(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 October 2009 (15.10.2009)

PCT

(10) International Publication Number
WO 2009/126244 A2

(51) International Patent Classification:
A61M 25/04 (2006.01)

(21) International Application Number:
PCT/US2009/002151

(22) International Filing Date:
6 April 2009 (06.04.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/123,251 7 April 2008 (07.04.2008) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

WO 2009/126244 A2

(54) **Title**: DEVICES, SYSTEMS, AND METHODS FOR JOINING BODY CONDUITS

(57) **Abstract**: Devices, systems, and methods are sized and configured for joining body conduits, desirably without the use of tissue-penetrating fasteners.

DEVICES, SYSTEMS, AND METHODS FOR JOINING BODY CONDUITS

Related Applications

This application claims the benefit of provisional patent application Serial No. 61/123,251 filed 7 April 2008.

Background of the Invention

Typically, to couple one body conduit to another body conduit (for example, during anastomosis), tissue piercing fasteners, such as sutures, are placed by the surgeon around the circumference of the conduit, in order to maintain the patency of its lumen or channel (see Figs. 1A and 1B). Suturing during anastomosis differs from straight line suturing, because each suture has a different orientation which is based on its position around the cross-sectional circumference of the conduit. Some of the sutures are easily made from on top of the conduit, while others are more difficult to complete as they are beneath the conduit. Furthermore, fast and effective control of bleeding through the tissue suture holes is required.

Surgical anastomsis involving suturing is therefore a complex operation, requiring a high degree of surgical expertise and experience. There remains a need to continuously refine and simplify these and other surgical procedures.

Summary of the Invention

The invention provides devices, systems, and methods for joining body conduits, such as blood vessels and gastro-intestinal channels, desirably without the use of tissue-penetrating fasteners, such as sutures or staples.

Brief Description of the Drawings

Figs. 1A and 1B are generally anatomic views of a human hand having a blood vessel that has been separated and an enlarged anatomic view of the conventional use of suture to re-join the separated blood vessels.

Figs. 2A, 2B, and 2C are anatomic fields of view showing use of a basic embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure.

Figs. 3A and 3B are anatomic fields of view showing use of another embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure.

Figs. 4A and 4B are anatomic fields of view showing use of another embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the body conduits having different interior dimensions.

Figs. 5A and 5B are anatomic fields of view showing use of another embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the body conduits having different interior dimensions.

Figs. 6A and 6B are anatomic fields of view

showing use of another embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector comprising telescopically fitted connector members.

Figs. 7A, 7B, and 7C are anatomic fields of view showing use of another embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector accommodating alignment of the body conduits along different axes separated by about ninety degrees.

Figs. 8A, 8B, and 8C are anatomic fields of view showing use of another embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector accommodating alignment of the body conduits along different axes separated by more than ninety degrees.

Figs. 9A, 9B, and 9C are anatomic fields of view showing use of another embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector accommodating alignment of the body conduits along different axes separated by less than ninety degrees.

Fig. 10A is a plane view of an embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector having a braided surface conformation that exposes endothelial tissue inside the body conduits to native fluid to moderate necrosis while tissue healing occurs.

Fig. 10B is an anatomic field view of the connector shown in Fig. 10A, showing how the braided

surface conformation exposes endothelial tissue inside the body conduits to native fluid.

Figs. 11A and 11B are anatomic fields of view showing the *in situ* expansion of the connector shown in Fig. 10A within the body conduits.

Figs. 12A, 12B, and 13 are plane views of embodiments of connectors that embody features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connectors each having an open scaffold conformation that exposes endothelial tissue inside the body conduits to native fluid to moderate necrosis while tissue healing occurs.

Figs. 14A, 14B, and 14C are anatomic fields of view showing the *in situ* expansion of a malleable connector of a type shown in Fig. 12 within the body conduits by use of a radially expandable device.

Figs. 15A, 15B, and 15C are anatomic fields of view showing the *in situ* expansion of a self-expanding connector of a type shown in Fig. 12 within the body conduits.

Fig. 16A and 16B are views of an embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector having a coiled conformation that exposes endothelial tissue inside the body conduits to native fluid to moderate necrosis while tissue healing occurs.

Figs. 17A, 17B, 17C, and 17D are anatomic fields of view of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector being flexible to accommodate different relative orientations of the body conduits.

Fig. 18 is an end view of the flexible connector shown in Fig. 17, taken generally in the

direction of the arrow in Fig. 17, showing the range of flexibility of the connector.

Fig. 19 is a plan view of a of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector having a coiled conformation in its end regions that exposes endothelial tissue inside the body conduits to native fluid to moderate necrosis while tissue healing occurs and a braided conformation in its intermediate region to impart flexibility.

Fig. 20 is a plan view of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector having a braided conformation in its end regions that exposes endothelial tissue inside the body conduits to native fluid to moderate necrosis while tissue healing occurs and an open scaffold conformation in its intermediate region to impart flexibility.

Fig. 21 is a plan view of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector having an open scaffold conformation in its end regions that exposes endothelial tissue inside the body conduits to native fluid to moderate necrosis while tissue healing occurs and a coiled conformation in its intermediate region to impart flexibility.

Figs. 22A and 22B are anatomic fields of view of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector carrying a tissue-adherent material.

Figs. 23A, 23B, and 23C are anatomic fields of view of a connector that embodies features of the

invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector carrying a tissue-adherent material that is enclosed in a protective sheath prior to use, which is removed for insertion of the connector into the body conduits.

Figs. 24A, 24B, 24C, and 24D are anatomic fields of view of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector carrying a tissue-adherent material that is activated upon exposure to moisture for its insertion into the body conduits.

Figs. 25A, 25B, and 25C, are anatomic fields of view of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector carrying a tissue-adherent material that is applied on-site at the instance of its insertion into the body conduits.

Figs. 26A, 26B, 26C, and 26D are anatomic fields of view of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector carrying a tissue-adherent material that is applied on-site at the instance of its insertion into the body conduits, the tissue-adherent material comprising a hydrogel that forms *in situ*.

Fig. 27A is an elevation view of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector having a surface conformation for receiving a tissue-adherent material.

Fig. 27B is a side section view of the connector shown in Fig. 27A, taken generally long line 27B-27B in Fig. 27A, showing the surface conformation for

receiving a tissue-adherent material.

Figs. 28A and 28B are elevation views of alternative embodiments of connectors that embody features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connectors having surface conformations for receiving a tissue-adherent material.

Figs. 29A, 29B, 29C, 29D, 29E, 29F, 29G, and 29F are anatomic fields of view of the use of an insertion tool to place a connector that embodies features of the invention into body conduits in a micro-surgical procedure, the connector being absorbable in generally the same timeframe as the tissue healing process.

Figs. 30 and 31 are plane views of embodiments of insertion tools that can be used to perform the procedure shown in Figs. 29A, 29B, 29C, 29D, 29E, 29F, 29G, and 29F.

Fig. 32 is a plane view of an alternative embodiment of an insertion tool for placing a connector that embodies features of the invention in a minimally invasive surgical procedure such as minimally invasive coronary artery bypass graft surgery (Mini-CABG).

Fig. 33 is an enlarged, sectional view of the handle of the insertion tool shown in Fig. 32, showing the coupling of the frangible filament to an actuator on the handle.

Fig. 34 is an enlarged, sectional view of the catheter body of the insertion tool shown in Fig. 32, showing the coupling of the frangible filament to the connector, and the position of the actuator on the handle holding the connector in abutment against the catheter body.

Fig. 35 is an enlarged, sectional view of the catheter body of the insertion tool shown in Fig. 32,

showing the breaking of the frangible filament to release the connector from the tool in response to manipulation of the actuator on the handle.

Figs. 36A, 36B, 36C, 36D, 36E, 36F, and 37G are anatomic fields of view of the use of an insertion tool like that shown in Figs. 32 to 35 to place a connector that embodies features of the invention into body conduits during a Mini-CABG procedure, the connector being absorbable in generally the same timeframe as the tissue healing process.

Figs. 37A and 37B are anatomic fields of view showing use of another embodiment of a connector that embodies features of the invention to re-join body conduits that have been separated by trauma or surgical procedure, the connector being sized and configured to join at least three body conduits in an end-to-end fashion as well as an end-to-side fashion.

Figs. 38A to 38F are anatomic field views showing the application of a tissue adherent composition to a braided stent-like connector of the type shown in Fig. 12B, during and after the insertion of the connector to join two body conduits.

Fig. 39 is a perspective view of a kit in which the various devices and systems described and illustrated above are packaged for use.

Description of the Preferred Embodiments

Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention, which may be embodied in other specific structure. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

Contents

As a general overview and guide, the description that follows is divided into the following main sections and sub-sections:

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The detailed description begins:

I. Connectors for Joining Body Conduits

A. Overview

Figs. 2A to 2C show a device 10 for joining together two body conduits 12 and 14 or other hollow body structures, such as blood vessels or tubular organs (e.g., loops of intestine). The device 10 comprises a connector 16 that is sized and configured to be

surgically inserted between the separated ends of body conduits 12 and 14, as Fig. 2A shows.

The separation of the body conduits 12 and 14 can have occurred as a result of unintended trauma, e.g., a mutilating injury. Alternatively, the separation of the body conduits 12 and 14 can have occurred as a result of a surgical procedure, during cardiac by-pass or reconstructive surgery.

As Fig. 2B shows, the insertion of the connector 16 serves to establish a connection site 18 between the two body conduits 12 and 14. The connector 16 is sized and configured to reform the separated ends at the connection site 18 to create a patent lumen or open fluid flow passage between the body conduits 12 and 14.

The connector 16 is further sized and configured to place tissue at the ends of the body conduits 12 and 14 into contact and otherwise establish the physiologic conditions conducive to tissue healing between the two conduits 12 and 14. The connector 16 is also sized and configured to resist separation of the body conduits 12 and 14 while tissue healing takes place.

In these ways, the connector 16 joins or rejoins the body conduits 12 and 14 and creates or restores normal physiologic functionality to the conduits 12 and 14, as Fig. 2C shows.

The size, configuration, and geometry of the connector 16 can vary, as will be exemplified in greater detail later. In its basic form, as shown in Fig. 2A, the connector 16 includes a structure 20 formed, e.g., by extrusion, or molding, or braiding, or thin film casting. The structure 20 peripherally defines an interior lumen 22.

The structure 20 is desirably formed of a biocompatible material suitable for implantation in the body. The material can comprise, e.g., a medical grade

polymer, or a medical grade metallic material, or a medical grade ceramic material, or a medical grade natural or synthetic textile material, or combinations or hybrids thereof. Examples of material well suited for the structure 20 will be described in greater detail later.

The material properties, physical properties, geometry, and dimensions of the structure 20 are selected to impart column or radial strength sufficient to reform and maintain an open lumen in the connection site between the body conduits 12 and 14 while tissue healing occurs. The column or radial strength of the structure 20 prevents collapse of the body conduits 12 and 14 along the connection site 18, thereby maintaining through the interior lumen 22 an open flow passage between the body conduits 12 and 14 during tissue healing.

In its basic form, the structure 20 includes end regions 24 spaced apart by an intermediate region 26. Each end region 24 is sized and configured to be inserted into the terminus of the respective body conduit 12 and 14. When inserted, the end regions 24 and intermediate region 26 are sized and configured to contact and support tissue along the interior of the respective body conduit 12 and 14.

In use (see Fig. 2B), the end regions 24 are inserted a sufficient distance into each body conduit terminus to bring tissue at the ends of the body conduits 12 and 14 into contact about the structure 20 along the connection site 18. Together, the end regions 24 and intermediate region 26 collectively present a surface area that is sized and configured to frictionally engage enough tissue inside the body conduits 12 and 14 to resist separation of the body conduits 12 and 14 along the connection site while tissue healing occurs.

As Fig. 2A also shows, one or both end regions

24 can be shaped to facilitate its inserting into a terminus. In Fig. 2A, for example, each end region 24 can be tapered to reduce the frictional forces encountered during insertion.

As Figs. 2A and 2B also show, one or both the end regions 24, or the intermediate region 26, or combinations thereof, can include surface projections 28 that enhance frictional forces between the structure 20 and tissue along the connection site 18. In this way, the structure 20 can establish and maintain patency between the two conduits 12 and 14 during tissue healing, without the use of tissue-penetrating fasteners, such as sutures or staples or clips.

If desired, as shown in Figs. 3A and 3B, if desired, the intermediate region 26 can include one or more exterior posts 30 spaced about its periphery. The exterior ports 30 include through-holes 32 to receive fasteners 34 (e.g., sutures or staples) applied through tissue at each terminus. The fasteners 34 physically hold the ends of the body conduits in contact about the structure 20 during tissue healing. The posts 30 can be used in combination with the surface projections 28, or the posts 30 and/or surface projections 28 can be used by themselves.

Desirably, and as will be described in greater detail later, the material properties, geometry, and dimensions selected for a given connector 16 make possible the joining of the body conduits 12 and 14 without the use of fasteners, such as staples or sutures or clips.

B. Physical Dimensions

The material properties, geometry, and dimensions selected for a given structure 20 of the connector 16 will, of course, vary depending upon the morphology of the body conduits 12 and 14 to be

connected. The morphology of a given body conduit or conduits 12 or 14 can be generally understood by medical professionals using textbooks of human anatomy, along with their knowledge of the site, the injury, or surgical procedure. The medical professional is also able to select the material properties, geometry, and dimensions for a given structure 20 based upon analysis of the particular morphology of the particular connection site.

For example, in a typical representative operative environment involving the attachment of blood vessels, the outer diameter of the structure 20 wall can vary between about 0.5 mm and about 3 mm. A typical length in this environment varies between about 1.0 cm to 4.0 cm.

The physical dimension of the structure 20 need not be uniform, e.g., it can vary from one end region 24 to another end region 24 and/or along the intermediate region 26. For example, considerations of anatomy or intended surgical results may dictate the selection of a structure 20 of physical dimensions that are not uniform, e.g., when connection between body conduits of different dimensions is desired, or when the anatomic circumstances otherwise dictate non-uniformity.

Figs. 4A/B, 5A/B, and 6A/B show representative embodiments of structures 20 having physical dimension that are not uniform.

In the representative embodiment shown in Figs. 4A and 4B, one end region 24A has a first diameter (e.g., 3 mm) and the other end region 24B has a different second diameter (e.g., 2 mm). In this arrangement, the intermediation region 26 steps from the larger diameter first end region 24A to the smaller diameter second end region 24B.

In the representative embodiment shown in Figs. 5A and 5B, one end region 24A similarly has a first

diameter (e.g., 3 mm) and the other end region 24B has a different second diameter (e.g., 2 mm). In this arrangement, unlike that shown in Figs. 4A and 4B, in Figs. 5A and 5B the intermediation region 26 tapers in a more uniform way from the larger diameter, first end region 24A to the smaller diameter, second end region 24B.

C. Mating Connector Elements

As shown in Figs. 6A and 6B, the structure 20 comprises a first connector element 16A including a male coupler C1 and an end region 24A sized and configured to be inserted into one of the body conduits 12. The structure 20 also comprises a second connector element 16B including a female coupler C2 and an end region 24B sized and configured to be inserted into another one of the body conduits 14.

The first and second end regions 24A and 24B can have different diameters or the same diameters, depending upon the morphology of the body conduits 12 and 14.

In the illustrated embodiment, both end regions 24A and 24B are tapered to reduce the frictional forces encountered during insertion. Furthermore, one or more of the end regions 24A and 24B can include surface projections, respectively 28A and 28B, that enhance frictional forces between the structure 20 and tissue along the connection site 18.

In this arrangement, the male coupler C1 and the female coupler C2 are mutually sized and configured to telescopically fit one within the other in an interference fit. The fit between the coupler C1 and C2 resists separation of the connector elements 16A and 16B and, therefore, separation of the body conduits 12 and 14 themselves along the connection site 18 while tissue healing occurs.

D. Physical Geometries

The physical geometry of the structure 20 can, like its material properties, physical properties, and dimensions, also vary depending upon the morphology of the body conduits 12 and 14 to be connected and other anatomic circumstances.

In Figs. 2A/B/C, 3A/B, 4A/B, 5A/B, and 6 A/B, the structure 20 defines a generally straight or linear path. In this arrangement, the flow passage between the body conduits 12 and 14 during and after tissue healing lays along a common axis 36, as shown, e.g., in Fig. 2C.

In alternative embodiments shown in Figs. 7A/B/C, 8A/B/C, and 9A/B/C, the structure 20 is formed with a curvilinear bend, comprising an elbow 38. In this arrangement, the open flow passage between the body conduits changes direction at the elbow 38. In this arrangement, during and after tissue healing, the flow passage in one body conduit 12 is oriented along an axis 40 different than the axis 42 of the other body conduit 14, as Fig. 7A shows. As shown in Figs. 7A/B/C, the elbow 38 forms an essentially right angle bend.

Another representative embodiment is shown in Figs. 8A/B/C. In this embodiment, the structure 20 includes a curvilinear bend 44 that is greater than ninety degrees. In this arrangement, as in the arrangement shown in Figs. 7A/B/C, during and after tissue healing, the flow passage between the body conduits 12 and 14 changes direction along the curvilinear bend 44 so that flow in one body conduit 12 is along an axis 40 different than the axis 42 of the other body conduit 14, as shown in Fig. 8C.

Another representative embodiment is shown in Figs. 9A/B/C. In this embodiment, the structure 20 includes a curvilinear bend 46 that is less than ninety degrees. In this arrangement, as in the previous

arrangements, during and after tissue healing, the flow passage between the body conduits 12 and 14 changes direction along the curvilinear bend 46 so that flow in one body conduit 12 is along an axis 40 different than the axis 42 of the other body conduit 14, as shown in Fig. 9C.

The medical professional is able to select the particular shape for a given structure 20 based upon analysis of the particular morphology of the particular connection site or according to the anatomy otherwise encountered at the site.

E. Surface Conformations

The end regions 24, or the intermediate region 26, or both desirably include surface configurations that support blood flow along the structure 20 sufficient to provide nourishment to endothelial tissue inside the body conduits and thereby prevent necrosis while tissue healing occurs.

The surface configurations conducive to tissue nourishment during tissue healing can vary. Various representative embodiments are shown.

(i) Braided conformations

In a representative embodiment shown in Fig. 10A, one or more end regions 24 and/or the intermediate region 26 of the structure 20 include a surface configuration that comprises a braided conformation 48. The braided conformation 48 includes filaments, or strips, or elongated members of material that have been laced or interleaved or interlooped in a crisscrossing pattern. The braided conformation 48 forms along the structure 20 an array of open regions 50, which communicate directly with the interior lumen 22.

The open regions 50 are sized and configured to expose the interface between the exterior wall of the structure 20 and interior enthothelial tissue of the body

conduit, into which the structure 20 has been inserted, to blood or native fluid flowing within the lumen, as the flow arrows in Fig. 10B illustrate. This exposure of the interior endothelial tissue along the structure 20 bathes the interior tissue with the nutrients needed that sustain tissue viability, to prevent tissue necrosis during the period of tissue healing. The braided conformation 48 also imparts flexibility to the structure 20, allowing it to better conform to the morphology of the tissue region in which it is implanted.

When the braided conformation 48 extends along the entire structure 20 (as Figs. 11A and 11B show), a controlled, *in situ* expansion of the structure 20 can be accomplished during its implantation. The expansion of the structure 20 during implantation facilitates its insertion into a body conduit at a smaller dimension and allows subsequent expansion to a larger diameter to conform closer to the particular dimension of the targeted body conduit. In a representative embodiment, the braided conformation 48 of the entire structure 20 can be formed with a resilient memory, which permits reduction of the diameter of the braded conformation 48 by applying an axial stretching force upon the braided conformation 48. In this arrangement, the braided conformation 48 will normally return to a normal, larger diameter upon release of the axial stretching force.

As shown in Fig. 11A, a peal-away constraint 52 wrapped around the structure 20 holds the braided conformation 48 of both end regions 24 in an axially stretched, smaller diameter condition during its insertion into the body conduits 12 and 14. After insertion of the structure 20 within the body conduits 12 and 14 (as shown in Fig. 11A), removal of the peal-away constraint 52 from the structure 20 (e.g., by pulling on a tear string 54 that extends through beyond the

connection site, as shown in Fig. 11A) allows the braided conformation 48 in each end region to resiliently enlarge within the body conduits 12 and 14 into its normal, larger diameter, as Fig. 11B shows.

(ii) Open Scaffold Conformations

Another representative embodiment is shown in Figs. 12A, 12B, and 13. In this embodiment, one or more end regions 24 and/or the intermediate region 26 of the structure 20 include a surface configuration that comprises an open scaffold conformation 56. The open scaffold conformation 56 includes an array of interconnected struts formed in a diamond pattern (see Figs. 12A and 12B), or zigzag or serpentine pattern (see Fig. 13), or other mesh-like or stent-like pattern. The open scaffold conformation 56 can also be accomplished using a braided structure, as will be described in greater detail later.

The open scaffold conformation 56, like the braided conformation 48, includes a pattern of open regions 50, which communicate directly with the interior lumen of the structure 20. As before described, the open regions 50 are sized and configured to expose the interface between the exterior wall of the structure 20 and interior enthothelial tissue of the body conduit to blood or native fluid flowing within the lumen (as is shown in Fig. 14C). This exposure sustains tissue viability and prevents tissue necrosis during the period of tissue healing. The open scaffold conformation 56 also imparts flexibility to the structure 20, allowing it to better conform to the morphology of the tissue region in which it is implanted.

When open scaffold structure 20 extends along the entire structure 20 (as Figs. 14A/B/C show), a controlled, *in situ* expansion of the structure 20 can be accomplished during its implantation. The *in situ*

expansion of the structure 20 can cause the structure 20 to conform closer to the particular dimension of the targeted body conduit.

For example, in one embodiment (see Figs. 14A to 14C), the scaffold conformation 56 of the entire structure 20 can be formed from a malleable material, such as malleable stainless steel or other metals. In use, after insertion of one of the end regions 24 of the structure 20 into a body conduit 12 (as shown in Fig. 14A), the scaffold conformation 56 of the entire structure 20 can be expanded *in situ*, e.g., by expanding a balloon or other radially expandable device 58 inserted within the scaffold conformation 56 of the structure 20, as shown in Fig. 14B. After collapsing and withdrawing of the radially expandable device 58 from the now-enlarged structure 20, the other body conduit 14 can be drawn onto the other end region, completing the connection site 18, as Fig. 14C shows.

In another embodiment, the scaffold conformation 56 of the entire structure 20 can be formed from a self-expanding elastic material, e.g., comprised of a shape memory alloy elastic stainless steel, nitinol, or the like. In this arrangement, the structure 20 is inserted into the body conduits with the scaffold configuration retained in smaller diameter within a peal-away constraint 52, as shown in Fig. 15A. Expansion of the structure 20 is accomplished by releasing scaffold conformation 56 from the peal-away constraint 52 (e.g., by pulling on an exposed tear string 54, as shown in Fig. 15B, to permit the scaffold conformation 56 of both end regions 24 to concurrently self-expand *in situ* at the implantation site, as shown in Fig. 15C.

(iii) Coiled Conformations

In another representative embodiment shown in Fig. 16A, one or more end regions 24 and/or the

intermediate region 26 of the structure 20 include a surface configuration that comprises a coiled conformation 60. The coiled conformation 60 includes material that is fashioned into a spiral or helical shape. The coiled configuration comprises a series of loops, separated by open regions 50. The loops can be separate, joined by intermediate struts. Desirably, the loops are wound in a continuous helical spiral. The material of the coiled confirmation can be rigid, but it is desirably flexible.

As before described, and as shown in Fig. 16B, the open regions 50 between the loops of the coiled conformation 60 are sized and configured to expose the interface between the exterior wall of the structure 20 and interior enthothelial tissue of the body conduit to blood or native fluid flowing within the lumen. This exposure sustains tissue viability and prevents tissue necrosis during the period of tissue healing.

The coiled conformation 60 also imparts flexibility to the structure 20, allowing it to better conform to the morphology of the tissue region in which it is implanted.

F. Flexible Structures

The intermediate region 26 may include a flexible surface configuration 62 that allows bending or flexure of the structure 20 along its longitudinal axis.

In the embodiment shown in Figs. 17A/B/C/D, the flexible surface configuration 62 includes a plurality of series connected segments 64 in the intermediate region. The segments 64 are sized and configured for relative pivotal movement. The relative pivotal movement allows the end regions 24 to be selectively articulated between a first position (Fig. 17A), in which the end regions 24 are generally aligned along the longitudinal axis of the structure 20, and a

range of alternative positions (e.g., as shown in Figs. 17B, 17C, and 17D), in which the end regions 24 are not aligned along a common axis.

The articulation of the series connected segments 64 makes it possible to flexibly bend the structure 20 to change the direction of the flow passage through the structure 20, to accommodate different orientations on the body conduits 12 and 14. The benefits of this technical feature have been previously discussed in connection with embodiments shown in Figs. 7 A/B/C, 8 A/B/C, and 9 A/B/C, in which the degree of articulation was pre-formed. In the embodiment shown in Figs. 17 A/B/C/D, the degree of articulation can be adjusted on site. The structure 20 can be flexed in a desired way prior to insertion, if desired. After insertion, flexure of the structure 20 *in situ* in response to dynamic tissue conditions accommodates relative movement of the body conduits 12 and 14 while tissue healing occurs. As Fig. 18 shows, the flexible surface configuration 62 accommodates the selective flexure of one end region 24A relative to another 24B in any direction (designated for the [purpose of illustration A to F in Fig. 18) about the longitudinal axis.

In the embodiment shown in Fig. 17A, the segments 64 comprise an array of annular hoops 66 series connected by a flexible material 68, which spans between adjacent pairs of hoops 66. The flexible material 68 can comprise, e.g., plastic or fabric.

Flexure of the structure 20 can be accomplished by other means. For example, forming in an intermediate region 26 an open conformation conducive to tissue nourishment during tissue healing, will also provide the technical feature of flexibility. Thus, for example, the intermediate region 26 can comprise a braided conformation 48 as previously described(as shown

in Fig. 19); or an open scaffold conformation 56 as previously described (as shown in Fig. 20); of a coiled conformation 60 as previously described (as shown in Fig. 22).

As Figs. 17A/B/C/D and 19 to 21 show, the surface conformations of the end regions 24 and the intermediate region 26 can differ. In Figs. 17 A/B/C/D, the end regions 24 include an open scaffold conformation 56, and the intermediate region 26 can include a flexible surface configuration 62. In Figs. 19 to 21, the end regions 24 comprise, respectively, a coiled conformation 60, a braided conformation 48, or a scaffold conformation 56, while the intermediate regions 26 comprise different surface conformations, respectively, a braided conformation 48, a scaffold conformation 56, and a coiled conformation 60.

It is thereby possible to optimize the surface configurations differently along the structure 20 to achieve different targeted therapeutic functions. For example, the surface configurations of the end regions 24 of the structure 20 can be optimized to achieve a desired therapeutic function (for example, to expose the interface between the exterior wall of the structure 20 and interior enthothelial tissue of the body conduit to blood or native fluid flowing within the lumen), while the surface configuration of intermediate region 26 can be optimized to achieve a different therapeutic function (for example, flexibility).

G. Material Selection

As before described, the structure 20 can be made from various biocompatible materials, e.g., a medical grade polymer, or a medical grade metallic material, or a medical grade ceramic material, or a medical grade natural or synthetic textile material, or combinations or hybrids thereof.

Just as the physical properties, geometry, and dimensions of the structure 20 can be selected to aid tissue healing, it is also desirable to select a material for the structure 20 that also facilitates the process of tissue healing.

Being biocompatible, the material selected for the structure 20 is desirably non-inflammatory and non-thrombogenic. It is also desirable that the material selected be itself actively therapeutic, e.g., being itself anti-inflammatory to help minimize inflammation and promote tissue healing.

It is also desirable that the material selected for the structure 20 be biodegradable or bioabsorbable in a timeframe that generally matches the timeframe of the tissue healing process, e.g., in blood vessel anastomosis, generally about fourteen (14) days. Thus, the biodegradable or bioabsorbable structure 20 will be absorbed at about the same time the tissue healing process is completed, such that no permanent implant remains at the connection site. As a result, the risk of late adverse effects (e.g., late thrombosis) occasioned by the presence of an implanted structure 20 is minimized. A structure is capable of being biodegraded or bioadsorbed when it can be gradually broken-down, resorbed, absorbed and/or eliminated by, for example, hydrolysis, enzymolysis, metabolic processes, bulk or surface erosion, and the like within a mammal.

For example, a material for the structure 20 can be selected among a family of polymers called polyanhydride esthers (PAEs). PAEs comprise salicylic acid and a linker. Salicylic acid is the well known anti-inflammatory and analgesic component of aspirin. The composition of the PAEs can be formulated to achieve controlled rate of absorption that conforms to the timeframe of tissue healing.

PAEs are absorbed by erosion at the surface of the structure 20, i.e., at the interface of the structure 20 with tissue along the body conduit. As the surface of structure 20 degrades, salicylic acid is released and taken up by tissue along the body conduits into which the structure 20 is inserted. The presence of the salicylic acid can reduce inflammation as tissue healing occurs.

[0078] The rate of release of the salicylic acid can be controlled by the design of the polyanhydride polymer and shape of the incorporating material or device, such that the degradation of the matrix and accompanying surface morphology changes dictate diffusion of the drug from the polymer into a body. The type of bond (or absence, thereof) used to combine the salicylic acid with the polymeric matrix also affects release rate.

A second therapeutic agent or material can, if desired, be (i) dispersed in the polymeric matrix and released upon degradation; (ii) appended to a polymer as a sidechain; and/or (iii) be incorporated into the backbone of the polymer. Additional drugs that can be dispersed, appended, and in some cases incorporated, include antiproliferative agents, antineoplastic agents, antimitotic agents, anti-inflammatory agents, antiplatelet agents, anticoagulant agents, antifebrin agents, antithrombin agents, antibiotics, antiallergic agents, antioxidants, analgesics, anesthetics, antipyretic agents, antiseptics, and antimicrobial agents.

Exemplary antiproliferative agents include actinomycin D, actinomycin IV, actinomycin I1, actinomycin X1, actinomycin C1, and dactinomycin (COSMEGEN®, Merck & Co., Inc.). Antineoplastics or antimitotics include, for example, paclitaxel (TAXOL®, Bristol-Myers Squibb Co.), docetaxel (TAXOTERE®, Aventis S.A.), methotrexate, azathioprine, vincristine,

vinblastine, fluorouracil, doxorubicin hydrochloride (ADRIAMYCIN®, Pfizer, Inc.) and mitomycin (MUTAMYCIN®, Bristol-Myers Squibb Co.), and any prodrugs, metabolites, analogs, homologues, congeners, derivatives, salts and combinations thereof. Antiplatelets, anticoagulants, antifibrin, and antithrombins include, for example, sodium heparin, low molecular weight heparins, heparinoids, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist antibody, recombinant hirudin, and thrombin inhibitors (ANGIOMAX®, Biogen, Inc.), and any prodrugs, metabolites, analogs, homologues, congeners, derivatives, salts and combinations thereof.

Exemplary cytostatic or antiproliferative agents include, for example, angiopeptin, angiotensin converting enzyme inhibitors such as captopril (CAPOTEN® and CAPOZIDE®, Bristol-Myers Squibb Co.), cilazapril or lisinopril (PRINIVIL® and PRINZIDE®, Merck & Co., Inc.); calcium channel blockers such as nifedipine; colchicines; fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid); histamine antagonists; lovastatin (MEVACOR®, Merck & Co., Inc.); monoclonal antibodies including, antibodies specific for Platelet-Derived Growth Factor (PDGF) receptors; nitroprusside; phosphodiesterase inhibitors; prostaglandin inhibitors; suramin; serotonin blockers; steroids; thioprotease inhibitors; PDGF antagonists including, triazolopyrimidine; and nitric oxide, and any prodrugs, metabolites, analogs, homologues, congeners, derivatives, salts and combinations thereof. Antiallergic agents include, pemirolast potassium (ALAMAST®, Santen, Inc.), and any prodrugs, metabolites, analogs, homologues, congeners, derivatives, salts and combinations thereof.

Other drugs/bioactive agents include free radical scavengers; nitric oxide donors; rapamycin; everolimus; tacrolimus; 40-O-(2-hydroxy)ethyl-rapamycin; 40-O-(3-hydroxy)propyl-rapamycin; 40-O-[2-(2-hydroxy)ethoxy]ethyl-rapamycin; tetrazole containing rapamycin analogs such as those described in U.S. Pat. No. 6,329,386; estradiol; clobetasol; idoxifen; tazarotene; alpha-interferon; host cells such as epithelial cells; genetically engineered epithelial cells; dexamethasone; and, any prodrugs, metabolites, analogs, homologues, congeners, derivatives, salts and combinations thereof.

Free radical scavengers include, but are not limited to, 2,2',6,6'-tetramethyl-1-piperinyloxy, free radical (TEMPO); 4-amino-2,2',6,6'-tetramethyl-1-piperinyloxy, free radical (4-amino-TEMPO); 4-hydroxy-2,2',6,6'-tetramethyl-piperidene-1-oxy, free radical (TEMPOL), 2,2',3,4,5,5'-hexamethyl-3-imidazolinium-1-yloxy methyl sulfate, free radical; 16-doxyl-stearic acid, free radical; superoxide dismutase mimic (SODm) and any analogs, homologues, congeners, derivatives, salts and combinations thereof. Nitric oxide donors include, but are not limited to, S-nitrosothiols, nitrites, N-oxo-N-nitrosamines, substrates of nitric oxide synthase, diazenium diolates such as spermine diazenium diolate and any analogs, homologues, congeners, derivatives, salts and combinations thereof.

While the surface of the structure 20 degrades at the tissue interface along the body conduit, the rest of the structure 20 remains, to continue to provide the desired physical properties, geometry, and dimensions conducive to the tissue healing process, as previously described. The rate of surface erosion is desirably controlled so that, at the end of the tissue healing process, the structure 20 has been fully absorbed,

leaving only native tissue and no permanent implant.

Further details regarding PAE polymers are disclosed in Uhrich United States Patent Nos. 6,486,214; 6,468,519; and 6,602,915, which are incorporated herein by reference. Further details of PAEs are also disclosed in United States Patent Application Publication No. 2007/0225472, which is also incorporated herein by reference.

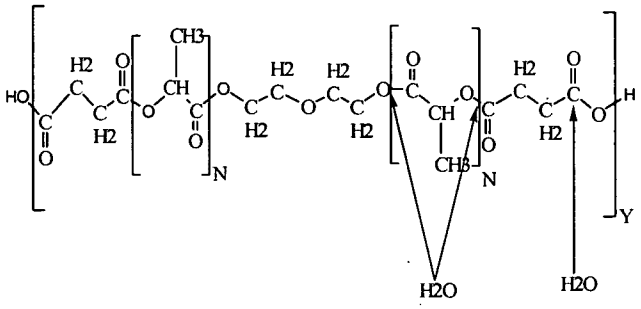
In a representative embodiment, the structure 20 can comprise a braided fiber configuration that forms an open scaffold or stent-like structure, such as shown in Fig. 12B. The braded fiber configuration includes monofilament or multifilament fibers formed of a biodegradable polyanhydride polymer comprising biocompatible multimer or polymer blocks that are linked in the polymer by anhydride linkages. In one general embodiment, the fibers are composed of anhydride-linked multimer blocks of the form:

salicylate-linker-salicylate,

where the linker is a hydrocarbon linear-chain di-acid containing between 5 and 20 carbon atoms, and the number of anhydride-linked blocks is between about 1 and 10.

Preferred salicylate-linker-salicylate polymers are salicylate-adipic acid-salicylate polymers and salicylate-sebacic acid-salicylate polymers.

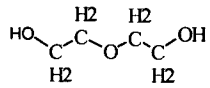
The bio-degredation of a biodegradable polyanhydride polymer as above described can be described as follows:



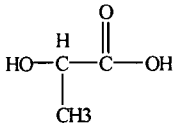
Polymer Chain Breakdown from Y = 12 to Y = 1

Polymer Chain Breakdown from N = 46 to N = 1

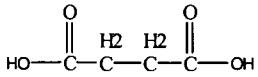
Monomer Segment = 6900 Daltons



Diethylene Glycol MW = 106



Lactic Acid MW = 90



Succinic Acid MW = 118

Conditions:

PH = 7.4
Temperature + 37C

Poly (L)PLA Anhydride Degredation

The raw polyanhydride polymer may be used to manufacture fibers having preselected thermal-mechanical properties. Such fibers are typically made by "melt spinning," which is known in the art. Melt spinning polymer fibers typically involves heating and extruding the polymer through a spinning head having a spinneret head having one or more extrusion dies.

Briefly, pellets or other raw forms of polymer material are dried under vacuum as needed to evolve residual solvents, and then heated to a temperature slightly above their glass transition (Tg) or softening temperature (e.g., from about 40°C to about 70°C, more particularly from about 45°C to about 65°C, and still more particularly from about 50°C to about 60°C). The molten/melted polymer is then extruded through a spinneret head with one or more extrusion dies to produce one or more individual raw polymer fibers or "threadlines," which are quenched/cooled using water or

air. Typically, individual fibers, or yarns or threads comprising multiple fibers, are then wound onto a spool in preparation for subsequent use or further processing.

Raw fibers may be drawn and optionally textured using heated rollers, shoes, or plates at a selected temperature between the glass-transition and crystallization temperatures of the fibers. This drawing step may be repeated at successively higher temperatures between the glass transition and crystallization temperatures of the fibers, until the fibers exhibit the thermal characteristics of a semi-crystalline polymer, as evidenced by the substantial absence of a glass-transition curve and a glass-crystallization curve. In a representative embodiment, a least one drawing stage is performed at a temperature above 82°C, preferably above 85°C, and preferably about 90°C or greater.

A braided, stent-like configuration 20 like that shown in Figs. 12B can be formed, e.g., by forming a cylindrical braid from the polymer filaments described above. In a representative embodiment, a braided-fiber stent-like structure 20 is prepared by weaving on a mandrel. The weaving process forms a tubular or cylindrical braid having a pick count -- corresponding to the number of times the fibers of the stent-like structure 20 cross over one another over a one-inch length of stent-like structure -- of, e.g., between about 10 and about 85 when constrained on a 3 mm diameter mandrel. Such tubular braided stent-like structures may then be cut into lengths corresponding to a selected length, as shown in Fig. 12B. Braiding machines for producing cylindrical braids are well known, as described for example, in U.S. Patent Nos: 6,997,948, 7,001,423, 7,213,495, and 7,311,031.

After cutting into desired-length sections, the free ends of the braided stent-like structures are

desirably fastened, woven, or sealed, to prevent the braided material from unraveling. A representative braided stent-like structure 20 having sealed free ends 21 is shown in Fig. 12B. Sealing may be accomplished by, e.g., (i) heat bonding by laser or ultrasonic weld, (ii) solvent or adhesive binding, (iii) crimping, or (iv) attachment to a separate band forming an end of the stent-like structure 20. The ends of a braided stent-like structure 20 may also be flared to ensure a smooth transition from the inside surface of the stent to the blood vessel wall, thereby minimizing restriction in the stented vessel.

The filaments forming the braided stent-like structure 20 may also be sealed or bonded by their internal crossover points, to form an open scaffold conformation, as previously described. This may be done, for example, by infusing an adhesive or polymer solution into the braid, with binding occurring as the infusate dries. The internal filaments may also be bonded by heat treatment, e.g., produced by heating the stent on the mandrel or spot welding the cross-over points with a laser beam. Bonding the internal filaments to one another can enhance the radial strength of the stent-like structure 20.

The braided, stent-like structure 20 can be delivered in a contracted, small-diameter condition, e.g., having a diameter of 20-50% of the expanded diameter, e.g., by stretching it lengthwise and placing a sleeve over it to hold the braided stent-like structure 20 in its contracted state. Released from the sleeve, the braided stent-like structure 20 expands within the body conduits at the connection site. Alternatively, the braided stent-like structure 20 can be crimped onto a balloon catheter for subsequent expansion into the body conduits.

II. Systems for Joining Body Conduits

Figs. 22A and 22B show a system 70 for joining together two body conduits or other hollow body structures 12 and 14, such as blood vessels or tubular organs (e.g., loops of intestine).

The system 10 comprises a connector 16, as previously described, which is sized and configured to be surgically inserted between the separated ends of body conduits, as Fig. 22B shows.

The system 10 also includes a biocompatible adhesive material 72 applied to the connector 16 along at least a portion of the interface between connector 16 and interior tissue within one or both of the body conduits 12 and 14. As shown in Fig. 22A, the adhesive material 72 is preferably applied along the intermediate region 26.

The biocompatible adhesive material 72 supplements the ability of the connector 16 to resist separation of the body conduits 12 and 14 while tissue healing takes place, thus further making possible the joining of body conduits without the use of fasteners like sutures or stables. Furthermore, both the adhesive material 72 and the connector 16 are desirably biodegradable in a timeframe that generally matches the timeframe of the tissue healing process, so that both the connector 16 and the adhesive material 72 are gone at the end of the healing process.

The composition of the adhesive material 72 and its application to the connector 16 can vary.

A. Adhesive Coatings

In one representative embodiment (see Fig. 23A), all or a portion of the connector 16 can carry a pre-applied coating 74 comprising a biocompatible biodegradable tissue-adherent or adhesive material 72. Desirably, prior to insertion of the connector 16 into the body conduits, the coating 74 of adhesive material 72

is inert, i.e., not tissue-adherent. This can be accomplished, e.g., by physically enclosing the coating 74 in a protective sheath prior to use, or by the chemical properties of the adhesive material 72 itself, or both. The adhesive material coating 74 is placed into an active, i.e., tissue-adherent, condition at the instance of use, when it is desired to insert the connector 16 into the body conduits 12 and 14. The activation can be accomplished, e.g., by removal of the protective sheath or by the exposure of the coating 74 to an activating agent, or both.

For example, as Fig. 23A shows, the coating 74 can comprise a composition that is normally tissue-adherent. The composition is protected from exposure to tissue prior to use by enclosure with a removable protective sheath 76 made of a material to which the composition will not adhere. The sheath 76 also protects the composition against breakdown or degradation prior to use.

At the time of insertion (shown in Fig. 23B), the sheath 76 is removed to expose the tissue-adherent composition 78 of the coating 74. With the sheath 76 removed, insertion of the connector 16 places the tissue-adherent composition 78 of the coating 74 in contact with tissue within the body conduits 12 and 14, as Fig. 23C shows. Adherence of the composition of the coating 74 to the tissue complements the other physical features of the connector 16, holding the body conduits 12 and 14 together and forming the system 70 shown in Fig. 23C, while tissue healing occurs.

Alternatively, as shown in Fig. 24A, the adhesive material coating 74 can comprise a composition that is normally inert and not tissue-adherent. In this arrangement, the composition becomes active and tissue-adherent in response to exposure to an activating agent,

e.g., moisture, or moisture and pressure. In this embodiment, if desired, a removable protective sheath 76 like that shown in Fig. 23A (shown in phantom lines in Fig. 24A) can house and protect the composition of the coating 74 prior to use.

In this arrangement, after insertion of the connector 16 between the body conduits 12 and 14 (following removal of the protective sheath 76, if present) (as shown in Fig. 24B), tactile pressure is applied to the connection site 18 (as shown in Fig. 24C). The tactile pressure brings the composition of the coating 74 into intimate contact with moisture of body fluids along the interface. The exposure to moisture activates the tissue-adherent properties of the composition of the coating 74. Tactile pressure also places the composition of the coating 74, now activated, into intimate contact with tissue along the connection site 18, adhering the connector 16 to the tissue along the interface, as Fig. 324D shows. Adherence of the composition to the tissue complements the other physical features of the connector 16, holding the body conduits together and forming the system shown in Fig. 36D, while tissue healing occurs.

B. *In Situ* Adhesive Materials

In another representative embodiment, prior to use, the connector 16 is free of a tissue-adherent adhesive coating 74 or composition. Thus, the connector 16 is itself inert, i.e., not tissue-adherent. In this arrangement, a biodegradable, tissue-adherent composition 78 is applied to the connector 16 at the instance of use, when insertion of the connector 16 into the body conduits is desired.

As shown in Fig. 25A, a biodegradable, tissue adherent composition 78 can be applied in the process of inserting the connector 16 into the body conduits, e.g.,

by dipping the connector 16 in the composition 78 on site, or by spraying the composition 78 on the connector 16 on site (as Fig. 25A shows), or by brushing the connector 16 with the composition 78 on site. Insertion of the connector 16, now carrying the biodegradable, tissue-adherent composition 78, places the tissue-adherent composition 78 in contact with tissue within the body conduits 12 and 14, as Fig. 25B shows. Adherence of the composition to the tissue complements the other physical features of the connector 16, holding the body conduits 12 and 14 together and forming the system 70 shown in Fig. 25C, while tissue healing occurs.

In a representative embodiment, the composition can comprise two or more components that are mixed together to form the biodegradable, tissue-adherent composition 78 *in situ*. For example, the composition can comprise a biodegradable, tissue-adherent hydrogel that is formed by mixing a nucleophilic component 80 with an electrophilic component 82. By well-known reactions, the nucleophilic component 80 and the electrophilic component 82, when mixed, cross-link *in situ* to form a hydrogel 84 that is biodegradable and possesses tissue adherent properties. The nucleophilic components 80 and electrophilic components 82 can be synthetic or natural. For example, poly(ethylene)glycol (PEG) can be derivatized to be either electrophilic or nucleophilic, and in either linear or multi-functional forms. Combinations of electrophilic PEG and nucleophilic PEG yield hydrogels that are tissue-adherent and biodegradable. As another example, an electrophilic water soluable polymer, e.g., PEG, can be combined with a nucleophilic buffered protein solution, e.g., solutions of albumin, gelatin, antibodies, serum proteins, serum fractions, and serum. Human serum albumin can be used due to its biocompatibility and its ready availability.

Additives, e.g., anti-neoplastic drugs, or pro-healing drugs such as estadiol - can also be incorporated into the hydrogel compound, if desired, for additional therapeutic benefits.

For example, as shown in Fig. 26A, the components 80 and 82 of the composition 78 can be mixed on-site by a dual-component applicator 86 and applied to the connector 16 (as Fig. 26A shows). The mixed components 80 and 82 cross-link *in situ* and form the biodegradable, tissue-adherent hydrogel 84, as Fig. 26B shows. Adherence of the hydrogel composition 84 to the tissue complements the other physical features of the connector 16, holding the body conduits together and forming the system shown in Fig. 26C, while tissue healing occurs. If desired (as Fig. 26D shows), the applicator 86 may also apply the mixed components 80 and 82 about the exterior of the connection site 18 itself, to form a barrier of adherent, biodegradable hydrogel 84 about the connection site 18 to resist fluid leakage while tissue healing takes place.

Figs. 38A to 38F illustrate the application of a biodegradable, tissue adherent hydrogel composition 84 to a braided stent-like connector 20 of the type shown in Fig. 12B, during and after the insertion of the connector 20 into body conduits 12 and 14. As shown in Fig. 38A, the tissue adherent hydrogel composition 84 comprises two components (as previously described) that are mixed on site by passage through a dual-component applicator 86. The mixed components are sequentially applied to the end regions 24 of the connector 20 to cross-link and form *in situ* a biodegradable, tissue-adherent hydrogel 84, which adheres the conduits 12 and 14 to the end regions 24. The components can comprise, e.g., an electrophilic PEG material solution and human serum albumin.

More particularly, as shown in Figs. 38A and

38B, the applicator 86 is manipulated to apply the mixed components first to one of the end regions 24. The applicator 86 can, e.g., spray the two component mixture directly onto the connector end region 24.

As Fig. 38C shows, the end region 24, now carrying the sprayed-on components is inserted into one of the body conduits 14. The viscosity of the two component composition has been observed to initially decrease at the outset of the cross-linking processes, so that the applied components serve at this stage of the process as a lubricant, which aids the insertion of the end region 24 into the body conduit 14.

As shown in Figs. 38D and 38E, the applicator 86 is next manipulated to apply the mixed components to the other connector end region 24. As Fig. 38E shows, the end region 24, now carrying the sprayed-on components is inserted into the other body conduit 12. The decrease in viscosity of the two component composition at the outset of the cross-linking process also acts as a lubricant, which aids the insertion of the end region 24 into the body conduit 12.

Further cross-linking of the components forms a tissue adherent hydrogel 84, which holds the body conduits 12 and 14 about the connector 20 at a connection site 18, while tissue healing occurs. The hydrogel 84 is biodegradable, desirable in the same timeframe of the tissue healing process at the connection site. Thus, both the connector 20 and the hydrogel 84 are gone at the end of the healing process.

As shown in Fig. 38F, after the insertion of the connector 20 to form the connection site 18, the applicator 86 can be further manipulated to apply the mixed components on exterior tissue around the connection site 18. A cross-linked barrier of adherent, biodegradable hydrogel 84 forms. The hydrogel barrier 84

around the connection site 18 resists fluid leakage while tissue healing takes place, and degrades within the timeframe of the tissue healing process.

C. Surface Conformations for Adhesive Materials

Fig. 27A shows a connector 16 having a surface conformation 88 sized and configured to carry a tissue-adherent material 72. As Fig. 27A shows, the connector 16 includes end regions 24 and an intermediate region 26, which is the basic structure for the connector 16 already described. In Fig. 27A, the intermediate region 26 includes a surface conformation 88 that increases the surface area of the region 26, to retain a greater volume of tissue-adherent material.

In the embodiment shown in Fig. 27A, the surface conformation 88 includes an array of circular indentations or wells 90. Each of the indentations or wells 90 retains a volume of tissue-adherent material 72 applied to the intermediate region 26, as Fig. 27B shows. A representative depth of a given indentation or well 90 is, e.g., about 0.04 mm. The volume of tissue-adherent material 72 retained by the indentations or wells 90 is in addition to the tissue-adherent material otherwise applied to the surface of the intermediate region 26. Thus, the overall volume of tissue-adherent material 72 is increased by the presence of the surface conformation 88.

As Fig. 27A also shows, the end regions 24 of the connector 16 include an open scaffold conformation 56, as previously described, to expose the interface between the exterior wall of the structure 20 and interior enthothelial tissue of the body conduit to blood or native fluid flowing within the lumen. Alternatively, the end regions 24 can comprise a previously-described coiled conformation 60, or a previously-described braided

conformation 48, or another equivalent conformation conducive to the therapeutic function of preventing necrosis. The different conformation of the intermediate region 26 serves a different therapeutic function - increased application of tissue-adherent material 72. Fig. 27A is another representative embodiment demonstrating how the surface configurations can differ along the connector 16 to achieve different targeted therapeutic functions.

Fig. 28A shows another representative embodiment of a connector 16 having a surface conformation 88 sized and configured to carry a tissue-adherent material 72. In Fig. 28A the intermediate region 26 includes a surface conformation 88 that increases the surface area of the region, to retain a greater volume of tissue-adherent material. In the embodiment shown in Fig. 28A, the surface conformation 88 includes an array of aligned elongated channels or trenches 92. In Fig. 28B, a different, staggered array of channels or trenches 92 is shown. As before described, the channels or trenches 92 shown in Figs. 28A and 28B, like the wells 90 shown in Fig. 27A, retain a volume of tissue-adherent material 72 applied to the intermediate region 26, in addition to the tissue-adherent material otherwise applied to the surface of the intermediate region 26. Thus, the overall volume of tissue-adherent material 72 is increased by the presence of the array of elongated channels or trenches 92.

As Figs. 28A and 28B also show, the end regions 24 of each connector 16 include an open scaffold conformation 56 conducive to the therapeutic function of preventing necrosis. Of course, other equivalent conformations can be provided on the end regions 24 to achieve the same therapeutic function.

III. Insertion Tools and Methods

A. Hand-Held Mandrel

Figs. 29A to 29H illustrate a representative method for introducing a connector 16 of a type previously described between the separated ends of two body conduits 12 and 14. Fig. 29A shows the operating field where the separated body conduits 12 and 14 lay. The separation of the body conduits 12 and 14 can have occurred as a result of unintended trauma, e.g., a mutilating injury, or as a result of a surgical procedure, during cardiac by-pass or reconstructive surgery.

Fig. 29B shows a surgeon S introducing a connector 16 of the type previously described into the operating field. In Fig. 29B, the surgeon introduces the connector 16 by manipulation of an insertion tool 94, which carries the connector 16. Fig. 21C shows the connector 16 in the operating field, carried on the end of the insertion tool 94.

In Fig. 29B, the surgeon is shown to be equipped for introducing the connector 16 using the insertion tool 94 by microsurgical techniques, including the use of an operating microscope 96. Microsurgical techniques allow the joining of smaller blood vessels and nerves (typically 1 mm in diameter). Microsurgical techniques have advanced the transfer of tissue from one part of the body to another and the re-attachment of severed parts. A connector 16 embodying one or more of the technical features described above is particularly well suited for insertion using microsurgical techniques.

Fig. 30 shows one representative embodiment of an insertion tool 94. As shown, the insertion tool 94 comprises a mandrel 98 having a proximal region 100 sized and configured for being held, e.g., like a pencil, by a hand of the surgeon, as Fig. 29B shows. The mandrel 98 includes a distal end 102. The distal end 102 in Fig. 30

is uniformly tapered to accommodate an interference slip-fit coupling with the connector 16 (as Fig. 29C shows). The terminus of the distal end 102 has an outer diameter less than the interior diameter of the interior lumen 22 at an end region 24 of the connector 16. From the terminus, the outer diameter of the distal end 102 increases along the taper to a diameter slightly greater than the interior diameter of the interior lumen at an end region of the connector 16, to make a slip fit with the connector 16. Fig. 29C shows the mandrel 98 carrying the connector 16 in an interference slip fit while being introduced into the operating field.

In a representative arrangement, the mandrel 98 is about 7 cm in overall length. The proximal end 100 has a diameter of about 2.8 mm. The tip of the distal end 102 tapers to a diameter of about 0.5 mm. The region of the taper is about 2.5 cm. The tapered region can include graduated markings 104 to aid placement of the connector 16.

Fig. 31 shows another representative embodiment of an insertion tool 94. As shown, the insertion tool 94 shown in Fig. 31 shares most of the same features as the insertion tool 94 shown in Fig. 30, and common reference numerals are thereby used. In Fig. 31, however, the distal end 102 is tapered in steps to accommodate an interference slip-fit coupling with connectors 16 of different interior diameters.

Fig. 29D shows the insertion of one end region 26A of the connector 16 into the terminus of one of the body conduits 12. The insertion tool 94 aids in placement of the end region 24A a sufficient distance reform the terminus of the separated body conduit 12.

As previously described, the connector 16 can carry a tissue-adhering material 72 at the time of its introduction into the operating field.

Fig. 29E shows the withdrawal of the insertion tool 94 from the other end region of the connector 16. Fig. 29F shows the surgeon manually advancing the terminus of the other body conduit 14 over the other end region 24B of the connector 16, to bring tissue of the body conduits 12 and 14 into contact together in the intermediate region 26 of the connector 16, as Fig. 29G shows. In this condition, the connector 16 resists separation of the body conduits while tissue healing takes place, to join or rejoin the body conduits and creates or restores normal physiologic functionality to the conduits, as Fig. 41G shows. In Fig. 29H, the healed connection site 18 is shown after adsorption of the connector 16, as previously described as beinbg desirable.

B. Non-Invasive Insertion Tools and Techniques

In certain surgical procedures, access of surgical tools into the operating field is limited by the use of relatively small incisions. For example, in minimally invasive coronary artery bypass graft surgery (mini-CABG), access to the surgical site is accomplished, not by a median sternotomy (dividing the breastbone), but by entry into the chest cavity through a mini-thoracotomy (a 2-to-3 inch incision between the ribs). Mini-CABG is sometimes referred to as "keyhole" heart surgery, because the operation is analogous to operating through a keyhole. The Mini-CABG approach is usually reserved for cases requiring one or two bypasses; typically bypassing arteries on the front of the heart, such as the left anterior descending (LAD) coronary artery. In most cases, the left internal thoracic artery (LITA) is used as the bypass conduit and is joined to the LAD.

Fig. 32 shows an insertion tool 94′ for introducing a connector 16 of a type previously described

during a "keyhole" incision, such mini-CABG. The insertion tool 94' includes a proximal handle 106 sized and configured to be gripped by a hand of the surgeon. The handle 106 can comprise, e.g., two half shells fabricated by injection molding a thermoplastic polymer material. A generally rigid catheter body 108 is coupled to the handle 106. The catheter body 108 can be made, e.g., from medical grade stainless steel, such as 304.SS, or a biocompatible plastic material. The catheter body 108 includes an interior lumen 110 (see Fig. 33).

As shown in Fig. 33, an elongated wire or filament 112, e.g., a polymeric fiber, extends through the interior lumen 110. Desirably, the filament 112, like the connector 16 itself, is made from a biodegradable material, as previously described.

A proximal end of the filament 112 enters the handle (see Fig. 33). The proximal end of the filament 112 is coupled to a sliding actuator 114 on the handle 106. In the illustrated embodiment, the filament 112 is connected to a bead 116 that is captured in a detent 118 in the actuator 114 within the handle 106 (as Fig. 33 shows). Sliding the actuator 114 in a proximal direction applies an axial pulling force on the filament 112.

A distal end of the filament 112 is coupled to an intermediate region 26 of a connector 16 of a type previously described (see Fig. 34). The distal end of the filament 112 adjacent the connector 16 includes an area of weakness 120. The area of weakness 120 comprises a frangible coupling between the filament 112 and the connector 16. The filament 112 will break at the area of weakness 120 in response to an axial force applied along the filament 112 in excess of a breakaway force magnitude.

In this arrangement, the connector 16 is not fixed to the insertion tool 94. Rather, an axial pulling

force of a first magnitude applied by sliding actuator 114 on the handle 106 will place tension in the filament 112. The first magnitude is less than the breakaway magnitude. The tension holds the intermediate region 26 of the connector 16 in abutment against the distal end of the catheter body 108, as Fig. 34 shows.

Increasing the axial pulling force by further sliding the actuator 114 on the handle 106 in a proximal direction (i.e., away from the connector 16) will increase the tension in the filament 112 until a second force magnitude, greater than the breakaway force magnitude is encountered. The filament 112 will break at the area of weakness 120, separating the filament 112 from the connector 16, as Fig. 35 shows.

Figs. 36A to 36G illustrate a representative surgical method for using the insertion tool 94' to introduce a connector 16 of a type previously described in an operating field during, e.g., a mini-CABG. Fig. 36A shows the operating field, where a region of plaque has blocked a section of a coronary artery, which is typically the left anterior descending (LAD) coronary artery. Fig. 36B shows the surgical separation of the coronary artery distal to the region of plaque at the outset of the mini-CABG procedure. The purpose of the mini-CABG procedure is to bypass the region of plaque by grafting another body conduit to the separated end of the coronary artery.

Fig. 36B also shows the introduction by a surgeon of the insertion tool 94' shown in Figs. 32 to 35, e.g., through a mini-thoracotomy incision between the ribs. The tool 94' carries a connector 16 of a type previously described. The connector 16 is coupled to the filament 112 that extends through the catheter body 108 of the tool 94' in the manner previously described.

As Fig. 36B shows, an axial pulling force of a

first magnitude less than the breakaway magnitude is applied by the sliding actuator 114 on the handle 106. This places tension in the filament 112 within the tool 94', which, in turn, holds the intermediate region 26 of the connector 16 in abutment against the distal end of the catheter body 108 during introduction into the operating field, as Fig. 36B shows.

Fig. 36C shows the insertion of one end region 24A of the connector 16 into the terminus of the separated distal end of the coronary artery. The insertion tool 94' stabilizes the connector 16 and otherwise aids its placement a sufficient distance into the coronary artery to reform the terminus of the separated distal end of the coronary artery.

The axial pulling force on the filament 112 is maintained at a magnitude less than the breakaway magnitude, so that the connector 16 remains stabilized and controlled by the tool. As previously described, the connector 16 can carry a tissue-adhering material 72 at the time of its introduction into the operating field.

Fig. 36D shows the separation of the connector 16 from the insertion tool 94'. As shown in Fig. 36D, the separation is accomplished by sliding the actuator 114 on the handle 106 in a proximal direction to increase the tension in the filament 112 until a second force magnitude, greater than the breakaway force magnitude is created. As a result, the filament 112 breaks at the area of weakness 120, separating the filament 112 from the connector 16, in the manner also shown in 35.

Fig. 36E shows the surgeon manually advancing the terminus of a bypass graft artery over the other end region 24B of the connector 16. This places tissue of the coronary artery and graft artery into contact together in the intermediate region 26 of the connector 16, as Fig. 36E shows. The bypass artery is typically the

left internal thoracic artery (LITA), which is joined to the LAD below the region of blockage.

In the resulting condition (as shown Fig. 36F), the connector 16 resists separation of the coronary artery and graft artery while tissue healing takes place, to restore normal physiologic circulation bypassing the blocked area. Blood flow is diverted past the blockage allowing more blood and oxygen to flow to the heart.

In Fig. 36G, the healed connection site 18 is shown after adsorption of the connector 16, as previously described.

In bypass graft surgery, as well as in other applications, a need may arise for an end-to-side connection site, as shown in Fig. 37A. In this arrangement, first and second body conduits 12 and 14 are joined end-to-end, as previously described, and a third body conduit 132 is joined along a side of the end-to-end connection.

Fig. 37B shows a connector 16 that is sized and configured to accommodate an end-to-side connection arrangement of the type shown in Fig. 37A. The connector 16 shown in Fig. 37B includes a structure 20, as already described, including spaced apart end regions 24 and an intermediate region 26. In Fig. 37B, the intermediate region 26 of the structure 20 include a side connector end 134 that communicates with the interior lumen 22 in common with the end regions. In use, as Fig. 37A shows, the end regions 24 are inserted a sufficient distance into the terminus of the first and second conduits to form an end-to-end connection site 18. As Fig. 37A also shows, the side connector end 134 is inserted a sufficient distance into the terminus of the third body conduit 132 to form an end-to-side connection site 136.

It should be appreciated that there may be more than one side connector ends 134, and the angular

orientation of the side connector end 134 relative to the end regions 24 may vary. In Figs. 37A and 37B the side connector end 134 forms a T-connection site.

IV. Kits and Instructions for Use

As Fig. 39 shows, the various devices and systems just described can be consolidated for use in a kit 122. The kit 122 can take various forms.

In a representative embodiment, the kit 122 comprises an assemblage of individual functional packages 124, 126, and 128, each comprising a sterile, wrapped, peel-open assembly. One or more the packages may include an interior tray made, e.g., from die cut cardboard, plastic sheet, or thermo-formed plastic material, which hold the contents. The kit 122 also preferably includes instructions or directions 130 for using the contents of the packages to carry out a desired procedure. Illustrative procedures using the contents of the kit 122 have been previously described.

In the representative embodiment, one functional package 124 includes one or more connectors 16. The connectors 16 may be provided individually or as a family of connectors 16 of different sizes and geometries anticipated to be useful in performing the particular procedure to which the kit is adapted.

If the connectors 16 are intended to be used in association with an adhesive material 72, e.g., as shown in Figs. 23A/B/C or 24A/B/C/D, the package 124 desirably includes sterile sealed packaging that protects the adhesive material 72 from degradation and activation prior to use.

If the connectors 16 are of the type to which an adhesive material 72 is applied on site, e.g., as shown in Figs. 25A/B/C or 26A/B/C/D, the kit 122 desirably includes a separate functional package 126 that contains the adhesive material 72 that is to be applied

to the connectors *in situ* and the applicators for accomplishing this. In this arrangement, the package 126 also desirably includes sterile sealed packaging that protects the components 80 and 82 of the adhesive material 72 and the applicator 84 from degradation and activation prior to use.

In the representative embodiment, another functional package 128 includes an insertion tool 94 or 94′ or the like for the connectors 16.

The instructions for use 130 can, of course vary. The instructions for use 130 can be physically present in one or more of the packages, but can also be supplied separately. The instructions for use 130 can be embodied in separate instruction manuals, or in video or audio recordings. The instructions for use 130 can also be available through an internet web page.

The instructions for use 130 are intended to guide the surgeon or caregiver regarding the use of the connectors 16, adhesive materials 72, and insertion tools 94/94′in the performance of a particular procedure or procedures. The technical features of the devices, systems, and methods described above are well suited for use in diverse surgical procedures throughout the body.

For example, the instructions for use may direct use of the using the devices, systems, and methods herein to surgically re-connect blood vessels that have been severed due to mutilating injuries or during hand/foot surgery, e.g., for post-traumatic finger or toe reconstruction. Figs. 29A to 29H illustrate representative contents for instructions in this regard.

As another example, the instructions for use may direct use of the using the devices, systems, and methods herein to couple two blood vessels together during surgical procedures such as cardiac by-pass. Figs. 32A to 32G illustrate representative contents for

instructions in this regard.

Other examples of environments where using the devices, systems, and methods herein described are well suited for use, and for which instructions for use can be drafted by persons of skill in the art based upon the disclosures herein, include the connection of blood vessels include autologous breast reconstruction (e.g., DIEP, SIEA, or Inner Thigh Flap procedures), or other forms of microvascular surgeries during which a composite block of tissue (called "a free flap") is transplanted from one part of the body to another distant site, where its circulation (artery and vein) is restored. Such procedures typically utilize microsurgical techniques, to which the devices, systems, and methods herein described are well suited. Such procedures can involve the breast (e.g., reconstruction with the free TRAM, superior and inferior gluteal flap, TFL flap, Ruben's flap, gracilis flap); or the trunk (e.g., coverage of the abdomen and chest, specifically following large wounds typically associated with radiation therapy and cancer resections); or the head and neck (e.g., reconstruction of the mandible, esophagus, scalp and cranial base); or the lower extremity (e.g., coverage of traumatic wounds and post-oncologic resections, salvage of amputation stumps, bony reconstruction, coverage of nonhealing lower extremity ulcers secondary to diabetes, arterial or venous insufficiency); or facial re-animation (e.g., restoration of facial expression following nerve injury / cancer resections); or the hand (e.g., wound coverage, digital replacement and reconstruction, functioning muscle transplantation).

Other examples of environments where using the devices, systems, and methods herein described are well suited for use, and for which instructions for use can be drafted by persons of skill in the art based upon the

disclosures herein, include the joining of body conduits or hollow body organs that are not blood vessels. For example, using the devices, systems, and methods described above, a segment of intestine can be resected and the two remaining ends can be joined.

V. Conclusion

The above-described embodiments of this invention are merely descriptive of its principles and are not to be limited. The scope of this invention instead shall be determined from the scope of the following claims, including their equivalents.

We Claim:

1. A connector device for joining body conduits comprising a structure peripherally defining an interior lumen, the structure including

a first end region sized and configured for insertion into a first body conduit to contact and support tissue,

a second end region sized and configured for insertion into a second body conduit to contact and support tissue, and

an intermediate region between the first and second end regions sized and configured for establishing a connection site between the first and second body conduits along which tissue healing occurs,

the structure including column strength to reform the first and second body conduits at the connection site to create a patent lumen between the first and second body conduits while tissue healing occurs.

2. A connector device according to claim 1 wherein at least one of the first and second end regions is shaped to aid insertion into the respective body conduit.

3. A connector device according to claim 1 wherein at least one of the first end region, the second end region, and the intermediate region includes a surface that enhances frictional forces between the structure and tissue.

4. A connector device according to claim 1 wherein at least one of the first end region, the second end region, and the intermediate region includes a surface that enhances establishment of the connection site without use of tissue penetrating fasteners.

5. A connector device according to claim 1

wherein at least one of the first end region, the second end region, and the intermediate region includes an aperture to receive a tissue penetrating fastener.

6. A connector device according to claim 1 wherein the first end region has a first physical dimension, and

wherein at least one of the second end region and the intermediate region has a second physical dimension that is different than the first physical dimension.

7. A connector device according to claim 1 wherein the structure comprises a first connector member that includes the first end region, a second connector member that includes the second end region, and mating couplers on the first and second connector members mutually sized and configured to fit together to join the first and second connector members and form the intermediate region.

8. A connector device according to claim 1 wherein the structure extends along a longitudinal axis.

9. A connector device according to claim 1 wherein the structure includes a curvilinear bend.

10. A connector device according to claim 1 wherein at least one of the first end region, the second end region, and the intermediate region includes a braided conformation.

11. A connector device according to claim 1 wherein at least one of the first end region, the second end region, and the intermediate region includes an open scaffold conformation.

12. A connector device according to claim 1 wherein at least one of the first end region,

the second end region, and the intermediate region includes a coiled conformation.

13. A connector device according to claim 1 wherein at least a portion of the structure is flexible.

14. A method comprising

providing a connector device comprising a structure peripherally defining an interior lumen, the structure including a first end region, a second end region, and an intermediate region between the first and second end regions,

inserting the first end region into a first body conduit to contact and support tissue within the first body conduit,

inserting the second end region into a second body conduit to contact and support tissue within the second body conduit, and

establishing a connection site in the intermediate region between the first and second body conduits along which tissue healing occurs.

15. A method according to claim 14 wherein the connection site is established without use of a tissue piercing fastener.

16. A method comprising

providing a connector device comprising a structure peripherally defining an interior lumen, the structure including a first end region, a second end region, and an intermediate region between the first and second end regions, and

joining first and second body conduits by inserting the first end region into the first body conduit and inserting the second end region into the second body conduit, and establishing a connection site in the intermediate region between the first and second body conduits along which tissue healing occurs.

17. A method according to claim 16

wherein the connection site is established without use of a tissue piercing fastener.

18. A system comprising

a connector device comprising a structure peripherally defining an interior lumen, the structure including a first end region, a second end region, and an intermediate region between the first and second end regions, and

at least one tool for manipulating the connector device to insert the first end region into a a first body conduit, to insert the second end region into a second body contact, and to establish in the intermediate region a connection site between the body conduits along which tissue healing occurs.

19. A system comprising

a connector device comprising a structure peripherally defining an interior lumen, the structure including a first end region, a second end region, and an intermediate region between the first and second end regions, and

at least one tool for manipulating the connector device to insert the first end region into a first body conduit, to insert the second end region into a second body contact, and to establish in the intermediate region, without use of a tissue-piercing fastener, a connection site between the body conduits along which tissue healing occurs.

20. A kit comprising

a connector device comprising a structure peripherally defining an interior lumen, the structure including a first end region, a second end region, and an intermediate region between the first and second end regions, and

instructions for using the connection device

comprising (i) inserting the first end region into a first body conduit; (ii) inserting the second end region into a second body conduit; (iii) establishing a connection site in the intermediate region between the first and second body conduits; and (iv) preserving the connector device between the body conduits while tissue healing occurs along the connection site.

21. A kit according to claim 20

wherein the connection site is established without use a tissue-piercing fastener.

22. A kit according to claim 20

further including at least one tool for manipulating the connector device according to the instructions for using.

23. A system comprising

a connector device for joining body conduits comprising a structure peripherally defining an interior lumen, the structure including a first end region sized and configured for insertion into a first body conduit to contact and support tissue, a second end region sized and configured for insertion into a second body conduit to contact and support tissue, and an intermediate region extending between the first and second end regions sized and configured for establishing a connection site between the first and second body conduits along which tissue healing occurs, and

a tissue adherent material on at least a portion of the connector device.

24. A system according to claim 23

wherein the tissue adherent material comprises a tissue adherent coating, and

further including a removable sheath covering the tissue adherent coating prior to an instance of use.

25. A system according to claim 23

wherein the tissue adherent material comprises

a coating that becomes tissue adherent in response to exposure to an activating agent.

26. A system according to claim 25

wherein the activating agent includes moisture, or pressure, or moisture and pressure.

27. A system according to claim 23

wherein the tissue adherent material includes a tissue adherent composition that is applied to the connector device at an instance of use.

28. A system according to claim 23

wherein the tissue adherent material includes a tissue adherent hydrogel that is applied to the connector device at an instance of use and that cross-links *in situ* on the connector device.

29. A system according to claim 28

further including an applicator for applying components of the tissue adherent hydrogel to the connector device at an instance of use.

30. A method comprising

providing a connector device comprising a structure peripherally defining an interior lumen, the structure including a first end region, a second end region, and an intermediate region between the first and second end regions,

applying a tissue adherent material to at least a portion of the connector device,

inserting the first end region into a first body conduit,

inserting the second end region into a second body conduit, and

establishing a connection site in the intermediate region between the terminated ends of the first and second body conduits along which tissue healing occurs.

31. A method according to claim 30

wherein the tissue adherent material is applied to the intermediate region.

32. A method according to claim 30

wherein the tissue adherent material is applied to at least one of the first and second end regions.

33. A method according to claim 30

wherein the tissue adherent material is applied to both of the first and second end regions.

34. A method according to claim 30

further including applying a tissue adherent material about the connection site.

35. A method according to claim 30

wherein the tissue adherent material comprises a hydrogel that cross-links *in situ* on the connection device.

36. A method comprising

providing a connector device comprising a structure peripherally defining an interior lumen, the structure including a first end region, a second end region, and an intermediate region between the first and second end regions, and

joining first and second body conduits by applying a tissue adherent material to at least a portion of the connector device, inserting the first end region into the first body conduit, inserting the second end region into second body conduit, and establishing a connection site in the intermediate region between the first and second body conduits.

37. A method according to claim 36

wherein the tissue adherent material is applied to the intermediate region.

38. A method according to claim 36

wherein the tissue adherent materials is applied to at least one of the first and second end

regions.

39. A method according to claim 36

wherein the tissue adherent material is applied to both of the first and second end regions.

40. A method according to claim 36

further including applying a tissue adherent material about the connection site.

41. A method according to claim 36

wherein the tissue adherent material comprises a hydrogel that cross-links *in situ* on the connection device.

42. A kit comprising

a connector device comprising a structure peripherally defining an interior lumen, the structure including a first end region, a second end region, and an intermediate region between the first and second end regions,

a tissue adherent material, and

instructions for using the connection device comprising (i) applying the tissue adherent material to at least at portion of the connector; (ii) inserting the first end region into a first body conduit; (ii) inserting the second end region into a second body conduit; (iii) establishing a connection site in the intermediate region between the first and second body conduits; and (iv) preserving the connector device between the body conduits while tissue healing occurs along the connection site.

43. A method according to claim 42

wherein the instructions for using include applying the tissue adherent material to the intermediate region.

44. A method according to claim 42

wherein the instructions for using include applying the tissue adherent material to at least one of

the first and second end regions.

45. A method according to claim 42

wherein the instructions for using include applying the tissue adherent material to both of the first and second end regions.

46. A method according to claim 42

wherein the instructions for using include applying a tissue adherent material about the connection site.

47. A method according to claim 42

wherein the tissue adherent material comprises a hydrogel that cross-links *in situ* on the connection device.

48. A kit according to claim 42

wherein the connection site is established without use a tissue-piercing fastener.

49. A kit according to claim 42

further including at least one tool for manipulating the connector device according to the instructions for using.

50. A connector device for joining body conduits comprising a structure peripherally defining an interior lumen, the structure including a first end region sized and configured for insertion into a first body conduit to contact and support tissue, a second end region sized and configured for insertion into a second body conduit to contact and support tissue, and an intermediate region extending between the first and second end regions sized and configured for establishing a connection site between the first and second body conduits along which tissue healing occurs, at least one of the first end region, the second end region, and the intermediate region includes a surface conformation sized and configured for carrying a tissue adherent material.

51. A connector device according to claim 50

wherein the surface conformation comprises indentations that increase the surface area of retention of the tissue adherent material.

52. A connector device according to claim 51 wherein the indentations comprise wells.

53. A connector device according to claim 51 wherein the indentations comprise channels.

54. A connector device for joining body conduits comprising a biodegradable structure peripherally defining an interior lumen, the structure including a first end region sized and configured for insertion into a first body conduit to contact and support tissue, a second end region sized and configured for insertion into a second body conduit to contact and support tissue, and an intermediate region extending between the first and second end regions sized and configured for establishing a connection site between the first and second body conduits along which tissue healing occurs.

55. A connector device for joining body conduits comprising a biodegradable polyanhydride polymer structure including salicylic acid, the polyanhydride polymer structure being formed to peripherally define an interior lumen, the polyanhydride polymer structure including a first end region sized and configured for insertion into a first body conduit, a second end region sized and configured for insertion into a second body conduit, and an intermediate region extending between the first and second end regions sized and configured for establishing a connection site between the first and second body conduits along which tissue healing occurs.

56. A connector device according to claim 55 wherein at least one of the first and second end regions is shaped to aid insertion into the respective body conduit.

57. A connector device according to claim 55 wherein at least one of the first end region, the second end region, and the intermediate region includes a surface that enhances frictional forces between the structure and tissue.

58. A connector device according to claim 55 wherein at least one of the first end region, the second end region, and the intermediate region includes a surface that enhances establishment of the connection site without use of tissue penetrating fasteners.

59. A connector device according to claim 55 wherein at least one of the first end region, the second end region, and the intermediate region includes a braided conformation.

60. A connector device according to claim 55 wherein at least one of the first end region, the second end region, and the intermediate region includes an open scaffold conformation.

61. A connector device according to claim 55 wherein at least a portion of the structure is flexible.

62. A method comprising

providing a biodegradable polyanhydride polymer structure including salicylic acid, the polyanhydride polymer structure being formed to peripherally define an interior lumen, the polyanhydride polymer structure including a first end region sized and configured for insertion into a first body conduit, a second end region sized and configured for insertion into a second body conduit, and an intermediate region extending between the first and second end regions sized and configured for establishing a connection site between the first and second body conduits,

joining first and second body conduits by

inserting the first end region into the first body conduit, inserting the second end region into second body conduit, and establishing a connection site in the intermediate region between the first and second body conduits, and

preserving the connector device between the body conduits while tissue healing occurs along the connection site.

63. A method according to claim 62 further including applying a biodegradable tissue adherent material to at least a portion of the polyanhydride polymer structure.

64. A method according to claim 62 further including applying a biodegradable tissue adherent material about the connection site.

65. A method according to claim 62 further including *in situ* degradation of the polyanhydride polymer structure at the connection site.

66. A kit comprising

a biodegradable polyanhydride polymer structure including salicylic acid, the polyanhydride polymer structure being formed to peripherally define an interior lumen, the polyanhydride polymer structure including a first end region sized and configured for insertion into a first body conduit, a second end region sized and configured for insertion into a second body conduit, and an intermediate region extending between the first and second end regions sized and configured for establishing a connection site between the first and second body conduits, and

instructions for using the biodegradable polyanhydride polymer structure comprising (i) inserting the first end region into a first body conduit; (ii) inserting the second end region into a second body conduit; (iii) establishing a connection site in the

intermediate region between the first and second body conduits; and (iv) preserving the connector device between the body conduits while tissue healing occurs along the connection site.

67. A kit according to claim 66

wherein the instructions for using include *in situ* degradation of the polyanhydride polymer structure at the connection site.

68. A kit according to claim 66

wherein the instructions for using include applying a biodegradable tissue adherent material to at least a portion of the biodegradable polyanhydride polymer structure.

69. A method according to claim 66

wherein the instructions for using include applying a biodegradable tissue adherent material about the connection site.

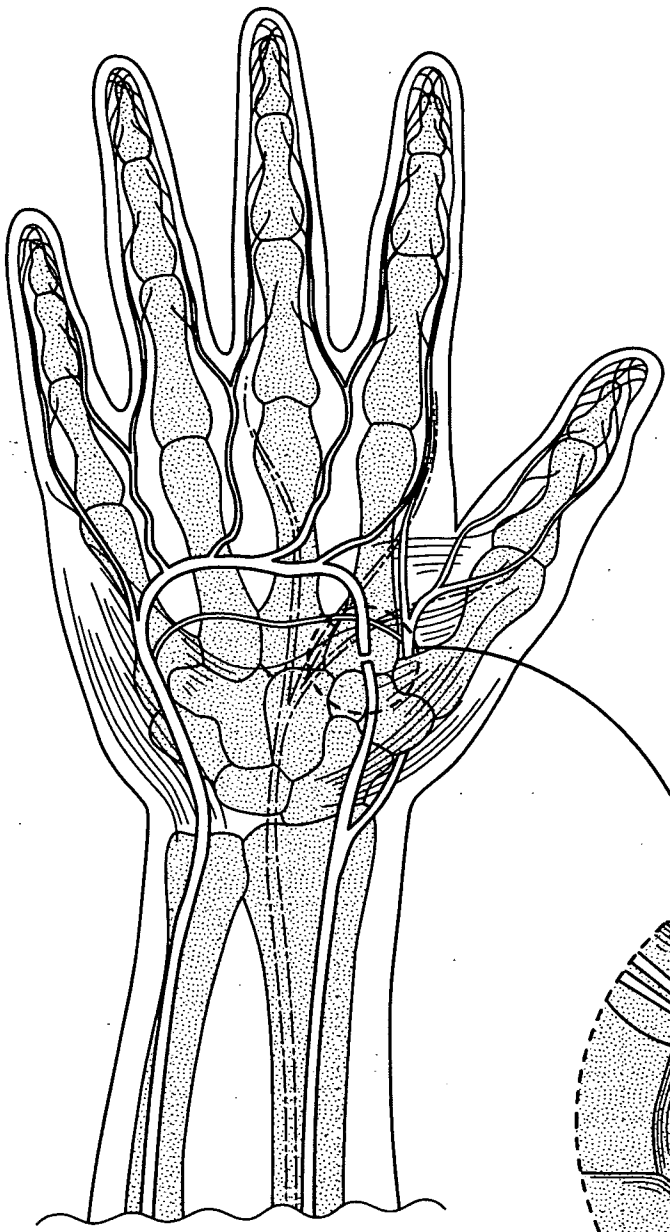


Fig. 1A
PRIOR ART

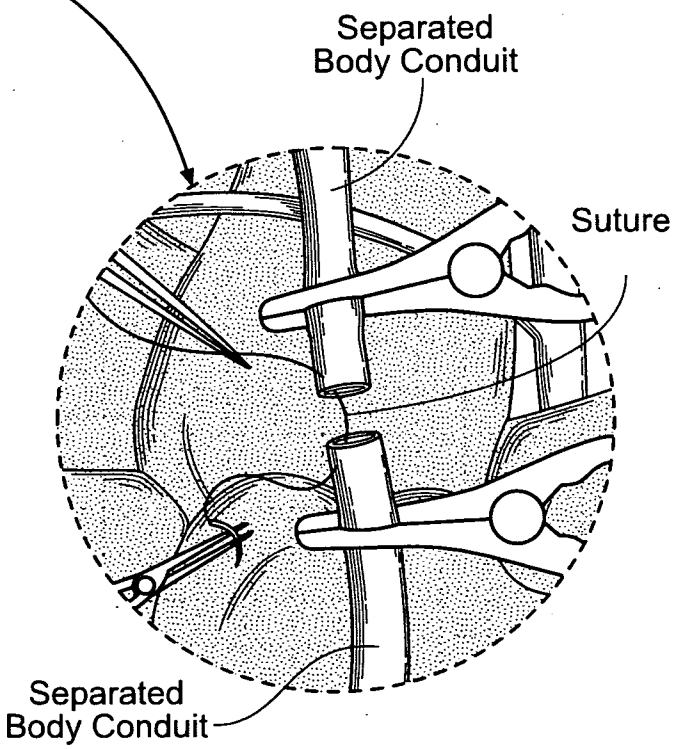


Fig. 1B
PRIOR ART

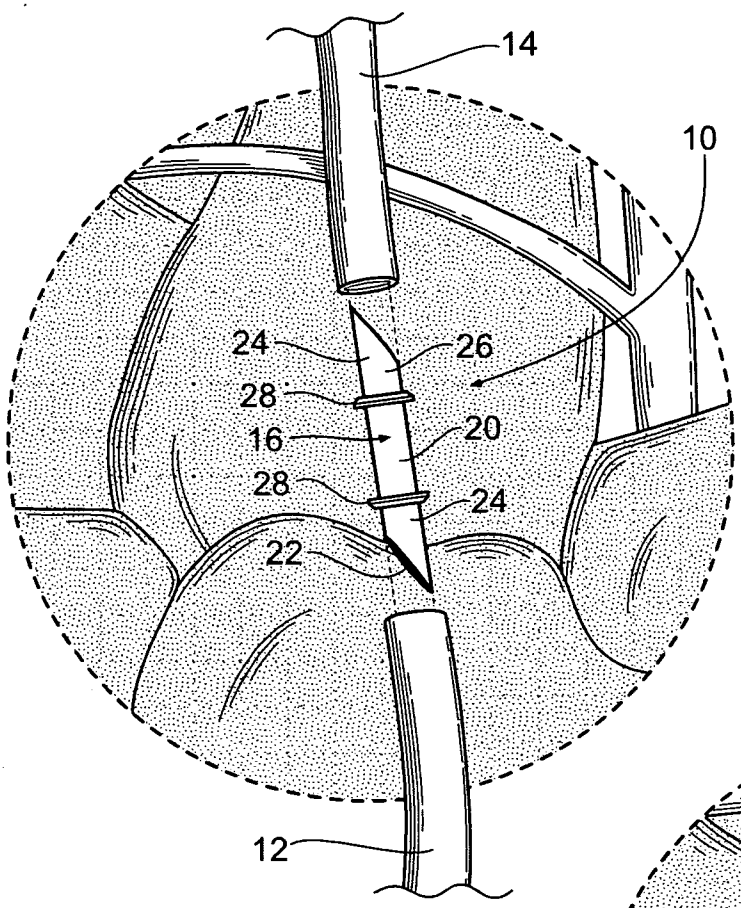


Fig. 2A

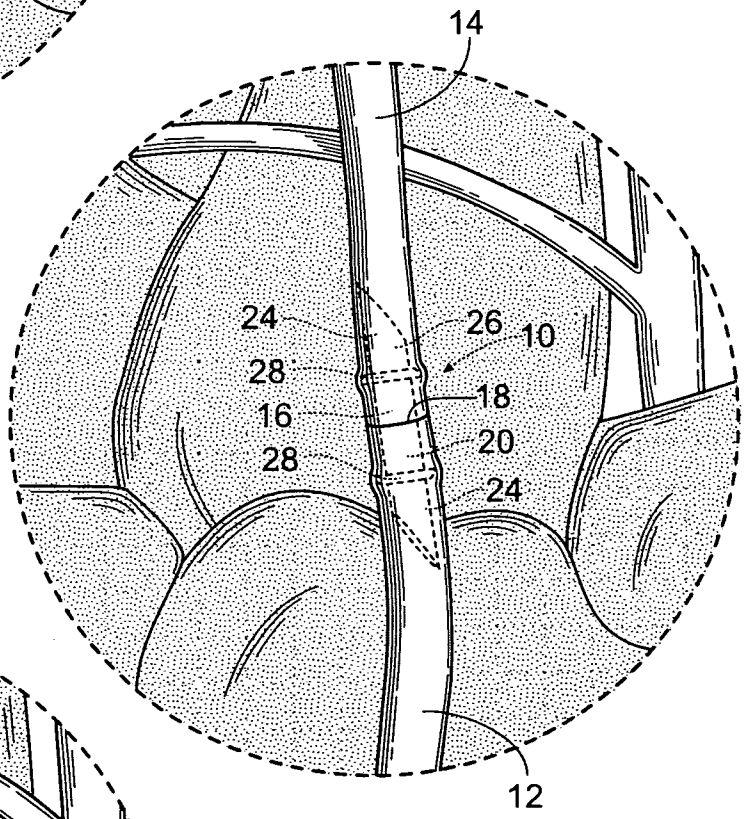


Fig. 2B

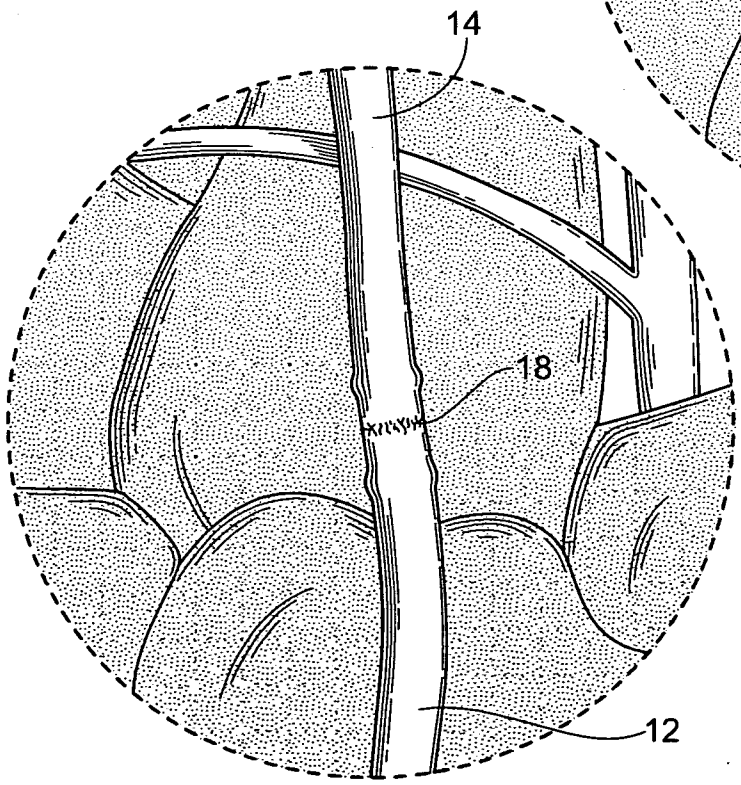


Fig. 2C

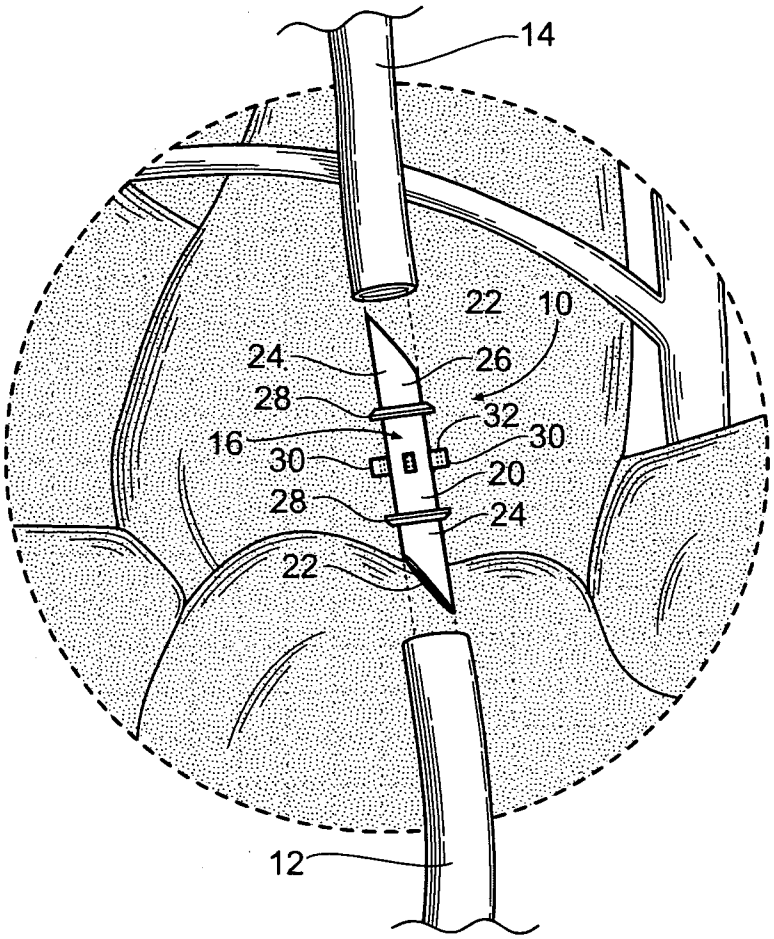

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Fig. 3A

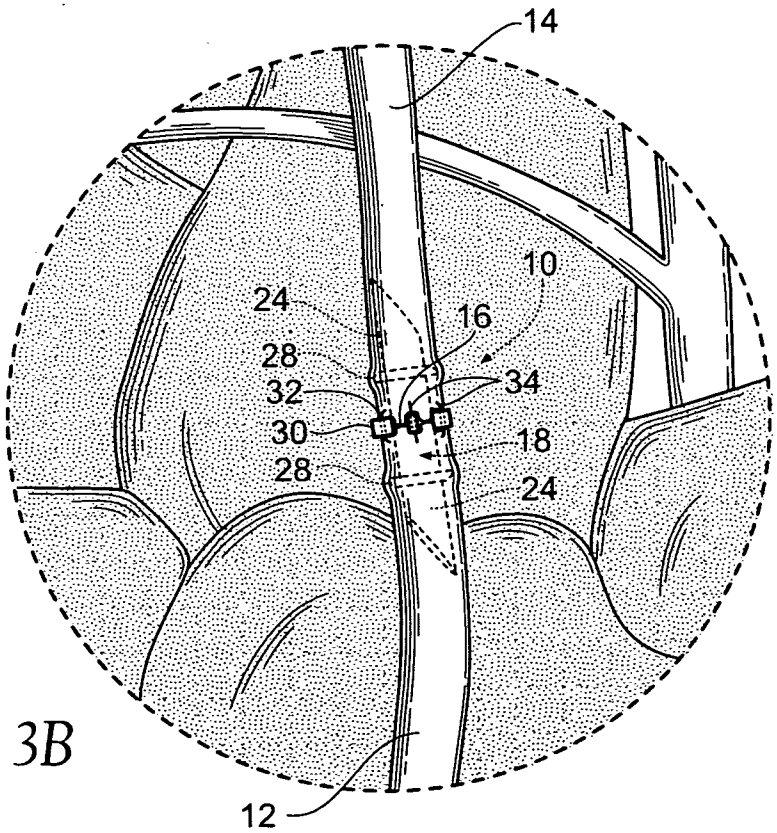
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Fig. 3B

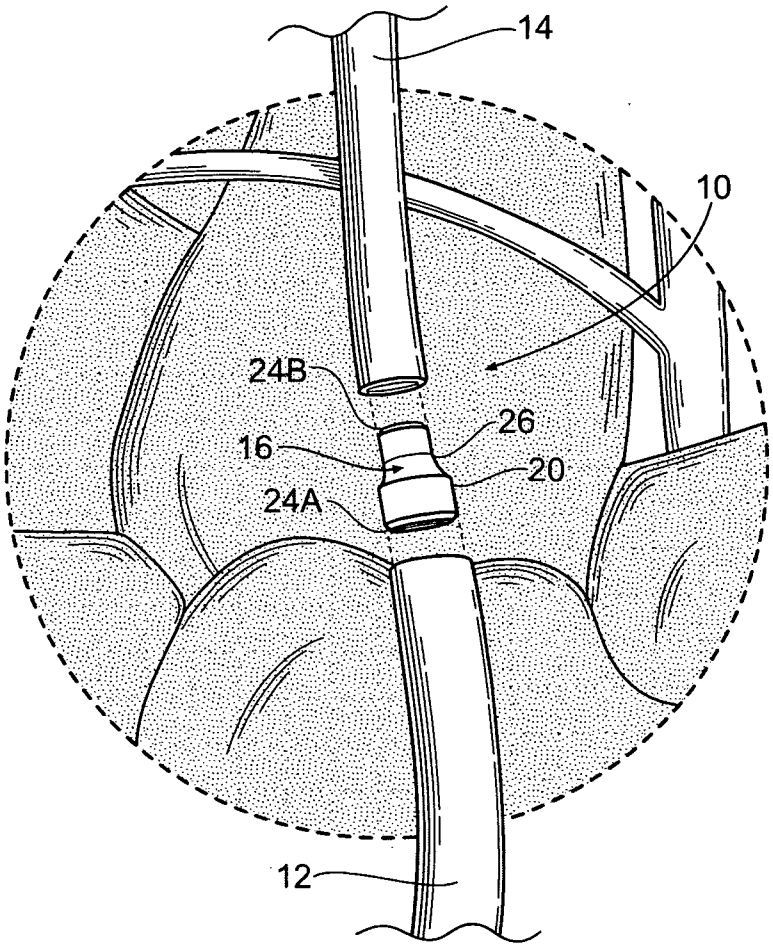


Fig. 4A

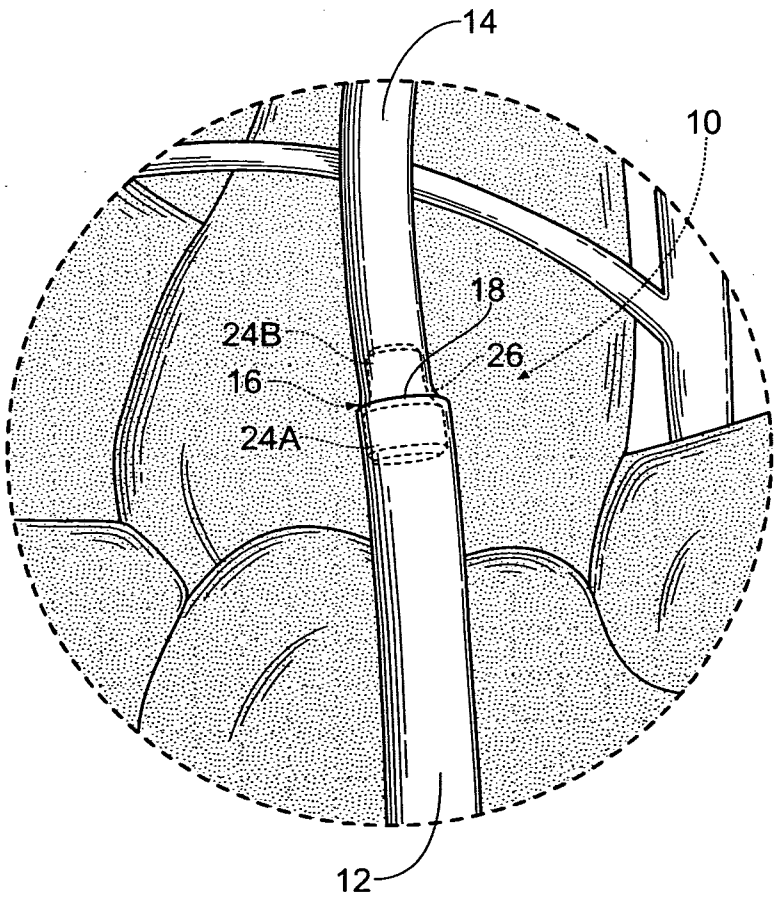


Fig. 4B

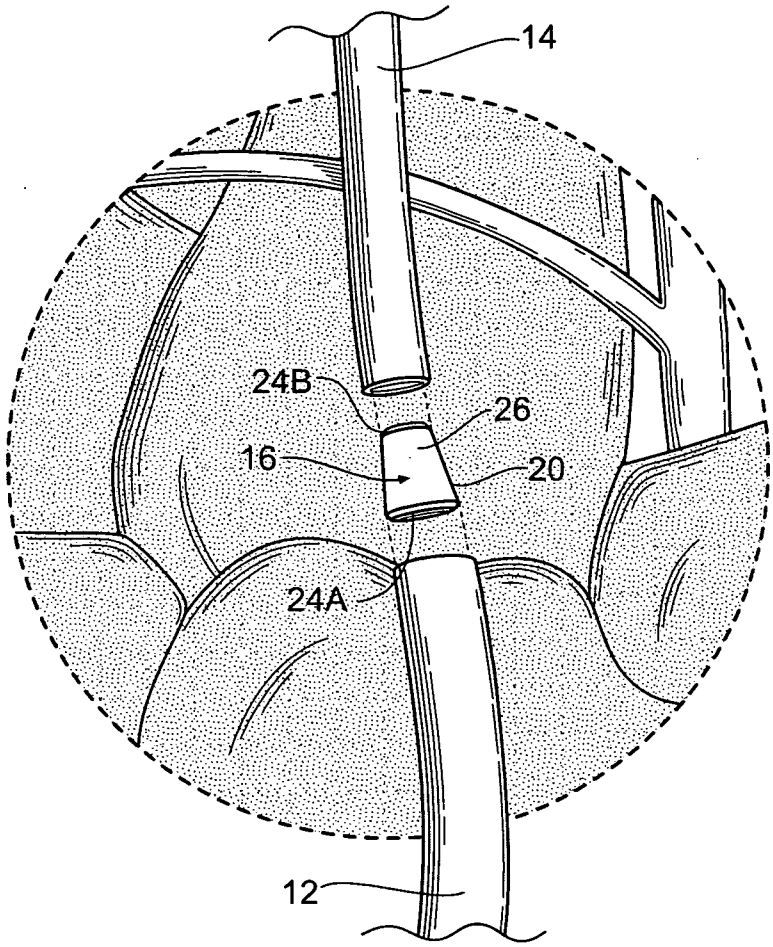


Fig. 5A

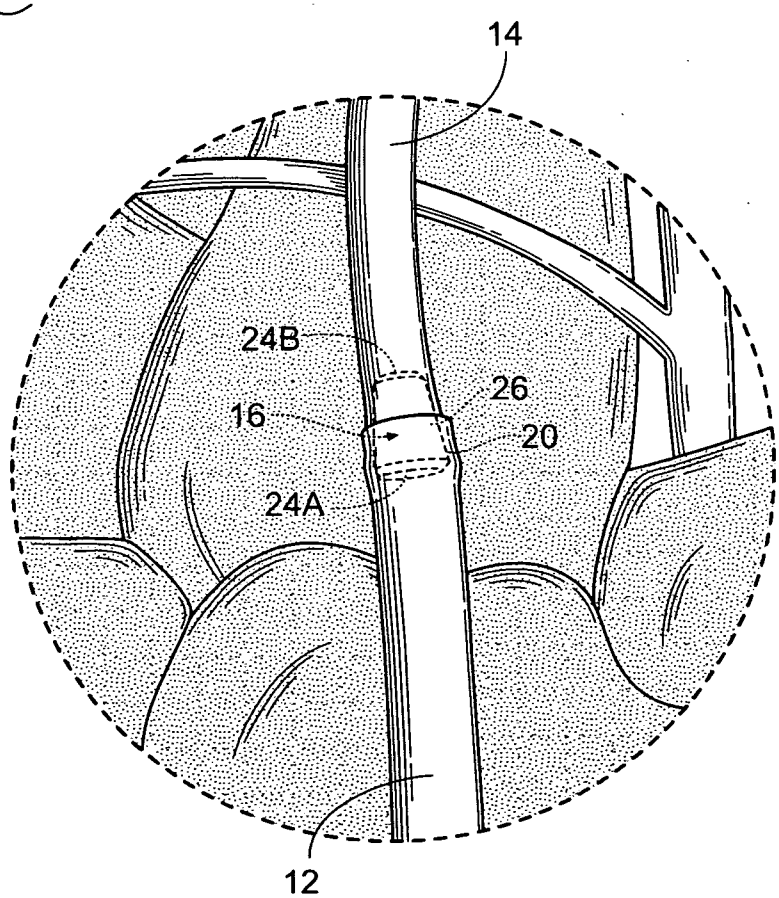
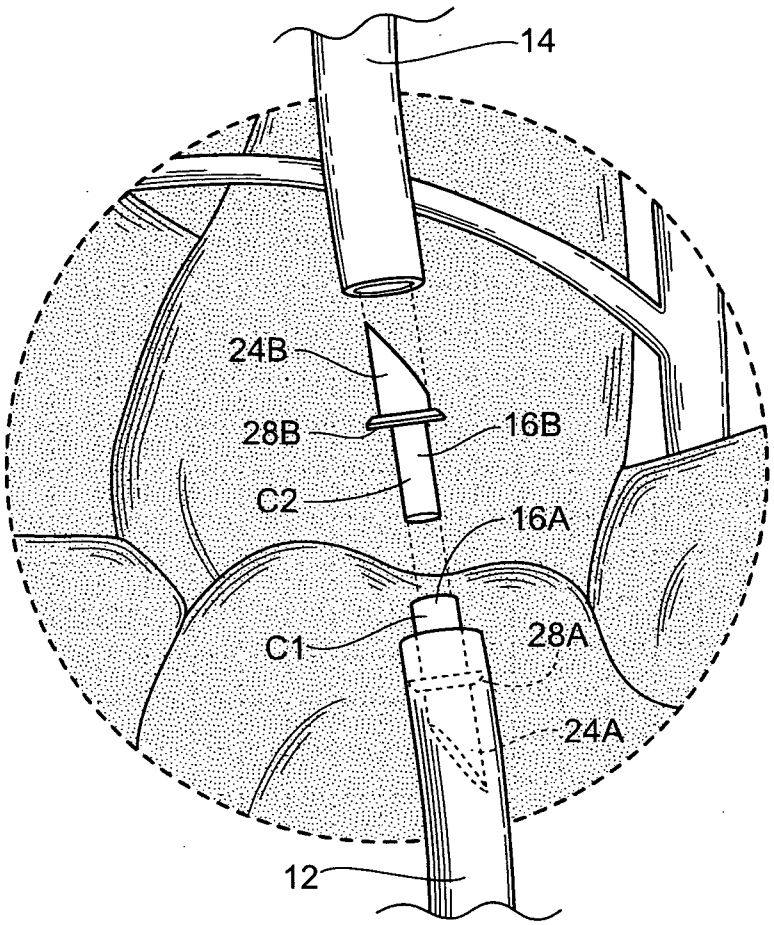


Fig. 5B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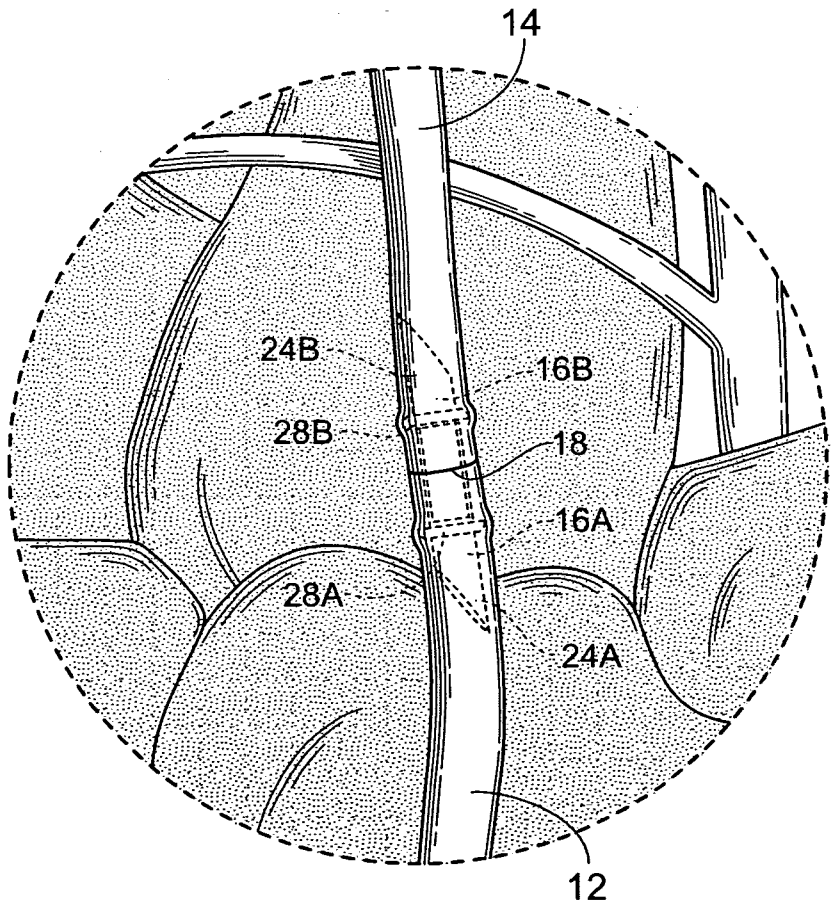
C1
28A
24A
12

Fig. 6A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28A
24A
12

Fig. 6B

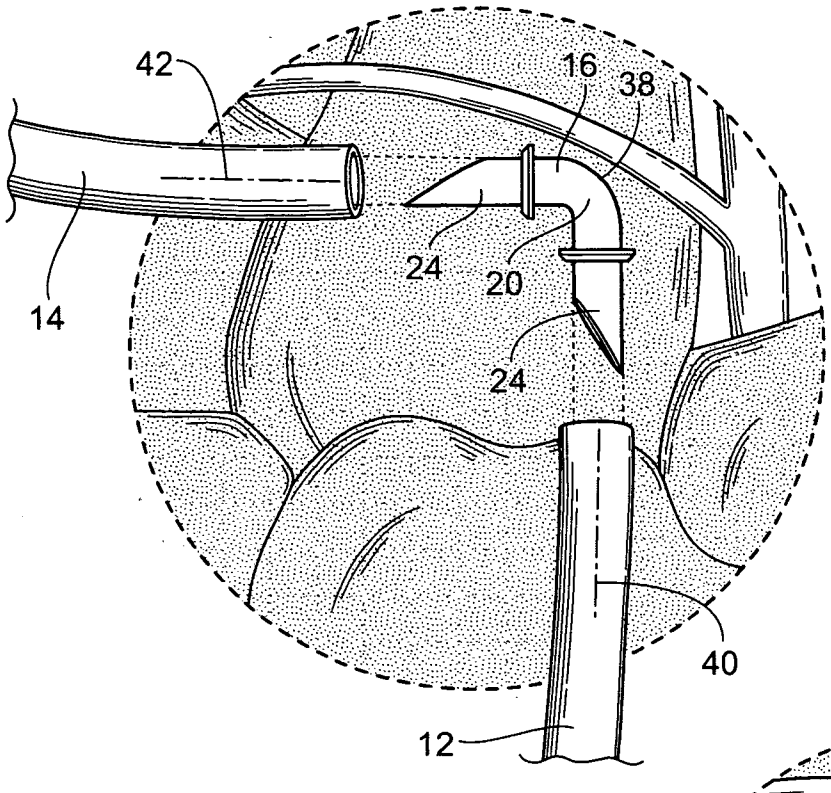

Fig. 7A

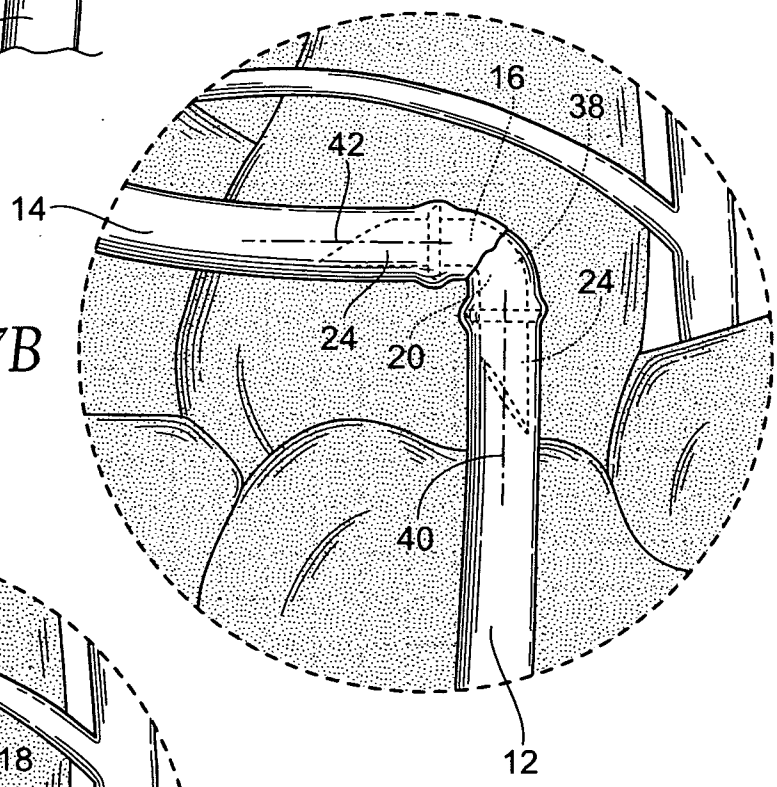

Fig. 7B

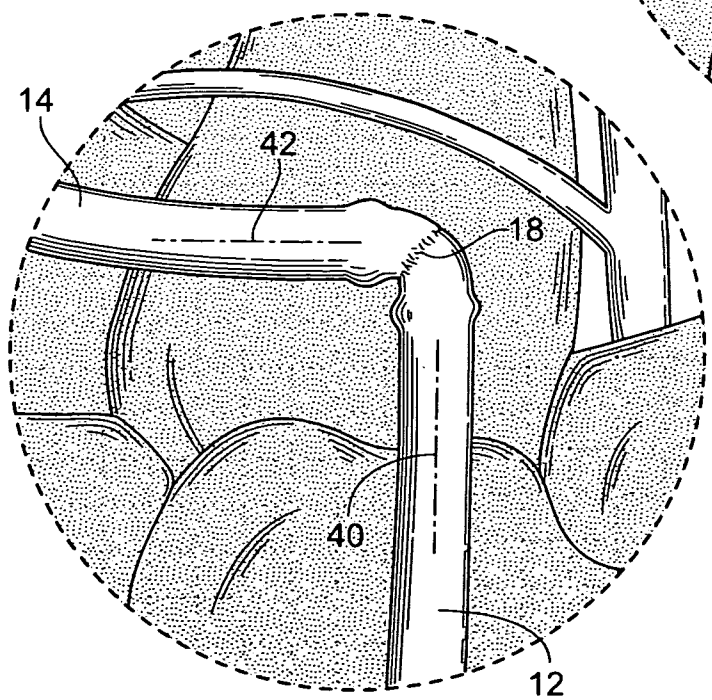

Fig. 7C

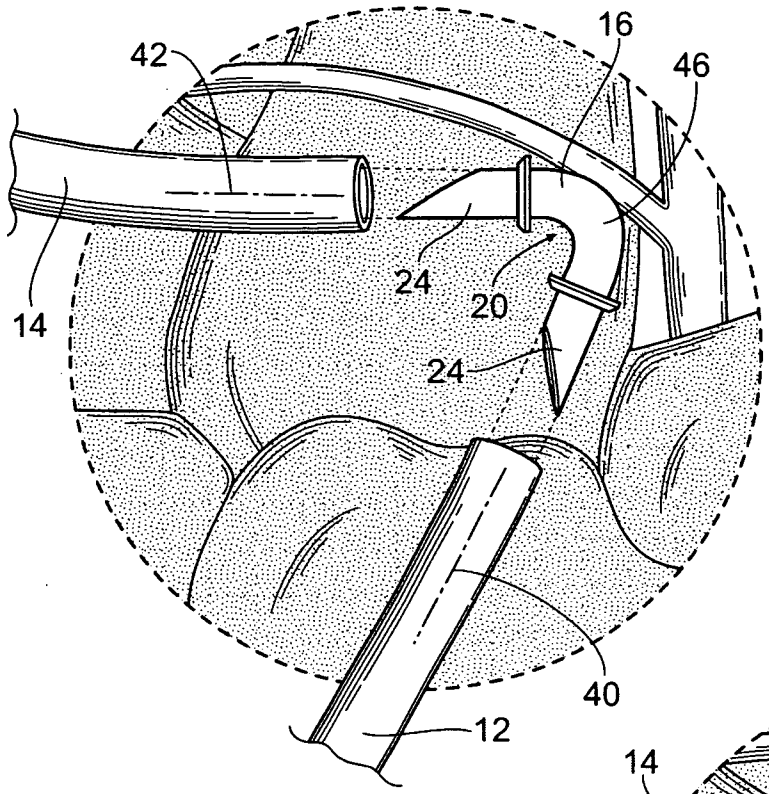

Fig. 8A

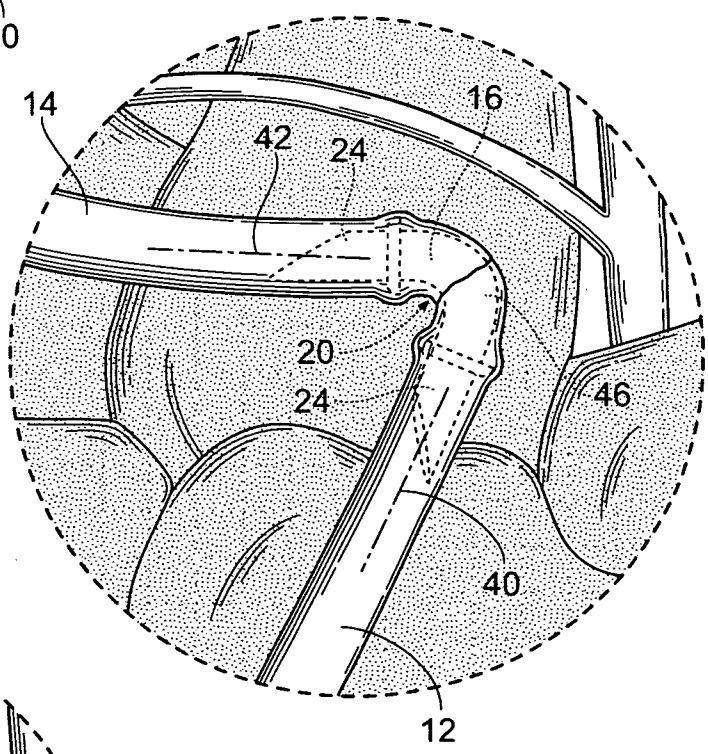

Fig. 8B

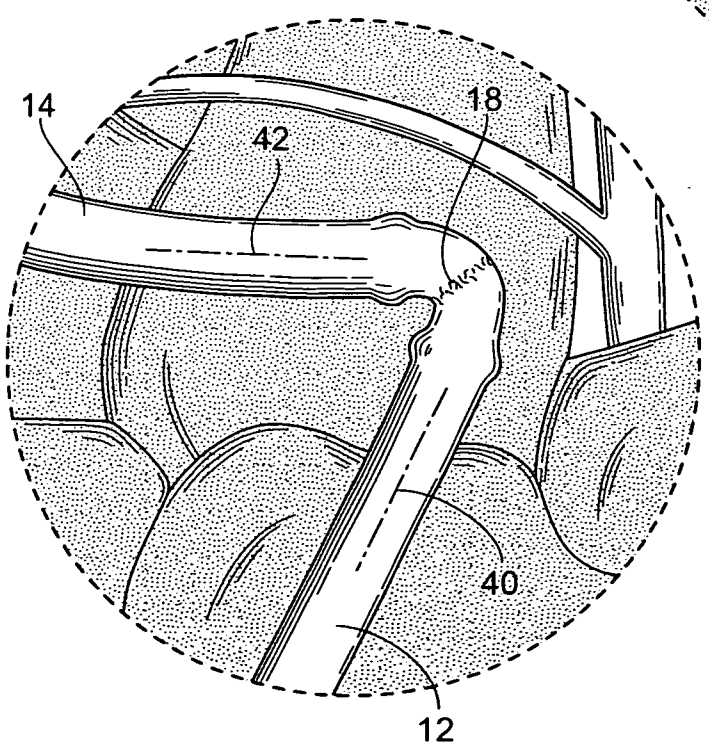

Fig. 8C

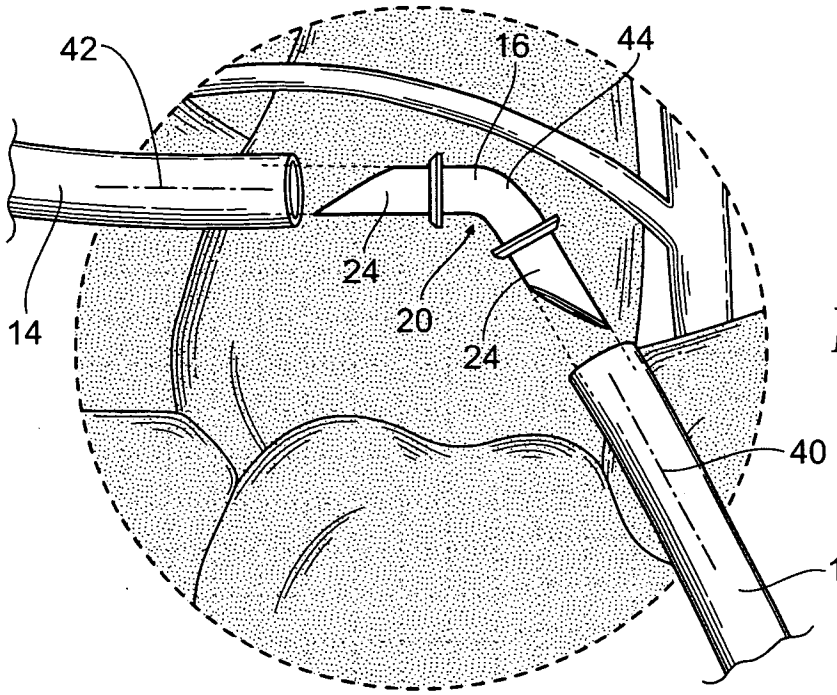

Fig. 9A

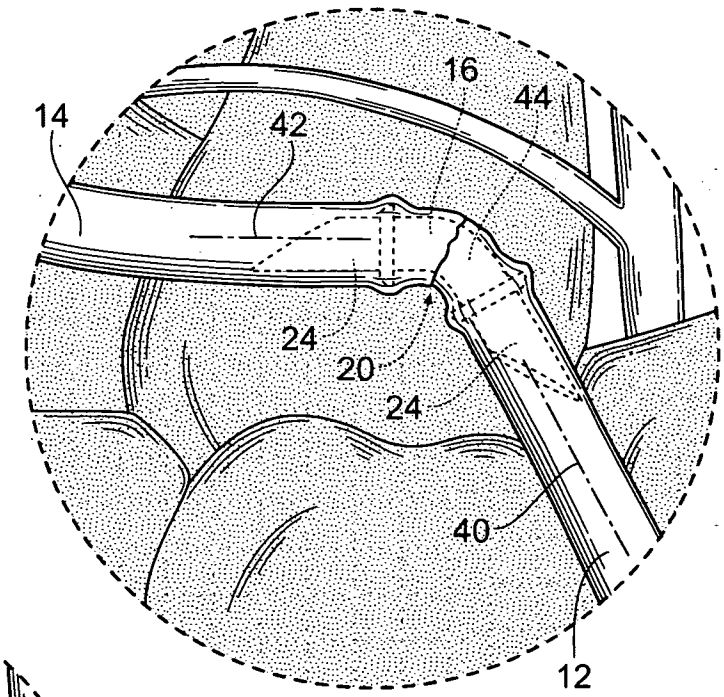

Fig. 9B

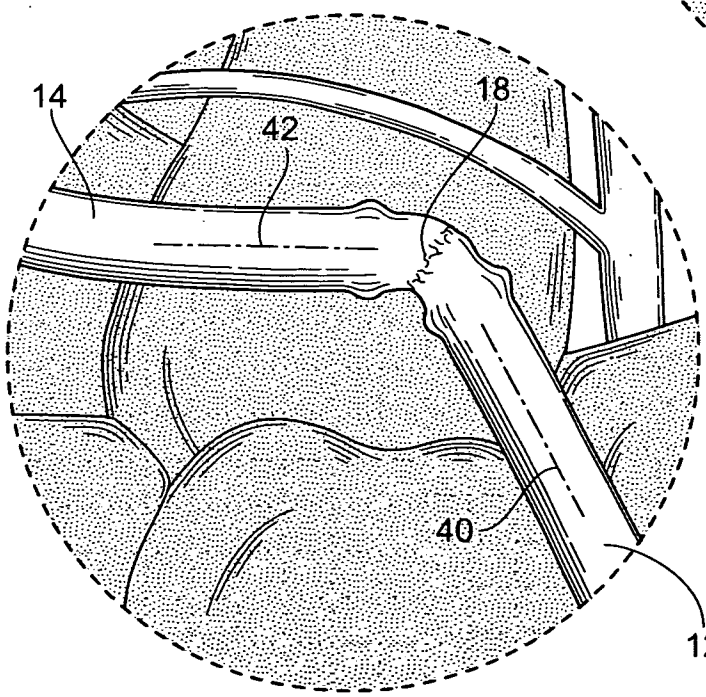

Fig. 9C

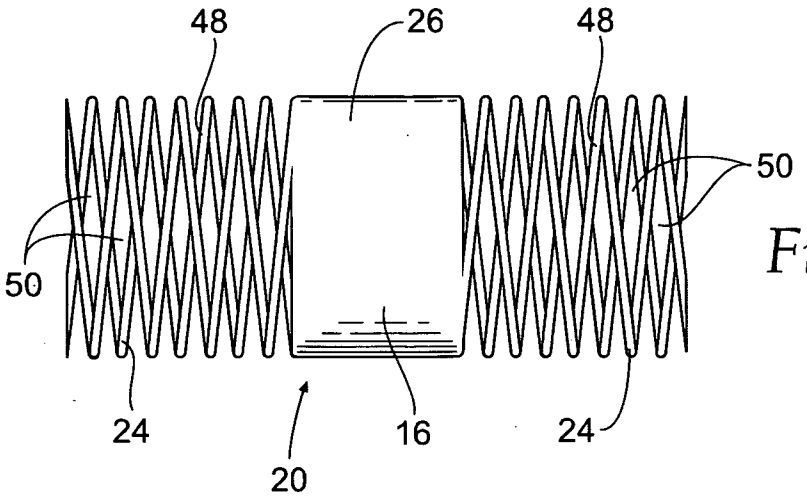

Fig. 10A

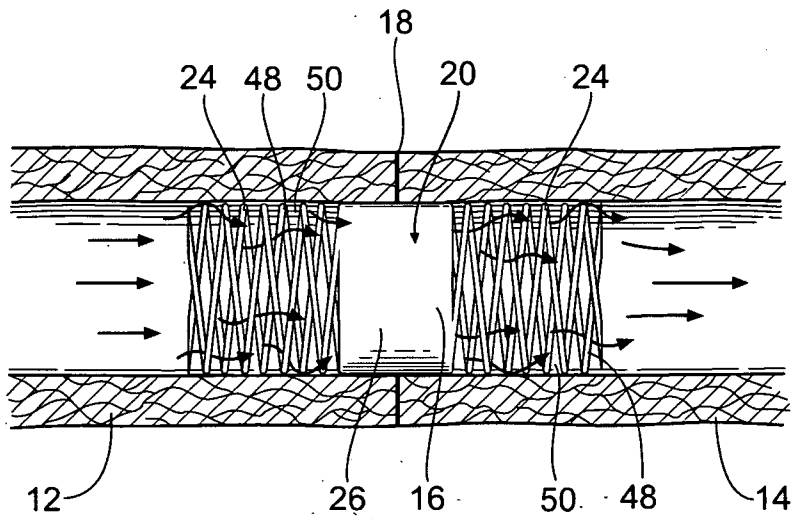

Fig. 10B

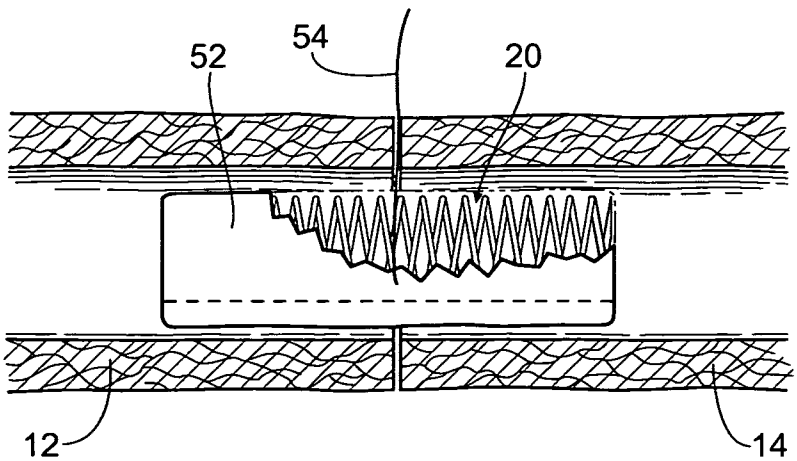

Fig. 11A

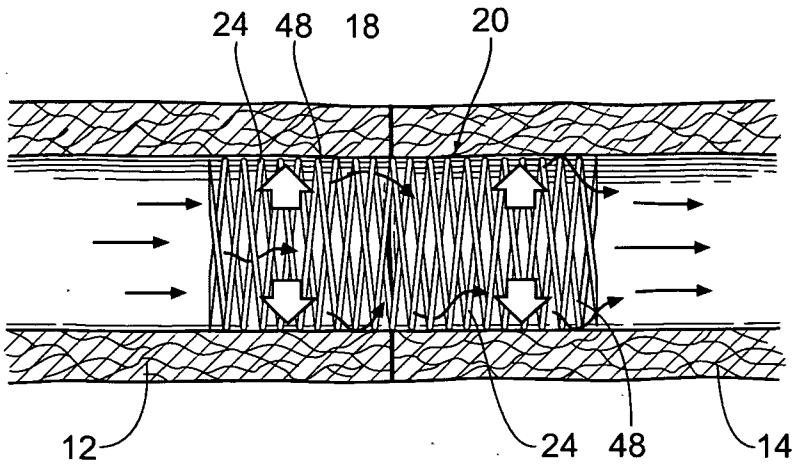

Fig. 11B

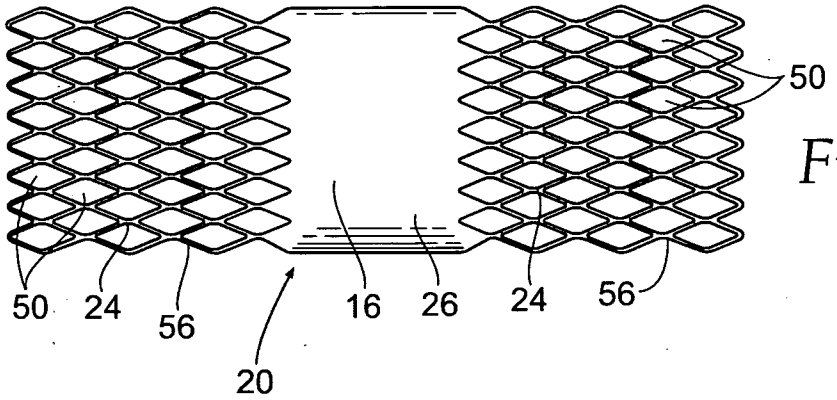

Fig. 12A

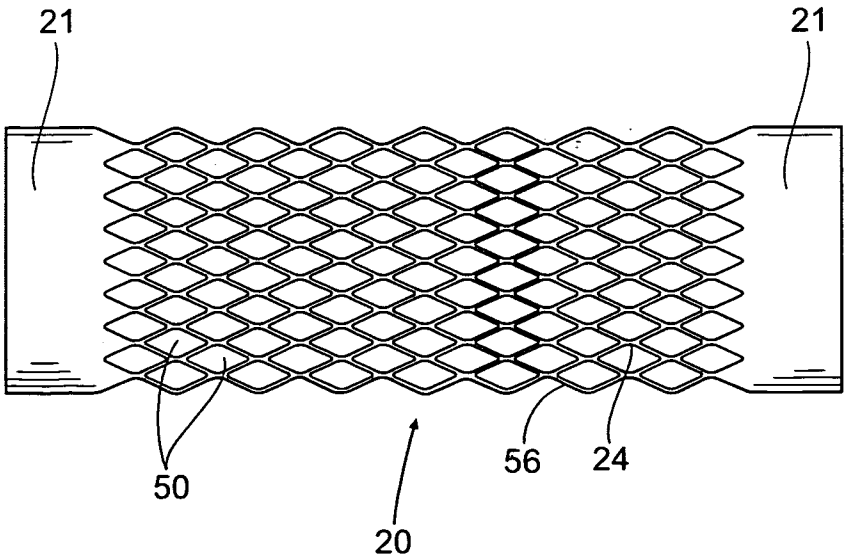

Fig. 12B

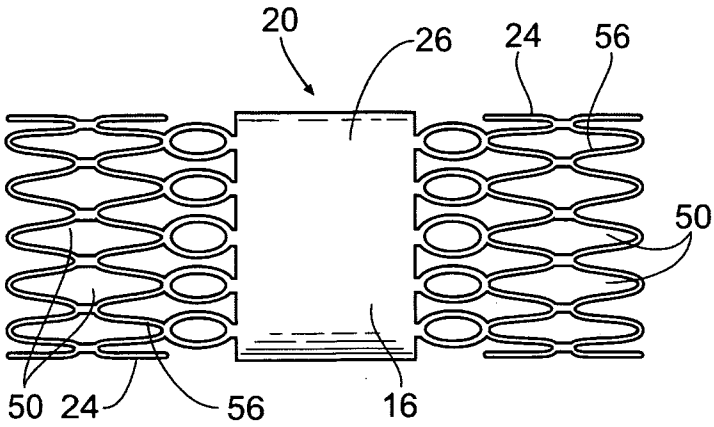

Fig. 13

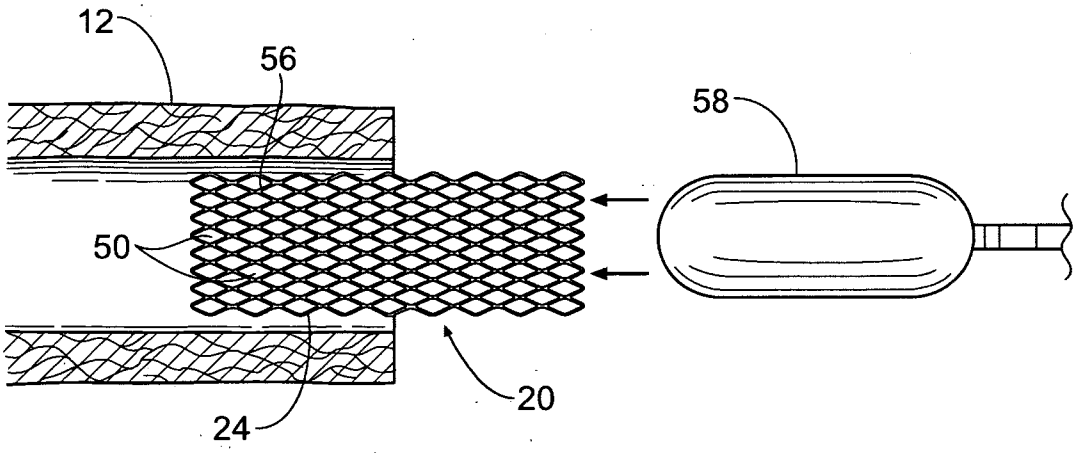

Fig. 14A

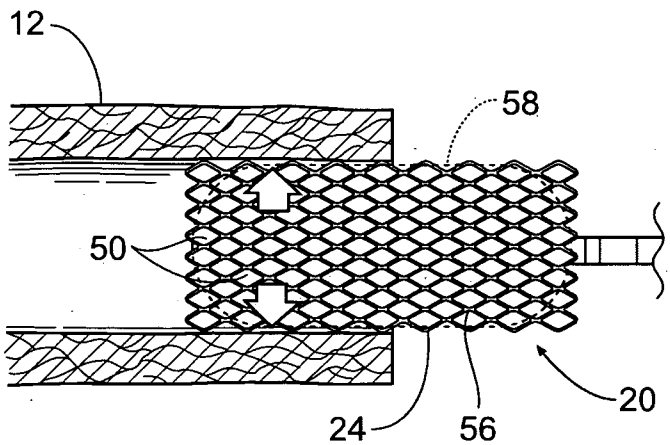

Fig. 14B

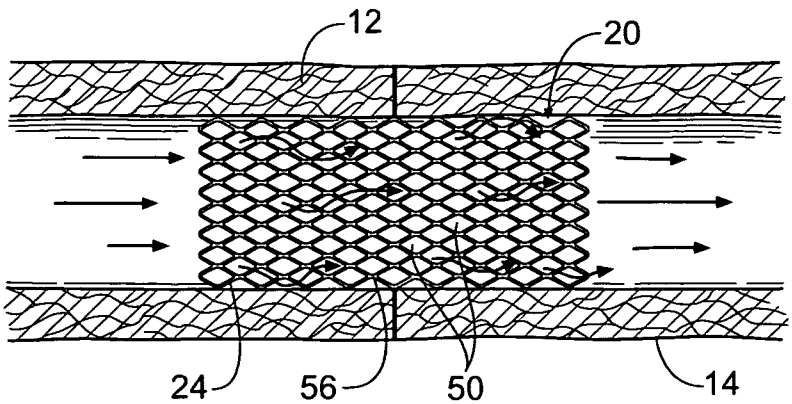

Fig. 14C

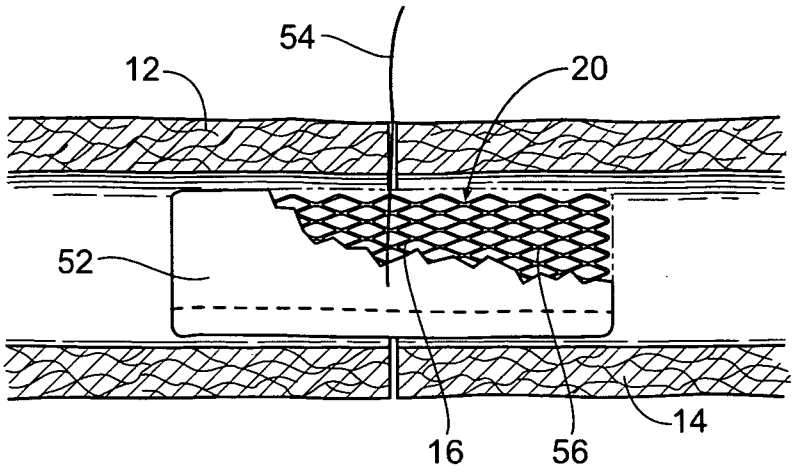

Fig. 15A

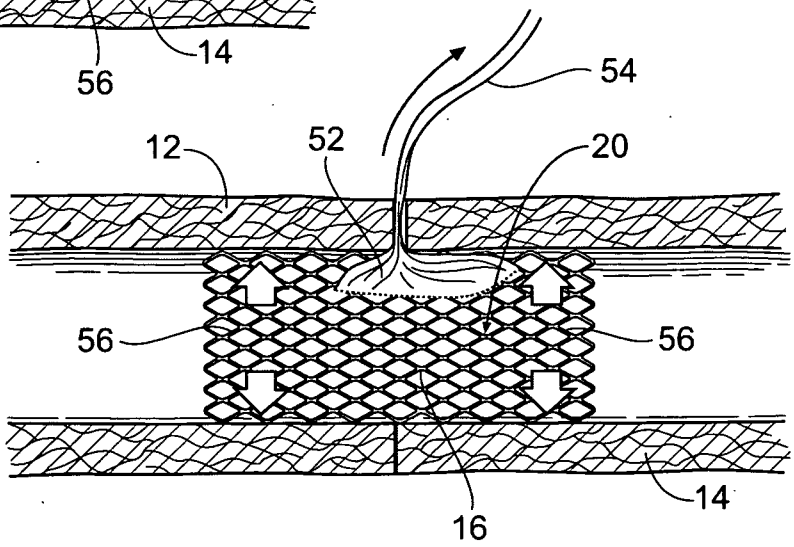

Fig. 15B

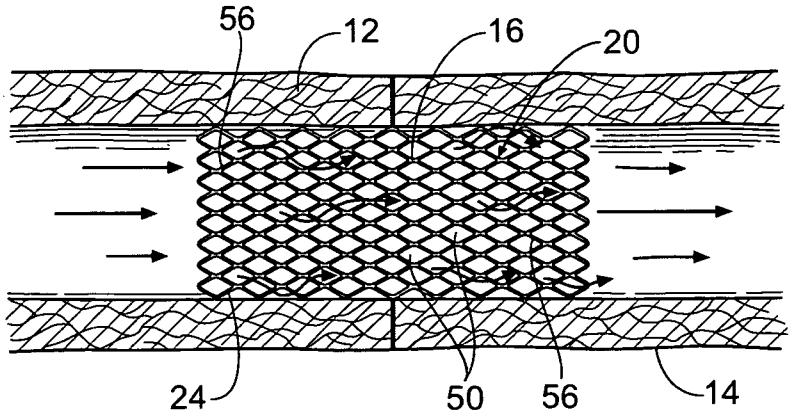

Fig. 15C

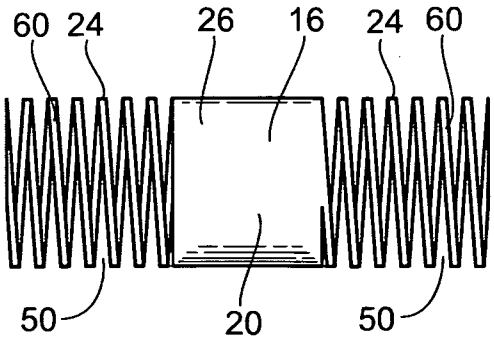

Fig. 16A

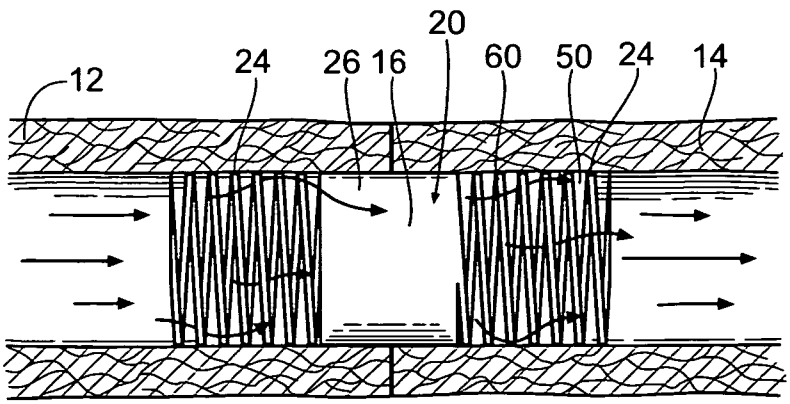

Fig. 15B

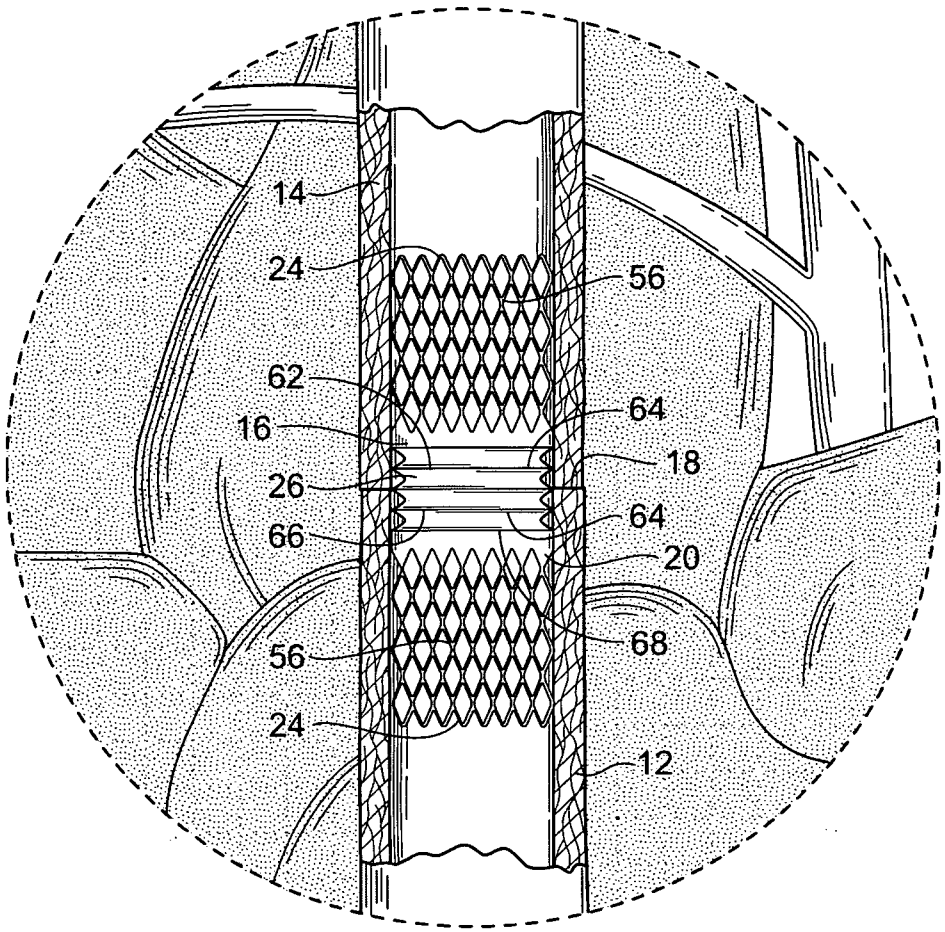

Fig. 17A

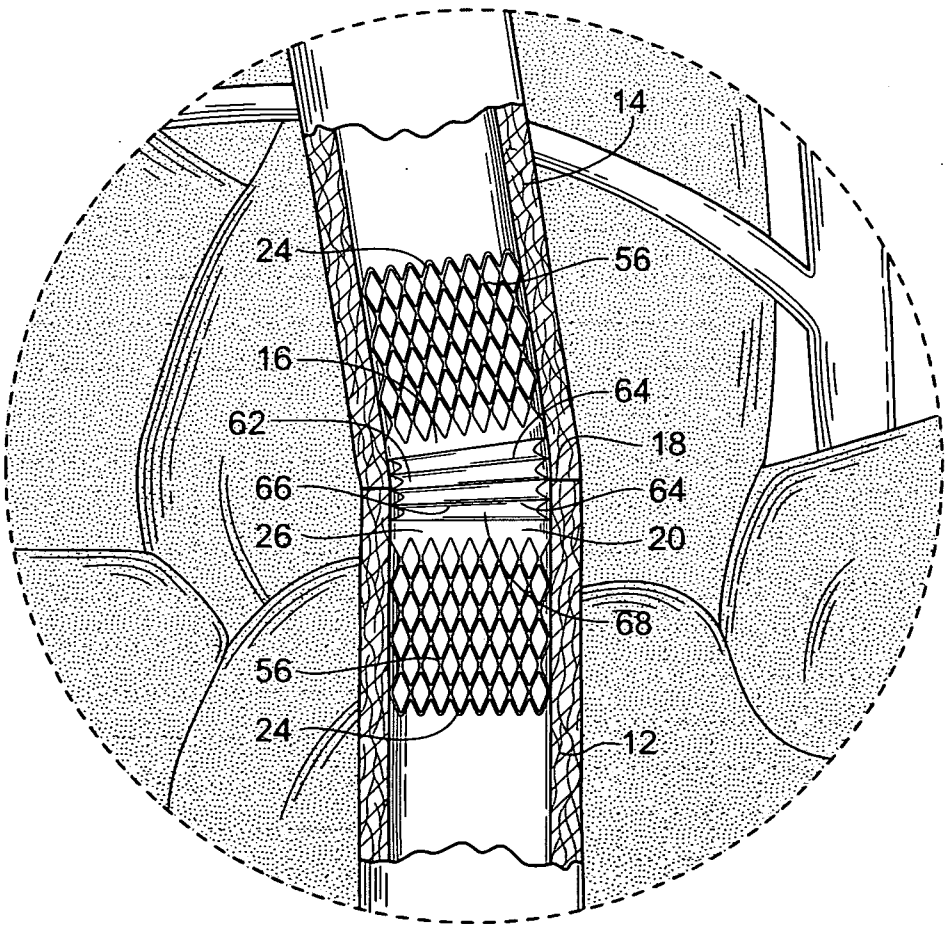

Fig. 17B

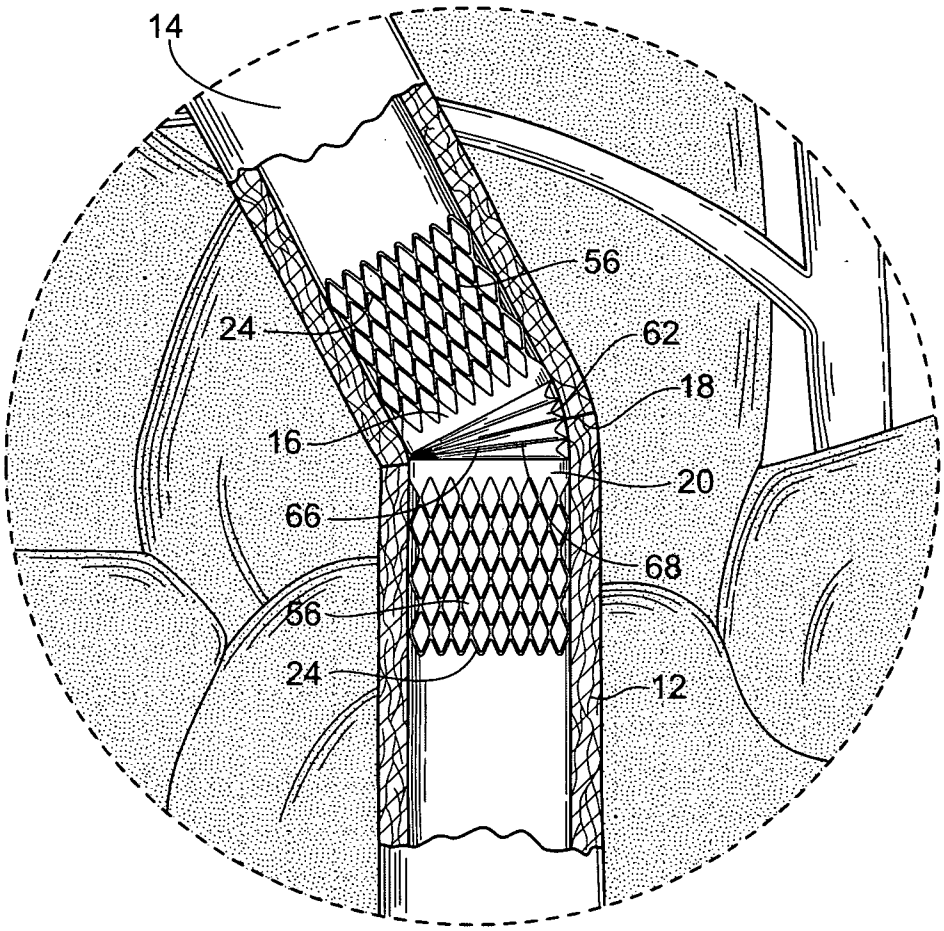

Fig. 17C

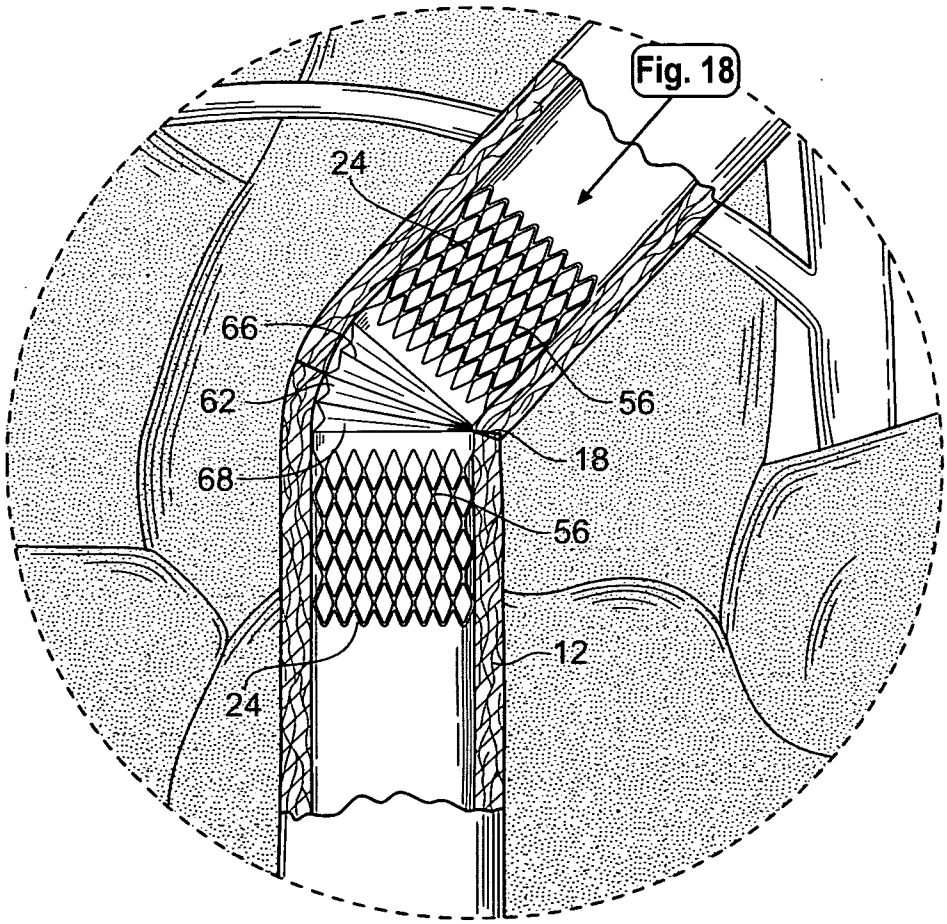

Fig. 17D

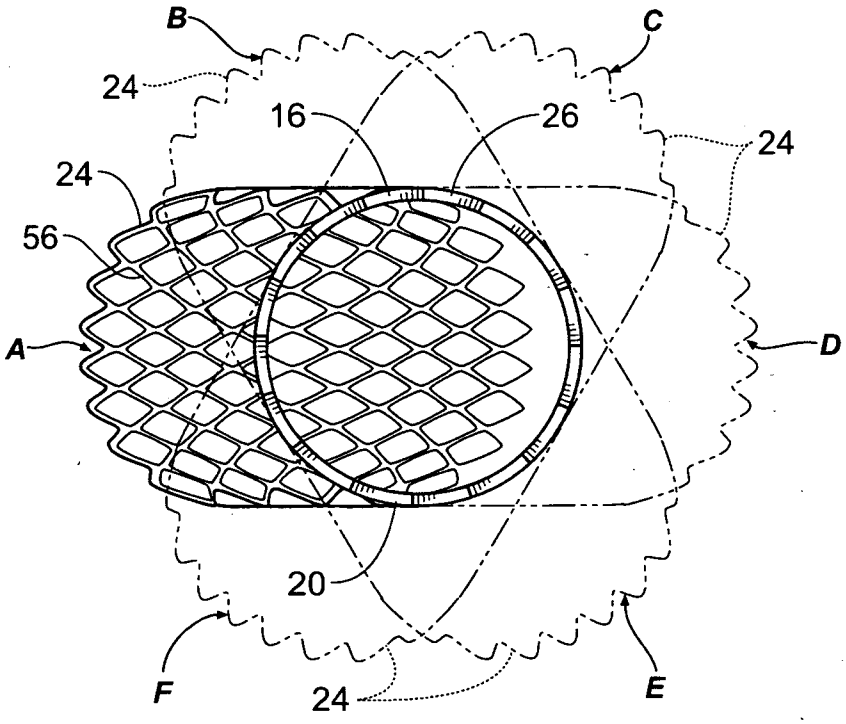

Fig. 18

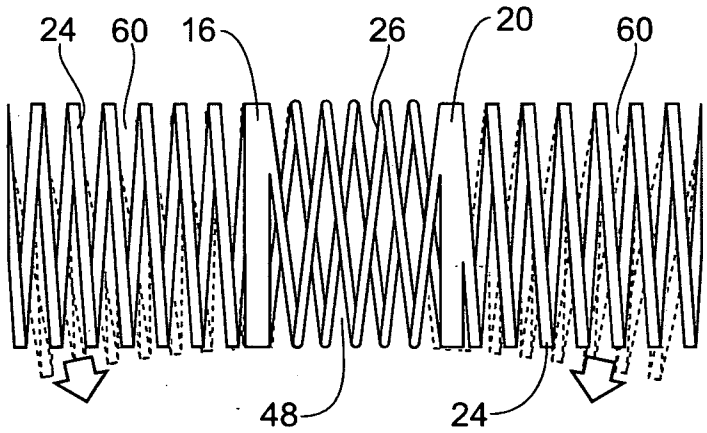

Fig. 19

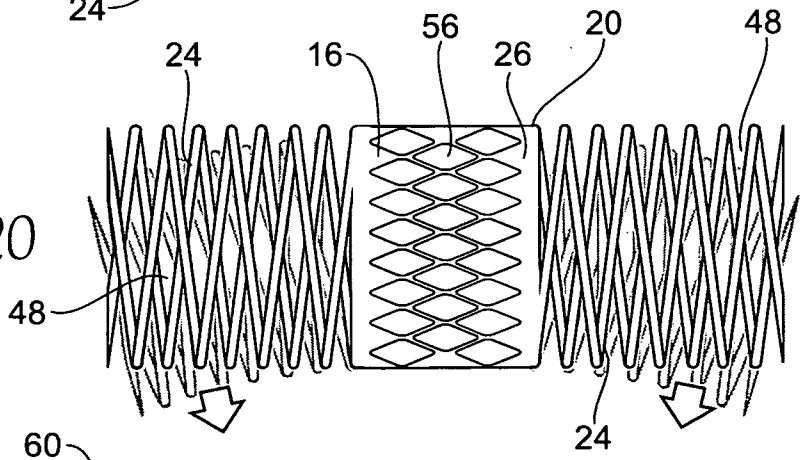

Fig. 20

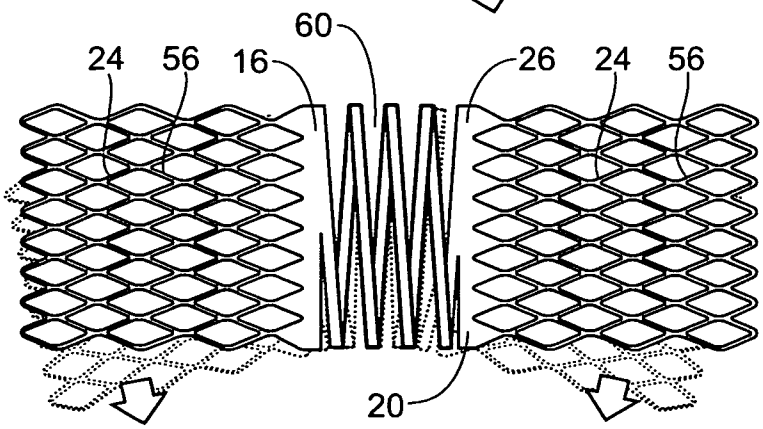

Fig. 21

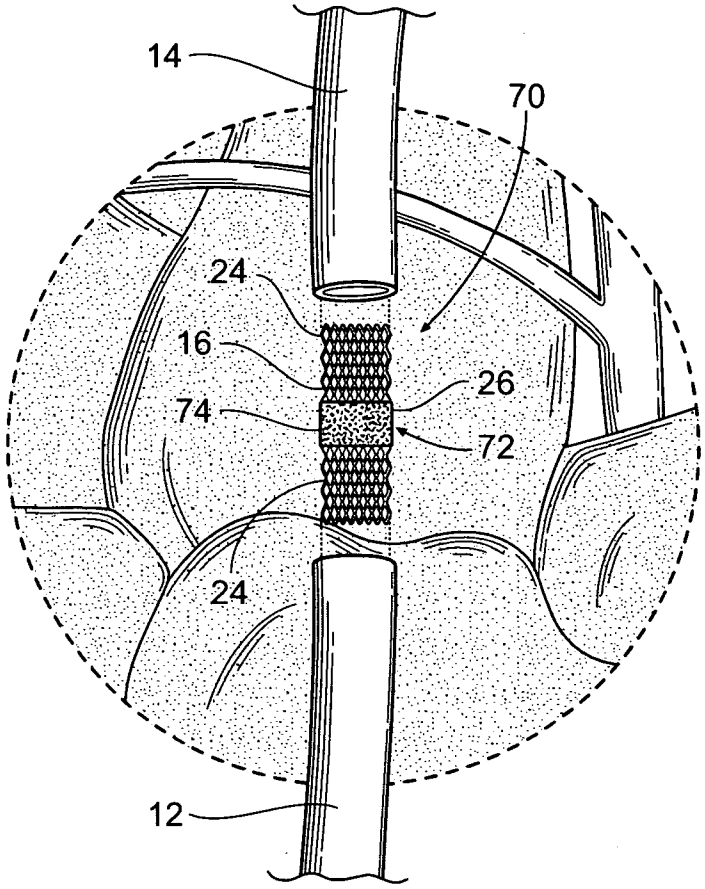

Fig. 22A

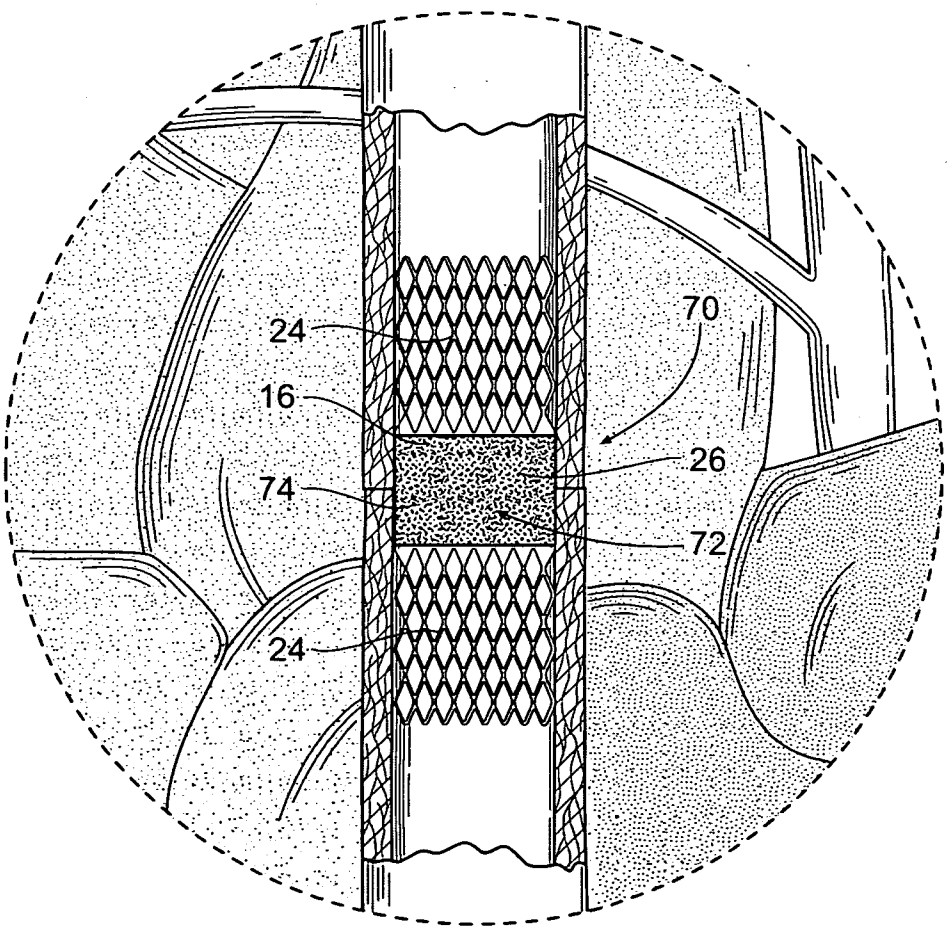

Fig. 22B

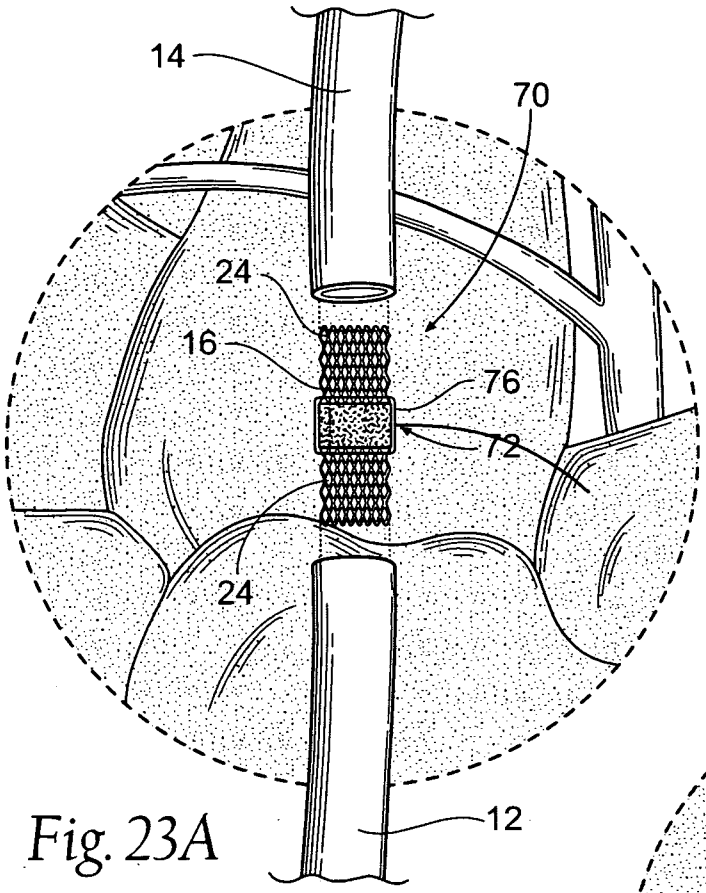

Fig. 23A

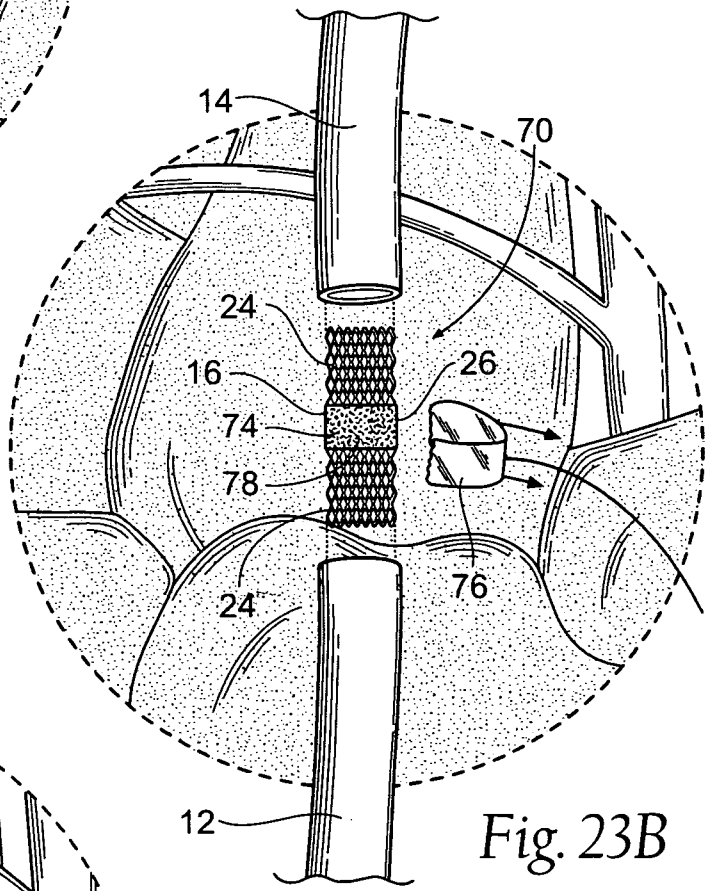

Fig. 23B

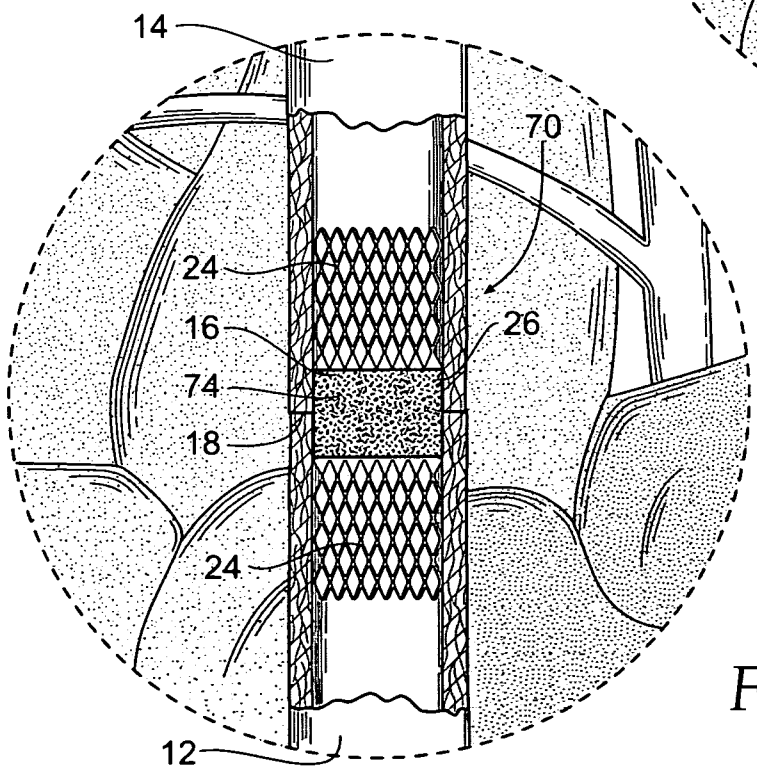

Fig. 23C

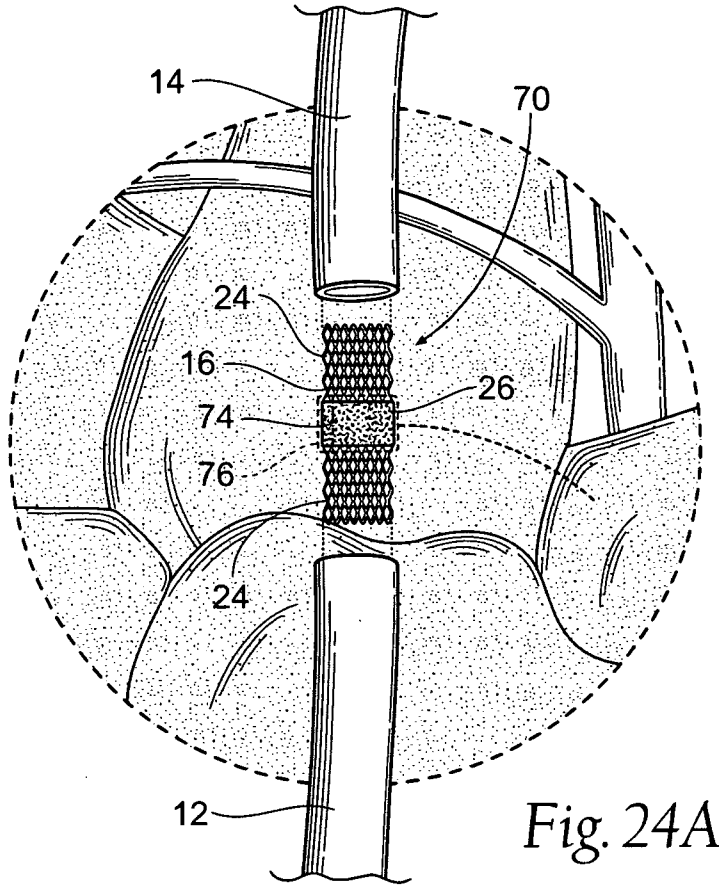

Fig. 24A

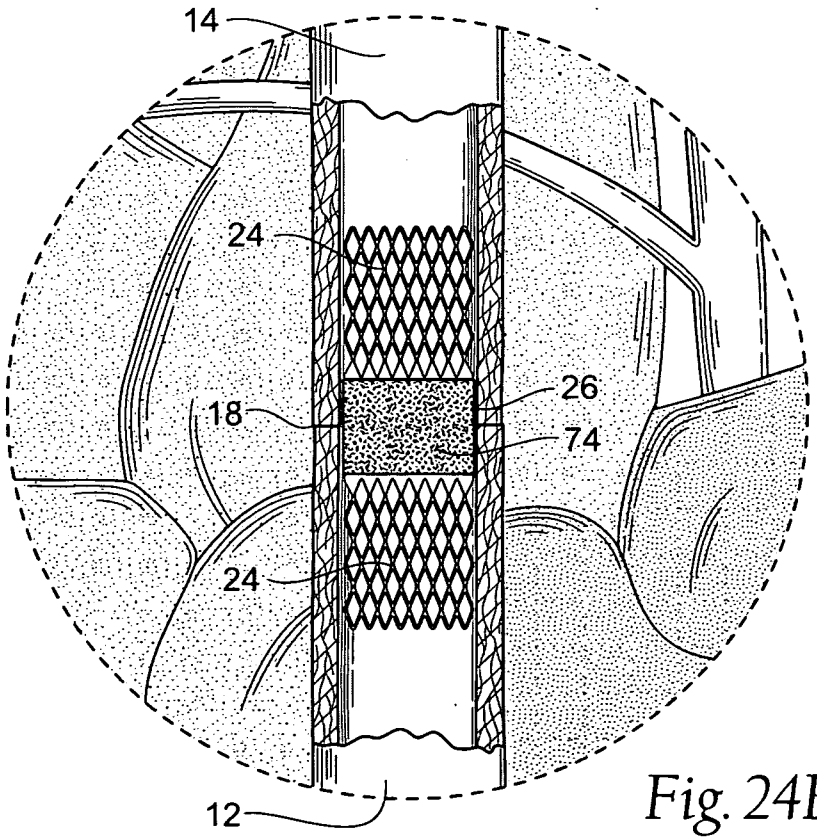

Fig. 24B

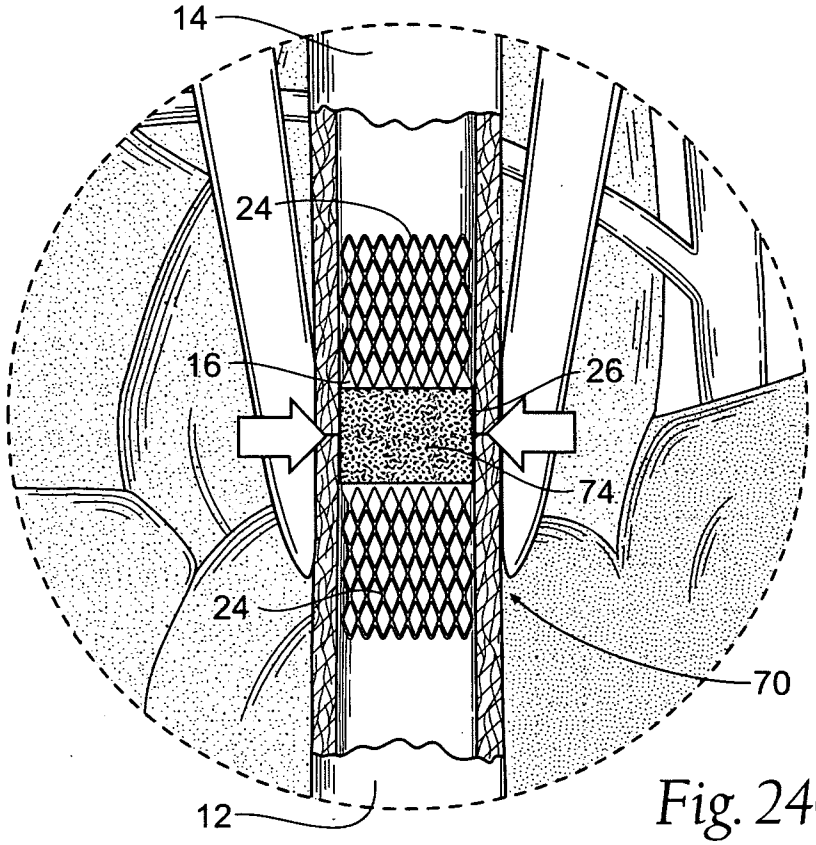

Fig. 24C

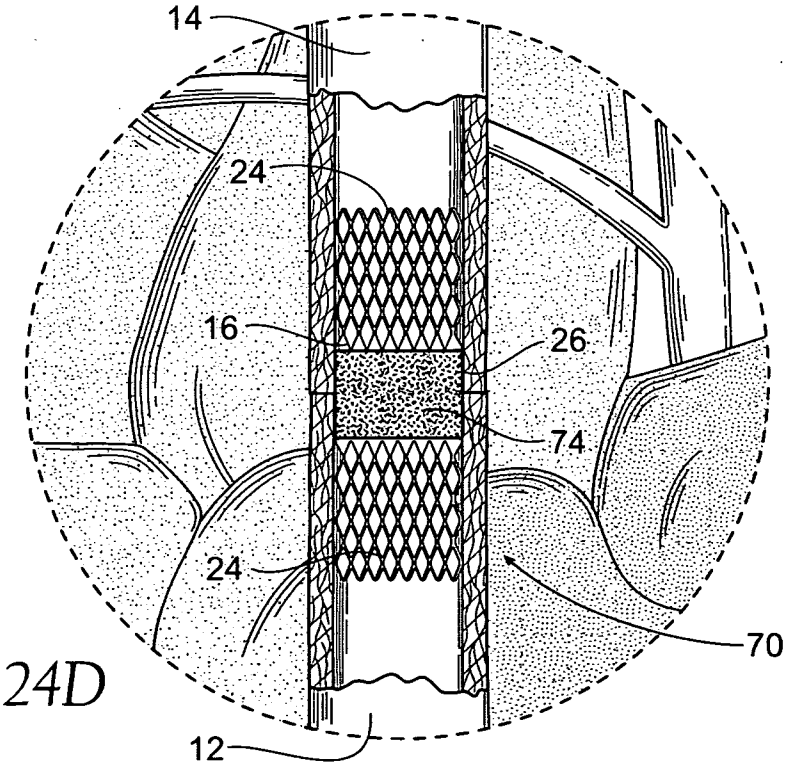

Fig. 24D

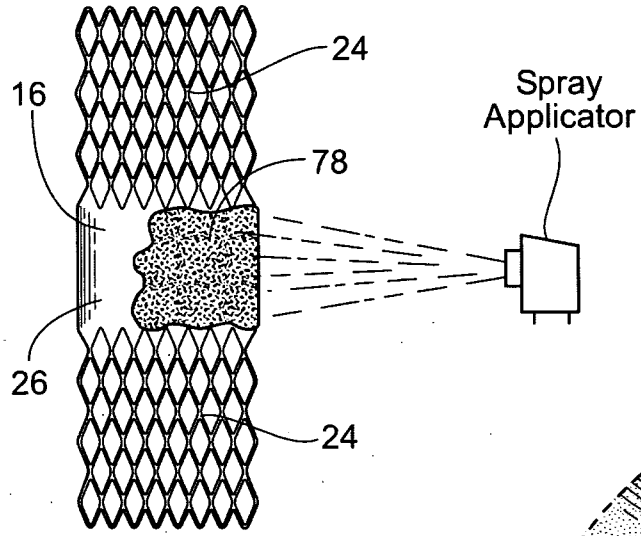

Fig. 25A

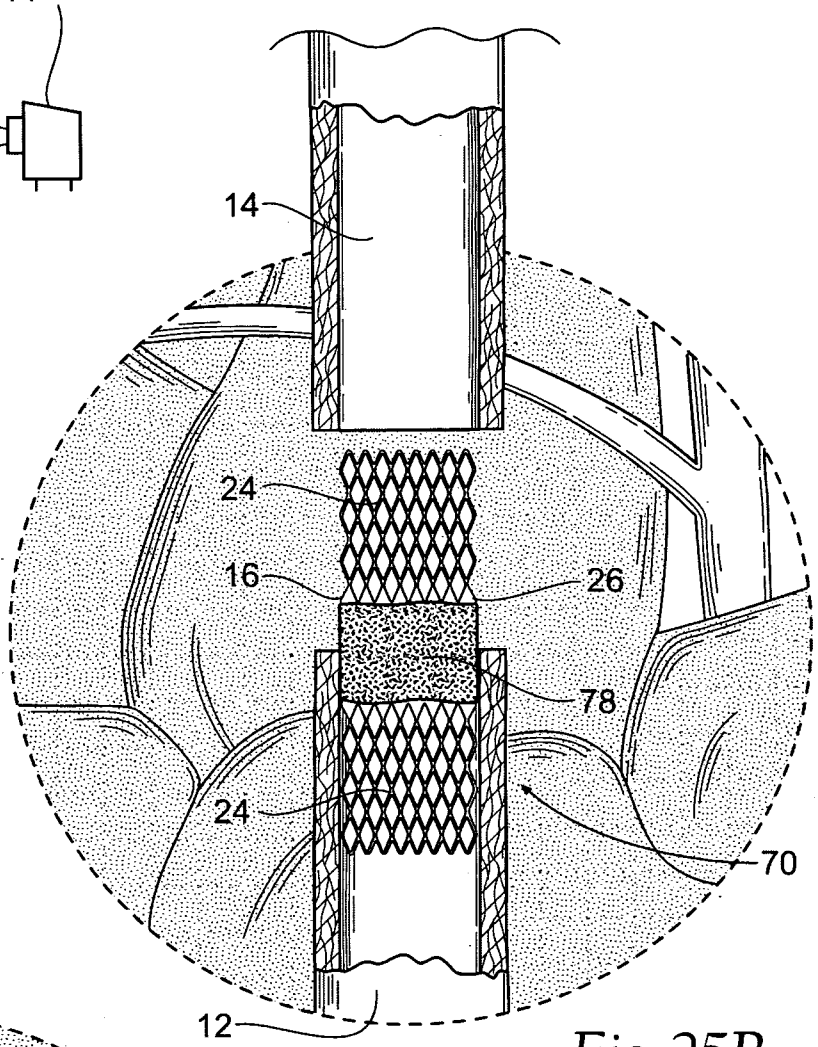

Fig. 25B

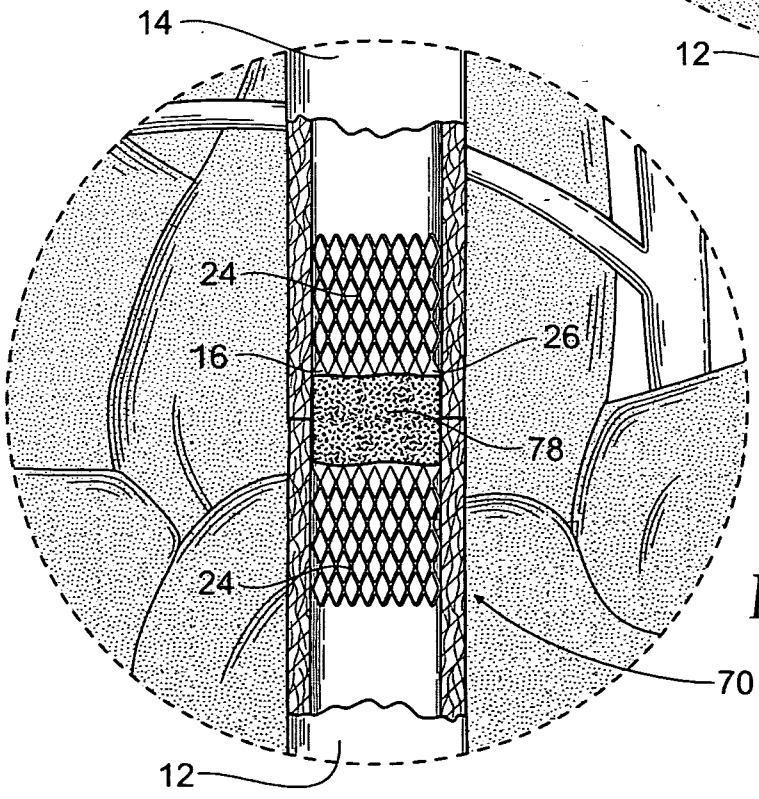

Fig. 25C

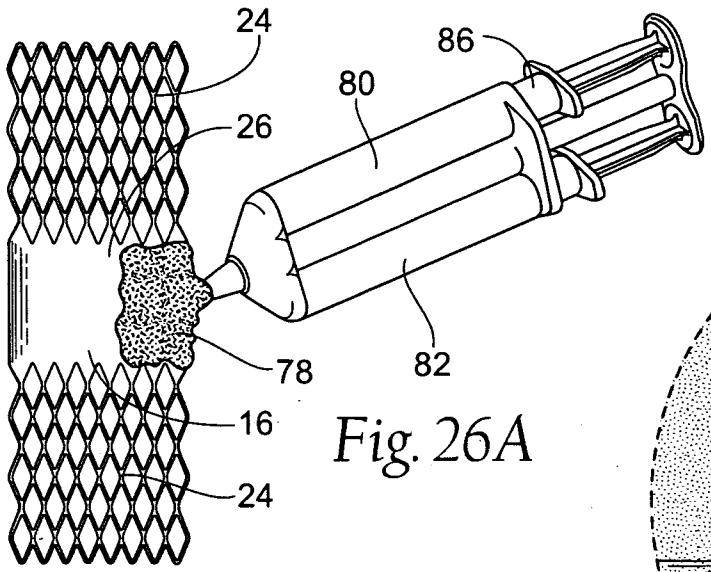

Fig. 26A

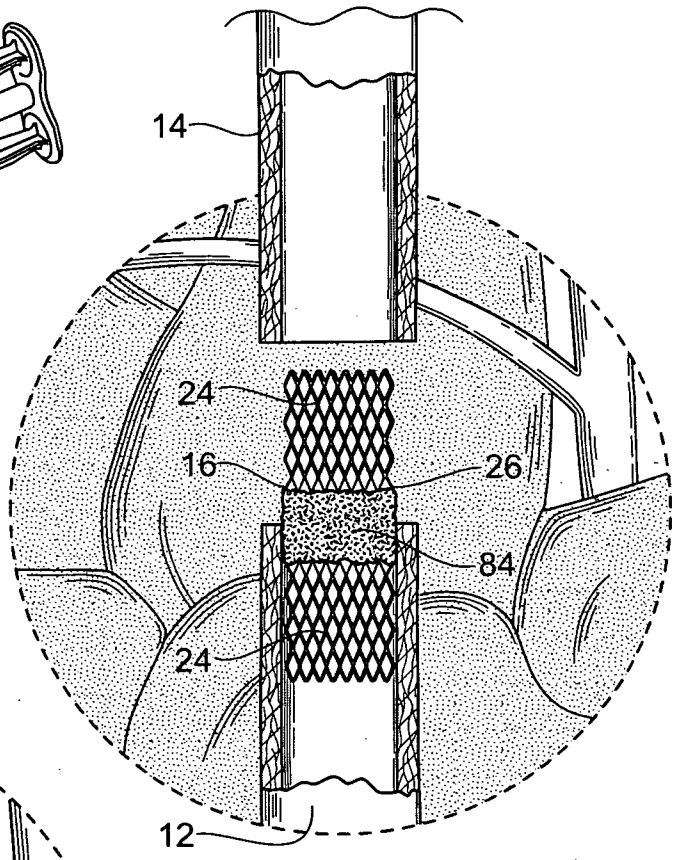

Fig. 26B

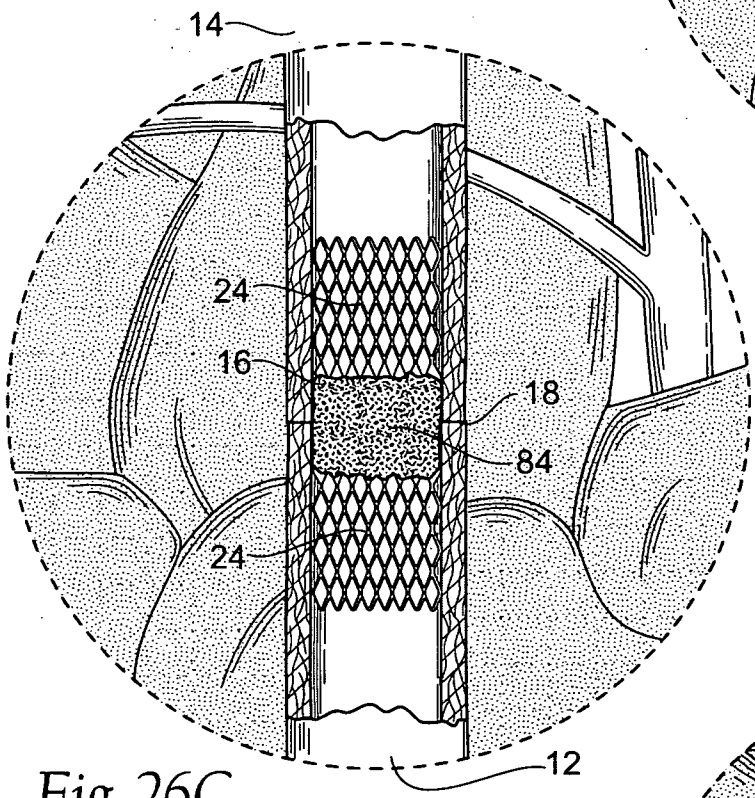

Fig. 26C

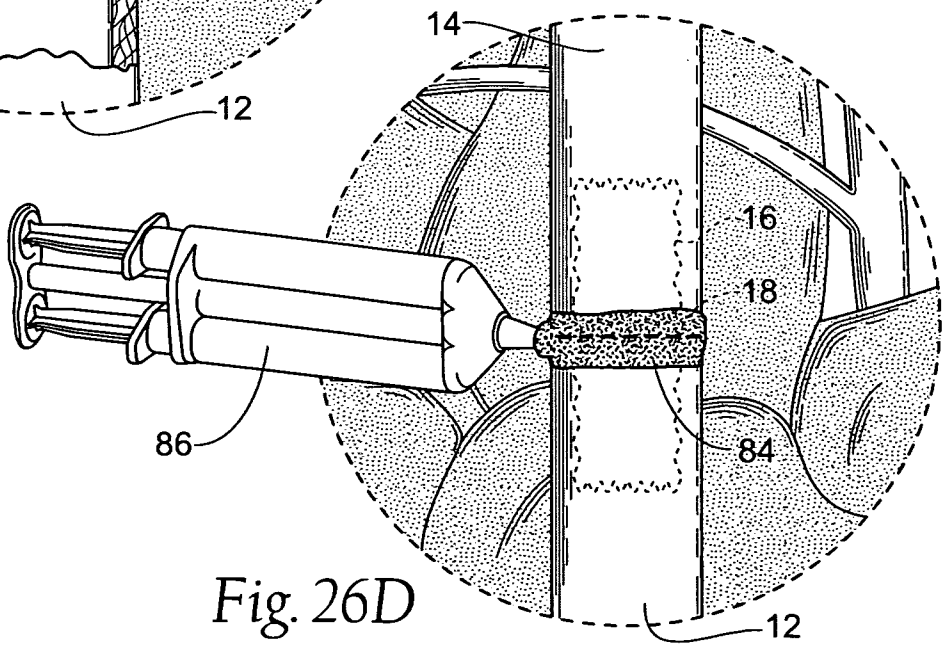

Fig. 26D

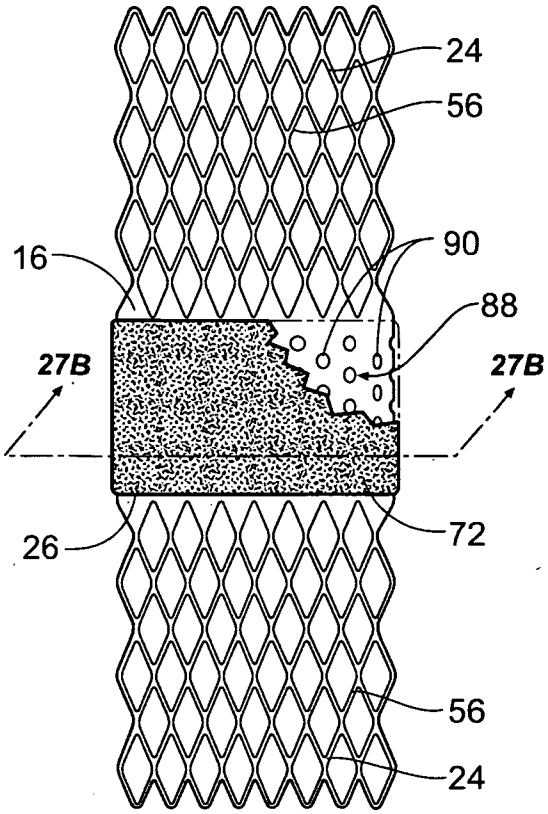

Fig. 27A

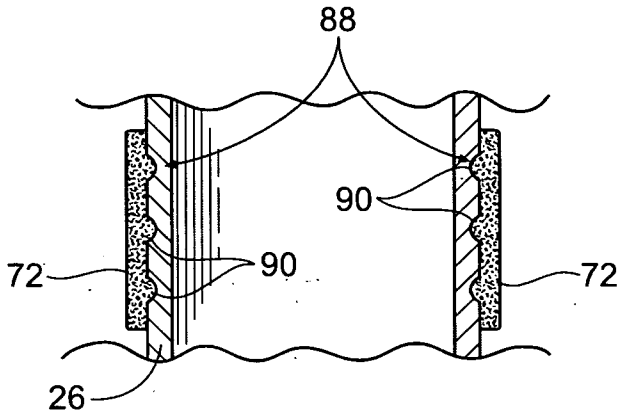

Fig. 27B

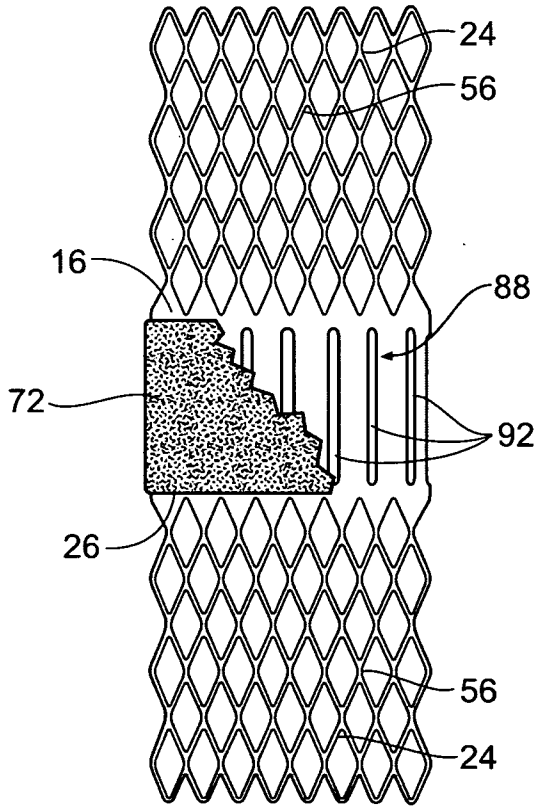

Fig. 28A

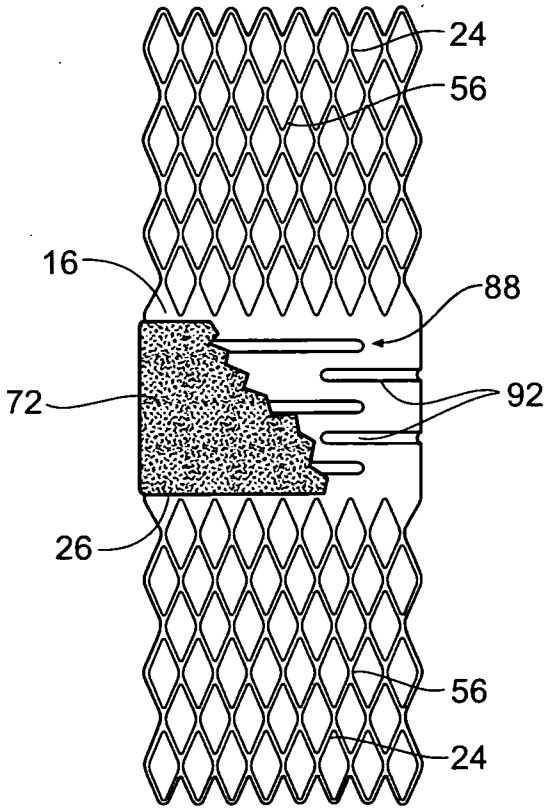

Fig. 28B

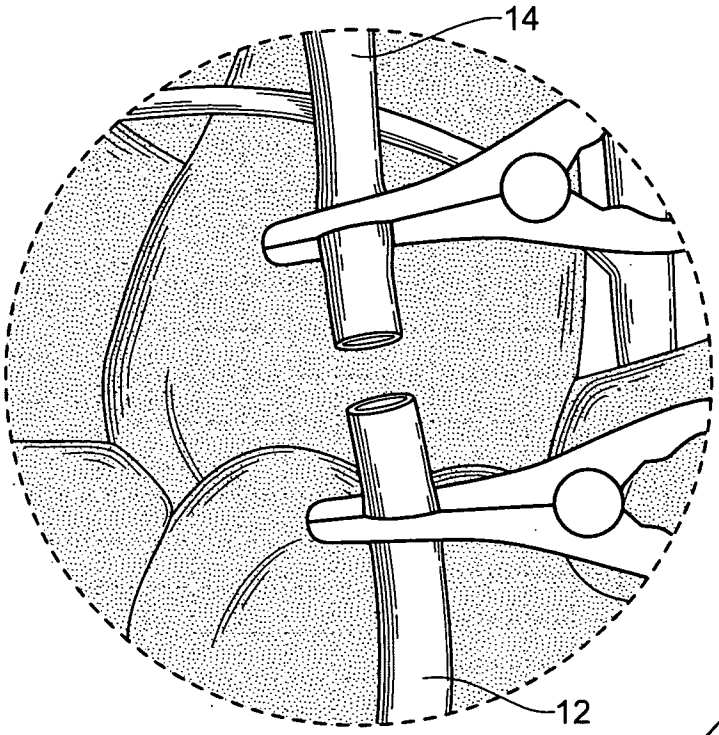

Fig. 29A

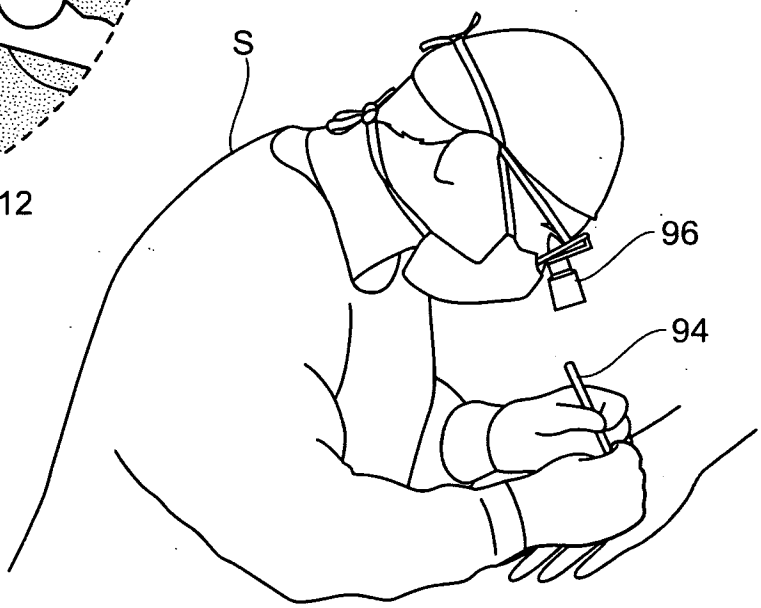

Fig. 29B

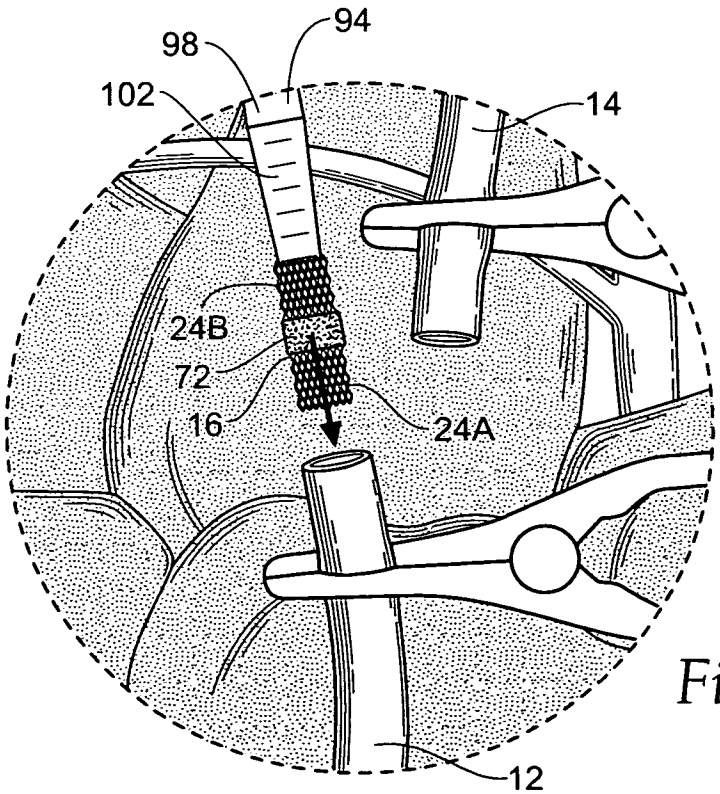

Fig. 29C

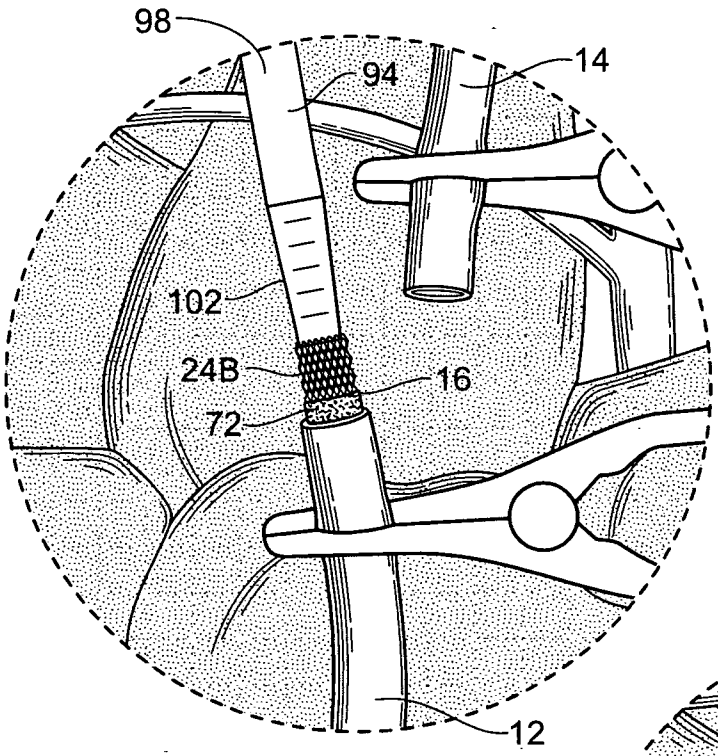

Fig. 29D

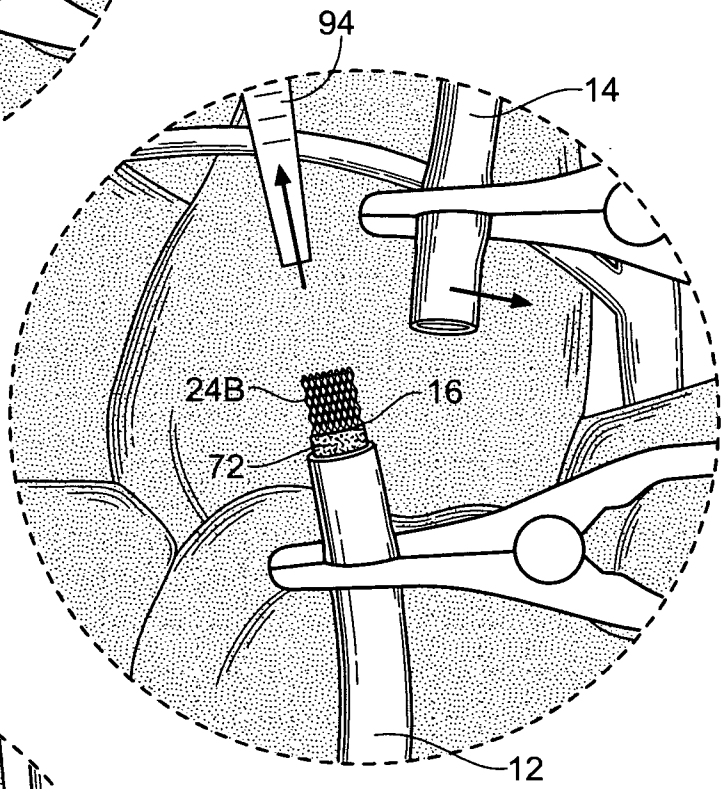

Fig. 29E

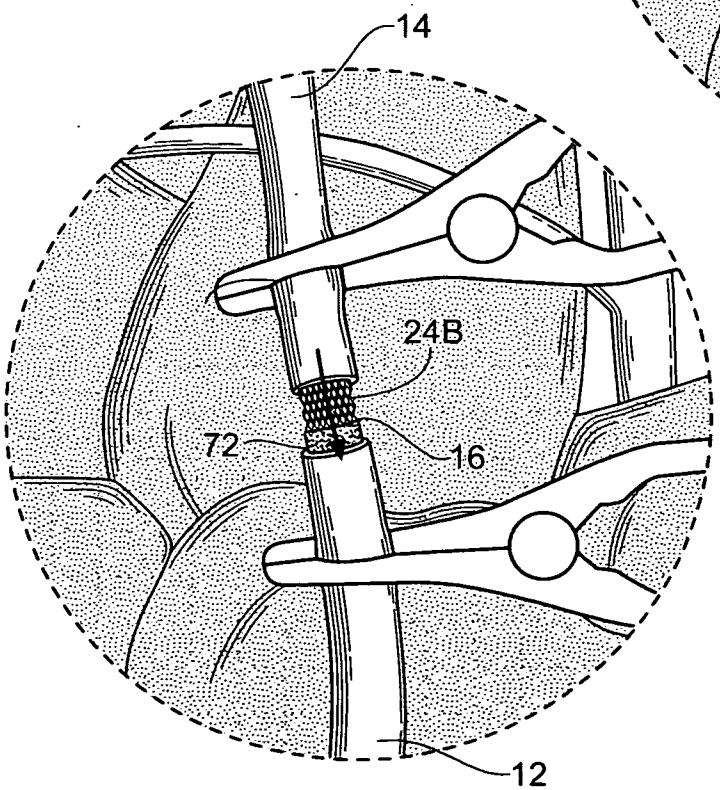

Fig. 29F

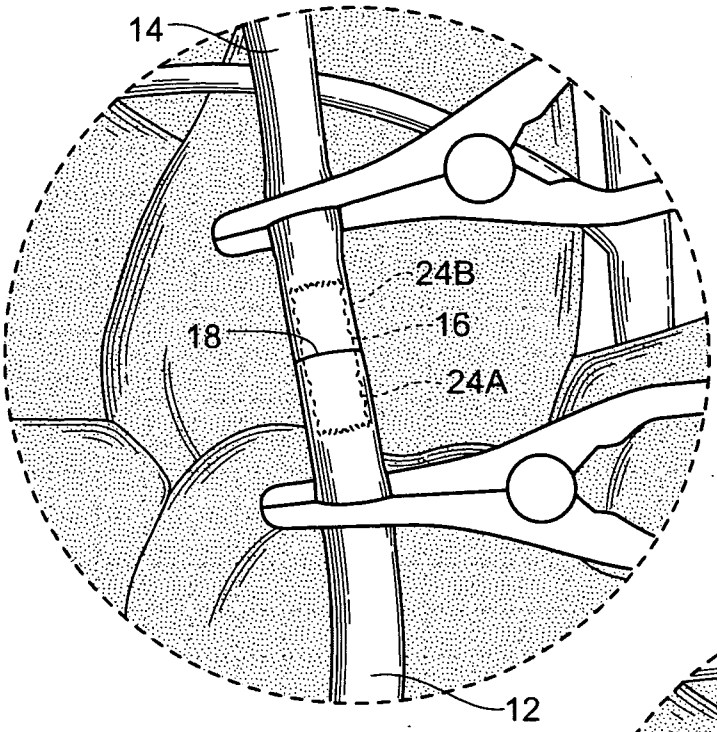

Fig. 29G

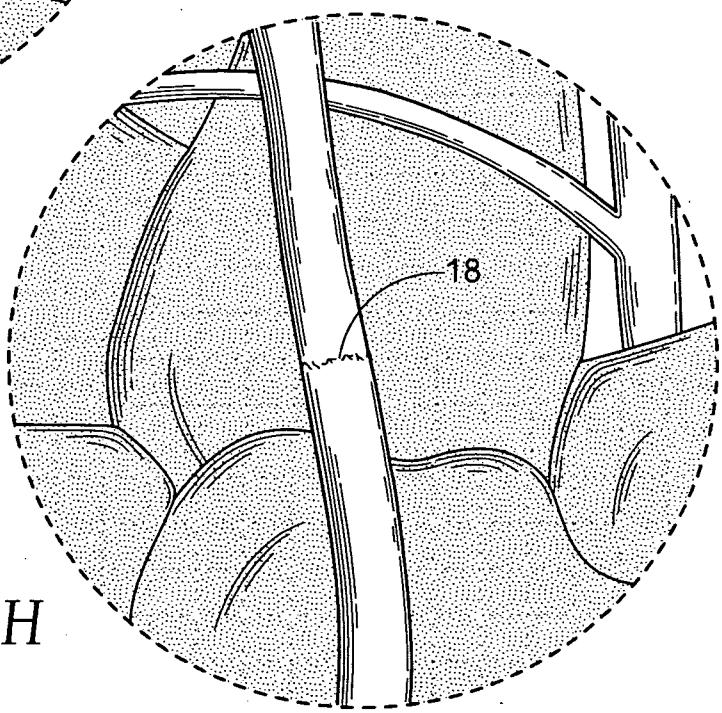

Fig. 29H

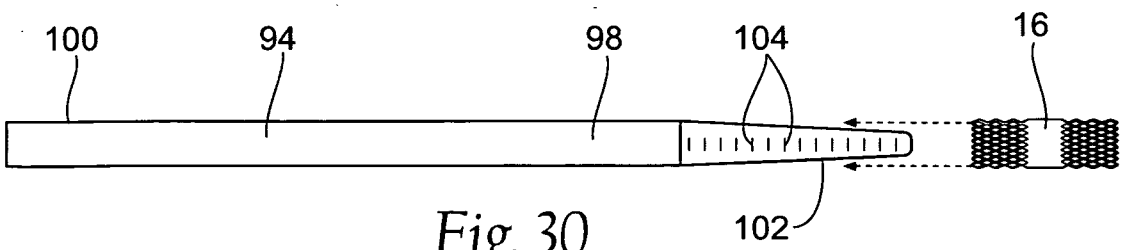

Fig. 30

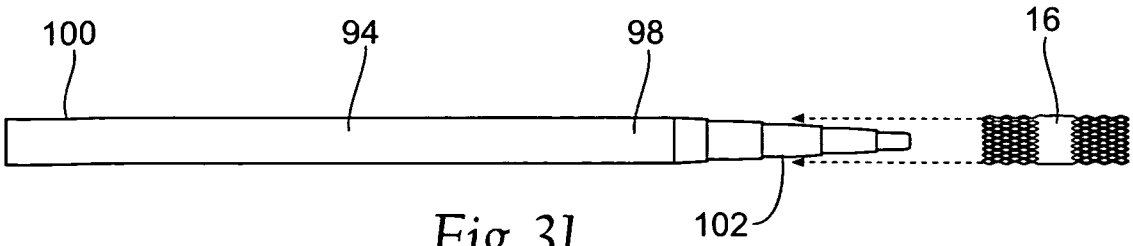

Fig. 31

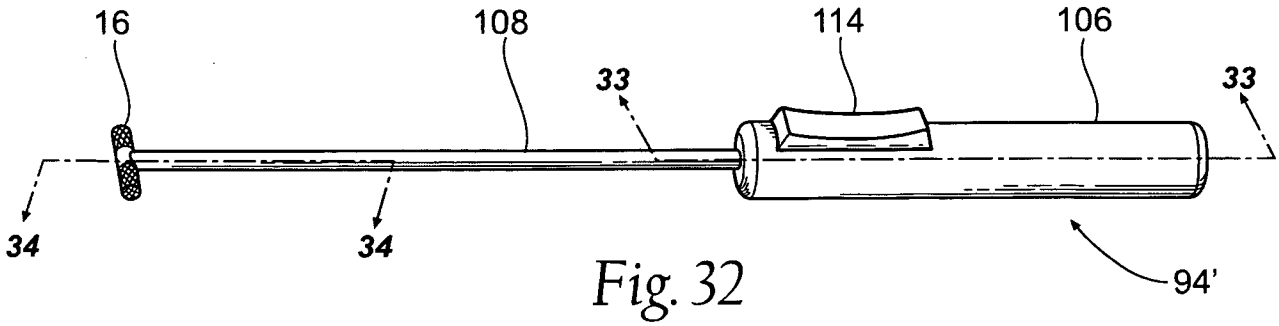

Fig. 32

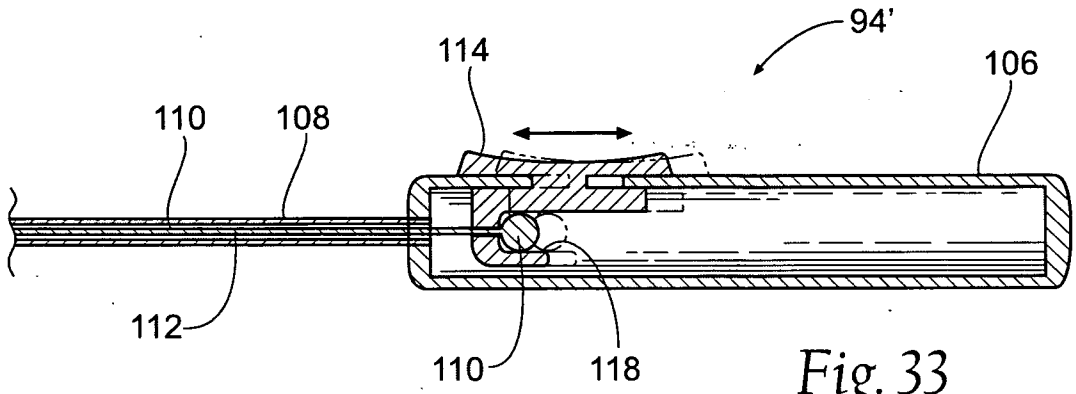

Fig. 33

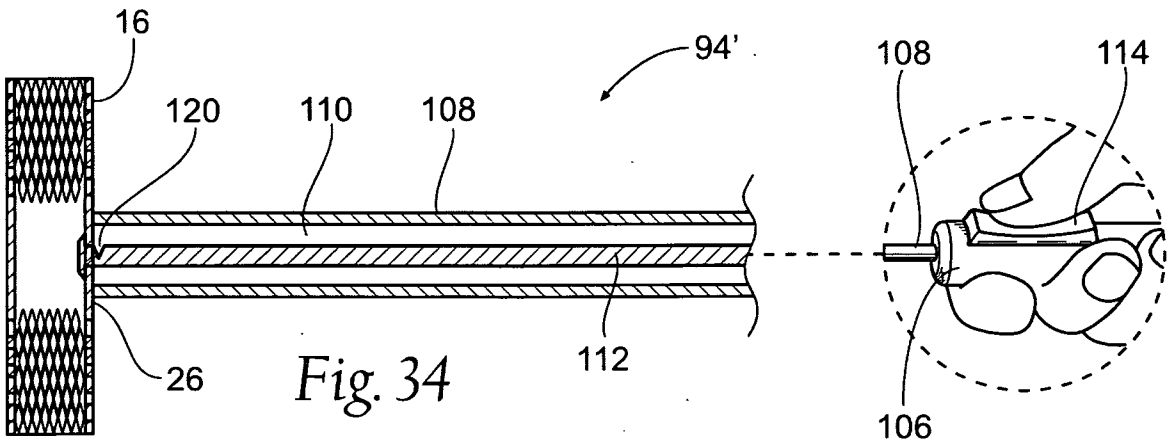

Fig. 34

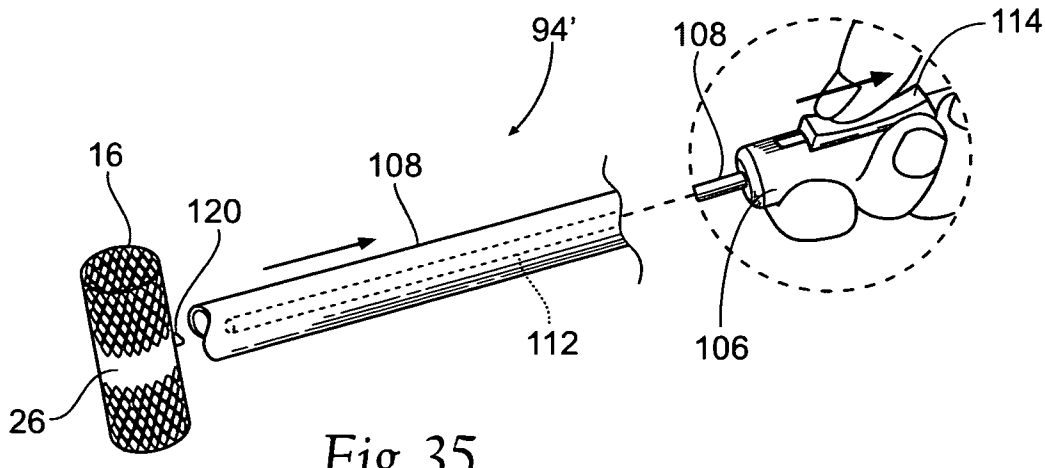

Fig. 35

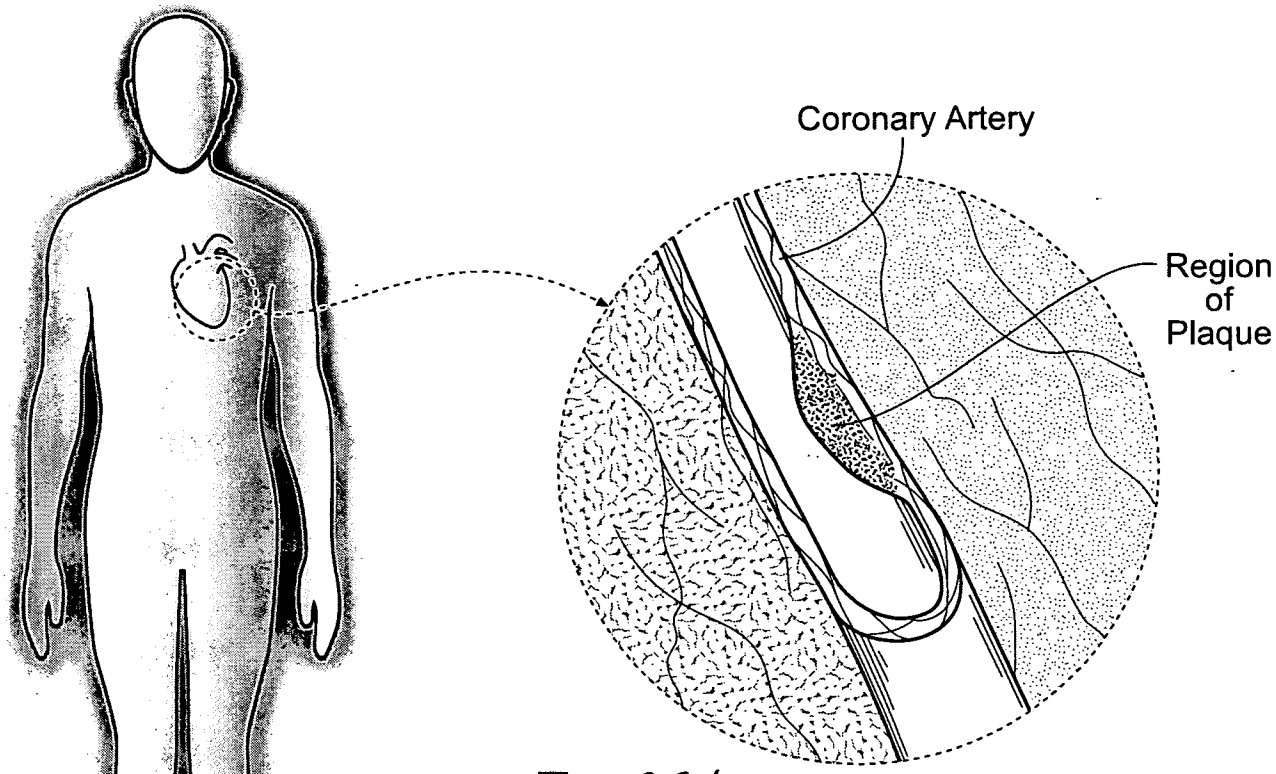

Fig. 36A

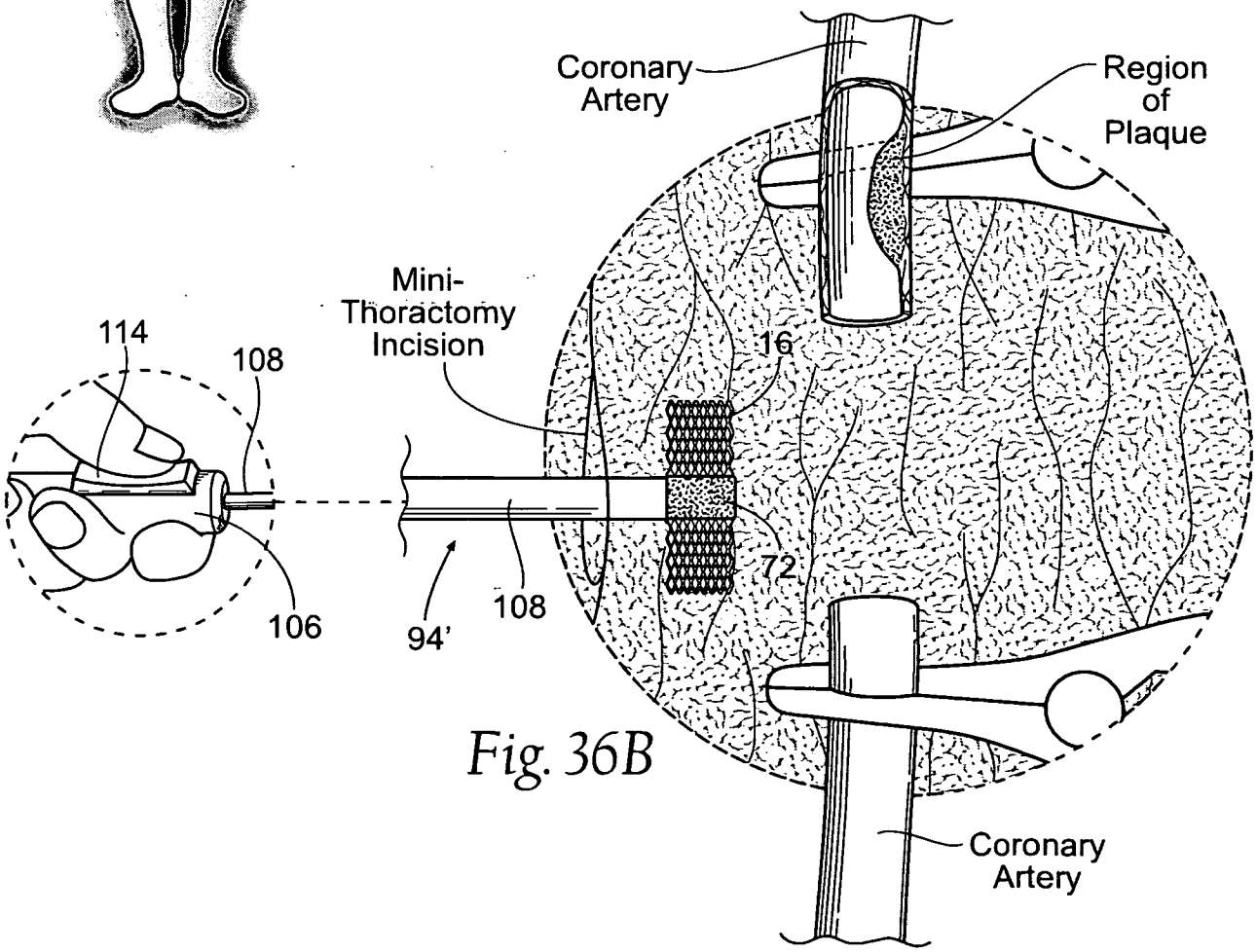

Fig. 36B

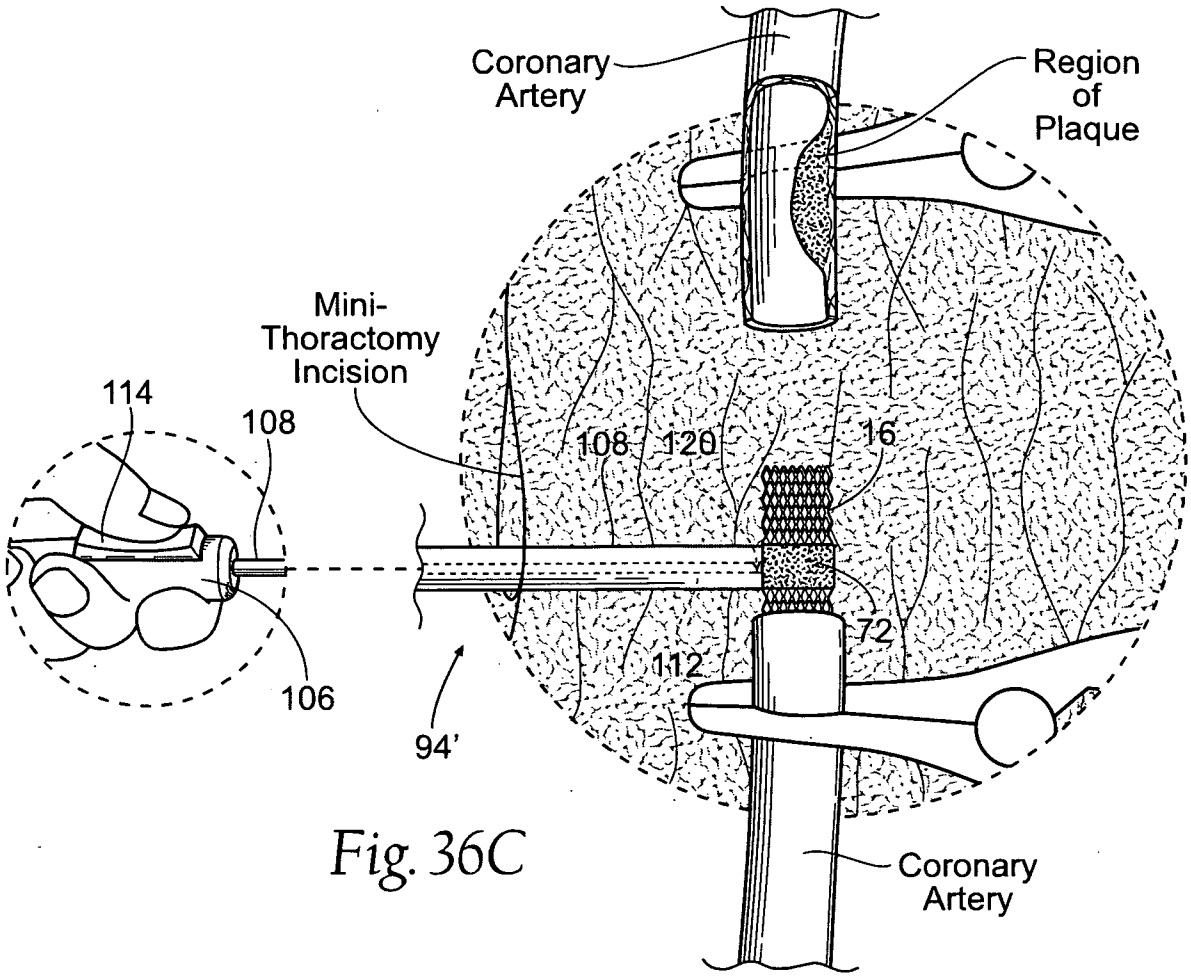

Fig. 36C

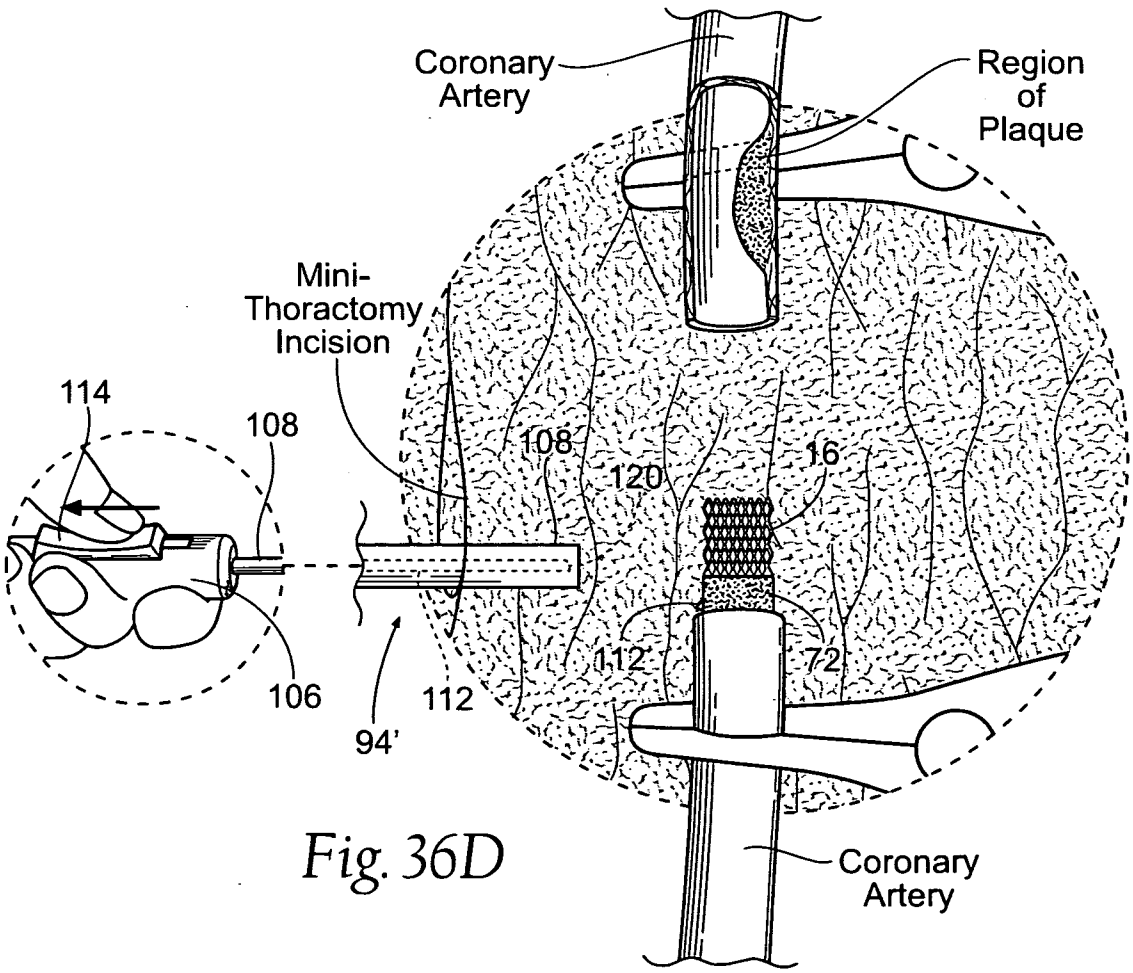

Fig. 36D

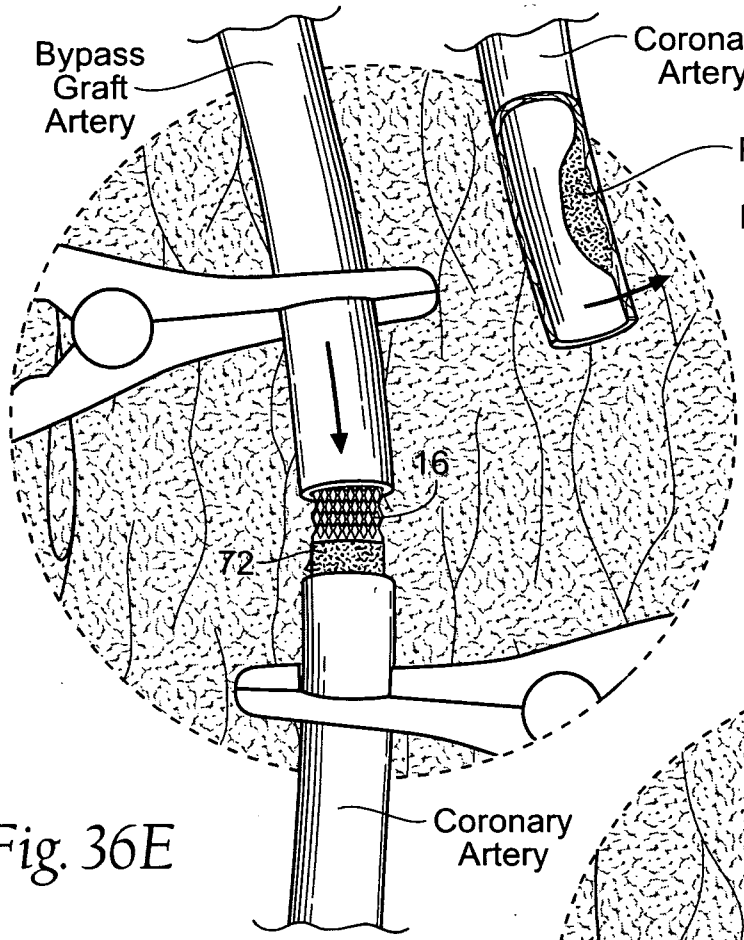

Fig. 36E

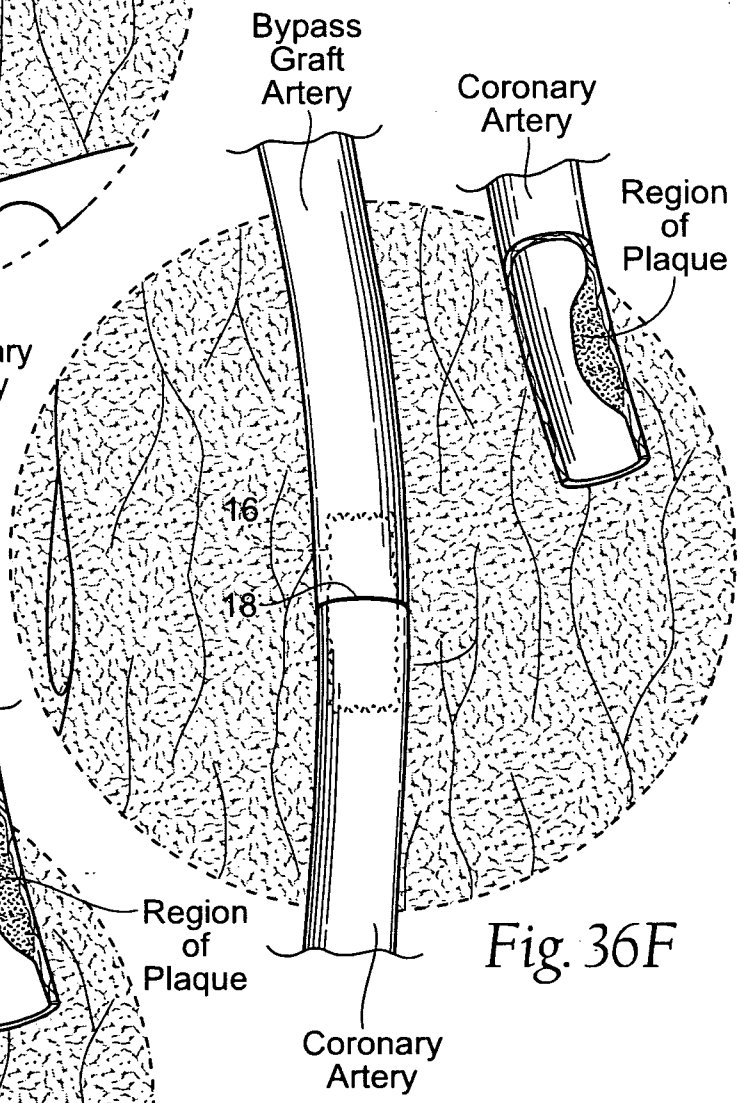

Fig. 36F

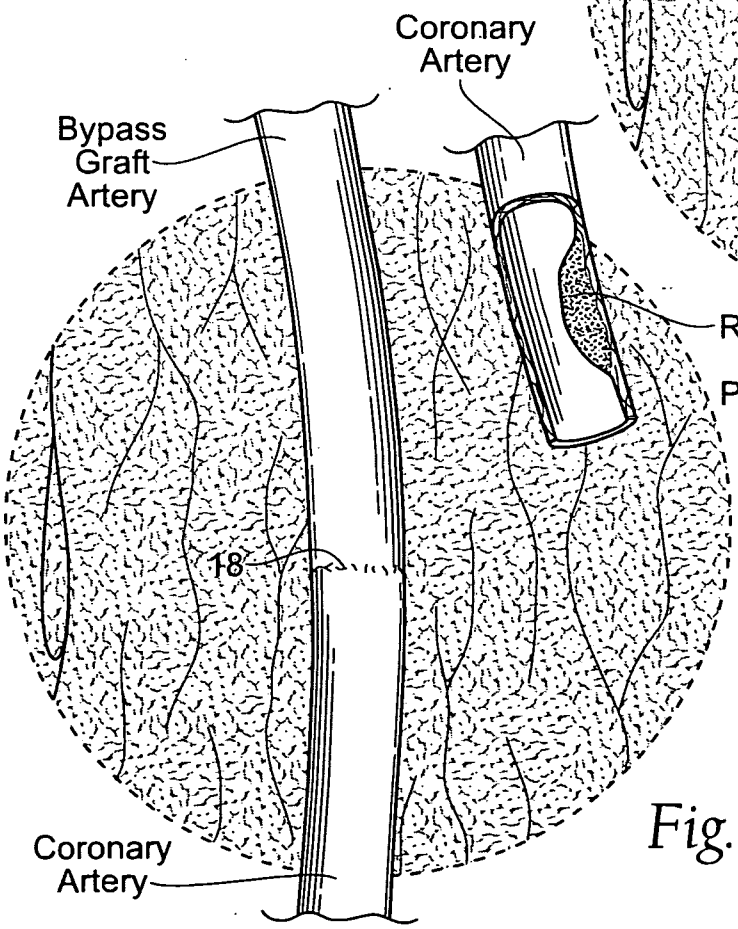

Fig. 36G

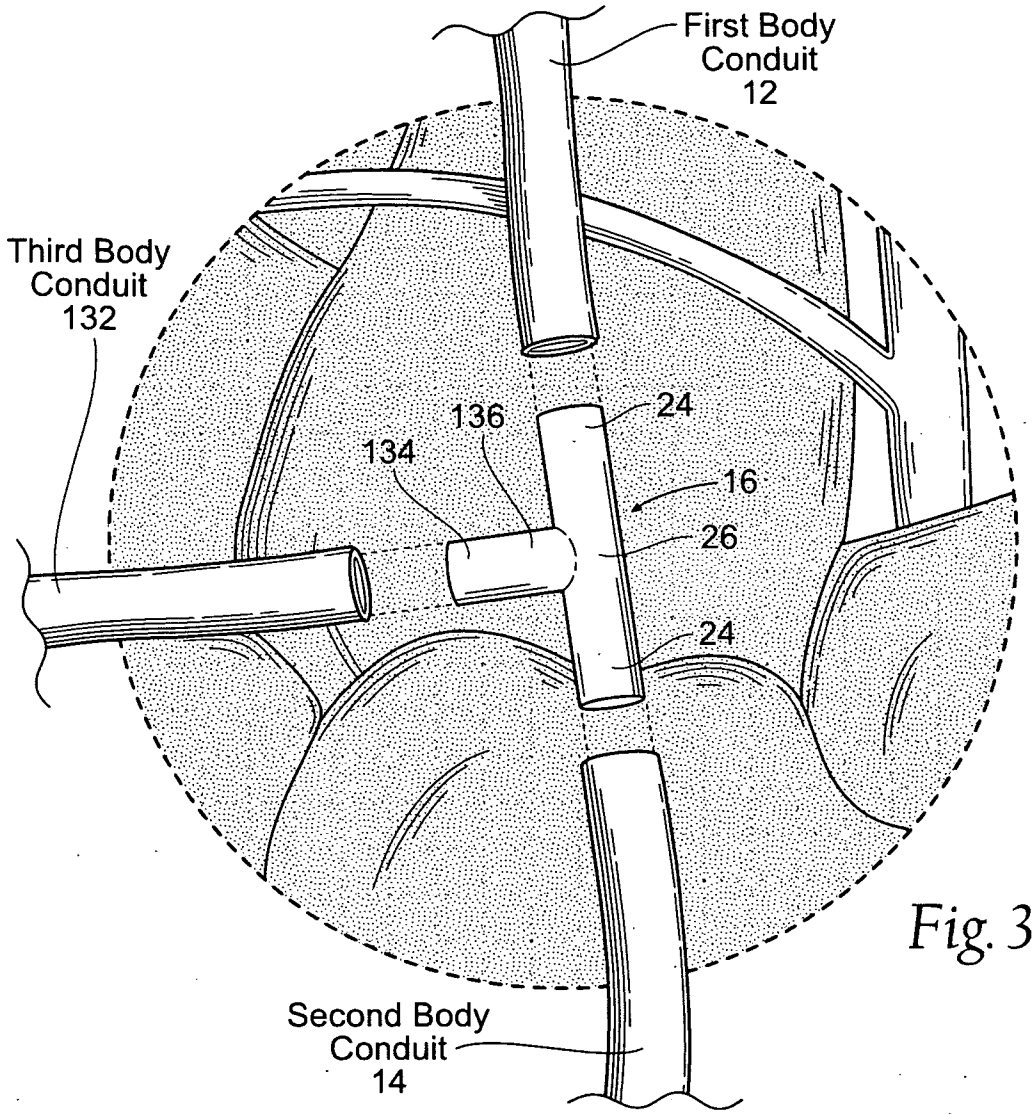

Fig. 37A

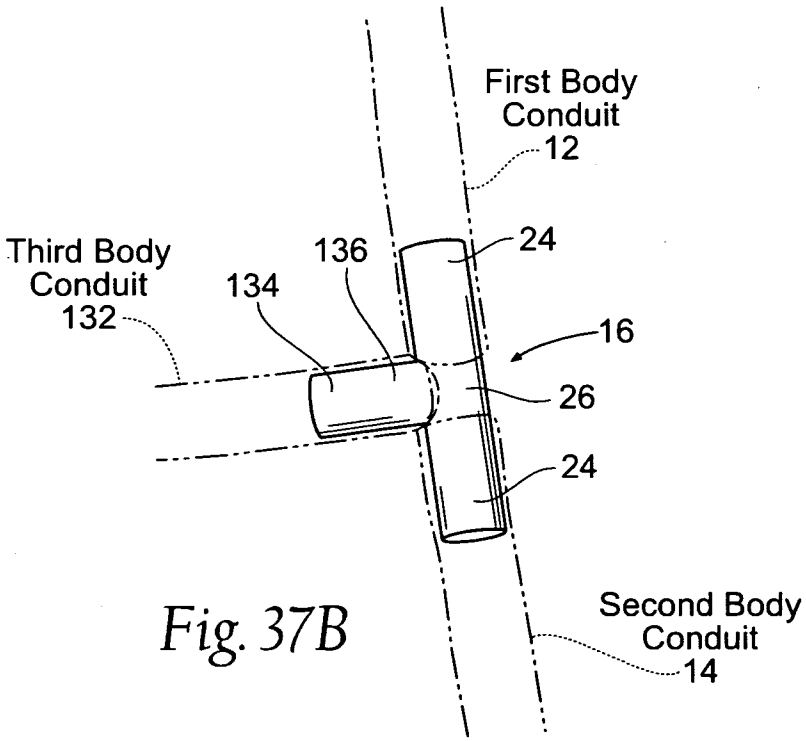

Fig. 37B

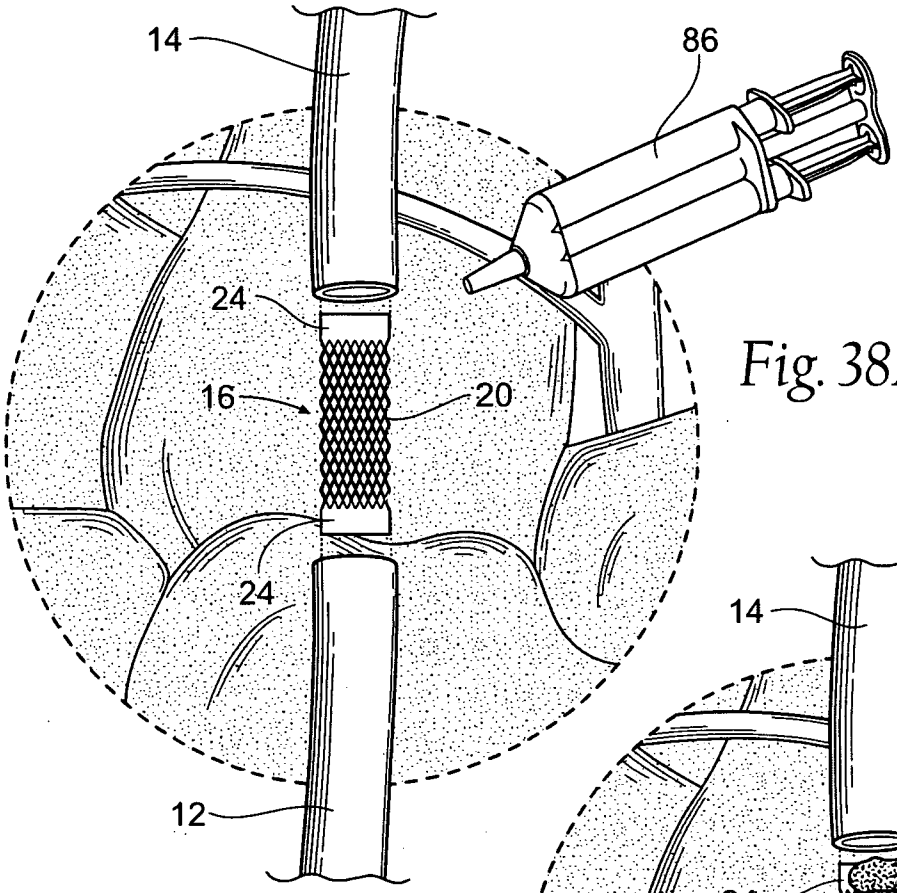

Fig. 38A

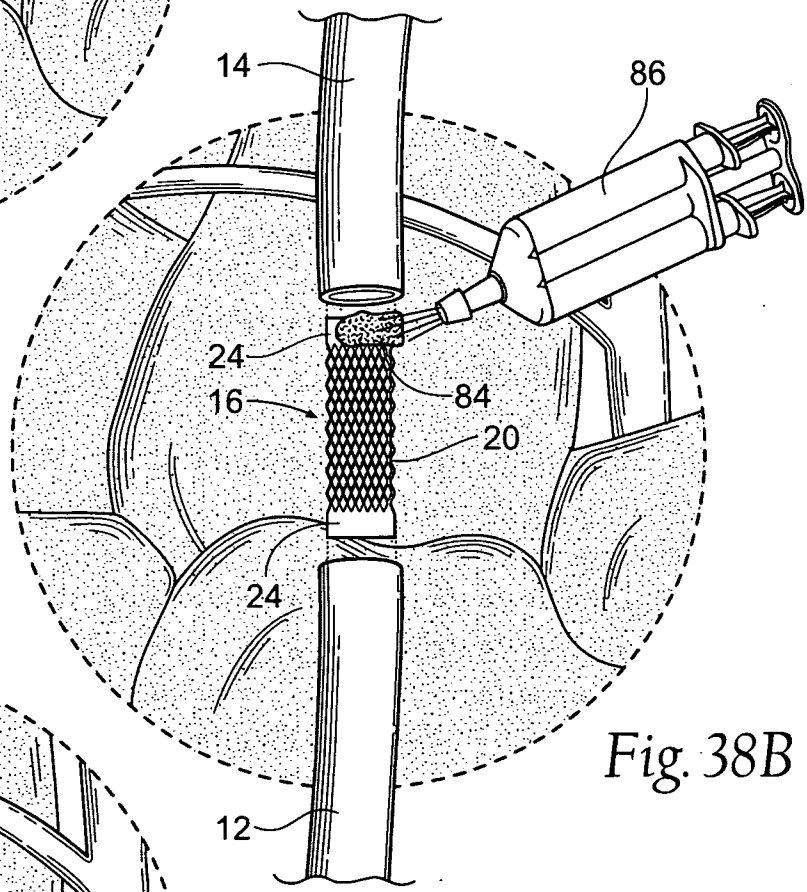

Fig. 38B

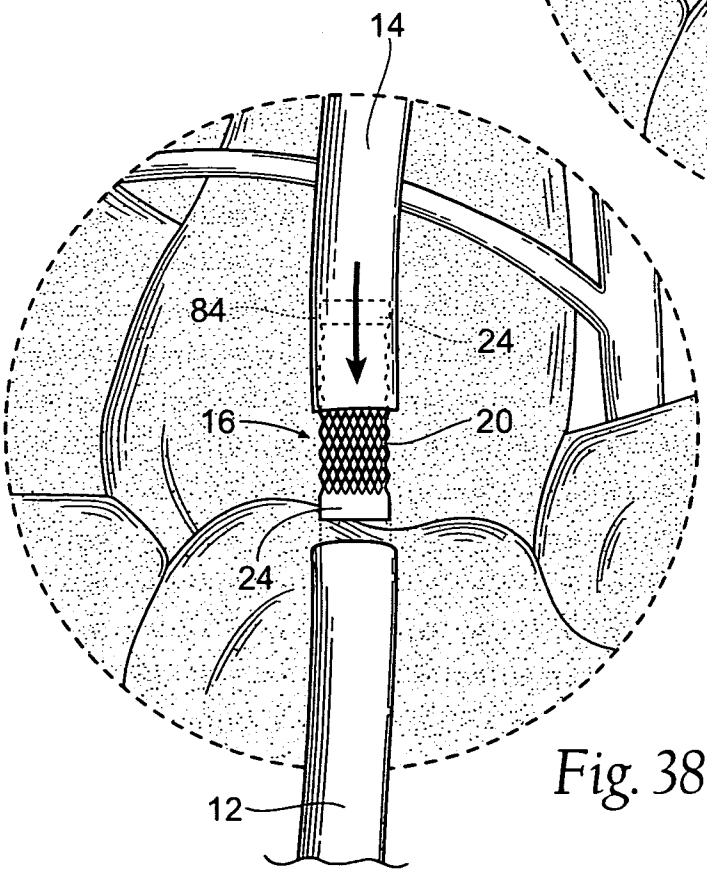

Fig. 38C

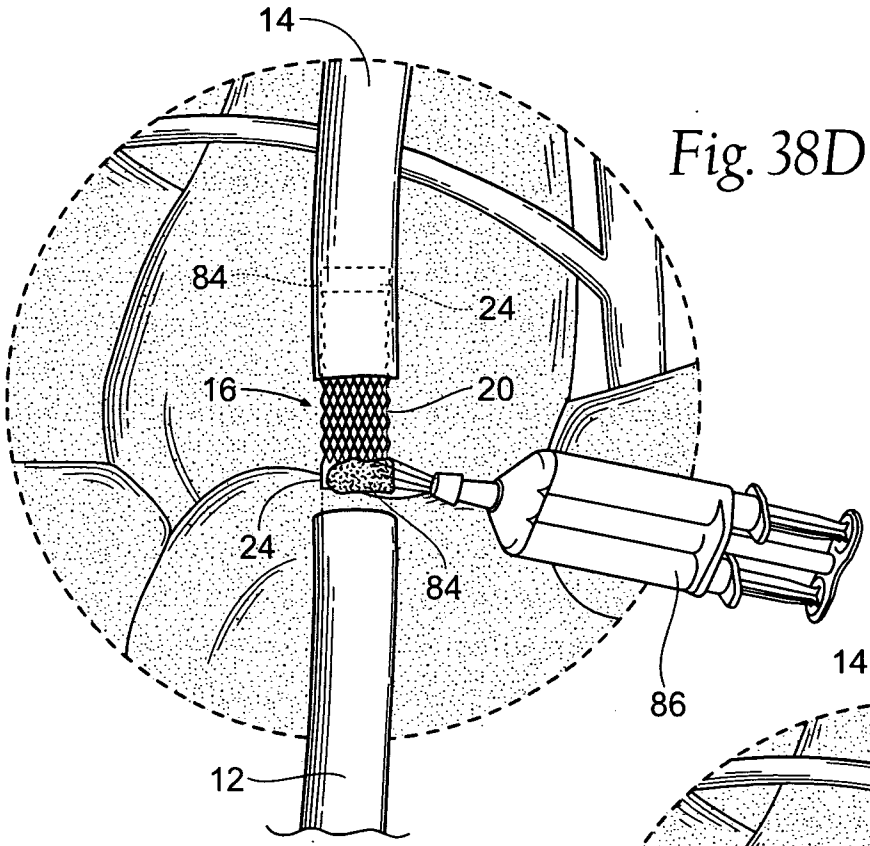

Fig. 38D

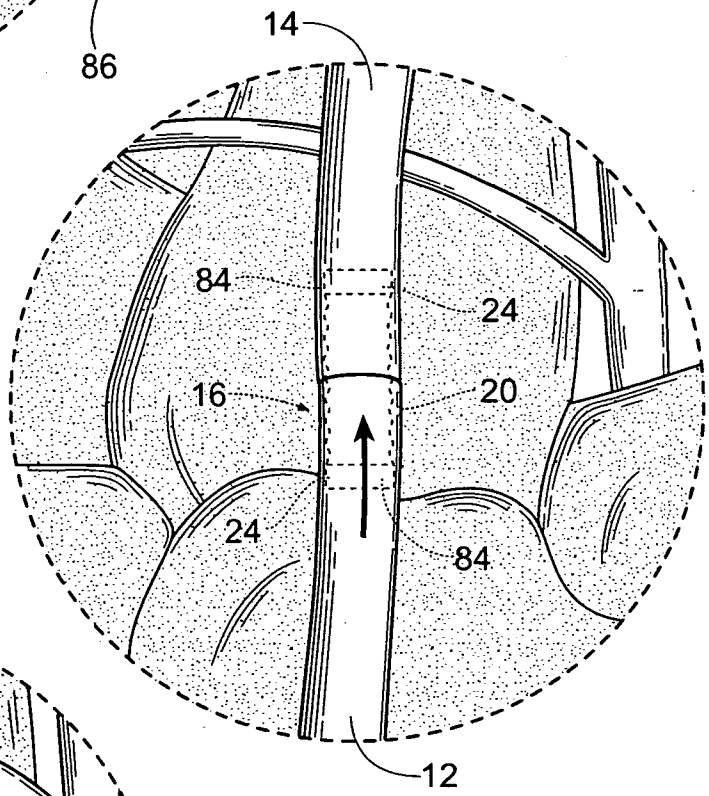

Fig. 38E

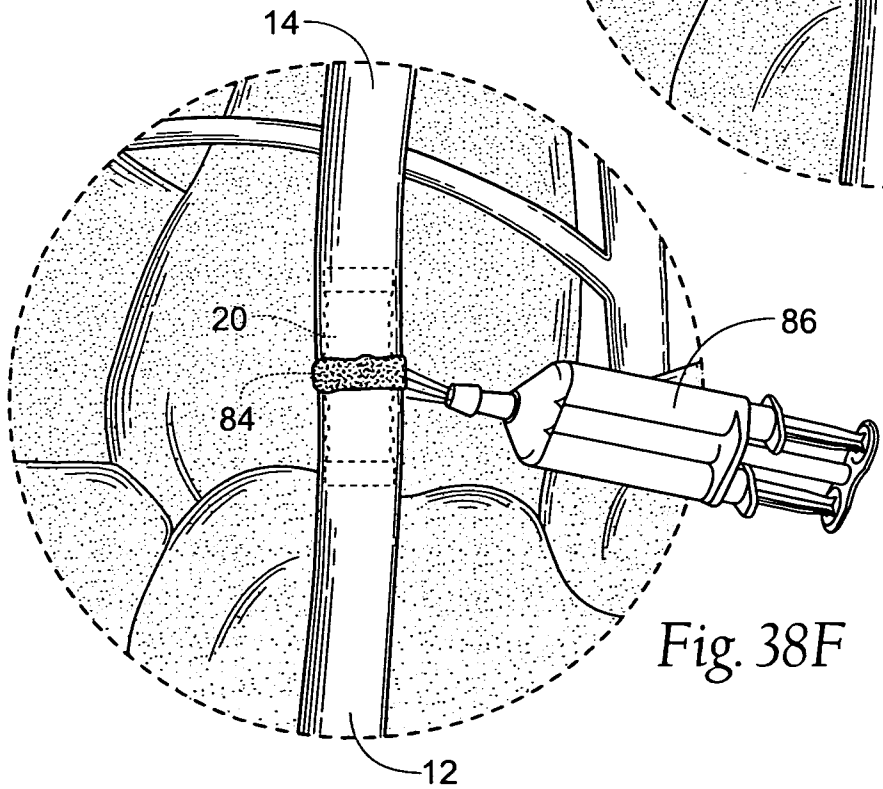

Fig. 38F

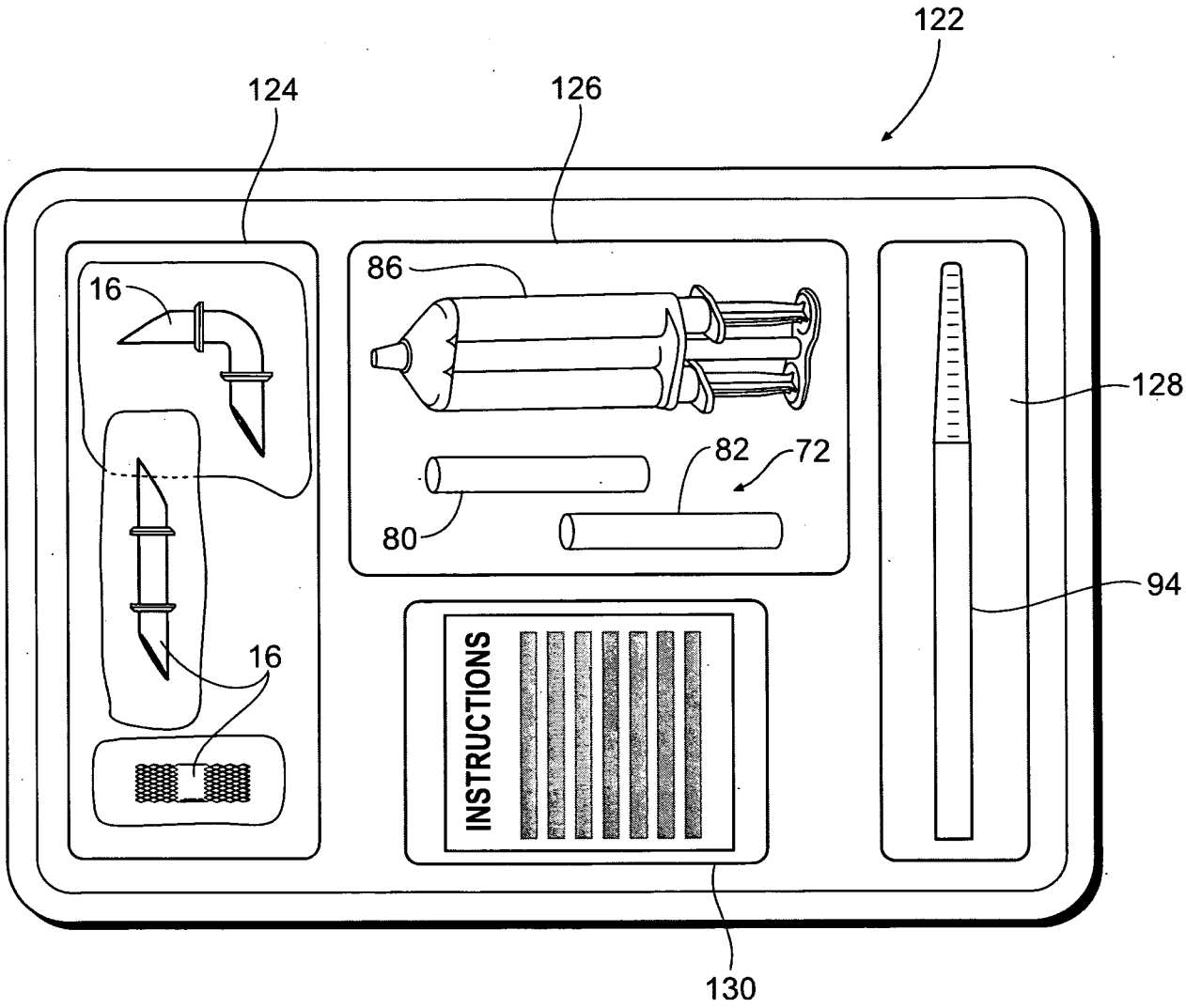

Fig. 39