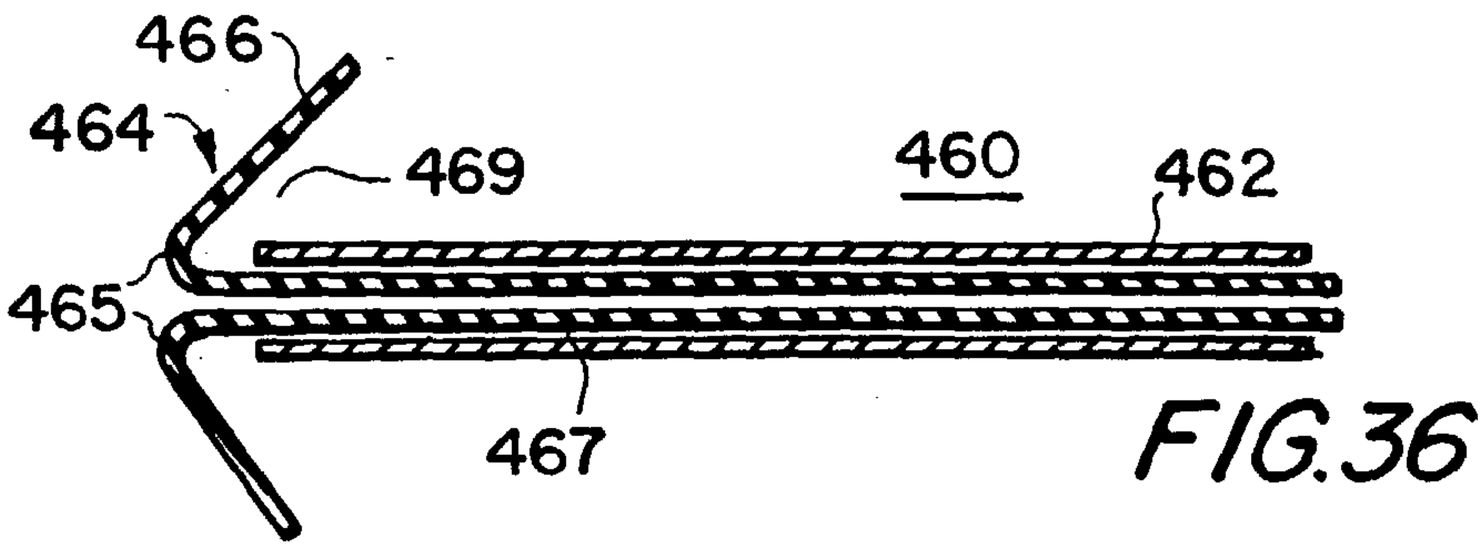



FIG.36

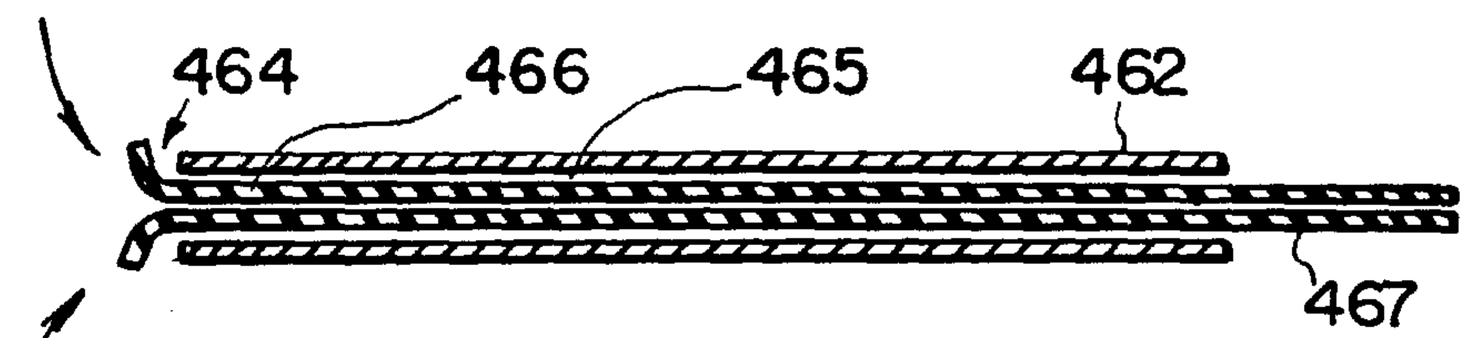



FIG.37

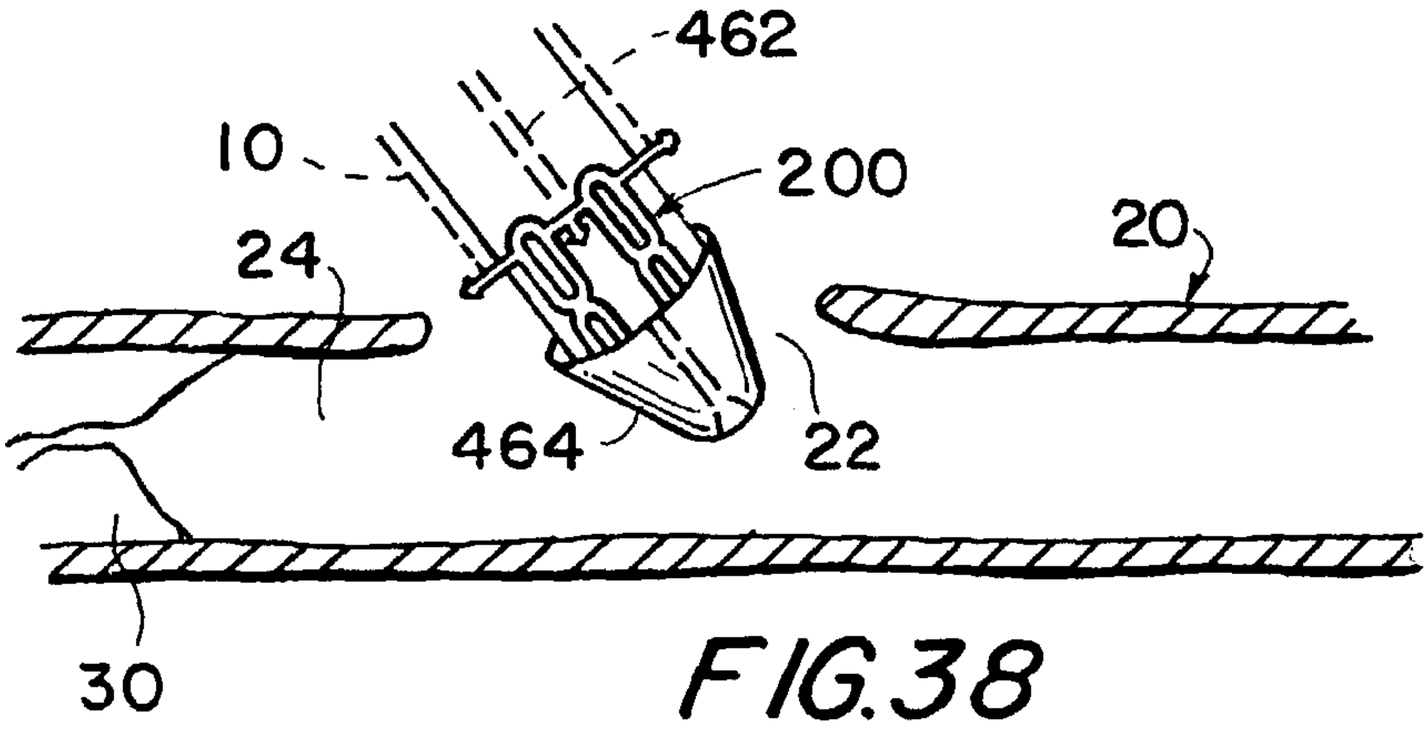



FIG.38

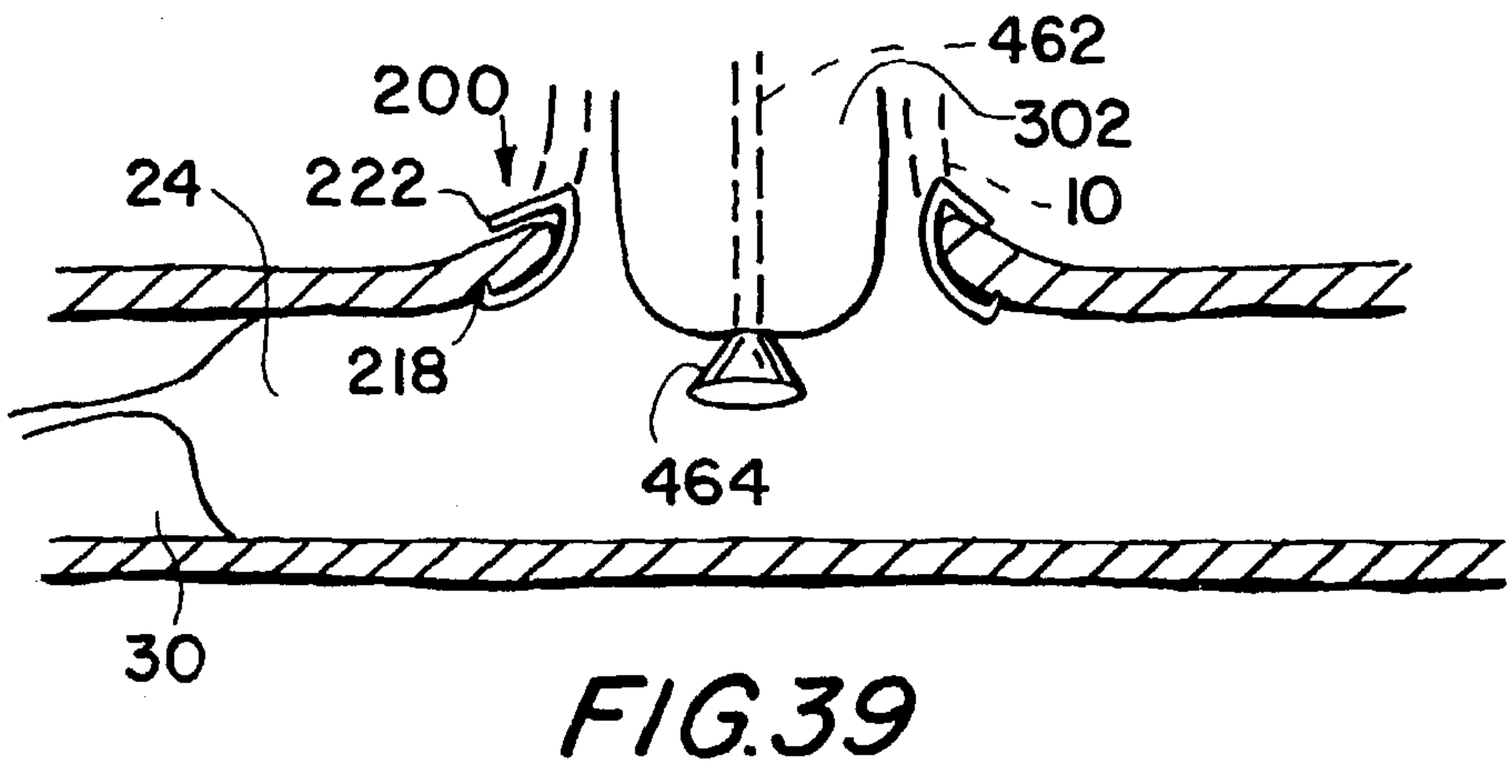



FIG.39

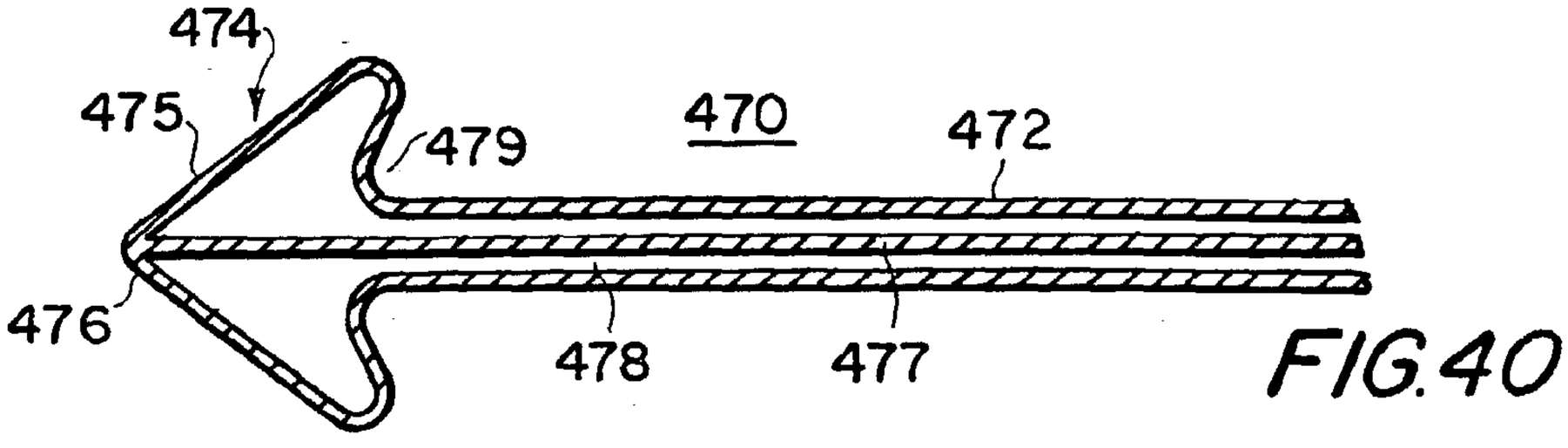



FIG. 40

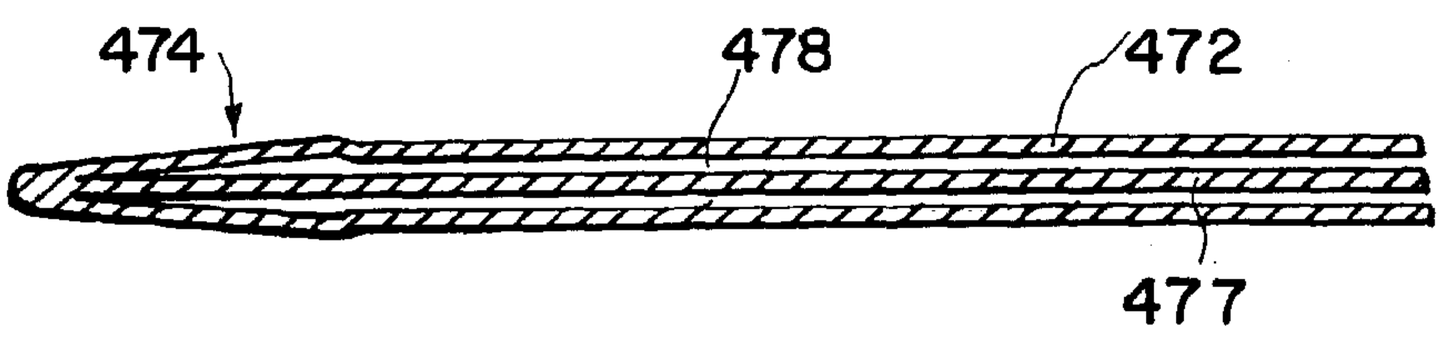



FIG. 41

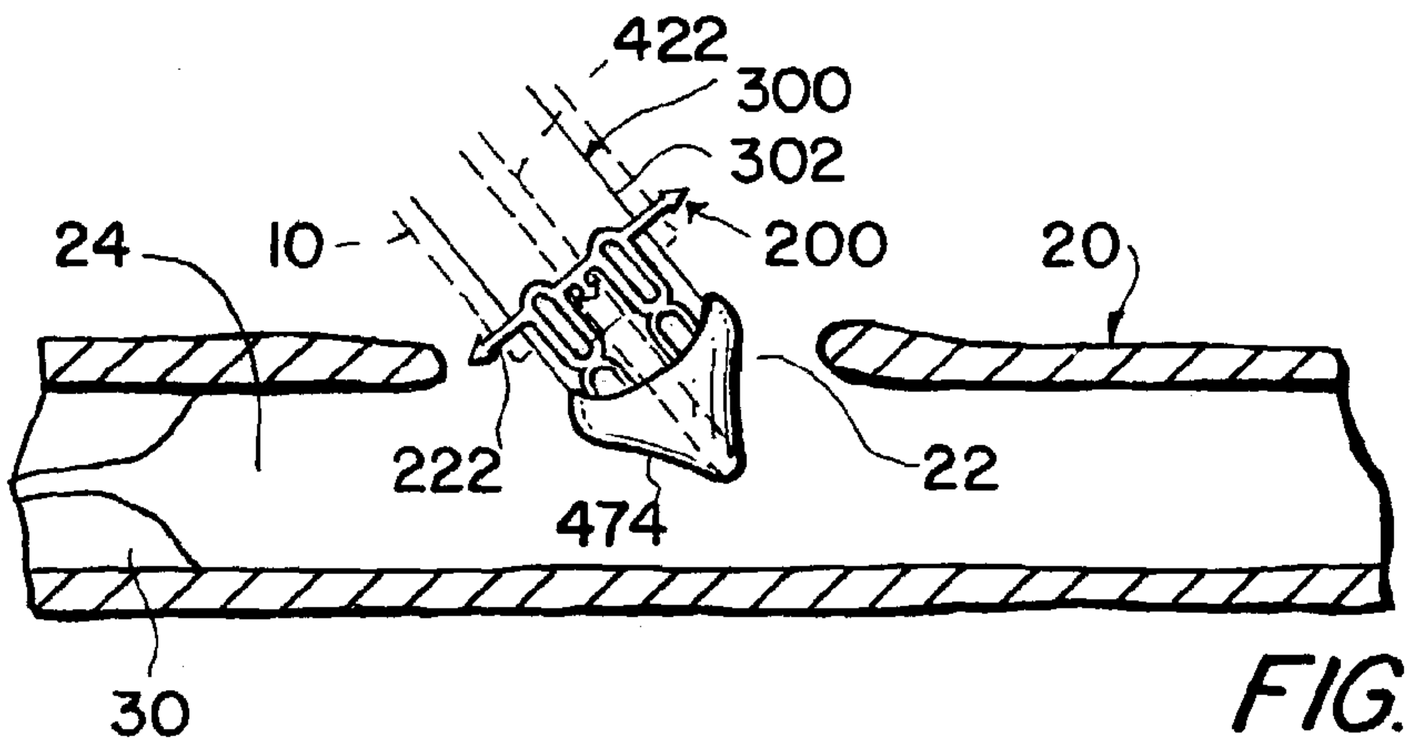



FIG. 42

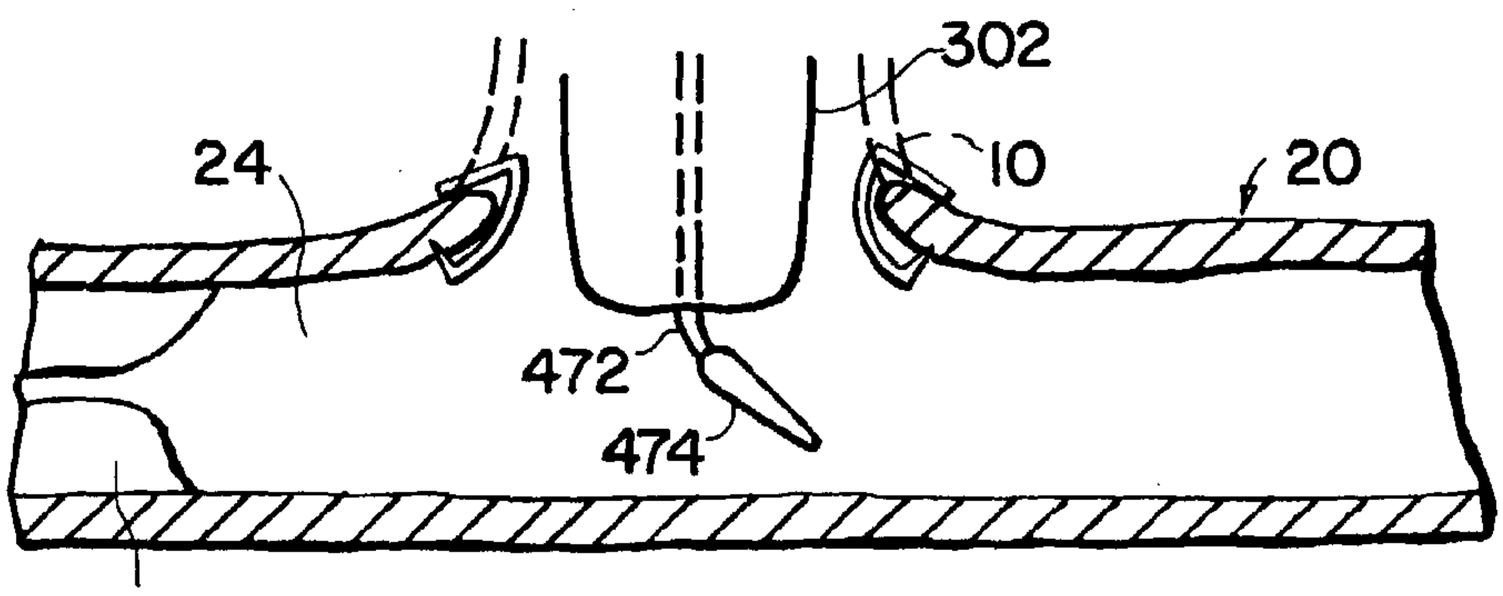



FIG. 43

# MEDICAL GRAFTING METHODS & APPARATUS

[0001] This application is a division of U.S. patent application Ser. No. 09/693,578, filed Oct. 20, 2000, which is a nonprovisional of U.S. provisional patent application No. 60/168,200, filed Nov. 30, 1999. 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 lumen 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 coronary 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, Sullivan et al. 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 the case of making a conventional end-to-side anastomosis between a vein graft and the coronary artery, there are additional difficulties which may arise. First, the relative sizes of the coronary artery and the vein graft are different. For example, the coronary artery may typically have an inner diameter of about 1.0 to 3.0 mm, whereas a vein graft, such as the saphenous vein, may typically have an inner diameter of about 4 to 8 mm. This discrepancy between vessel diameters, i.e., a "caliber mismatch," may present a challenge to the physician to match the end of the relatively larger vein graft to an aperture in the side wall of the relatively smaller coronary artery. The resulting quality and amount of flow between the vein graft and the coronary artery, along with the provision of an effective hemodynamic seal between the two conduits, is often dependent upon the physician's skill in making an effective junction between the two conduits.

[0006] Second, conventional end-to-side anastomosis typically joins the graft conduit to the coronary artery at an angle with respect to the lumen of the coronary artery, thus forming a junction at the wall of the coronary artery. Further away from this junction, the vein graft tends to lie against the heart structure, or substantially parallel to the lumen of the coronary artery. The transition of the vein graft from a substantially perpendicular juncture to the coronary artery to a substantially parallel position with respect to the coronary artery wall often occurs abruptly, which may result in kinking of the vein graft, with possibly reduced blood flow.

[0007] Third, joining vessels having relatively small diameters (e.g., 1-4 mm) presents the additional consideration of keeping the vessels open after the anastomosis has been made. It is therefore helpful to provide the anastomosis with a diameter equal to or larger than the diameter of the smaller vessel being joined. The larger anastomosis is performed in order to minimize the risk of closing off the flow due to the natural healing response. However, it is a challenge to provide a delivery system which is compatible with the dimensions of the anastomosis.

[0008] 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.

[0009] 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.

[0010] 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.

[0011] 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).

[0012] It is a further 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.

[0013] It is another object of the invention to provide apparatus for making a high quality anastomotic connection when joining two conduits having different relative diameters.

[0014] It is another object of the invention to provide apparatus for making a high quality anastomotic connection when joining two conduits having relatively small diameters.

[0015] It is another object of the invention to provide apparatus for making high quality anastomosis which allows the conduits to be positioned in a substantially flat configuration with respect to one another and which prevents kinking of the conduits.

## SUMMARY OF THE INVENTION

[0016] An apparatus including a connector is provided to create an anastomosis between two conduits. A particular application of this invention is to join a saphenous vein graft (SVG) to a coronary artery in a side-to-side anastomosis. The connector structure has a first set of members that are used to secure the first conduit, typically the SVG, and a second set of members that engage the second conduit, typically the coronary artery.

[0017] The connector structure is mounted on a balloon catheter, which when pressurized, expands to a significant extent at the distal end thereof. The balloon enlarges the connector structure when positioned at the distal end portion of the balloon to create the anastomosis, and at the same time reduces the axial length of the connector, thereby compressing the first conduit to the second conduit, creating a hemodynamic seal and a firm attachment of the two conduits. After enlargement, the connector structure remains in place and adds structure to the anastomosis.

[0018] The second set of members is covered by a nosecone assembly to prevent trauma to the second conduit while the apparatus is being introduced. The nosecone assembly has a flexible structure which may change configuration to expose the second set of members after insertion into the second conduit and to allow removal of the nosecone after deployment.

[0019] The method for creating the anastomosis may comprise providing a connector and a delivery apparatus including an expansion balloon and a nosecone assembly. A next step may include making an aperture in the wall of the first conduit proximal to the distal end of the first conduit. The first conduit is then attached to the connector structure. More particularly, the first set of members of the connector structure may then pierce the wall of the first conduit. A locating ring, which may be colored with titanium dioxide, is placed about the first conduit adjacent the first set of members to provide an indication to the physician during delivery.

[0020] At the operative site, a second aperture is made in the second conduit wall. According to one embodiment, the second conduit may be cut and then dilated. The delivery system and the connector is introduced into the aperture in the second conduit. More particularly, the nosecone, in an introduction configuration, is inserted into the second conduit substantially axially to the lumen of the second conduit. The locating ring provides an indication that the first aperture in the first conduit is positioned adjacent the second aperture in the second conduit. The locating ring may provide a visual indication or a tactile indication when the locating ring is in contact with the wall of the second conduit.

[0021] The nosecone may then be changed to the removal configuration to uncover the second set of members. In an embodiment, the nosecone is a balloon structure which is inflated to uncover the second set of members. The nosecone assembly may be flexible, such that further advancement of the nosecone allows the nosecone to be positioned substantially parallel to the lumen of the second conduit. The delivery system may then be turned from a substantially axial position to a position at 90 degrees with respect to the lumen and the wall of the second conduit.

[0022] The balloon catheter is designed to allow significant expansion at its distal end portion. The connector, which has been positioned adjacent this distal end portion, may then be enlarged by expanding the balloon to make the anastomosis between the first and second conduits. More particularly, the connector structure enlarges radially and may shorten axially to approximate the first and second set of members of the connector, and thereby approximate the tissue of the first and second conduits to provide a seal, which is hemodynamic and has sufficient mechanical integrity and strength to provide durability. Once the connector structure is enlarged, the balloon and/or nosecone is deflated, and the delivery system may be removed and the first conduit may be ligated distal to the anastomosis without compromising the first conduit lumen.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0023] **FIG. 1** is a simplified sectional view of the apparatus and a first conduit in accordance with the invention.

[0024] **FIG. 2** is a planarized projection of a component apparatus of **FIG. 1** in accordance with the invention.

[0025] **FIG. 3** is a perspective view of the component apparatus of **FIG. 2** in accordance with the invention.

[0026] **FIG. 4** is a planarized projection of the component apparatus of **FIG. 2** in another configuration in accordance with the invention.

[0027] **FIG. 5** is a perspective view similar to **FIG. 3** of the component apparatus of **FIG. 2** in another configuration in accordance with the invention.

[0028] **FIG. 6** is a planarized projection of another embodiment of the component of **FIG. 2** in accordance with the invention.

[0029] **FIG. 7** is a sectional view of the component of **FIG. 6** in another configuration in accordance with the invention.

[0030] **FIG. 8** is a sectional view of another component apparatus of **FIG. 1** in accordance with the invention.

[0031] **FIG. 9** is a sectional view of a prior art apparatus.

[0032] **FIG. 10** is a simplified view of the component apparatus of FIGS. **2-5** and the component apparatus of **FIG. 8** in accordance with the invention.

[0033] **FIG. 11** is a sectional view taken along line **11-11** of **FIG. 10** in accordance with the invention.

[0034] **FIG. 12** is a sectional view of the component apparatus shown in **FIG. 8** and the component apparatus of FIGS. **2-5** in another configuration in accordance with the invention.

[0035] **FIG. 13** is a sectional view of a component apparatus of **FIG. 1** in a first condition in accordance with the invention.

[0036] **FIG. 14** is a sectional view of the component apparatus of **FIG. 13** in a second condition in accordance with the invention.

[0037] **FIG. 15** is perspective view of additional apparatus in accordance with the invention.

[0038] **FIG. 16** is a sectional view of the apparatus of **FIG. 15**, illustrated with the first conduit, in accordance with the invention.

[0039] **FIG. 17** is a sectional view similar to **FIG. 16**, illustrating the apparatus of **FIG. 1** in an earlier stage of the procedure in accordance with the invention.

[0040] **FIG. 18** is a sectional view similar to **FIG. 17**, illustrating additional apparatus in accordance with the invention.

[0041] **FIG. 19** is an elevation view of a component apparatus of **FIG. 1** in accordance with the invention.

[0042] **FIG. 20** is a side view of the component apparatus of **FIG. 19**, taken from direction **20** of **FIG. 19** in accordance with the invention.

[0043] **FIG. 21** is a view in partial section of the apparatus of **FIG. 1** in an early stage of a procedure in accordance with the invention.

[0044] **FIG. 22** is a view similar to **FIG. 21** illustrating a further stage of a procedure in accordance with the invention.

[0045] **FIG. 23** is a view similar to **FIG. 22** illustrating a later stage of a procedure in accordance with the invention.

[0046] **FIG. 24** is a view similar to **FIG. 23** illustrating a still later stage of a procedure in accordance with the invention.

[0047] **FIG. 25** is a view similar to **FIG. 24** illustrating yet another stage of a procedure in accordance with the invention.

[0048] **FIG. 26** is a sectional view taken along lines **26-26** of **FIG. 25** in accordance with the invention.

[0049] **FIG. 27** is an elevational view in accordance with the invention.

[0050] **FIG. 28** is a sectional view similar to **FIG. 21**, illustrating another procedure in accordance with the invention.

[0051] **FIG. 29** is a sectional view similar to **FIG. 21**, illustrating yet another procedure in accordance with the invention.

[0052] **FIG. 30** is a sectional view similar to **FIG. 1**, illustrating another procedure in accordance with the invention.

[0053] **FIG. 31** is a perspective view of component apparatus similar to that illustrated in **FIG. 18**, according to another embodiment, in accordance with the invention.

[0054] **FIG. 32** is a perspective view of the component apparatus of **FIG. 31** in another configuration, in accordance with the invention.

[0055] **FIG. 33** is a sectional view similar to **FIG. 22**, illustrating the component apparatus of FIGS. **31-32** in an early stage of the procedure in accordance with the invention.

[0056] **FIG. 34** is a sectional view similar to **FIG. 33**, illustrating a later stage of the procedure in accordance with the invention.

[0057] **FIG. 35** is a sectional view similar to **FIG. 34**, illustrating a still later stage of the procedure in accordance with the invention.

[0058] **FIG. 36** is a sectional view of component apparatus similar to that illustrated in **FIG. 18**, according to another embodiment, in accordance with the invention.

[0059] **FIG. 37** is a perspective view of the component apparatus of **FIG. 36** in another configuration, in accordance with the invention.

[0060] **FIG. 38** is a sectional view similar to **FIG. 22**, illustrating the component apparatus of FIGS. **36-37** in an early stage of the procedure in accordance with the invention.

[0061] **FIG. 39** is a sectional view similar to **FIG. 38**, illustrating a later stage of the procedure in accordance with the invention.

[0062] **FIG. 40** is a sectional view of component apparatus similar to that illustrated in **FIG. 18**, according to still another embodiment, in accordance with the invention.

[0063] **FIG. 41** is a perspective view of the component apparatus of **FIG. 40** in another configuration, in accordance with the invention.

[0064] **FIG. 42** is a sectional view similar to **FIG. 22**, illustrating the component apparatus of FIGS. **40-41** in an early stage of the procedure in accordance with the invention.

[0065] **FIG. 43** is a sectional view similar to **FIG. 42**, illustrating a later stage of the procedure in accordance with the invention.

## DETAILED DESCRIPTION OF THE DRAWINGS

[0066] Although the invention has other possible uses, the invention will be fully understood from the following explanation of its use in providing a bypass around an obstruction in a patient's vascular system.

[0067] **FIG. 1** illustrates the apparatus **100** in accordance with the invention, which is illustrated along with a connector structure **200**, and a first conduit **10**, which is typically a graft conduit and may be a natural conduit, such as a saphenous vein graft (SVG) or similar, or an artificial conduit. Apparatus **100** comprises a number of component

elements for delivery and deploying the connector apparatus **200** and the first conduit **10** to the operative site to make an anastomotic connection between first conduit **10** and a second conduit, which is typically a patient's natural body conduit (see, e.g., **FIG. 21**). An apparatus for deploying the connector structure **200**, such as balloon catheter **300**, is useful for enlarging the connector structure **200** to join the two conduits. A nosecone apparatus **400** is useful to assist insertion of apparatus **100** into an aperture in the second conduit and to shield the connector structure **200** from damaging the second conduit during such insertion into the second conduit. A location ring **500** is positioned about an aperture **12** in the first conduit **10** and about the connector structure **200**. The location ring **500** may be helpful to indicate the position of the first conduit **10** and the connector structure **200** during the anastomosis procedure.

[**0068**] Apparatus **100** and connector structure **200** are particularly useful in making a side-to-side anastomosis between the first and second conduits. This procedure accommodates the connector structure **200** to different sizes of conduits, provides an anastomosis size approximately equivalent to the second conduit diameter, and provides an optimal takeoff angle for the first conduit to prevent kinking. Apparatus **100** and connector structure **200** are also useful in making an end-to-side anastomosis.

[**0069**] **FIG. 1** illustrates that the aperture **12** has been made in the first conduit **10** adjacent to the distal end portion **14** of the first conduit **10**. This configuration, as will be described in greater detail below, permits a side-to-side anastomotic connection to be made with the second conduit. More particularly, a fluid tight connection is made through the side wall of first conduit **10** and through the side wall of the second conduit. Moreover, the apparatus **100** may be inserted through the end portion **14**, such that the opposite end portion of first conduit **10** (not shown) is free. This configuration allows the side-to-side anastomosis to be made after a first anastomosis, e.g., at the aorta of the patient. Alternatively, the apparatus **10** may be used to make an end-to-side anastomosis, when the end portion **14** of the first conduit **10** is attached to the connector structure **200**, and which is described in greater detail herein with respect to **FIG. 30**.

## Connector Structure

[**0070**] **FIGS. 2 and 3** illustrate an embodiment of the connector structure **200**. **FIG. 2** shows a planar development of what is actually an integral, one-piece (unitary), annular structure. (Additional features of the connector structure and apparatus for applying the connectors are disclosed in Berg et al. published PCT patent application WO 99/38454; Swanson et al. U.S. Pat. No. 6,113,612; and Grudem et al. published PCT patent application WO 00/53104, each of which is incorporated by reference in their entirety herein.) In particular, the left and right edges of the structure shown in **FIG. 2** are actually joined to and integral with one another. Thus, the actual structure is as shown in **FIG. 3**, although **FIG. 2** is useful to more clearly reveal the details of various features of the structure.

[**0071**] An illustrative material for connector structure **200** is **316** stainless steel. Other examples of suitable materials include tantalum, tungsten, platinum, other steels, and nitinol. Connector structure **200** may be advantageously produced by starting with a single, unitary metal tube, such as a hypotube, and removing selected material until only the structure shown in **FIG. 3** remains. For example, laser cutting may be used to remove material from the starting tube in order to produce connector structure **200**. Although connector structures **200** can be made in various sizes for various uses, a typical connector structure has an inner diameter in the range from about 0.025 to about 0.100 inches. For example, an embodiment may have an initial inside diameter of about 0.042 inches, an outside diameter of about 0.05 inches, a material thickness of about 0.004 inches, and an initial length of about 0.075 to about 0.085 inches.

[**0072**] Connector structure **200** may be described as including axially spaced first and second cell portions **202** and **204**, respectively. According to one embodiment, the connector structure **200** comprises six repeating first cell portions **202** and six repeating second cell portions **204**. The connector structure **200** may have fewer or more than six each of first cell portions **202** and second cell portions **204**, depending on the diameter of the tube used to manufacture the connector structure **200** and the resulting enlarged diameter desired. Alternatively, the connector structure **200** may have different configurations of cells and geometries.

[**0073**] The width **210** of the members which make up the first and second cell portions **202** and **204** is typically in the range of about 0.003 to about 0.0035 inches. The dimensions **212**, **214**, and **216** are each about 0.021 inches in the preferred embodiment. The segment of the connector structure associated with dimension **212** defines a distal portion **206** of the connector structure **200**. The segment associated with dimension **214** defines a medial portion **207**, and the segment associated with dimension **216** defines a proximal portion **208**. These dimensions **212**/**214**/**216** may be varied from these examples to suit the dimensions of the conduit and the aperture of the proposed anastomosis.

[**0074**] First cell portion **202** includes annularly spaced, but adjacent, longitudinal members **230***a* and **230***b*. The ends of these members are connected to one another at **232***a*, **234***b*, and **236***b*. Annularly adjacent ones of these cells are connected to one another at **234***b*. As will be described below, annular expansion of cells **202** permits annular enlargement of connector structure **200**. A pair of members **230***a*, along with the portion **232***a* joining adjacent members **230***a* together, may comprise one of a second plurality of fingers **233** for engaging the second conduit **20**, as will be described herein. The embodiment shown in FIGS. **2-5** are illustrated with six of the second plurality of fingers **233**, for example.

[**0075**] Some of the first cell portions **202** may include an annularly spaced distal member **218** that in this case has a free end portion **220**, that is sharply pointed and that points toward proximal portion **208**. Member **218** may be about 0.004 to about 0.020 inches in length for thin-walled conduits. The dimensions may be altered according to the thickness of the conduits to be joined. Each of members **218** is deflectable radially outwardly from the remainder of connector structure **200** as shown, for example, in **FIG. 3**. Distal members **218** may be deflected radially outward or angled backward towards the proximal end portion **208** of the connector structure **200**. This outward deflection is preferably at least partly plastic.

[0076] First cell portion **202** may also include an annularly spaced proximal member **222** that in this case has a free end portion **224** that is sharply pointed and that points toward distal portion **206**. Proximal members **222** are about 0.008 to about 0.120 inches in length, wherein a length of about 0.030 inches is preferable for the aorta. Each of proximal members **222** is deflectable radially out from the remainder of connector structure **200** as shown, for example, in **FIG. 3**. Again, this outward deflection is preferably at least partly plastic.

[0077] The above-mentioned outward deflection of distal members **218** and proximal members **222** may be produced by putting the connector structure on a mandrel and prying members **218** and **222** radially outward. Following deflection of members **218** and **222**, an initial axial spacing **250** of about 0.050 inches is defined therebetween. This dimension is appropriate for thin-walled vessels. The dimension may be changed depending on the thickness of the first and second conduits to be joined.

[0078] Second cell portions **204** may include annularly adjacent longitudinal members **230***b*, and **230***c*, the axially spaced ends of which are connected at **234***b*, **236***b*, and **238***c*. (It should be noted that members **230***b* are in common with cells **202** and **204**.) Annularly adjacent cells of this kind are connected to one another at locations like **236***b*. As will be described below, annular expansion of second cell portions **204** permits annular enlargement of connector structure **200**. A pair of members **230***c*, along with the portion **238***c* joining adjacent members **230***c* together, may comprise one of a first plurality of fingers **235** for engaging the first conduit **10**. The embodiment shown in FIGS. **2-5** are illustrated with six of the first plurality of fingers **235**, for example.

[0079] The connector structure **200** is preferably annealed. The connector structure **200** may also be used in the full hard or partially hard state. The connector structure **200** will also typically require other processing appropriate for an implantable device such as, for example, polishing, passivation, and cleaning.

[0080] **FIGS. 4 and 5** illustrate the enlarged condition of connector structure **200**. A design consideration for connector structure **200** is that its enlarged diameter should be similar to the inner diameter of the smaller of the two conduits being joined. Connector structure **200** 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 structure, such as balloon catheter **300**, as will be described in greater detail herein). An embodiment of the connector structure **200**, enlarged with a balloon of 3.5 mm in diameter, will typically enlarge to an internal diameter of about 0.115 inches if unconstrained and to about 0.09 to about 0.11 inches when connecting two conduits, such as an SVG and a coronary artery. (Such difference is due to the constricting effect of the conduits, as will be described in greater detail herein.)

[0081] A planar development of the annularly enlarged condition of connector structure **200** is shown in **FIG. 4**. The annular enlargeability of connector structure **200** is provided by annularly expanding cell portions, such as first and second cell portions, described above. In this way connector structure **200** is annularly enlargeable by annularly enlarging each of the above-mentioned first cell portions **202**. In addition to the cells that are described above, connector structure **200** includes other, similarly annularly expandable cell portions **204** that are axially and annularly offset from the first-described cell portions **202**. Thus again the connector structure **200** is annularly enlargeable by annularly enlarging these cell portions **204**.

[0082] It will be appreciated that as connector structure **200** annularly enlarges, it generally axially shortens. In other words, as cell portions **202** and **204** widen in the annular direction, they shorten in the axial direction. As the connector structure **200** is enlarged in position to join the two conduits together, it is desirable for the distal portions **206** and the proximal portions **208** to deflect radially outward to greater diameter (distal diameter **240** and proximal diameter **242**, respectively) than the medial diameter **244** associated with the medial portion **207**. (See, e.g., **FIGS. 5 and 12**.) The overall annular enlargement of connector structure **200** along with the relatively greater enlargement of distal portion **206** and proximal portion **208** together decrease the axial spacing between cell portions **202** and **204**, and more particularly decrease the axial spacing between distal members **218**, and proximal members **224** to a reduced axial spacing **250** (**FIG. 5**). The approximation of members **218** and **222** also helps to draw the edges of the two conduits together to create a good seal therebetween (See, FIGS. **24-25**).

[0083] Another embodiment of the connector structure is connector structure **270**, which is illustrated in FIGS. **6-7**. Connector structure **270** is substantially identical to connector **200**, with the differences noted herein. As shown in **FIG. 6, a** plurality of spacer members **272** are added between pairs of members **230***a* and pairs of members **230***b*. Each spacer member **272** is an integral portion of connector structure **270**, and it may have a length of about 0.010 inches. The spacer members **272** extend the dimension **214'** associated with the medial portion **207'** of the connector structure **270**.

[0084] The spacer members **272** extend the overall length of the connector structure **270**, without substantially changing the diameters of the enlarged connector structure. This is helpful where the thickness of the vessel walls increases, but the anastomosis diameter remains constant. More particularly, when the connector **270** is enlarged, the end portions **206** and **208** are deflected to diameters **240** and **242**, respectively, which is substantially the same extent as for a connector **200** not having a spacer member. In addition, the diameter **244** associated with the medial portion **207'** remains substantially constant as well. However, the axial distance **250** between members **218** and **222** is increased, preferably to accommodate an increased thickness of the conduit walls.

[0085] Another embodiment of connector structure is contemplated which is substantially identical to connector structure **200** described above, with the following distinctions. This connector structure also has a third set of members located between members **218** and **222** described above. The third set of members are located on the connector structure distal to the point of the connector structure's minimum enlarged diameter, as described above. The third set of members are used such that the perimeter of the hole made in the first conduit is pressed down against them. This configuration assists in drawing the perimeter of the hole in the first conduit through and into the hole in the second

conduit before the connector structure is enlarged. The embodiment of the connector structure with three sets of prongs is useful for either a side-to-side anastomosis or an end-to-side anastomosis.

[**0086**] A typical use of connector structure **200** is in a coronary artery bypass procedure, to provide an anastomosis between an aperture in a first conduit, such as a tubular graft conduit, and an aperture in a side wall of a second conduit, such as a coronary artery.

Balloon Catheter

[**0087**] A balloon catheter **300** in accordance with the invention is illustrated in **FIG. 8**. The balloon catheter **300** may be comprised of the balloon **302**, an outer tubular shaft **304**, an inner tubular shaft **306**, and a hub **308**. The hub **308** has a port **310** which allows access to the lumen **312** of the inner tubular shaft **306**, and another port **314** which allows access to the lumen **316** defined between the inner tubular shaft **306** and the outer tubular shaft **304**. The lumen **316** is in communication with the interior of the balloon **302** and introduces fluid to inflate the balloon **302**. The balloon **302** may comprise a substantially constant diameter barrel portion **318**, a tapered distal portion **320**, and a tapered proximal portion **322**.

[**0088**] A balloon catheter **30** known in the art is shown in **FIG. 9**, and may include a balloon **32** and a tubular structure **34**. A port **36** is typically defined in the tubular structure **34** to supply the fluid to the balloon **32**. The balloon **32** may include a constant diameter barrel portion **38**, a distal tapered portion **40**, and a proximal tapered portion **42**. The tapered portions **40** and **42** are attached to the tubular structure **34** in an "un-inverted manner." The term "un-inverted," as used herein, shall refer to the condition of an end portion of the balloon which gradually tapers from one axial end to another. For example, the tapered portions **40** and **42** of balloon **32** are mounted to the tubular shaft **34** in an un-inverted manner, i.e., the tapered portions **40** and **42** gradually are reduced in size from the barrel portion **38** to the end portions attached to the tubular shaft. Similarly, the proximal end portion **322** of balloon **302** (as shown in **FIG. 8**) is un-inverted. A characteristic of the un-inverted configuration is that the portion of the balloon having the largest diameter is typically a proportionally long distance from the attachment point of the balloon.

[**0089**] Conversely, the term "inverted" shall refer to the condition of the balloon wherein an inflated portion of the balloon extends beyond the distal bond **352**. Thus, the tapered portion of the balloon does not taper gradually, but may "double-back" on itself. With continued reference to **FIG. 8**, the distal portion **320** of the balloon **302** may be attached to the inner tubular shaft **306** in an inverted manner. An advantage of an inverted configuration is that the distalmost portion of the balloon **302** may achieve a relatively large diameter at a shorter distance from the distal end portion of the balloon. As will be described in greater detail herein, the inverted attachment configuration of distal tapered portion **320** permits the connector structure **200** to be positioned close to the distal end portion of the balloon **302**, and still be sufficiently enlarged by the balloon **302** when the balloon **302** is expanded to install the connector structure **200**.

[**0090**] The connector structure **200** may be placed annularly about the balloon **302** of balloon catheter **300**, as illustrated in **FIGS. 10 and 11**. The connector structure **200** is typically installed when balloon **302** is disposed in its unexpanded configuration. As illustrated in **FIG. 11**, the unexpanded configuration of balloon **302** may define a plurality of folded portions **330** that are expanded upon introduction of fluid into the balloon **302**.

[**0091**] With continued reference to **FIG. 10**, the connector structure **200** is oriented such that distal members **218** are positioned adjacent to the distal end portion of the balloon **302**. As will be described in greater detail herein, the design of balloon **302** allows the connector structure **200** to be positioned as close as possible to the distal end portion of the balloon **302**. Certain features may be useful to hold the connector structure **200** in place on the balloon **302**. Particularly when the connector is mounted adjacent the distal end of the balloon **302** as described above, it is important to prevent the connector from slipping forward, where it may not be enlarged as fully as desired because it is positioned over a smaller diameter region of the balloon **302**. In one embodiment, the connector structure **200** is mounted over the balloon **302**, which is "pre-inflated," or inflated to a low pressure to hold the balloon **302** in place without enlarging the connector structure **200**. According to another embodiment, a larger diameter may be heat set in the balloon **302** just distal of the distal portion of the connector structure **200** to prevent the connector from sliding forward. According to yet another embodiment, the balloon **302** may be covered with a material having a high coefficient of friction to create higher frictional forces between the balloon and the connector. A material such as, for example, urethane in the 30D-60D durometer range may be useful for this purpose. This material may be provided with a separate sleeve or with a co-extrusion of the softer material and the base balloon material at the time of extruding the balloon blank. According to yet another embodiment, nosecone **400** (described in greater detail herein) may be positioned distal to the connector structure **200** to hold the connector structure **200** in position on the balloon **302** at least until the nosecone **400** is deployed to permit connector enlargement.

[**0092**] As illustrated in **FIG. 12**, there are several design considerations with regard to the construction of the balloon **302**.

[**0093**] First, the configuration of the balloon **302** should allow the distal end of the connector structure **200** (approximately adjacent the free end portion **220** of member **218**) to be positioned at a reduced distance **340** from the distal end of the balloon **302**. Distance **340** is advantageously as small as possible because the anastomosis is made by inserting the distal end of the balloon **302** and the connector structure **200** into an aperture in the second conduit to be joined. More particularly, this distance **340** should fit within the conduit to be joined when the delivery apparatus **100** is at 90 degrees with respect to the conduit prior to deploying the connector structure **200** (see, **FIG. 23**). Therefore, the balloon **302** should be designed to avoid contacting the opposite inner wall of the second conduit, or dilating the inner lumen of the second conduit.

[**0094**] Second, the balloon **302** should expand sufficiently at distance **340** in order to adequately enlarge the connector structure **200**. Consequently, the balloon **302** must achieve a minimum required dimension **342** (radius of the balloon **302** is shown in **FIG. 12**) which is sufficient to enlarge the

connector structure **200** to the required dimension. Moreover, since the end portions **206** and **208** of the connector are designed to expand to a greater extent than the medial portion **207**, balloon **302** should be designed to expand to a dimension larger than the enlarged dimension of the connector structure.

[**0095**] Third, the balloon **302** should be configured to expand to a dimension at least as large as the diameter of the lumen of the second connector to be joined.

[**0096**] To meet these design objectives, the balloon **302** is configured to expand to a minimum required dimension **342** as close to the distal end of the balloon **302** as possible. In other words, balloon **302** is designed to achieve a substantially large diameter adjacent the distal end portion. This configuration may be achieved by maintaining the inverted configuration of balloon **302** and by minimizing the average radius of curvature **344** of the distal end portion of the balloon. As the radius of curvature **344** decreases, the distance **346** from the distal end of the balloon **302** to minimum required dimension **342** also decreases.

[**0097**] With reference to **FIGS. 8 and 12**, several features of the balloon catheter **300** are helpful to maintain the inverted configuration and to minimize the radius of curvature **344**. First, the balloon catheter **300** may be designed to prevent relative movement between tubular shafts **304** and **306**. This feature may help to prevent the distal end portion **320** of the balloon **302** from un-inverting when the balloon **302** is pressurized. If the distal end **320** of the balloon **302** is permitted to become partially un-inverted, the distance **346** from the end of the balloon **302** to the minimum required dimension **342** may increase. For example, the proximal balloon bond **350** may also provide an attachment of the inner tubular shaft **306** to the outer tubular shaft **304**. This bond may be an adhesive bond, a thermal weld, or by using a single extrusion having several lumens instead of the inner tubular shaft **304** and outer tubular shaft **306**. (It is understood that the connection of inner tubular shaft **306** to outer tubular shaft **304** permits fluid flow into balloon **302** and does not completely block lumen **316**.)

[**0098**] Another feature which may maintain the inverted configuration and reduce the radius of curvature **344** of the balloon **302** is the strength of the inner tubular shaft **306** which resists elongation when under tension generated by the inflation of the balloon **302**. Elongation of the inner tubular shaft **306** may also allow the distal portion **320** of the balloon **302** to partially un-invert. Therefore, the portion of the inner tubular shaft **306** between the location **350** where the inner tubular shaft **306** and the outer tubular shaft **304** are bonded together and the distal balloon bond **352** should have relatively high tensile strength. According to a preferred embodiment, this may be accomplished by using a polymer encased stainless steel braid tubing for the inner tubular member **306**. This tubing may have a PTFE inner layer for lubricity for introducing additional apparatus, such as nosecone **400**, as will be described in greater detail herein; a stainless steel middle layer; and a nylon outer layer which is bonded to the balloon **302** and the outer tubular shaft **304**. Alternative configurations for achieving adequate tensile strength and stiffness for this segment of the inner tubular shaft **306** may include reinforcing the tubing with straight wires, sheathing this region with a stiffer tubing material, or by using thicker wall dimensions or stiffer materials.

[**0099**] A further feature which may maintain the inverted configuration and reduce the radius of curvature **344** of the balloon **302** concerns which portions of the balloon **302** are inverted. The balloon configuration may include inversion of the distal tapered portion **320** of the balloon **302** as well as inversion of a portion of the constant diameter barrel **318**. Typically, inverting only the distal tapered portion **320** of the balloon **302** may result in a larger radius of curvature **344** than inverting the distal tapered portion **320** along with a portion of the constant diameter barrel **318**.

[**0100**] Yet another feature that maintains the inverted configuration and a reduced radius of curvature **344** of the balloon **302** is providing resistance to bending of the balloon **302**. If the balloon **302** is permitted to bend, this may increase the radius of curvature **344** of the balloon **302** as well. Resistance to bending may be promoted by providing uniform wall thickness of the balloon **302** and by providing resistance against balloon elongation. Providing uniform wall thickness is largely a function of providing uniform wall thickness in the extruded balloon blanks. Other procedures known in the art promote uniform wall thickness. For example, balloon elongation may be minimized by reducing the overall length of the balloon and by forming the balloon from relatively inelastic, highly oriented materials. In a preferred embodiment, the balloon **302** may have a length of about 0.5 to about 1 cm. The balloon **302** may be manufactured from a material, such as for example, a polyamide, such as Nylon 12. Other preferred materials may include PET, polyamide copolymers, polyimide, or other materials known in the art.

[**0101**] In use, the balloon may be subject to stresses, such as longitudinal forces during insertion into the opening in the second conduit. As a result of these stresses, the balloon **302** may "roll," or shift proximally with respect to tubular shafts **304** and **306**. This proximal rolling may cause the distal end portion of the balloon **302** to become partially un-inverted. Another feature may be provided to inhibit the expanded balloon **302** from rolling. As illustrated in **FIG. 8**, an outer sleeve **376** may be positioned about the periphery of the proximal end portion **322** of the balloon **302**, and spaced apart from the proximal bond **350**. The outer sleeve **376** provides additional stability to the balloon against rolling, by contacting the proximal portion **322** and maintaining the inverted configuration illustrated in **FIG. 8**.

[**0102**] The combination of any or all of these design features are useful in providing a balloon structure having a preferred distance **340** of 2.0 mm or less (**FIG. 12**). This reduced distance **340** is very valuable when the balloon **302** is to be used to enlarge a connector structure **200** in conduits smaller than 4 mm. For distances **340** greater than about 2 mm, then the connector structure **200** may be mounted on a portion of the balloon that is tapered distally (i.e., it is in a portion that has yet reached the minimum required dimension **342**) or the connector structure **200** may not be seated properly with respect to the conduit, if the tip of the balloon **302** is in contact with the back wall of the second conduit when the system is rotated to its perpendicular configuration.

[**0103**] In addition to minimizing the elongation of the balloon, there are yet other design factors which are important in selecting the balloon material. One factor is the pressure requirements of the balloon. To properly enlarge

the connector, the balloon should be able to withstand a balloon inflation pressure of about 18 atmospheres for a 3.5 mm diameter balloon. Another factor is the ability to produce a predictable diameter when inflated to high pressures. The same materials described above which have low elongation as balloons are useful to meet the high pressure requirements and also have a predictable diameter at high pressure.

[**0104**] In order to create the greater deflection of the ends of the connector structure **200** as described above with respect to **FIG. 12, a** balloon **302** having a diameter larger than the connector structure **200** may be used to enlarge the connector structure. The size of the balloon **302** in its expanded state and the required pressure of the balloon to enlarge the connector structure along with the conduit are related. For example, a connector structure being enlarged by a balloon **302** which is 0.5 mm larger than the connector structure's enlarged diameter may require 18 atm of pressure to reach full enlargement, while a balloon having a diameter 1 mm larger than the connector's enlarged diameter may require 14 atm of pressure to reach full enlargement. The design of the connector, when positioned around the balloon, may affect the expansion characteristics of the balloon.

[**0105**] As described above, several design considerations with respect to the balloon and connector sizing are (1) the configuration of the balloon should allow the connector to be placed close to the distal end of the balloon so that the balloon does not dilate the inner lumen of the second conduit; (2) the diameter of the expanded balloon should be larger than the enlarged diameter of the connector to allow the end portions to enlarge to a greater degree than the medial portion; and (3) the diameter of the enlarged connector should be similar to the diameter of the smaller of the two conduits. An additional design consideration is that the diameter of the expanded balloon should be smaller than the inner diameter of the first conduit to avoid dilating the first conduit. Taking these design considerations into account, it is desirable to use a balloon with an expanded diameter that is about 0.5 mm to about 1.25 mm larger than the enlarged diameter of the connector. If the connector is mounted adjacent the distal end portion of the balloons constant diameter barrel portion **318**, and the expanded diameter of the balloon **302** is 0.5 mm or more greater than the diameter of the expanded connector, then the connector structure **200** may constrain the expansion of the balloon distal to the connector by anywhere from 0.25 mm to about 0.5 mm depending on how close to the end of the barrel portion **318** the connector structure **200** is located. This is illustrated by the difference in the unconstrained diameter of balloon **302** (**FIG. 8**) and the constrained diameter (**FIG. 12**). This constraint of balloon **302** by connector **200** is useful to reduce the diameter of the balloon **302** inside the second conduit thereby reducing the risk of dilating the second conduit with the balloon while simultaneously expanding the connector.

[**0106**] Continuing with the present example, the connector may be mounted 1.5 mm from the end of a 3.5 mm balloon wrapped (as illustrated in **FIG. 11**) to a profile of 0.038. This system is useful to join a larger first conduit **10** to a smaller second conduit of about 2.5 mm in diameter with a resulting anastomosis diameter of 2.25 mm to about 2.5 mm. When the balloon **302** is pressurized to deploy this connector structure **200**, the portion of the balloon extending beyond the connector will typically have a diameter of about 3.0 mm and a length of about 1.5 mm. In this case, the short length of the distal end portion of the balloon allows it to be inflated inside the 2.5 mm conduit, such that the conduit takes on an oval shape over the 3.0 mm by 1.5 mm balloon portion without being dilated or stretched by it.

[**0107**] As will be described herein, the system is introduced in a substantially axial direction into the second conduit (see, **FIG. 21**), and subsequently rotated to a radial direction with respect to the second conduit (see, **FIG. 23**). For this type of installation, the diameter of the connector structure **200** and the distance from the distal members **218** to the end of the balloon should both be shorter than the diameter of the second conduit. The distal members **218** are less likely to snag the back wall of the second conduit if the diameter of the connector structure at the distal members **218** is at least 0.01 inches smaller than the diameter of the pressurized second conduit. The diameter of the connector structure at the distal members **218** depends, in part, on the length of the distal members **218** and on the diameter of the balloon **302** under the connector. The length of the distal members **218** necessary to have them engage the tissue of the second conduit results in them adding about 0.5 mm to the diameter of the balloon distal end. Consequently, the wrapped balloon **302** may have a diameter at least 0.5 mm less than the inner diameter of the second conduit, and preferably 1-1.5 mm less. The distal members **218** are also less likely to be pushed out of the aperture **22** in the second conduit when the system is rotated to an orientation perpendicular to the second conduit if the distance from the distal members **218** to the distal end portion of the balloon **302** is less than the diameter of the second conduit.

[**0108**] It is contemplated that the balloon **302** may be configured for removal and reattachment with respect to the shaft portion **304/306** (see, **FIG. 8**). According to one embodiment, the catheter shafts **304** may include a junction **370** in a region just proximal to the balloon **302** which would allow the shaft portions proximal to the junction **370** and the shaft portions distal to the junction **370** to be separated and reconnected, repeatedly, as required. Similarly, the catheter shaft **306** may include a junction **372** in a region just proximal to the balloon **302** which would allow the shaft portions proximal to the junction **372** and the shaft portions distal to the junction **372** to be separated and reconnected. These junctions **370/372** may be achieved by a pair of luer fittings to connect the two lumens **312** and **316** of the shafts **304/306**. A benefit of this construction when providing an anastomosis between a first and second conduit is to reduce the size and weight of the apparatus attached to the first conduit prior to performing the connection to the second conduit. This arrangement may be beneficial in cases where a connector is being used on each end of a conduit so that the connection apparatus for use at the first end is not in the way of the connection apparatus at the second end while the anastomosis at the first end is being made. This arrangement may also be beneficial in loading the first conduit onto the connector structure.

## The Nosecone Assembly

[**0109**] The nosecone assembly **400** is illustrated in FIGS. **13-14**, and may comprise an elongated tubular shaft **402**, a nosecone balloon **404**, and an indicator wire **406**. The tubular shaft **402** may be made of nitinol, a composite braid

tubing, a metal hypotube (e.g., steel), or of a polymer extrusion such as nylon. According to one embodiment, the tubular shaft **402** has an outer diameter of approximately 0.014 inches and an inner diameter of approximately 0.010 inches. The nosecone balloon **404** may be fabricated of a number of materials such as, e.g., polyethylene, polyolefin copolymers, ethylene vinyl acetate, urethane, or other materials suitable for manufacturing an inflatable balloon. It is preferable that a relatively soft material be used (such as those described above) for the requirements of the application described herein. The nosecone balloon **404** may comprise a distal tapered portion **408** and a proximal portion **410**. The proximal portion **410** may be attached to the tubular shaft **402**. The internal cavities of the distal tapered portion **408**, the proximal portion **410**, and the lumen **412** of the tubular shaft **402** are preferably in fluid communication. An indicator wire **406** is attached to the distal tip **414** of the nosecone balloon **404**, and extends proximally through the tubular shaft **402**. In a preferred embodiment, the wire **406** is set in place by means of an adhesive **407**. The nosecone assembly **400** is flexible, and capable of bending to an angle of about 100 degrees or more with respect to the longitudinal axis thereof (see, e.g., **FIG. 23**).

[**0110**] The nosecone balloon **404** is illustrated in its "introduction configuration" or folded configuration in **FIG. 14**. **FIG. 13** illustrates the nosecone balloon **404** in its "removal configuration" or unfolded configuration. In the introduction configuration, the proximal portion **410** is folded back in a concave manner, and defines an annular recess **420** for receiving the connector structure **200** or the like, as will be described in greater detail herein. Expanding the nosecone balloon **404** is typically achieved by introducing fluid into the nosecone balloon **404** from the tubular shaft **402**, thereby changing the configuration of the nosecone balloon **404** from the introduction configuration to the removal configuration, i.e., from the folded configuration of proximal portion **410** depicted in **FIG. 14** to the unfolded condition depicted in **FIG. 13**. When the balloon moves from the introduction configuration of **FIG. 14** to the removal configuration of **FIG. 13**, the nosecone balloon **404** defines a smaller outer dimension. and smooth proximal surface to facilitate removal of the nosecone balloon **404** from the second conduit and the connector structure **200**, as will be described in greater detail herein.

[**0111**] The indicator wire **406** moves within the tubular shaft **402** with the distal tip portion **414**. Consequently, a proximal length of the indicator wire **406** may extend out of the shaft a short length **406***a* when the nosecone balloon **404** is folded (**FIG. 14**). When the nosecone balloon **404** is expanded (unfolded), distal tip **414** and the distal tapered portion **408** advance distally with respect to the tubular shaft **402** (see also, FIGS. **21-22**). When the distal tip portion **414** advances distally, the proximal length **406***a* of wire **406** is drawn into the tubular shaft **402** (**FIG. 13**). In this manner, the indicator wire **406** provides a visual indication that the nosecone balloon **404** has unfolded. During the distal advancement of distal tapered portion **408**, the tubular shaft **402** remains stationary. Alternatively, the nosecone could be advanced mechanically, e.g., by advancing a substantially rigid indicator wire. According to another embodiment, the nosecone assembly may be manufactured without an indicator wire.

[**0112**] The dimensions of the nosecone balloon **414**, i.e., the diameter and length, are selected in order to cover the distal members **218** of the connector structure **200** during introduction of the apparatus into the second conduit.

[**0113**] While filled with expansion fluid in the unfolded condition of **FIG. 13**, the nosecone balloon **404** may define a degree of rigidity. Typically, the rigidity is proportional to the pressure of the expansion fluid; the balloon **404** becomes more flexible as more fluid is drained from the balloon **404**.

[**0114**] The tubular shaft **402** is configured to be axially received in the lumen **312** of balloon catheter **300**. **FIG. 1** illustrates the nosecone assembly **400** positioned with respect to balloon catheter **300**. The nosecone balloon **404** is folded about the expansion balloon **302** and the connector structure **200**. In the folded condition, the distal members **218** of the connector structure **200** are covered, so that the periphery of the aperture in the second conduit does not snag on these members as the connector is inserted into this aperture, as will be described in greater detail herein.

[**0115**] According to another embodiment of the invention, the nosecone balloon **404** may be substituted by a solid cap, which covers the distal members during insertion into the aperture of the second conduit. Additional details of the nosecone structure are described in Swanson et al. U.S. Pat. No. 6,113,612, incorporated by reference in its entirety herein. Additional embodiments of the nosecone assembly are described herein with respect to FIGS. **31-43**.

[**0116**] The first conduit **10** is subsequently mounted to the connector structure **200** about an aperture **12** made in the first conduit **10**. The first conduit **10** 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).

[**0117**] An opening **12** may be made in the first conduit **10** at a location spaced from the end portion **14** of the conduit **10**. The size of the opening **12** in the first conduit **10** is an important consideration. (It is understood that the description concerning opening **12** is applicable to the opening **22** in second conduit **20**.) If the opening is too large, then a satisfactory hemodynamic seal may not be created between the two conduits. Conversely, if the opening is too small, one or more of the following undesirable effects may occur: the conduit wall may tear excessively when the connector **200** is enlarged, or the conduit may constrict enlargement of the connector. (When making the opening in the second conduit, the opening may not permit the nosecone **400** to be inserted therethrough if it is too small.) Which of these above effects occurs is determined in part by tissue quality, the dimensions of the apparatus being used, and the inflation pressure of the balloon.

[**0118**] The opening in the conduit should preferably be sized such that enlargement of the connector structure **200** does not cause significant additional tearing of the wall to expand the periphery of the opening. Rather, it is generally desirable that the expansion of the opening to accommodate

the enlarged connector is achieved within the elastic expansion range of the conduit wall. The elastic expansion is important since the distal members **218** engage the conduit wall as the connector structure expands. If the conduit wall tears a significant amount, e.g., at the locations of engagement with the distal members **218** (rather than elastically expanding), it is possible that the desired tension created in the wall between the distal members **218** would be relieved, which may prevent the creation of a seal between the conduits being joined. As an example, the diameter of the aperture in the conduit should be between about 0.25 to about 1.0 mm smaller than the expanded diameter of the connector. This will preferably allow the elasticity of the conduit tissue to assist in creating a seal between the conduits as they are stretched to the diameter of the expanded connector.

[**0119**] The openings in the conduits can be made by cutting, mechanical dilation, or by a combination of both. According to a preferred embodiment, the initial opening is made by cutting the conduit with a 20 gauge needle and then dilating the opening using a dilator between 2.0 and 2.5 mm to prepare an opening for a 2.25 mm connector. The size of the initial cut and the size of the dilator may be selected based upon the elastic characteristics of the conduits being used. In this case, the opening may recoil back to a range of about 1.5 to 2.0 mm after the dilator is withdrawn. An advantage of the cutting and dilating procedure is that the physician is able to effectively reduce the influence of the possible variations in conduit wall elasticity by dilating to a diameter similar to the connector size. Thus the amount of recoil, as a function of the elasticity of the conduit wall, is irrelevant to sizing the opening.

[**0120**] According to another embodiment, an initial opening is made by piercing the conduit with a 20 gauge needle, and then dilating the opening by inserting and then expanding a 2.0 to 2.5 mm balloon. This embodiment provides the advantage of applying uniform dilating force from both the inside and the outside of the conduit. The use of balloon expansion reduces the risk of dissecting the layers of the conduit since a minimum of radial force is applied. This is particularly helpful in the case of diseased conduits, where the inner layer is typically harder than the outer layer. The harder inner layer may resist the application of radial force more strongly than the outer layer, which may result in the inner layer peeling away from the outer layer. A balloon may minimize this undesirable effect since the balloon is first introduced into the initial opening with a reduced profile, and then is expanded. Due to the resistance of the conduit wall, the balloon tends to expand on both the inside and outside of the conduit, and counteracts any unbalanced radial force that might separate the layers of the conduit.

[**0121**] The opening in the conduit may also be created without a dilation step. This may be particularly useful where the conduit is diseased, and it is desired to reduce the risk of dissecting tissue layers. In the absence of a dilation step, the elasticity of the conduit wall may be reasonably estimated in order to cut an opening of the proper size to receive the connector therethrough. According to another embodiment, the opening in the conduit may be created by a cutting instrument. In this case, the deflated conduit is advanced a known distance into a scissors or semicircular cutter, and then the conduit is cut to yield a hole of known diameter and length.

[**0122**] According to yet another embodiment, a coring cutter apparatus may be used to core an opening of known diameter in the conduit wall. The coring apparatus is useful if the conduit is stretched over the end of a loading sheath, or can be used with a pressurized conduit, or with a vacuum port in the bore of the cutter to support the wall of the conduit to be cut.

Transfer Sheath

[**0123**] A transfer sheath **600** and rod **603**, illustrated in **FIG. 15**, may assist in the mounting of the first conduit **10** onto the apparatus **100**, without compromising the delicate intima of the first conduit **10**. The transfer sheath **600** and rod **603** may be fabricated from a low friction, biocompatible polymer such as, e.g., polyethylene or polytetrafluoroethylene, or similar material. The transfer sheath **600** may alternatively be made of metal, such as, e.g., stainless steel. The rod **603** may be rigid or expandable, as described below. The transfer sheath **600** may have an elongated body portion **602** with a distal end portion **601** and an internal lumen **606**. A rod **603**, having a tapered end portion **604**, is sized to be coaxially positioned within lumen **606** such that the tapered end **604** extends beyond the end of the lumen **606** of transfer sheath **600**. The tapered end portion **604** may be rigid or it may be configured to expand and contract. For example, the tapered end portion **604** may be configured to expand as large as the outer diameter of the transfer sheath **600** for a smooth transition from the tapered end portion **604** to the sheath body **602**, and then be configured to collapse to a smaller dimension to be retracted through internal lumen **606**. This allows the first conduit **10** to be loaded over the transfer sheath **600**, in the direction indicated by arrow A.

[**0124**] The transfer sheath **600** assists the physician by serving as a sizing instrument. The outer diameter of the body portion **602** is selected to accommodate the first conduit **10**, such as a graft, having a diameter which is compatible with the connector structure **200**. For example, a first conduit that is too narrow will not be able to receive the sheath **600** therethrough. Moreover, the internal diameter of the first conduit should be sufficiently large to allow for expansion of balloon **302** and connector structure **200** without dilating the first conduit **10** during such expansion. Therefore, body portion **602** of transfer sheath **600** has a diameter of about 3.5 mm, according to a preferred embodiment. The diameter of body portion **602** may be fabricated with a different diameter, and corresponding connector size, depending upon the specific clinical indication of the graft size and desired anastomosis size.

[**0125**] Once the first conduit **10** is harvested, it is positioned over transfer sheath **600**. As illustrated in **FIG. 16**, the distal end portion **14** of conduit **10** is positioned over the transfer sheath **600**. Entry through the distal end portion **14** allows the remainder of the conduit **10** to be free, which is useful, for example, when the proximal end of the first conduit **10** is to be attached to another vessel, such as the aorta of the patient. As illustrated in **FIG. 16**, the tapered end portion **604** of rod **603** extends distally from transfer sheath **600** to provide a smooth transition as transfer sheath **600** and rod **603** are advanced within the lumen of first conduit **10** in direction indicated by arrow B.

[**0126**] When the transfer sheath is positioned at the location **11** where opening **12** is to be made in first conduit **10**,

rod **603** is withdrawn proximally, while transfer sheath **600** remains in position. The wall of the first conduit **10** is held taut over the distal end **601** of the transfer sheath **600**. Opening **12** is made in the wall of first conduit **10**. This opening **12** can be created by a combined cutting and dilating procedure as described herein.

[**0127**] As illustrated in **FIG. 17**, the balloon catheter **300**, nosecone assembly **400**, and connector structure **200** are advanced through the internal lumen **606** of transfer sheath **600** to the opening **12**.

[**0128**] **FIG. 18** illustrates that nosecone assembly **400** is advanced until connector structure **200** partially protrudes through the opening **12**. Subsequently, the first conduit **10** is retained in position (e.g., with an atraumatic grasping instrument), and the sheath **600** is removed by passing the transfer sheath **600** coaxially over the balloon catheter **300**.

[**0129**] With continued reference to **FIG. 18**, the periphery of an opening **12** in first conduit **10** is placed about the connector structure **200**. More particularly, conduit **10** is positioned so that proximal members **222** penetrate and pass through the side wall of the graft conduit **10** (e.g., as a result of compressing the graft against the fingers by tool **440** such as the vein piercing tool described in Logan et al. U.S. patent application Ser. No. 09/587,112, filed Jun. 2, 2000, and incorporated by reference in its entirety herein, thereby forcing the fingers to pierce through the graft wall). The sharpened free ends **224** of members **222** facilitate penetration of conduit **10** by members **222**. The blunt rear surfaces of enlarged free end portions **224** resist withdrawal of members **222** from conduit **10** after members **222** have penetrated the conduit. The graft may be additionally or alternatively directly sutured to the connector body. If the alternative of suturing graft **10** to the connector structure **200** is used, then the second cell portion **204** of the connector may not need radially outwardly deflectable members **222** for engagement of the graft conduit. Alternatively, the first conduit **10** may be secured to the connector structure **200** with glues, clips, or other connector elements.

[**0130**] As an alternative to securing first conduit **10** to connector structure **200** after balloon catheter **300** has been associated with the connector, balloon catheter **300** may be installed in connector structure **200** after the first conduit **10** has been secured to the connector structure.

## The Locating Ring

[**0131**] A later step in preparing the first conduit **10** for anastomosis may be to place a locating ring **500** about the periphery of the opening, as illustrated in **FIG. 1**. Further details of the locating ring **500** are illustrated in FIGS. **19-20**. Locating ring **500** may be fabricated in a toroidal or serpentine ring configuration from silicone with high elastic strength. The locating ring **500** may also be provided with apertures **502** extending radially through the material for receiving proximal members **222** therein once the locating ring **500** has been placed about the periphery of the aperture **12** in the first conduit **10** as illustrated in **FIG. 1**. Use of the locating ring **500** is optional, and may be omitted from the procedure as determined by the physician.

[**0132**] The locating ring **500** provides benefits to the procedure in accordance with the invention. The locating ring **500** provides a visual indication of the edge of the aperture **12** of the first conduit **10**. This assists the physician when delivering the first conduit **10** to the anastomosis site, in order to properly align the apertures in the first and second conduits prior to deploying the connector. The locating ring **500** also provides some protection to the second conduit by shielding the tissue of the second conduit from the proximal members **222** when the apparatus is being introduced into the second conduit. In addition, the locating ring **500** provides an abutment surface or a stop to inhibit the proximal members **222** from being axially introduced into the second conduit when the tip of the balloon catheter **302** and the distal end of the connector structure **200** are being introduced in the second conduit.

[**0133**] Another embodiment of the locator ring is a structure which surrounds the periphery of the aperture in the first conduit **10** about the proximal members **222** as locator ring **500** described hereinabove, and is also removable from the first conduit **10** prior to completion of the procedure. This embodiment of the locator ring may have a clip structure (or "C"-shaped structure) having an opening in the circumference to allow removal from the conduit. According to another embodiment, the locator ring structure may be substituted with a plurality of individual components which may be attached one or more members **222**. According to yet another embodiment, the locator ring may be substituted by applying a color marking to the periphery of the aperture to provide a visual indication useful to the physician in aligning the first and second conduits.

## Operation of the Apparatus

[**0134**] FIGS. **21-24** illustrate a typical use of apparatus **100** to deliver first conduit **10** for connection to an aperture **22** in a side wall of second conduit **20**, typically the patient's tubular body conduit (e.g., a coronary artery requiring a bypass graft).

[**0135**] Aperture **22** is typically made in second conduit **20** in a manner described herein above with respect to making the aperture **12** in the first conduit **10**. The aperture **22** is typically made downstream from an occlusion or lesion **30** in the second conduit **20**. As illustrated in **FIG. 21**, the nosecone balloon **404** of nosecone assembly **400** may be gradually forced into the aperture **22** in a direction substantially coaxial with the lumen **24** of the second conduit **20**. As the nosecone balloon **404** passes through the aperture **22**, the annular space **420** defined by the inverted proximal tapered portion **410** may shield the distal members **218** from snagging on the tissue of the second conduit **20**. As long as nosecone balloon **404** remains in the introduction configuration, a distal portion **406***a* of indicator wire **406** may extend partially beyond the proximal end portion of tubular shaft **402**. Locating ring **500** may provide a visual indication that aperture **12** of first conduit **10** and aperture **22** of second conduit **20** are approximated. Locating ring **500** may also inhibit proximal members **222** from passing through the aperture **22** of second conduit **20**.

[**0136**] The physician may determine if the connector structure **200** has been properly positioned with respect to the apertures **12** and **22**. As shown in **FIG. 22**, the next step in the use of apparatus **100** may be to inflate nosecone balloon **404** by introducing fluid into tubular shaft **402** and balloon **404**. As the nosecone balloon **404** expands (i.e., moves from the introduction to the removal configuration),

the distal tip **414** moves distally into the lumen **24** of the second conduit **20**, and the proximal tapered portion **410** returns to an unfolded condition similar to that shown in **FIG. 19**. In the unfolded condition, the distal members **218** of connector structure **200** are exposed within the lumen **24** of the second conduit. The distal advancement of distal tip portion **414** also advances the indicator wire **406** into the tubular shaft **402**. The position of the indicator wire **406** with respect to the tubular shaft **402** thus provides a visual indication that the nosecone balloon **414** has successfully moved to the removal configuration.

[**0137**] A next step in the use of apparatus **100** is to drain the expansion fluid from the nosecone balloon **404**, as shown in **FIG. 23**. The nosecone balloon **404** is flexible, which allows the portion of the apparatus **100** comprising balloon catheter **300**, connector apparatus **200**, and a proximal portion of nosecone assembly **400** to be turned to a position at approximately a 90 degree angle with respect to the lumen **24** of the second conduit **20**. As described above, the axial distance **250** between the distal members **218** and the proximal members **222** when the connector structure **200** is in the unenlarged condition is sufficient to prevent the distal members **218** from being moved out of the aperture **22** of the second conduit **20** during rotation to the perpendicular orientation. As described hereinabove, the distance between the connector apparatus **200** and the distal end of the balloon **302** is minimized to prevent dilating the inner lumen **24** of the second conduit **20** when the balloon **302** is inflated.

[**0138**] A next step in the use of apparatus **100** is to inflate balloon **302** as shown in **FIG. 24**. In order to create the greater deflection of the ends of the connector structure **200** as described above with respect to **FIGS. 5 and 10**, balloon **302** has an inflated diameter larger than the connector structure **200** to enlarge the connector structure **200**. Inflation of balloon **302** causes the connector structure **200** to annularly enlarge by enlarging cells **202** (defined by members **230***a*/**230***b*) and **204** (defined by members **230***b*/**230***c*) in the annular direction. In addition, the proximal portion **208** and distal portion **206** of connector structure **200** are deflected radially outwardly beyond the medial portion **207** of connector structure **200**. These two actions, i.e., overall annular enlargement of connector structure **200** and relatively greater enlargement of portions **206** and **208**, decrease the axial spacing between portions **202** and **204**, and more particularly decreases the axial spacing **250** between distal members **218**, on the one hand, and proximal members **222**, on the other hand (**FIG. 5**). The free ends **220** of distal members **218** preferably penetrate the side wall of second conduit **20** to help ensure that first conduit **10** is securely attached to the second conduit **20** and remains open where it connects to second conduit **20**. Consequently members **218** and **222** are positioned to better engage the tissue of the conduits at the perimeter of the aperture **22** in the second conduit **20** being joined. The approximation of members **218** and **222** also helps to draw the edges of the two conduits together to create a good seal therebetween. With this connector structure, the seal between the conduits is typically a lap joint between the two sets of prongs, wherein the edge of the hole in one of the conduits sits under the edge of the hole in the other conduit as the connector structure is expanded; or alternatively a butt joint may be formed between the two vessels.

[**0139**] Assuming that the connector structure **200** is approximately properly positioned relative to the side wall of second conduit **20** prior to inflation of balloon **303**, the connector structure **200** is effectively self-centering on the second conduit side wall as the balloon **302** is inflated. Moreover, since the connector structure **200** is positioned adjacent the distal end portion of balloon **302**, it is possible to position the connector structure **200** about the wall of the second conduit **20** without dilating or damaging the opposite wall of the second conduit **200** with the balloon **302**.

[**0140**] A next step in the use of apparatus **100** is to deflate balloon **302** and withdraw all of the elements **300** and **400** (e.g., by pulling them proximally out of the first conduit **10**). Subsequently, the distal end portion **14** of the first conduit **10** may be tied off with a ligature **50**, to direct flow from the first conduit **10** into the second conduit **20**. This leaves the side wall of first conduit **10** connected to the side wall of second conduit **20** by enlarged connector structure **200** as shown in FIGS. **25-27**. In particular, in this example connector structure **200** provides a side-to-side anastomosis between a first conduit **10** and a second conduit **20**. Body fluid from first conduit **10** is able to flow into second conduit **20** via this connection. Connector **200** presses the aperture **12** through the side wall of the first conduit **10** radially outward against the aperture **22** through the side wall of second conduit **20** all the way around the apertures **12**/**22**, thereby preventing body fluid from leaking out of conduits **10** and **20**. Connector structure **200** also prevents first conduit **10** from pulling away from the side wall of second conduit **20**.

[**0141**] According to another embodiment of the invention, the apparatus described herein may be useful in connection with creating an anastomosis between two body conduits in-situ. As illustrated in **FIG. 28**, the physician may wish to form an anastomosis between first conduit **10** and second conduit **20**, wherein both conduits are relatively adjacent to one another, and it is not necessary to move either conduit a great distance to perform the anastomosis. Under these circumstances, the apparatus **100** may be introduced into first conduit **10**, in the manner described above with respect to FIGS. **16-18**. More particularly, transfer sheath **600** may be introduced percutaneously into the patient's vascular system and advanced to the anastomosis site, and an opening **12** is made at the anastomosis site. The nosecone assembly **400**, connector structure **200**, and balloon catheter **300** are subsequently introduced to the anastomosis site within the lumen of the transfer sheath **600**. Once the nosecone assembly **400** protrudes from the opening **12** in the first conduit **10**, the free ends **222** of connector structure **200** are secured about the periphery of opening **12**. A locating ring **500** may be used. An opening **22** is made in the second conduit **20** as described above. The anastomosis is performed substantially as described above with respect to FIGS. **21-25**.

[**0142**] According to another embodiment, the apparatus described herein may be useful for creating a series of anastomoses along the length of a single conduit or between two conduits. As illustrated in **FIG. 29**, the procedure described herein may be performed at a first anastomosis site **700**. After the connector structure **200** is deployed, the nosecone assembly **400** and the balloon catheter **300** are withdrawn; however, the first conduit **10** remains open and is not tied off as described above with respect to **FIG. 25**. According to this embodiment, a second connector structure **200**, along with the balloon catheter **300** and nosecone

assembly **400** are positioned within the first conduit **10** at a second anastomosis location **702**. The second anastomosis is performed substantially as described herein.

[**0143**] According to yet another embodiment, the apparatus described herein also be useful for making an end-to-side anastomosis. As illustrated in **FIG. 30**, the connector structure **200** is attached to the end portion **15** of the first conduit **10**, rather than about the periphery of an opening **12** made in the side wall of the first conduit **10**. The connector structure **200**, the balloon catheter **300**, and the nosecone assembly **400** are loaded onto the first conduit substantially as described above with respect to FIGS. **16-18**, with the following differences described herein. The transfer sheath **600** is advanced within the lumen of the first conduit **10** until it protrudes slightly from the end portion **15**. The connector structure **200**, balloon catheter **300**, and the nosecone assembly **400** are subsequently advanced within the lumen **606** of the transfer sheath **600** until members **222** protrude from the end portion **15** of the first conduit **10**. (Transfer sheath **600** may then be removed.) The free end portions **224** are used to pierce the wall of the first conduit **10** about the end portion **15**. A locating ring **500** may be used. The anastomosis procedure is performed substantially as described herein with respect to the side-to-side anastomosis procedure.

[**0144**] According to still another embodiment, the apparatus described herein may also be useful in making an anastomosis between a first vessel, such as a graft conduit, e.g., SVG, and the aorta or other arterial blood source.

[**0145**] Another embodiment of the nosecone assembly is illustrated in FIGS. **31-35**, and is generally denoted by reference number **450**. Nosecone assembly **450** may comprise an elongated tubular shaft **452**, and a nosecone **454**. The tubular shaft **452** may be substantially similar to tubular shaft **402**, described hereinabove. However, tubular shaft **452** may be a solid member. The nosecone **454** may comprise a distal tip portion **456**, which is attached to the tubular shaft **452**. A plurality of cone sections **458** extend from the tip portion **456**, and are each individually, flexibly attached to the distal tip portion **456**.

[**0146**] **FIG. 31** illustrates the nosecone **454** in its introduction configuration, which facilitates the introduction of the nosecone assembly **450** and the connector structure **200** into the second conduit **20**. In this configuration, the cone sections **458** extend both proximally and radially outward from distal tip portion **456**. The cone sections **458** define an annular space **459** for receiving the connector structure **200**. **FIG. 32** illustrates the nosecone **454** in the compacted, removal configuration, which facilitates the removal of the nosecone assembly from the second conduit **20**. In the removal configuration, the cone sections **458** extend distally from the tip portion **456**. Preferably, the cone sections **458** may be positioned closer together in the removal configuration to define a lower profile. The dimensions of the nosecone **454**, i.e., the diameter and length, are selected in order to cover the distal members **218** of the connector structure **200** during introduction of the apparatus into the second conduit.

[**0147**] FIGS. **33-35** illustrate a typical use of the nosecone assembly **450**. As illustrated in **FIG. 33** (which corresponds to **FIG. 21**, above), the nosecone **454** is used to introduce the connector structure **200** and the balloon catheter **300** into the opening **22** in the second conduit. Nosecone **454** is in the introduction configuration, and shields the first members **218** (not visible in **FIG. 33**). As illustrated in **FIG. 34** (which corresponds to **FIG. 22**, above), nosecone **454** is advanced into the lumen **24** of second conduit **20**, thereby exposing the first members **218**. Such advancement may be achieved by remotely advancing tubular member **452**. **FIG. 35** illustrates the condition in the procedure after balloon **302** has been expanded to enlarge connector structure **200** and attach first conduit **10** (illustrated with dashed lines) to second conduit **20**. Nosecone **454** may be removed from the operative site by proximally withdrawing tubular shaft **452**. When the cone sections **458** comes in contact with the balloon **302**, they are deflected distally to the removal configuration shown in **FIG. 32**.

[**0148**] Yet another embodiment of the nosecone assembly is illustrated in FIGS. **36-39**, and is generally denoted by reference number **460**. Nosecone assembly **460** may comprise an elongated tubular shaft **462**, and a nosecone **464**. The tubular shaft **462** may be substantially similar to tubular shaft **402**, described hereinabove. The nosecone **464** may comprise a collapsible cone portion **466**, a flexible distal tip portion **465**, and a proximal portion **467**. The proximal portion **467** is configured for longitudinal movement within the lumen of tubular shaft **462**. The distal tip portion **465** may be biased to define a bend, or "knee" portion between the proximal portion **467** and the cone portion **466**.

[**0149**] **FIG. 36** illustrates the nosecone **464** in its introduction configuration, which facilitates the introduction of the nosecone assembly **460** and the connector structure **200** into the second conduit **20**. In this configuration, the cone portion **466** extends both proximally and radially outward from distal tip portion **465**. The cone portion **466** defines an annular space **469** for receiving the connector structure **200**. **FIG. 37** illustrates the nosecone **464** in the compacted, removal configuration, which facilitates the removal of the nosecone assembly from the second conduit **20**. In the removal configuration, the proximal portion **467** is withdrawn proximally, and the distal tip portion **465** bends against its bias towards parallelism with the lumen of the tubular shaft **462**. The cone portion **466** is collapsed and also withdrawn into the tubular shaft **462**.

[**0150**] FIGS. **38-39** illustrate a typical use of the nosecone assembly **460**. As illustrated in **FIG. 38** (which corresponds to **FIG. 21**, above), the nosecone **464** is used to introduce the connector structure **200** and the balloon catheter **300** into the opening **22** in the second conduit. Nosecone **464** is in the introduction configuration, and shields the first members **218** (not visible in **FIG. 38**). Nosecone **464** may be advanced into the lumen **24** of second conduit **20**, as illustrated in **FIG. 34**, above. **FIG. 39** illustrates the condition in the procedure after balloon **302** has been expanded to enlarge connector structure **200** and attach first conduit **10** (illustrated with dashed lines) to second conduit **20**. Nosecone **464** may be removed from the operative site by proximally withdrawing proximal portions **467** into tubular shaft **462**. The distal tip portion **465** will straighten as it is withdrawn into tubular shaft **462**, which in turn will cause the cone portion **466** to collapse to a size which can also be removed into tubular shaft **462**.

[**0151**] Still another embodiment of the nosecone assembly is illustrated in FIGS. **40-43**, and is generally denoted by reference number **470**. Nosecone assembly **470** may com-

prise an elongated tubular shaft **472**, and a nosecone **474**. The tubular shaft **472** may be substantially similar to tubular shaft **402**, described hereinabove. The nosecone **474** is fabricated from a highly elastic material that may be expanded from a substantially narrow cylindrical configuration to substantially tapered configuration upon the introduction of expansion fluid. Upon draining the expansion fluid, nosecone **474** returns to the narrow initial configuration.

[**0152**] **FIG. 40** illustrates nosecone **474** in its introduction configuration, which facilitates the introduction of nosecone assembly **470** and connector structure **200** into second conduit **20**. In this configuration, a distal portion **475** extends both proximally and radially outward from distal tip portion **476**. In this configuration, nosecone **474** defines an annular space **479** for receiving the connector structure **200**. A central longitudinal member **477** may be optionally provided for additional stability. A lumen **478** allows expansion fluid to be introduced into nosecone **474** to expand it to the configuration shown in **FIG. 40**. **FIG. 41** illustrates nosecone **474** in the compacted, removal configuration, which facilitates the removal of the nosecone assembly from second conduit **20**. In the removal configuration, nosecone **474** elastically returns to a narrow configuration having approximately the same profile as tubular shaft **472**.

[**0153**] FIGS. **42-43** illustrate a typical use of nosecone assembly **470**. As illustrated in **FIG. 42** (which corresponds to **FIG. 21**, above), nosecone **474** is used to introduce connector structure **200** and balloon catheter **300** into opening **22** in the second conduit. Nosecone **474** is in the introduction configuration, and shields first members **218** (not visible in **FIG. 42**). Nosecone **474** may be advanced into the lumen **24** of second conduit **20**, as illustrated in **FIG. 34**, above. **FIG. 43** illustrates the condition in the procedure after balloon **302** has been expanded to enlarge connector structure **200** and attach first conduit **10** (illustrated with dashed lines) to second conduit **20**. Nosecone **474** may be removed from the operative site by draining the expansion fluid and allowing nosecone **474** to return to the configuration of **FIG. 41**, and by subsequently withdrawing tubular shaft **472** and nosecone **474**.

[**0154**] 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 **200**). For example, a connector may have one, two, 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.

[**0155**] 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. 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. **2-5**, for example, annular enlargement of cells defined by members **230***a*/**230***b*/**232***a*/**236***b* and **230***b*/**230***c*/**234***b*/**238***c* causes a decrease in the axial spacing between members **218**, on the one hand, and members **222**, 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.

[**0156**] 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 **218** and **222**, etc., and the above-described radial enlargement of the connector.

[**0157**] The radially outwardly deflectable members or portions of the connector may also include barbs, hooks, spikes, loops, clips, or suture rings.

[**0158**] 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. **2-5**, the portions of the structure associated with lengths **212** and **216** in **FIG. 2** may be made so that they are less resistant to inflation of a balloon **302** inside the connector **200** than portions of the structure associated with length **214**. In an application of the type shown in FIGS. **2-5** this causes these less resistant portions to annularly enlarge by deflecting radially out inside second conduit **20** before the remainder of the connector begins to significantly annularly enlarge. This early response of the less resistant portions inside second conduit **20** may help to ensure that the connector does not slip out of engagement with second conduit **20** during annular enlargement of the connector **200**. 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 **302** which is shaped, molded, or phased in that way. For example, balloon structure **302** 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.

[**0159**] Radiologically (e.g., x-ray) viewable markers can be used anywhere on the connectors **200** and/or delivery apparatus (e.g., **300** or **400**) or locating ring **500** 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. For example, clad tubing may have a tantalum layer over a stainless steel layer. The tantalum layer provides radiodensity, thereby making a connector **200** that is cut from this material radiologically viewable. The stainless steel layer 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 connector **200** 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 is platinum.

[**0160**] 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.

[**0161**] 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 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 **300**, **400**) through relatively small instrumentation such as laparoscopic apparatus, a cannula, or an intraluminal catheter. Thus a connector and associated apparatus (e.g., apparatus **300**, **400**) 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 above-mentioned 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 **300**, **400**) 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.

[**0162**] 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 improved 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 conduits. 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.

What is claimed is:

**1**. Introducing apparatus associated with a first vessel for introduction of a portion of the first vessel into an opening of a second vessel for making an anastomotic connection between the first vessel and the second vessel with a connector structure, comprising:

a distal tapered portion;

a intermediate portion extending from the distal tapered portion and flexible between a compacted configuration and an un-compacted configuration; and

an elongated tubular portion extending from the intermediate portion and configured for positioning within an internal lumen of the first vessel;

wherein the moving the intermediate portion from the compacted configuration to the uncompacted configuration advances the distal tapered portion distally with respect to the elongated tubular portion.

**2**. Introducing apparatus defined in claim 1, wherein the distal tapered portion, the intermediate portion and the elongated tubular portion define a common internal space in fluid communication.

**3**. Introducing apparatus defined in claim 1, wherein the intermediate portion is configured to flexibly move between the compacted configuration and the un-compacted configuration upon introduction of fluid into the common internal space.

**4**. Introducing apparatus defined in claim 2, wherein the distal tapered portion and the intermediate portion in the tapered configuration define a substantially rigid structure in proportion to the pressure of the expansion fluid in the common internal space.

**5**. Introducing apparatus defined in claim 1, wherein the intermediate portion, the distal tapered portion and the elongated tubular portion are flexible between a substantially straight configuration and a substantially curved configuration defining an angle of between about 0 degrees and about 90 degrees.

**6**. Introducing assembly defined in claim 1, wherein the intermediate portion in the compacted configuration defines an annular recess for receiving a portion of the connector structure.

**7**. Introducing apparatus associated with a first vessel for introduction of a portion of the first vessel into an opening of a second vessel for making an anastomotic connection between the first vessel and the second vessel with a connector structure, comprising:

an elongated tubular portion configured for positioning within an internal lumen of the first vessel and defining a distal tip; and

a plurality of tabs flexibly attached to the distal tip of the elongated tubular portion, movable between a first configuration extending proximally and radially outward from the distal tip to define a substantially conical configuration and a second configuration extending distally from the distal tip.

**8**. Introducing apparatus associated with a first vessel for introduction of a portion of the first vessel into an opening of a second vessel for making an anastomotic connection between the first vessel and the second vessel with a connector structure, comprising:

an elongated tubular portion configured for positioning within an internal lumen of the first vessel and defining a distal tip; and

an expandable balloon structure attached to the distal tip of the elongated tubular portion, expandable between a first unexpanded configuration and a second configuration defining a substantially conical shape.

**9**. Introducing apparatus associated with a first vessel for introduction of a portion of the first vessel into an opening of a second vessel for making an anastomotic connection between the first vessel and the second vessel with a connector structure, comprising:

an elongated tubular portion configured for positioning within an internal lumen of the first vessel and defining an internal lumen; and

an expandable structure defining a first collapsed configuration when positioned within the internal lumen of the elongated tubular portion and a second configuration expandable to conical configuration when released from the internal lumen of the elongated tubular configuration.

**10**. Apparatus for use with a connector structure for making an anastomotic connection between the first vessel and the second vessel, the connector structure expandable between a first size and a second size to attach the first vessel and the second vessel, the apparatus comprising:

a support structure;

an expandable balloon comprising a proximal portion attached to the support structure and a distal portion attached to the support structure in an inverted manner, such that the expandable balloon defines a maximum diameter at a position substantially adjacent the distal end portion of the expandable balloon.

**11**. Apparatus defined in claim 10, wherein the expandable balloon defines the maximum diameter at a distance of about 2.5 mm from the distal end portion of the expandable balloon.

**12**. Apparatus defined in claim 10, wherein the support structure comprises an inner tubular shaft and an outer tubular shaft, and wherein the proximal portion of the expandable balloon is attached to the outer tubular shaft and the distal portion of the balloon is attached to inner tubular shaft in the inverted manner.

**13**. Apparatus defined in claim 12, wherein the outer tubular shaft and the inner tubular shaft are attached at a location adjacent to the location of attachment of the proximal portion of the balloon to the outer tubular shaft.

**14**. Apparatus defined in claim 10, wherein the expandable balloon comprises a shoulder portion adjacent the distal end portion to retain the connector structure in position about the expandable balloon.

**15**. Apparatus defined in claim 10, wherein the support structure and the expandable balloon are each provided with a junction to allow the support structure and the expandable balloon to be separated and reconnected.

**16**. Apparatus for inserting a distal portion of a hollow annular anastomotic connector into an aperture in a side wall of a body tissue conduit in a patient comprising:

a structure comprising a selectively inflatable and deflatable balloon, the structure having an exterior surface that is reconfigurable, in use, from an early configuration to a subsequent configuration, the early configuration having annular periphery that gradually increases from a first relatively small value at a distal end of the early configuration to a second relatively large value at a more proximal portion of the early configuration, and the subsequent configuration having annular periphery that is substantially free of abrupt increases in annular periphery in the distal direction, the structure inside the more proximal portion of the early configuration defining an annular hollow that is open in the proximal direction for substantially concentrically receiving the distal portion of the connector.

**17**. The apparatus defined in claim 16 wherein the structure is further configured so that in the subsequent configuration the distal portion of the connector is no longer disposed in an annular hollow.

**18**. The apparatus defined in claim 16 wherein the structure is further configured so that in the subsequent configuration the structure can be withdrawn from the patient by pulling it proximally through the connector.

**19**. The apparatus defined in claim 16 wherein the structure is further configured to convert from the early configuration to the subsequent configuration while inside the lumen of the body tissue conduit and without injuriously deforming the body tissue conduit.

**20**. The apparatus defined in claim 16 wherein the structure comprises a member of flexible polymeric material.

**21**. The apparatus defined in claim 16 wherein the balloon has a proximal annular portion that initially defines the annular hollow when the balloon is not inflated.

**22**. The apparatus defined in claim 21 wherein the balloon is configured so that inflation of the balloon substantially eliminates the hollow and thereby exposes the distal portion of the connector.

**23**. The apparatus defined in claim 16 wherein the balloon has a proximal annular portion that initially defines the annular hollow when the balloon is inflated.

**24**. The apparatus defined in claim 23 wherein the balloon is configured so that deflation of the balloon substantially eliminates the hollow and thereby exposes the distal portion of the connector.

**25**. The apparatus defined in claim 16 wherein a proximal portion of the balloon is initially folded in the proximal direction over the distal portion of the connector.

**26**. The apparatus defined in claim 25 wherein the balloon is configured to unfold when inflated and to thereby uncover the distal portion of the connector.

**27**. The apparatus defined in claim 16 wherein a wire is attached to the distal end of the structure such that the wire runs out of the structure and connector in the proximal direction.

**28**. The apparatus defined in claim 27 wherein the wire is substantially rigid and capable of altering the structure from the early configuration to the subsequent configuration by advancing the wire in the distal direction.

**29**. The apparatus defined in claim 27 wherein the wire is utilized to indicate when the transformation from the early configuration to the subsequent configuration is complete.

**30**. Apparatus for inserting a distal portion of a hollow annular anastomotic connector into an aperture in a side wall of a body tissue conduit in a patient comprising:

a structure having an exterior surface that is reconfigurable, in use, from an early configuration to a subsequent configuration, the early configuration having annular periphery that gradually increases from a first relatively small value at a distal end of the early configuration to a second relatively large value at a more proximal portion of the early configuration, and

the subsequent configuration having annular periphery that is substantially free of abrupt increases in annular periphery in the distal direction, the structure inside the more proximal portion of the early configuration defining an annular hollow that is open in the proximal direction for substantially concentrically receiving the distal portion of the connector; and

annularly enlargeable componentry disposed substantially concentrically inside the connector and configured to selectively annularly enlarge the connector.

**31**. The apparatus defined in claim 30 wherein the componentry is additionally configured to selectively return to a less enlarged state after annularly enlarging the connector.

**32**. The apparatus defined in claim 31 wherein the componentry is configured, in its less enlarged state, for proximal removal from the annularly enlarged connector.

**33**. The apparatus defined in claim 30 wherein the componentry comprises:

a selectively inflatable and deflatable balloon.

**34**. The apparatus defined in claim 30 wherein the structure and the componentry are separately controllable for substantially independent operation.

**35**. The apparatus defined in claim 30 wherein the componentry has a hollow annular configuration disposed substantially concentrically inside the connector, and wherein the structure is at least partly supported relative to the componentry by support elements that pass concentrically through the hollow annular configuration.

**36**. The apparatus defined in claim 30 wherein the componentry is further configured to annularly enlarge the connector into engagement with the side wall of the body tissue conduit.

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