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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :
A61M 39/10, 39/04, A61F 2/06

A1

(11) International Publication Number: **WO 00/47271**

(43) International Publication Date: 17 August 2000 (17.08.00)

(21) International Application Number: PCT/US99/02997

(22) International Filing Date: 11 February 1999 (11.02.99)

(30) Priority Data:
Not furnished 10 February 1999 (10.02.99) US

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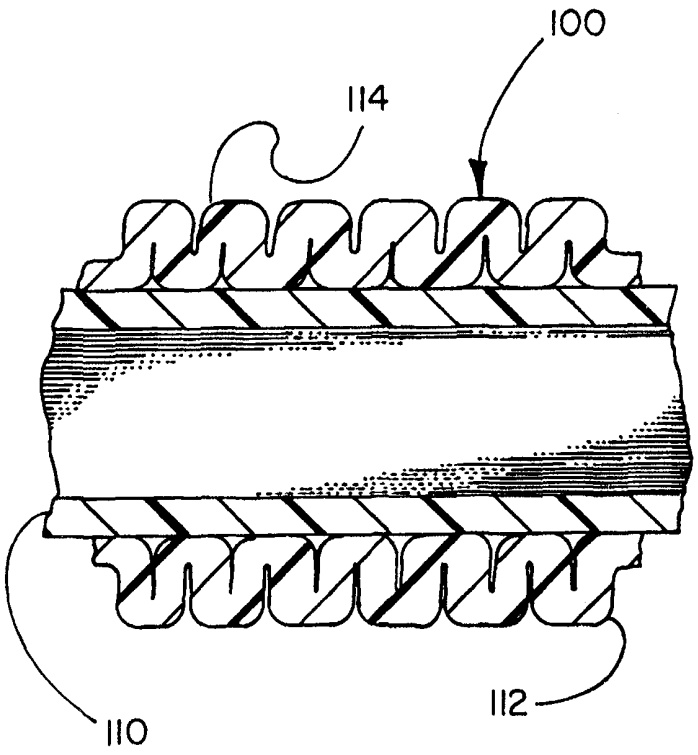
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: MULTIPLE–LAYERED LEAK–RESISTANT TUBE

(57) Abstract

The tubular device for carrying liquids or gases employs two or more concentrically mounted tube elements (110 and 112) that are adapted to move relative to one another following puncture and removal of the puncturing device. This relative movement creates a discontinuous opening through the device that is resistant to fluid leakage. Additionally, one of the tubular elements may be corrugated. A corrugated tube element forms a flap when punctured, which assists in the sealing of the hole. The device of the present invention is particularly useful as an implantable device, such as a vascular graft.



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TITLE OF THE INVENTION

MULTIPLE-LAYERED LEAK-RESISTANT TUBE

RELATED APPLICATIONS

The present application is a continuation-in-part of co-pending United States Patent Application Serial Number 08/977,465, filed November 24, 1997.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to tubular structures, such as vascular grafts and the like, that are adapted to carry a fluid stream, and particularly to tubular structures that are resistant to leakage following a puncture.

2. Description of Related Art

Tubular structures are used to carry a variety of fluid streams, including both liquids and gases. It is desirable for many of these tubular structures to be resistant to punctures, either accidental or intentional, and/or to provide some degree of self-healing following a puncture so as to minimize fluid leakage.

Of particular interest to the present invention is the possibility of creating a tubular structure for carrying blood or other body fluids that will provide improved self-healing characteristics. For instance, in vascular grafts, these devices often must be punctured both in initial installation (for example, while being sutured in place) and in subsequent medical procedures (for example, to provide an injection, to place a catheter, or the like). As a result, it is highly desirable that blood loss is minimized after each puncture through such tubes.

Even more critical is when vascular grafts are used as an access site for dialysis and the like. In the case of an arterial-venous ("AV") access graft, these vascular grafts must withstand several punctures a week over the life of the graft. This is a highly demanding environment that inevitably leads to graft failures due to excessive numbers of puncture holes, often requiring installation of two or more grafts over the course of a year. Unfortunately, each new AV access graft generally will not function properly until it has achieved tissue in-growth in a patient, a process that can take weeks after installation to occur adequately. Puncture of these tubes ("cannulation") before full tissue in-growth may result in excessive subcutaneous bleeding and serious complications.

A number of solutions have been proposed to reduce tubular leakage following punctures. For example, in United States Patent 4,184,489 to

Martinez it is proposed to use two concentric elastomeric sleeves, with the outer sleeve sized to radially compress the inner sleeve. This construction is reported to improve the sealing of the device following puncture. Similarly, in United States Patent 4,184,489 to Burd it is taught to surround a blood conduit tube with an elastomeric sleeve and then a C-shaped needle-impenetrable member partially surrounding the sleeve. This device is again asserted to prevent leakage into and out of the tube during and after needle penetration by maintaining a radial compression on the tube.

A number of other devices teach employing two or more layers of different materials to achieve some degree of puncture hole contraction following removal of the puncture device. For example, in United States Patent 4,619,641 to Schanzer it is proposed to employ two concentric expanded polytetrafluoroethylene (PTFE) tubes having a gap between them and then filling the gap with a silicone adhesive layer. Comparing the performance of this device with a device having the same two expanded PTFE tubes and no silicone layer filling the gap between them, Schanzer reports significantly reduced blood loss with the three layered PTFE-silicone PTFE hemoaccess tube.

While the various elastomer devices may provide some improvement in leakage protection over puncturing through a single layer tube, they work on a similar principle that the puncture hole should be constrained with an elastomer or similar material so that it will more quickly contract to reduce leakage upon removal of a needle. There are a number of serious drawbacks with this approach. First, these elastomer tubes tend to have poor handling characteristics, with some surgeons referring to them as "rubber hoses" because they bend and handle so poorly. Second, these tubes generally do not sew in place well, again making them difficult for surgeons to handle and install. Third, these tubes tend to be difficult to "revise" if a blockage occurs in them. Finally, since these tubes rely only on the elastic qualities of the tube wall to seal holes, there will always remain a hole all the way through the wall of the device following needle removal. Even with rapid contraction around the hole, some leakage through the hole after needle removal will be expected to occur. Additionally, the presence of a continuous hole through the wall of the device also is believed to compromise device integrity over time.

Another problem with multiple layered devices is that size is often a constraint in creating any implantable device. Most implantable devices must be as small as possible since space is almost always quite limited.

Unfortunately, most of the devices that reduce leakage rely on an increase in the bulk of wall layer or layers to accomplish rapid hole reduction (that is, the thickness of the wall is increased by laminating together multiple layers or simply by using thicker wall material). This demands a compromise between effective leakage reduction and the total acceptable size of the device.

Finally, many of these previous devices require use of less than preferred implantable materials. While PTFE is a preferred artificial material for implantation, since it is highly bio-compatible, it has rather poor recovery properties following puncture. As a result, prior devices have employed other materials to aid in quickly reducing hole size, such as silicone or other elastomeric materials. This creates devices that have better elastic properties, but with possibly less than ideal bio-compatibility.

United States Patent 5,700,287 to Myers et al. describes a tube of biocompatible material wherein a substantial portion of the outer surface of the base substrate is provided with an outer covering of deflectably secured material. "Deflectably secured" is defined to mean that the outer covering may move with respect to the base substrate when pierced with a needle. The outer surface of deflectably secured materials may be fibers, film, or discrete pieces. In practice, the Myers device has some drawbacks including difficulty in trimming to length and revising. Additionally, the Myers device is larger and less flexible than is preferred by many physicians.

Accordingly, without intending to limit or define the scope of the present invention with the following purposes, the present invention addresses deficiencies found in prior devices.

It is a purpose of the present invention to create a tubular structure that exhibits limited leakage following puncture.

It is another purpose of the present invention to provide a reduced-leakage tubular structure that incorporates reduced leakage properties with minimal increased space requirements.

It is another purpose of the present invention to provide a reduced-leakage tubular structure that can be constructed substantially from highly bio-compatible material, such as PTFE.

It is another purpose of the present invention to provide a tubular structure that can easily be cut to length, providing for easily customizable lengths and end configurations.

It is another purpose of the present invention to provide a graft that allows early cannulation following implantation.

These and other purposes of the present invention will become evident from review of the following specification.

SUMMARY OF THE INVENTION

The present invention comprises a tubular device that is resistant to leakage when punctured. The device of the present invention employs a first tube element at least partially covered with a second element that is adapted to move relative to the first tube element when the device is punctured diagonally with a needle. The device is constructed so that misaligned holes will be left through the device when the needle is removed, thus reducing leakage through the device.

Preferably, a first tube element and a second tube element are mounted concentrically with one another and have an interference fit therebetween. The interference fit assures that tensions or stresses applied to either or both of the tube elements will remain resident within the device in use. The tube elements are adapted to move relative to one another when punctured. By maintaining different stresses on the tube elements, the result is that relative movement will more readily occur between the tube elements during and after a puncture, assuring hole misalignment following needle removal.

This misalignment of openings vastly decreases fluid leakage from the device following a puncture. Additionally, the device can be constructed to provide self-healing properties by providing one of the tube elements with a compressive stress, causing the opening in it to close-up following needle removal.

Most preferably, a first tube element and a second tube element are mounted concentrically with one another and have an interference fit therebetween and the second tube element is made from a film and has a longitudinal compressive stress applied such that the second tube becomes corrugated. This corrugation results in advantages in addition to advantage of hole misalignment. The corrugation of the second tube element provides a flap of extra material which assists in closing the hole in the first tube layer. Another advantage, in a vascular graft application, is that the corrugations provide an increased surface area and large spaces for tissue incorporation.

The device of the present invention is believed to have a variety of useful applications, but is particularly intended for use as an implantable

device, such as a vascular graft and particularly to an AV access graft. In fact, the device of the present application is believed to be beneficially employed as an early cannulation vascular access graft.

As an implantable device, the present invention can be constructed from highly bio-compatible materials, such as polytetrafluoroethylene, without the need to introduce elastomeric materials, such as silicone, which are less desirable in implantable devices. Additionally, the leak resistant properties of the present invention are achieved with little increase in the dimension of the final product, again making it especially suitable for implantation within the tight confines of a body.

DESCRIPTION OF THE DRAWINGS

The operation of the present invention should become apparent from the following description when considered in conjunction with the accompanying drawings, in which:

Figure 1 is a three-quarter isometric view of one embodiment of a tubular device of the present invention;

Figure 2 is a cross-section view of the device of Figure 1;

Figure 3 is a three-quarter isometric view of another embodiment of a tubular device of the present invention;

Figure 4 is a cross-section view of the device of Figure 3;

Figure 5 is an enlarged cross-section view of a wall segment of a device of the present invention, showing a needle preparing to enter the device;

Figure 6 is the enlarged cross-section view of Figure 5, with the needle having penetrated an outer layer of the device;

Figure 7 is the enlarged cross-section view of Figure 5, with the needle having entered both the outer layer and an inner layer of the device;

Figure 8 is the enlarged cross-section view of Figure 5, with the needle having been removed from the device and illustrating the discontinuous nature of the openings left in the device through the outer and inner layers;

Figure 9 is a top plan view of the wall segment of the device of the present invention shown in Figure 8, showing the opening in the outer layer and showing in phantom the discontinuous opening in the inner layer;

Figure 10 is a three-quarter isometric view of another embodiment of a device of the present invention, this embodiment comprising a base tube covered with a tape-wrapped second tube;

Figure 11 is a longitudinal cross-section of the device of Figure 10;

Figure 12 is a three-quarter isometric view of still another embodiment of a device of the present invention, this embodiment comprising a three layer tubular construction;

Figure 13 is a longitudinal cross-section of the device of Figure 12;

Figure 14 is a three-quarter isometric view of still another embodiment of a tubular device of the present invention;

Figure 15 is a cross-section view along line 15 - 15 of Figure 14.

Figure 16 shows a cross section of a human arm with the tubular device of the present invention being used a vascular graft;

Figure 17 is a three-quarter isometric view of another embodiment of the present invention, this embodiment employing a strip of adhesive between the first tube element and the second tube element;

Figure 18 is a three-quarter isometric view of the first tubular element of the device of Figure 17;

Figure 19 is a three-quarter isometric view of the device of Figure 17 showing slits in the second tube element;

Figure 20 is a three-quarter isometric view of the device of Figure 17 showing a pair of tweezers disconnecting the second element at one of the slits;

Figure 21 is a longitudinal cross section of another embodiment of the tubular device of the present invention, this embodiment comprising a corrugated surface on the second tube element;

Figure 22a is a top view of the device of Figure 21 showing a misalignment between a hole in the first tube element and the slit hole in the second tube element;

Figure 22b is an enlarged longitudinal cross section at segment A-A of the device of Figure 21 before being punctured;

Figure 22c is the longitudinal cross section of Figure 22b, showing the flap of the second tube element filling the hole of the first tube element following a puncture;

Figure 22d is a longitudinal cross section of Figure 22c, showing the flap of the second tube element covering the slit hole of the second tube element following a puncture;

Figure 22e is a longitudinal cross section of another embodiment of the tubular device of the present invention, this embodiment comprising a

corrugated surface on the second tube element mounted on the inside of the device;

Figure 23a is a side elevation view of another embodiment of the device of the present invention, this embodiment including partially circumferential slits located along the axis of the tubular device;

Figure 23b is a side elevation view of the device of Figure 23a, showing a pair of tweezers grasping the second tube element and separating the tube at one of the slits;

Figure 23c is a side elevation view of the device of Figure 23a, showing a pair of tweezers completely separating "disconnecting" the second tube element at one of the slits;

Figure 23d is a side elevation view of the device of Figure 23a, after a portion of the second tube has been removed by tweezers;

Figure 24 is a longitudinal cross section view showing one method of corrugating the surface of the second tube element, such as may be accomplished by hand;

Figure 25 is a longitudinal cross section showing a method of corrugating the surface of the second tube element by a machine process;

Figure 26 is a photomicrograph of one embodiment of the device of the present invention showing the misalignment between the hole in the first tube element and the slit hole in the second tube element;

Figure 27 is a photomicrograph of another embodiment of the device of the present invention showing a close up view of the misalignment between the hole in the first tube element and the slit hole in the second tube element;

Figure 28 is a photomicrograph of one embodiment of the device of the present invention showing a flap of the second tube element;

Figure 29 is a histological section of the device of the present invention following implantation in a chronic canine model showing the flap of the second tube element partially filling the hole of the first tube element; and

Figure 30 is a histological section of the device of the present invention following implantation in a chronic canine model showing misalignment between the hole in the first tube element and the slit hole in the second tube element.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is an improved tubular device that is resistant to leakage following a puncture with a needle and subsequent removal of the

needle. As the term "needle" is used herein it is intended to include any object that can cause and/or maintain a puncture hole in the tubular device of the present invention, including without limitation: a pin; a sewing or suture needle; a hypodermic needle; a catheter device; a cannula device; a scalpel or knife; a thorn or other sharp, pointy object; et cetera.

The tubular device of the present invention is particularly intended for use as an implantable device, such as a vascular graft, that is capable of transferring body fluids. As is explained in greater detail below, the device of the present invention is especially useful as an AV access graft or the like. Especially preferred is use of the device of the present invention to allow for "early cannulation," whereby the device may be safely punctured with minimal leakage soon after implantation without the need to wait for device in-growth. It should be appreciated, however, that the device of the present invention may have numerous other applications wherein a tubular device carrying a fluid must be resistant to leakage following a puncture. Examples of other possible applications include: a tube adapted for sampling from a fluid stream, such as in laboratory analysis equipment; a self-healing tube or bag for carrying a liquid or pressurized gas, such as in a hose, shock absorber, tire inner tube, sample bag, etc.; a filter bag; chemical transport bladders; et cetera.

Figures 1 and 2 illustrate one embodiment of a tubular device 10 of the present invention. The device 10 comprises at least a first tube element 12 and a second element 14, preferably tubular, each mounted concentrically with one another and having an "interference fit," with one another.

The term "interference fit" as used herein connotes a sufficiently tight contact between the tube elements, at least when the device 10 is installed in place and under normal operating pressures, so that a longitudinal stress applied to one of the tube elements will be maintained. For example, if the first tube element is stretched longitudinally (that is, has a positive stress applied along its length) and an interference fit is established with the second element, then the first tube element will retain at least some of its stretched orientation due to the tight fit between the first tube element and the second element. It should be evident that to whatever degree the first tube element may contract from its stretched dimensions in this example, the second element will then be compressed to that degree (that is, the second element will have a negative stress applied along its length).

It is preferred that the second element is tubular, providing a ready means for forming a snug fit between the first tube element and the second element. However, as is explained in greater detail below, the second element may alternatively comprise a strip or other configuration of material that is attached to the first tube element in such a way as to allow relative movement between the first tube element and the second element.

When two tubular elements are employed, the interference fit employed with the present invention is preferably sufficiently tight to maintain a stress differential between the tube elements, as will become clear from the following description. The interference fit between the tube elements should allow for the relative movement between the tube elements during and after a diagonal puncture. Thus, it is not desired to have a fit that is so tight that at least portions of the tube elements cannot slide longitudinally with respect to each other. On the other hand, it is likewise not desirable to have a fit between the tubes that is so loose a stress differential cannot be maintained between the tubes or that significant liquid leakage can occur in the space between the tubes.

In a preferred embodiment of the present invention, at least two tube elements 12, 14 are employed and each of the elements 12, 14 should have a stress applied and maintained along its length, with the longitudinal stress applied to the first tube element 12 being different from the longitudinal stress applied to the second tube element 14. For example, the first tube element may have a positive stress applied along its length (that is, it is stretched longitudinally), with the second tube element having no stress (that is, it maintains its natural resting state of stress) or a negative stress applied along its length (that is, it is compressed longitudinally). Conversely, the second tube element may have a positive stress applied along its length, with the first tube element having no stress or a negative stress applied along its length. The important aspect is that a stress differential is established between the tube elements so that they will each react differently when a puncture is applied through the device.

By way of example, a vascular graft having a 7 mm final outer diameter and 5.8 mm final inner diameter can be constructed from two tubes of expanded polytetrafluoroethylene (PTFE), a first tube having an initial inner diameter of about 6 mm, an outer diameter of about 7.2 mm, a wall thickness of about 0.6 mm, and an initial length of about 30 cm, and a second tube having

an initial inner diameter of about 6 mm, an initial outer diameter of about 6.9 mm, a wall thickness of about 0.45 mm, and an initial length of about 50 cm. These two tubes can be mounted coaxially with one another and will establish an interference fit between each other.

In this instance a longitudinal stress differential can be established between the two expanded PTFE tubes by applying a longitudinal tensile strain to the first tube, and applying a longitudinal compressive strain to the second tube to reduce its length to about 70% of its original length. In this instance, when the two tubes are released from their strain and constraint, the first tube will slightly recover, with the second tube undergoing some degree of compression. In this unrestrained state, the first tube will have a tensile strain applied along its length of about 30% (that is, it is about 30% longer than its initial length) and the second tube will have a compressive strain applied along its length of about 60% (that is, it is about 60% of its initial length).

These properties can also be expressed by the degree of compression applied to each of the tubes. By placing at least two measured marks on each of the tubes in their resting states, the degree of stretch or compression between the two tubes can be measured by the amount of change in distance between the pre-measured marks on the two tubes. For example, a first set of marks may be placed on a first tube 1 cm apart longitudinally and a second set of marks may be placed on a second tube 1 cm apart longitudinally. When the two tubes are attached together with an interference fit and a stress differential placed on the tubes, then the distance between the marks in either the first set of marks or the second set of marks will be either increased or decreased. In fact, for most applications it would be expected that expansion of one tube during construction will create some degree of compression in the other tube in the final device, thus causing the distance between both sets of marks to change.

Using these criteria, for vascular access applications it is believed desirable to have at least a 50 to 70% compression on one of the tubes in the completed device, with a preferred compression of about 55 to 65%. In the instance of tubes with 1 cm marks on them, this means that following placing the tubes together the two marks on the compressed tube will be approximately 0.4 to 0.6 cm apart, and more preferably 0.45 to 0.55 cm apart. A differential in tension between the two tubes (that is, one tube under compression and the

other tube under stretch) might result in the compressed tube having marks 0.5 to 0.7 cm apart and the stretched tube having marks 1.2 to 1.4 cm apart.

When considering a completed device of the present invention the relative stresses applied to the tube elements may be measured by applying the same principles in reverse. For example, measured sets of marks may be placed on the inside and outside tubes of the complete device and then the device may be disassembled, relieving any stress differential on the tubes. Any change in the distance between the measured marks may then be measured to provide the degree of change. For example, a vascular graft having two tubes with an interference fit between them may have sets of 1 cm marks placed on both the inside tube and the outside tube. Once disassembled, stress differential between the tubes will be relieved, which will either lengthen or shorten the distance between the marks in each set. A change of distance from 1 cm to about 1.67 cm on one of the tubes will indicate a degree of compression of about 60%. Using this method, one can readily determine whether a multiple layered tube has stress differentials between its various tube elements.

Alternatively, a stress differential can be confirmed by performing a simple puncture test on a device of the present invention. As is illustrated in Figures 5 through 9 and is explained in detail below, when a diagonal puncture is placed through the device 10 with a needle, a stress differential between the layers will cause the two layers of the device to move relative to each other when the needle is removed, creating a discontinuous hole through the device. Thus a stress differential between the tube elements can also be shown through this simple puncture test.

It should be appreciated that the present invention will also function by using materials with different moduli of elasticity for the first tube element and the second element. In this manner, each of the layers will react differently to a diagonal puncture, again causing a hole misalignment when the needle is removed. A further refinement of the present invention employs materials with different moduli of elasticity and a stress differential applied to each of the layers. Other physical properties, such as differentials in thicknesses, density, materials, and other mechanical and physical properties may be incorporated into devices of the present invention to provide suitable performance.

An alternative embodiment of a device 10 of the present invention is illustrated in Figures 3 and 4. In this embodiment a first tube element 16 is

employed that is longer in length than the second tube element 18. Again, the two tube elements 16, 18 should have an interference fit established between them and a stress differential between the two elements 16, 18. The device of this embodiment is intended to address those instances where the device as a whole does not need to be cannulated, but only that segment corresponding to the length of the second tube element 18.

Again, the stresses applied to each of the two tube elements 16, 18 may be positive, none, or negative, so long as a stress differential is established. As used herein, the term "tensile stress" refers to a longitudinal positive "pull" on the tube component; the term "compressive stress" refers to a negative compression of the tube component. Since the anchorage of this device will be through attachment of the first tube element 16 at its ends 20, 22, it is preferred to have a tensile stress applied along the first tube element 16.

The operation of the present invention is illustrated in Figures 5 through 9. As is shown, a wall segment 24 of the device 10 is shown comprising an inner or first tube element 26 and an outer or second tube element 28. In this embodiment, the first tube element 26 is the one with a positive stress along its length.

A needle 30 is shown in Figures 5 through 7, in this instance a 15 gauge hypodermic needle having a cutting tip 32. The needle 30 is oriented at a diagonal to the wall segment 24 (that is, it is positioned at an angle other than directly perpendicular to the wall segment). Normally a needle of this type will be introduced diagonally at an angle of about 15 to 60 degrees from perpendicular, with an angle of about 45 degrees from perpendicular illustrated.

Shown in Figure 6 is the needle 30 after it has penetrated the second tube element 28 forming a first opening 34. As can be seen, since the two tube elements are attached together with an interference fit that allows for relative movement between the two tube elements 26, 28, the second tube element 28 undergoes some initial movement, shown as a slight bulge 36.

Figure 7 illustrates the needle 30 after it has penetrated both the second tube element 28 and the first tube element 26 to form a second opening 38. As can be seen, the first tube element 26 also undergoes relative movement, in this instance a downward distortion 40.

As is shown in Figures 8 and 9, once the needle is removed, the relative stresses on the first tube element 26 and the second tube element 28 cause them to return to different resting states. As a result, the first opening 34 and

the second opening 36 do not align with one another. This separation of the two openings 34, 36 is referred to herein as being a "misalignment" of the openings or "discontinuous opening" through the wall segment 24. Since a continuous opening is not left in the wall, this vastly decreases the amount and duration of fluid that will pass through the wall following needle removal. Additionally, while the first tube element 26 is under tensile stress, causing the second opening 36 to be somewhat enlarged, the second tube element 28 is actually under a compressive stress, causing the first opening 34 to close up, thus further limiting the amount and duration of fluid that will escape the device.

For use as an implantable device, it is preferred that the present invention be constructed from materials suitable for implantation, and especially bio-compatible material or materials, such as polytetrafluoroethylene (PTFE), expanded PTFE, DACRON® polymer, polyurethane, silicone elastomer, and the like.

Particularly preferred is a device constructed from expanded PTFE, such as that disclosed in United States Patents 3,953,566, 3,962,153, 4,096,227, and 4,187,390, each incorporated by reference. Tubes made in accordance with these patents adapted for use as a vascular graft are commercially available from W. L. Gore & Associates, Inc., Flagstaff, AZ, under the trademark GORE-TEX®.

In particular, a device of the present invention can be constructed by combining commercially available vascular grafts in the following manner. A Stretch GORE-TEX® Vascular Graft may be used as a base graft. These stretch grafts are available from W. L. Gore & Associates, Inc., in a variety of internal diameters (ranging from about 5 to 10 cm) and a nominal wall thickness of about 0.6 mm. The base graft is placed onto an assembly mandrel and secured at one end. A load is placed on the opposite end to apply tension to the graft.

A second GORE-TEX® vascular graft may be used as the outer graft, preferably one having a relatively thin wall. Thin wall vascular grafts are available from W. L. Gore & Associates, Inc., in a variety of internal diameters (ranging from about 3 to 10 cm) and a nominal wall thickness of about 0.45 mm. The second vascular graft should be sized to be approximately the same internal diameter as that of the base graft, thus forming an interference fit when the two grafts are combined together.

The second vascular graft is pulled over the base graft and the assembly mandrel, creating an interference fit between the two grafts. The outer graft is then longitudinally compressed along its length. The outer graft may be compressed from about 50 to 70 % of its original length, with a compression of about 60% being most preferred. This provides longitudinal compression in the outer graft. The combined grafts are then removed from the assembly mandrel. In use, longitudinal forces applied to the graft will be applied to the base graft so that the outer graft will remain in compression.

It should be evident that two, three, or more grafts may be combined in this manner, with compression or tension applied to one or more of the layers to support relative movement between the graft layers during and after a puncture.

It should be further evident from the above description that the present invention solves many of the prior deficiencies with leak-resistant tubular devices. First, the combination of discontinuous openings through the device wall and the negative stress on one of the tube elements, causing the tube to "close up," combine to provide a device that is very resistant to leakage. Second, the device can be constructed from very few components and in dimensions that are similar to those of conventional single wall tubes. As a result, the device of the present invention is very compact and requires little or no additional space for use over more conventional vascular grafts and similar products. Third, the device of the present invention can be constructed substantially or even entirely from highly bio-compatible material, such as PTFE, without the need to introduce elastomers or other products that might cause compatibility problems or other complications.

A further preferred embodiment, of the present invention described below, one of the tube elements is corrugated. Puncturing a corrugated tubular element causes a flap to form at the puncture point. The flap also helps reduce leaking by either filling the hole in the non-corrugated tube element or by covering the slit hole left in the corrugated tube element. This advantage combined with hole misalignment creates a tube that is very resistant to leakage after puncture.

For other applications, the device of the present invention can be constructed from a wide variety of materials and in a variety of different constructions. For instance, Figures 10 and 11 illustrate a two-layer construction of a leak-resistant tube 42 of the present invention. In this

embodiment, a continuous base tube 44 is covered with an outer layer of a helically wound tape 46, thus creating the outer tubular element 48. Once again, by applying either tension or compression on the base tube 44 during the wrapping process, the outer tubular element 48 will retain the differential stress within the device 42.

Still another embodiment of the present invention is shown in Figures 12 and 13. This leak-resistant tube 50 employs three tube elements 52, 54, and 56 connected together with an interference fit. Base tube 52 is surrounded by an intermediate tube 54 that is further covered by an outer tube 56. Tension, compression, or no stress may be applied to one or more of these tube elements to impart a differential stress to the device as a whole. It should be evident that this embodiment allows for even greater misalignment of holes through the device upon removal of a puncture since stresses can be imparted to the device to move each of the layers in different directions during and after a diagonal puncture.

Figures 14 and 15 illustrate a further embodiment of a vascular graft 58 of the present invention. In this embodiment a first tube element 60 is partially covered with a second element 62 comprising a strip of material. In this form, the second element 62 is anchored to the first tube element 60 on the second element's ends 64a, 64b and perhaps along its longitudinal sides 66a, 66b. In order to function properly, the operative piercing surface 68 of the second element 62 should be free to move relative to the first tube element 60 in order to provide the hole misalignment previously described.

Anchorage between the first tube element 60 and the second element 62 may be accomplished through a variety of means. For example, thin strips of adhesive may be applied near the ends 64a, 64b of the device to anchor the ends in place. Suitable adhesives include fluorinated ethylene propylene (FEP), Silicone, etc. Adhesive may also be applied along the sides 66a, 66b. Other anchorage means that may be employed with this embodiment include sutures, staples, clips, etc.

When the second element 62 is constructed from the same material as the first tube element 60 (or constructed from a material with a similar modulus of elasticity as the first tube element 60), it is preferred that a stress differential is applied between the first tube element 60 and the second element 62. This can be accomplished by stretching or compressing the second element 62 before attaching it to the first tube element 60. Alternatively or additionally, the

first tube element 60 may be stretched or compressed prior to attachment to establish a stress differential. Again, the second element 62 may be made with materials having different mechanical and physical properties to provide suitable performance.

This device of the present invention has particular application as a vascular graft, and particularly as an A-V shunt for use in dialysis treatments. Figure 16 shows a graft 74 of the present invention implanted into a human arm. Vascular graft 74 is attached between vein 70 and artery 72.

Figures 17 and 18 illustrate another embodiment of the present invention. In this embodiment a first tube element 80 is stretched longitudinally such that it is under tension (that is, has a positive stress along its length) and a second element 82 is attached over the first tube element 80 with an interference fit between the first and second tube elements. The second element 82 is compressed longitudinally such that is under compression (that is has a negative stress along its length) to 50 to 70 % of the original length, preferably 55 to 65%. This creates a differential longitudinal stress between the first and second tube elements 80, 82. Additionally, a strip of adhesive 84 is disposed longitudinally along the first tube element 80. The strip of adhesive assists in holding the first tube element 80 to the second tube element 82, helping to maintain proper differential stress on the tubes even when being handled.

For some applications it may be helpful to be able to readily shorten the length of a graft of the present invention without disabling its self-sealing properties. One such method of providing easy length adjustment is illustrated in Figure 19. As shown in Figure 19, the second tubular element may be provided with a plurality of partially circumferential slits 88 located at predetermined intervals along the longitudinal axis of the second tube element. These slits act as stress concentrations so that sections of the outer covering can be easily removed by tugging on the covering at the ends of the graft. This will "disconnect" a section of the graft loose for easy removal. These slits provide a means where a portion of the second tube element can be easily removed from first tube element at the ends of the device after cutting the device to length. The slits may be positioned at regular intervals or at other desirable locations along the length of the tube.

The slits may be positioned at regular intervals or at other desirable locations along the length of the tube. Figure 20 illustrates a pair of tweezers

89 removing a portion of the second tube element by "disconnecting" the covering. Commercially available grafts provide a tubular structure that can easily be cut to length, providing for easily customizable lengths and end configurations. With a portion of the second tube element removed, the ends of the device comprises a first tube element which is similar to commercially available vascular grafts and can be cut and sewn to the host vessel using established techniques.

Figure 21 illustrates a further preferred embodiment of the present invention. In this embodiment, a first tube element 110 is stretched longitudinally such that it is under tension (that is, has a positive stress along its length). The second element 112 comprises a corrugated tubular film that forms an interference fit with the first tube element 110. The second element 112 is a tubular film compressed longitudinally such that it is under compression and forms a corrugated surface. The corrugations of the second element 112 provide large convoluted spaces 114 for tissue incorporation and attachment.

Additionally as is explained in greater detail below, the corrugated second element 112 also provides further improved sealing properties for the device. As shown in Figure 22a, the differential stress between the corrugated tubular film second element 112 and the first tube element 110 creates a misalignment 122 between the second element 112 and the first tube element 110 after puncture of the device 100. Hole 118 in the first tube element 110 moves relative to slit hole 120 in the corrugated second element 112, creating a misalignment 122.

The tubular film may be made from a variety of materials, but is preferably an expanded ePTFE film. The film can be uniaxially or biaxially expanded. Expansion of the film provides strength oriented in the direction of expansion. Preferably, the film is from about 0.0005 inch (0.013 mm) to about 0.002 inch (0.05 mm) thick.

One manner of producing a suitable film is as follows. A tube is made by wrapping a mandrel with multiple layers of film then sintering the film at 380° C for several minutes. After sintering, the film tube is removed from the mandrel. A film tube provides several advantages. The second tube element must withstand the radial forces from the interference fit and from the fluid pressure in the graft. An oriented film has more strength and is less compliant in the direction of orientation. Wrapping a film around a mandrel to form a film

tube forms a tube with more radial strength and resistance to radial dilatation than an unoriented tube of the same mass, such as an extruded tube. Since the direction of orientation is placed in the orientation needed to achieve low leak performance, a film tube may provide the necessary mechanical properties with less mass than an unoriented extruded tube. Reduced mass is very desirable in an implantable medical device. Further, the reduced mass and orientation allows the tube to become corrugated when compressed perpendicular to the axis of orientation. These corrugations allow a sealing flap to form and provide areas for tissue attachment and ingrowth.

A preferred embodiment of the present invention utilizes a 1 inch (2.54 cm) wide length of biaxially oriented expanded PTFE film. The film can be made according to Example 2 of United States Patent 5,814,405 to Branca et al., incorporated by reference. The film has a nominal thickness of 0.0125 mm and a density of approximately 0.2 gm/cc. About 25 layers of film are wound unto a 6.5 mm mandrel. The film is sintered at 380° C for about 9 minutes. Once the mandrel has cooled, the film tube is removed from the mandrel.

In addition to providing an interference fit and a resulting hole misalignment following puncture, this embodiment has the additional advantage of providing extra material in the device wall that will form a sealing flap following puncture. The sealing flap will form either a hole filling flap or a slit hole covering flap once a puncturing needle is withdrawn from the device. This sealing flap helps to reduce the amount and time of leakage after cannulation.

Figures 22b – 22d show a cross section of the most corrugated device described above. Figure 22b illustrates an enlarged section of the wall of the device shown in Figure 22a. In Figure 22c, the device has been punctured and the needle removed. A misalignment 122 has been created by the differential stress between the two tubular elements 110,112. In addition to hole misalignment, a flap 124, formed after puncture of the corrugated tubular film 112, is left that may partially fill the hole 118 left after the puncture of the first element 110. If the flap 124 does not fill the hole 118, it may cover the slit 120 in the corrugated tubular film 112, as is shown in Figure 22d. The flap's ability to fill the hole in the first tube element or to cover the slit in the second tube element helps decrease leakage amounts and time by further obstructing the path for any leakage.

Figure 22e illustrates a similar construction of a low-leakage graft 100 of the present invention. In this embodiment the first tube element 110 and the second tube element 112 have been reversed so as to created a corrugated inner surface. Again, the second element 112 comprises a corrugated tubular film that forms an interference fit with the first tube element 110. The second element 112 is a tubular film compressed longitudinally such that it is under compression and forms a corrugated surface. This construction can be accomplished by corrugating the second tube element 112 once it is mounted within the first tube element 110. Alternatively, the second tube element 112 may be corrugated on the outside of the first tube element 110 in the manner described below, and then the device may be turned inside out to achieve the final configuration.

As has been described, the corrugated tubular film may be provided with a plurality of partially circumferential slits 130 located at regular intervals along the longitudinal axis of the corrugated tubular film 112. These slits act as stress concentrations so that sections of the outer covering can be easily removed by disconnecting the covering at the ends of the graft. Figures 23a-d illustrate a pair of tweezers 132 removing a portion 133 of the corrugated tubular second element 112 by grasping and then "disconnecting" the covering. This leaves a tubular device, as is shown in Figure 23d, with a shortened second element 112. The first element 110 may then be trimmed to length for installation.

Figure 24 illustrates a basic method of creating the corrugations of the corrugated tubular film of second element 112. A thin tubular film is placed over the first tubular element 110 and anchored at end 115. The thin tubular film is then compressed longitudinally towards end 115 in small increments to create corrugations.

This compression process may be performed manually or through the use of apparatus. One embodiment of suitable apparatus to form a corrugated second element is shown in Figure 25. An upper belt unit 140 includes two rolls 144a, 144b and a belt 142a around the two rolls. Lower belt unit 141 also includes two rolls 144c, 144d and a belt 142b around the two rolls. First tube element 110 is placed and secured onto a mandrel 156. The thin tubular film 111 is placed over the first tube element 110 and secured at end 115. Both the upper and lower belt units 140, 141 move along the longitudinal axis of the

mandrel 156 in direction 150. The rolls rotate to create belt speed 148. Both upper and lower belt units 140, 141 are synchronized to operate at the speed and apply the same force. They may be either mechanically or electronically synchronized. The belt speed 148 is set higher than the speed the belt units move in direction 150. This difference overfeeds the thin tubular film 111 onto the first tubular element 110, creating a corrugated second element 112, as shown.

The preferred corrugated second element of the present invention has approximately 20 to 60 convoluted folds per centimeter. Each fold 114 is preferably approximately 0.1 to 0.6 mm in depth.

As the term "corrugated" is used therein it is intended to define one or more elements of a device that has multiple folds or ripples along its surface visible without magnification. These folds or ripples comprise excess material that may aid in sealing punctures formed through the devices in the manner described herein.

In addition to a tube or a strip, the second element may also be constructed in a variety of other shapes and sizes. Examples of other configurations include: square, circular, rectangular, or other shaped patches. Additionally, the second element may be combined in multiple layers and/or in multiple configurations to provide specific properties to the final device.

In the context of a non-tubular second element, the term "interference fit" is intended to define a snug connection between the first tube element and the second element so that the elements can retain differential stresses established between them.

Without intending to limit the scope of the present invention, the following examples illustrate how the present invention may be made and used:

EXAMPLE 1 -- Leak Resistant Two Layer Tube:

A leak-resistant vascular graft of the present invention may be made in the following manner. A commercially available expanded PTFE 6 mm Stretch GORE-TEX® Vascular Graft is used as the base tube (first element). This tube has a nominal internal diameter of 6 mm and a nominal wall thickness of 0.60 mm. The first element is placed onto an assembly mandrel and secured at one end. A load is placed on the opposite end to apply tension to the first element. A thin wall 6 mm expanded PTFE GORE-TEX® graft is used for the outer

second element. It has nominal internal diameter of 6 mm and a nominal wall thickness of 0.45 mm. It is pulled over the first element and the assembly mandrel to create an interference fit between the two tubes. The outer second element is then compressed uniformly along its length to about 60% of its original length. This provides longitudinal compression in the outer second graft. The tubes are then removed from the assembly mandrel. In use, longitudinal forces applied to the composite tube will be applied to the first element so that the outer second element will remain in compression.

EXAMPLE 2 -- Ultra Thin Wall Outer Graft:

A 6 mm Stretch GORE-TEX® expanded PTFE Vascular Graft is used for the inner first element. This graft has a nominal internal diameter of 6 mm and a nominal wall thickness of 0.60 mm. The first element is placed onto an assembly mandrel and secured at one end. A load is placed on the opposite end to apply tension to the first element. An ultra thin wall expanded PTFE 6 mm GORE-TEX® graft is used for the outer second element. It has nominal internal diameter of 6 mm and a nominal wall thickness of 0.25 mm. It is pulled over the first element and the assembly mandrel creates an interference fit between the two tubes. The outer second element is then compressed uniformly along its length to about 60% of its original length. This provides longitudinal compression in the second element. The composite tube is then removed from the assembly mandrel. Longitudinal forces applied to the composite tube will be applied to the first element so that the outer second element will remain in compression. Figure 26 shows the misalignment between the hole in the first tube element and the slit hole in the second tube element.

EXAMPLE 3 -- Bonded Grafts:

Means can be provided to assure that the compression in the outer graft is not disturbed during handling and implantation and which still allows the grafts relative motion during cannulation to provide the low leak feature.

In this example, a strip of bio-compatible, adhesive material is placed between the grafts. This material is used to bond the two grafts along a narrow strip that is located opposite the side that will be cannulated. This material can

be constructed from a number of possible materials, including fluorinated thermoplastics (such as, fluorinated ethylene propylene (FEP) or perfluoroalkoxy polymer (PFA)) as well as silicones or polyurethanes. The material can be applied along a strip as a film or coating. It can also be applied over the entire graft and only be sealed along a narrow strip opposite the cannulation site.

An expanded PTFE 6 mm Stretch GORE-TEX® Vascular Graft is used as a base graft. This graft has a nominal internal diameter of 6 mm and a nominal wall thickness of 0.60 mm. A full length and 0.4 cm wide strip of FEP film is applied lengthwise along the graft. The base graft is placed onto an assembly mandrel and secured at one end. A load is placed on the opposite end to apply tension to the graft. A thin wall 6 mm GORE-TEX® graft is used for the outer graft. It has nominal internal diameter of 6 mm and a nominal wall thickness of 0.45 mm. It is pulled over the base graft and the assembly mandrel, creating an interference fit between the two grafts. The outer graft is then compressed uniformly along its length to about 60% of its original length. This provides longitudinal compression in the outer graft. Heat and pressure are applied along the outer graft on top of the FEP strip, bonding the two tubes together along a narrow strip opposite the side to be cannulated. The grafts are then removed from the assembly mandrel. Longitudinal forces applied to the graft will be applied to the base graft so that the outer graft will remain in compression. The two tubes are able to displace during cannulation along the cannulation side, but the compression of the outer tube is resistant to change during handling and implantation

EXAMPLE 4:

Additional tubes of varying thickness, density and structural orientation can be combined to further maximize hole misalignment and/or hole healing effects, as is illustrated in Figures 12 and 13, as previously described.

For example, a base tube of an expanded PTFE 6 mm Stretch GORE-TEX® Vascular Graft is positioned on a vacuum mandrel in a longitudinally relaxed state. Vacuum is applied to the mandrel, collapsing the outer diameter (OD) of the graft. An ultra thin wall expanded PTFE 6 mm GORE-TEX® graft is positioned on top of the base graft in a fully distended condition. A second ultra thin wall 6 mm GORE-TEX® graft is positioned over

the first two grafts and compressed uniformly along its length to about 60% of its original length. The grafts are then removed from the vacuum mandrel. The graft provides a middle layer that bears most of the axial loads, a neutrally loaded inner layer that is easily displaced relative to the other two layers by penetration forces, and an outer layer that is compressively loaded to provide a healing effect.

EXAMPLE 5:

As an example of creating an interference fit, a commercially available expanded PTFE 6 mm Stretch GORE-TEX® Vascular Graft is used for the first tube element. The first tube element is placed onto an assembly mandrel and secured at one end. A load is placed on the opposite end to apply tension to the tube. Film is made according to Example 2 of United States Patent 5,814,405 to Branca et al. A film tube is made by winding 25 layers of a one inch (2.54 cm) wide, 0.0005 inch (0.013 mm) thick expanded PTFE film on a 6.5 mm mandrel. The wound film is sintered at 380° C on the mandrel to form a tube. After removing the film tube from the mandrel, the film tube is then pulled over the base graft and the assembly mandrel as the second tube element. The film tube is then compressed uniformly along its length to about 60% of its original length. This provides longitudinal compression in the film tube. This graft has a nominal internal diameter of 6 mm and a nominal wall thickness of 0.6 mm and provides an interference fit with resulting hole misalignment following puncture.

Illustrations of a device made in accordance with this example are shown in Figures 27 through 30. Figure 27 shows a close up view of the misalignment between the hole in the first tube element and the slit hole in the second tube element. Figure 28 shows the flap of the second tube element. Figure 29 shows the flap of the second tube element partially filling the hole of the first tube element. Figure 30 shows the misalignment between the hole in the first tube element and the slit hole in the second tube element.

EXAMPLE 6:

An adjustable length leak resistant vascular graft of the present invention may be made in the following manner. A commercially available 6

mm Stretch GORE-TEX® expanded PTFE Vascular Graft is used for the first tube element. This graft has a nominal internal diameter of 6 mm and a nominal wall thickness of 0.6 mm. A full length and 0.4 cm wide strip of FEP film is applied lengthwise along the first tube element. The first tube element is placed onto an assembly mandrel and secured at one end. A load is placed on the opposite end to apply tension to the tube.

A film tube is made by winding 25 layers of a 1 inch (2.54 cm) wide, 0.0005 (0.013 mm) thick expanded film made according to Example 2 of United States Patent 5,814,405 to Branca et al., incorporated by reference on a 6.5 mm mandrel. The wound film is sintered at 380° C on the mandrel to form a tube for the second tube element. Slits are cut into the film tube to provide a means for quick and easy removal of a short sections of the film tube after the graft has been cut to length in use. Typically, the slits are 1/4 to 1/3 of the tube circumference in length. Multiple slits are made, evenly spaced along the length of the tube. The slits in the film tube are oriented such that the mid-point of the slit is aligned with the FEP strip on the base graft.

The film tube is pulled over the first tube element and the assembly mandrel to create an interference fit between the first tube and the film tube. The film tube is then compressed uniformly along its length to about 60% of its original length, resulting in compression in the film tube and a corrugated surface on the film tube.

Heat and pressure are applied along the film tube on top of the FEP strip, bonding the two tubes together along a narrow strip opposite the side to be cannulated. The film tube covered graft is then removed from the assembly mandrel. Any longitudinal forces applied to the graft will be taken by the base graft so that the outer film tube will remain in compression. The film tube is able to displace during cannulation along the cannulation side, but the compression of the film tube is resistant to change during handling and implantation.

The graft may be made easier to handle by placing the completed graft on 6 mm mandrel, fully compressing the graft longitudinally and the heating the graft to 120° C for 1 hour. The graft is removed from the mandrel and pulled out to finished length by applying a 500 gm load.

While particular embodiments of the present invention have been illustrated and described herein, the present invention should not be limited to

such illustrations and descriptions. It should be apparent that changes and modifications may be incorporated and embodied as part of the present invention within the scope of the following claims.

The invention claimed is:

1. A tube resistant to leakage when punctured comprising

a first tube element having a length;

a second element having a length;

the second element placed over the first tube element with an interference fit between the first tube element and the second element;

wherein the second element is corrugated.

2. The tube of claim 1 wherein the first tube element and second element are adapted to move relative to one another when a diagonal puncture is place through the tube with a needle creating a misalignment of a hole through the first tube element and a slit hole in the second element when the needle is removed.

3. The tube of claim 2 wherein the tube comprises polytetrafluoroethylene.

4. The tube of claim 3 wherein the tube comprises expanded polytetrafluoroethylene.

5. The tube of claim 1 wherein when in an interference fit between the first tube element and the second element, the first tube element has a stress applied along its length different from a stress applied to the second element along its length.

6. The tube of claim 5 wherein

the first tube element and the second element each has a natural resting state of stress along its length; and

the first tube element is stretched from its natural state of stress and the second element is compressed from its natural state of stress.

7. The tube of claim 5 wherein

the first tube element and the second tube element each has a natural resting state of stress along its length; and

the second element is stretched from its natural state of stress and the first tube element is compressed from its natural state of stress.

8. The tube of claim 1 wherein the second element comprises a film tube.

9. The tube of claim 8 wherein when in an interference fit between the first tube element and the second element, the first tube element has a stress applied along its length different from a stress applied to the second element along its length.

10. The tube of claim 8 wherein the second element includes at least one slit therein that assists in shortening the second element.

11. The tube of claim 1 wherein the second element includes at least one slit therein that assists in shortening the second element.

12. A tube resistant to leakage when punctured comprising

a first tube element having a length;

a second element having a length;

the second element placed over the first tube element with an interference fit between the first tube element and the second element;

one of the first element or the second element is compressed to form a corrugated surface;

wherein the first tube element and second element are adapted to move relative to one another when a diagonal puncture is place through the tube with a needle creating a misalignment of a hole through the first tube element and a slit hole in the second element when the needle is removed.

13. The tube of claim 12 wherein the first tube element comprises polytetrafluoroethylene and the second element comprises polytetrafluoroethylene.

14. The tube of claim 13 wherein the first tube element comprises expanded polytetrafluoroethylene and the second element comprises expanded polytetrafluoroethylene.

15. The tube of claim 12 wherein the first tube element is stretched from its natural state of stress and the second element is compresses from its natural state of stress.

16. The tube of claim 12 wherein the first tube element is attached to the second element with a strip of adhesive

17. The tube of claim 16 wherein the first tube element is attached to the second element with a strip of FEP.

18. The tube of claim 12 wherein the second element is a tube.

19. The tube of claim 12 wherein the second element includes at least one slit therein that assists in shortening the second element.

FIG. 1

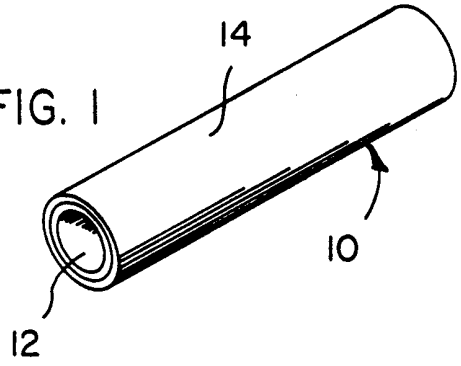


FIG. 2

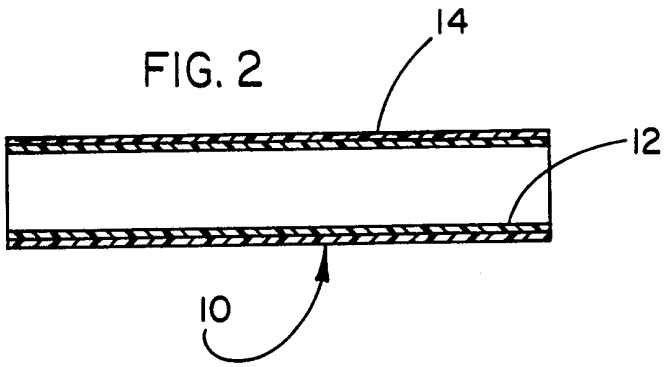


FIG. 3

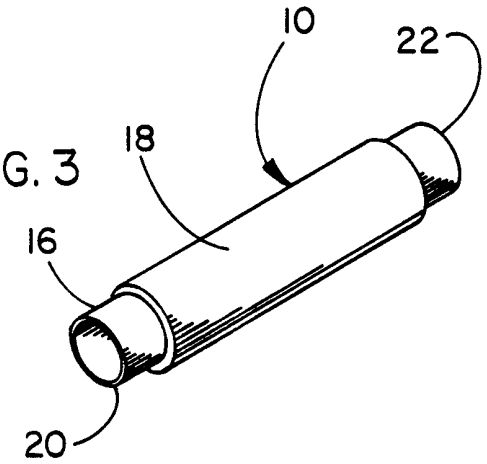


FIG. 4

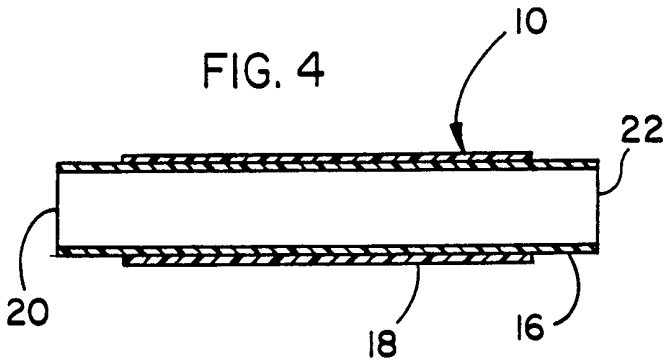


FIG. 5

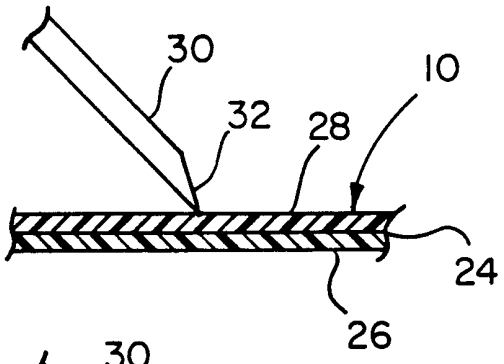


FIG. 6

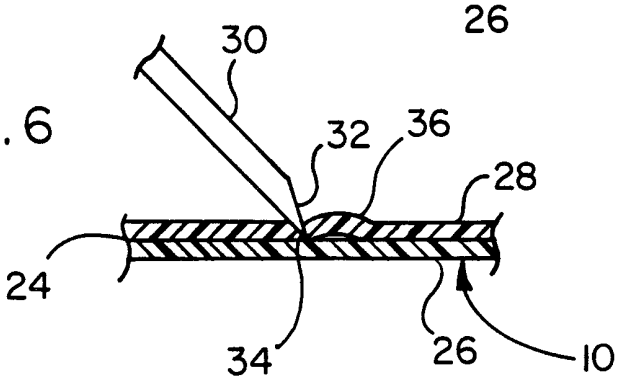


FIG. 7

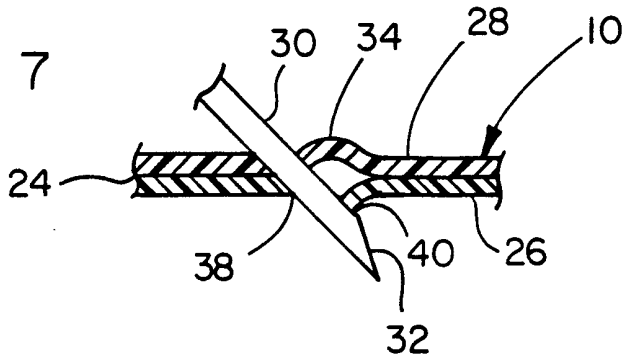


FIG. 8

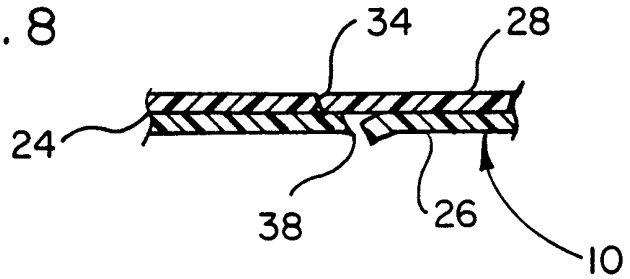


FIG. 9

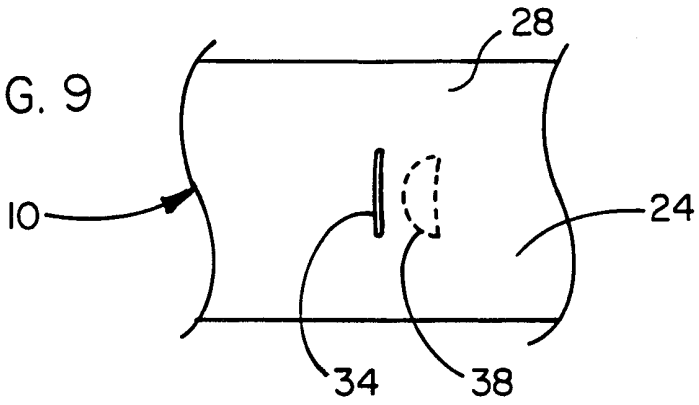


FIG. 10

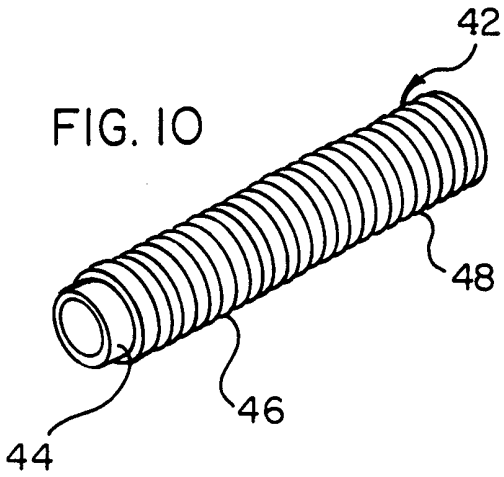
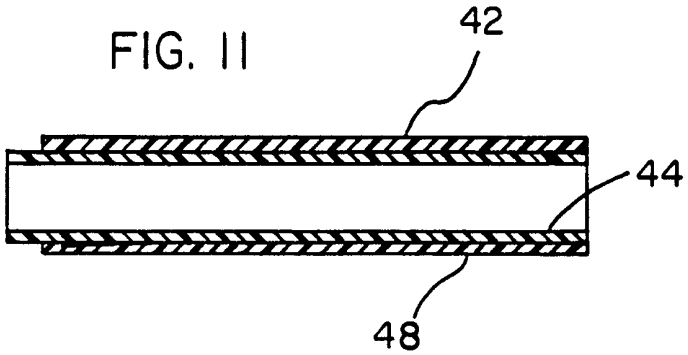


FIG. 11



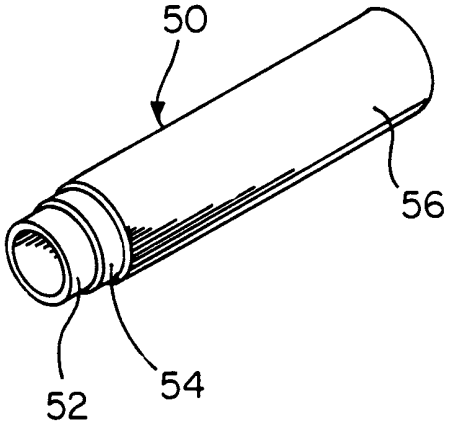


FIG. 12

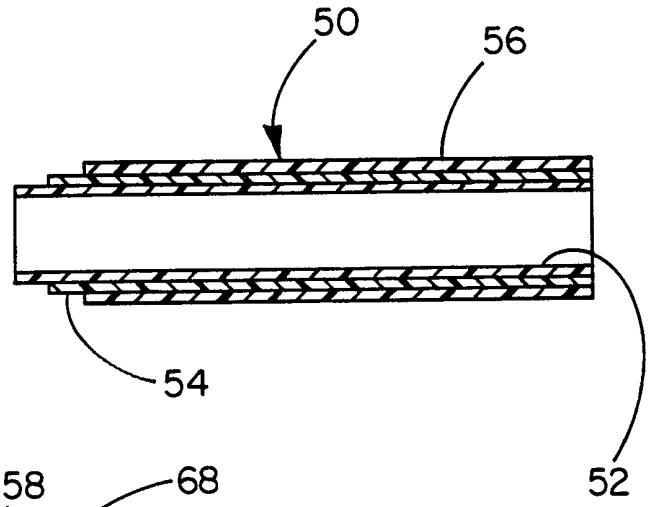


FIG. 13

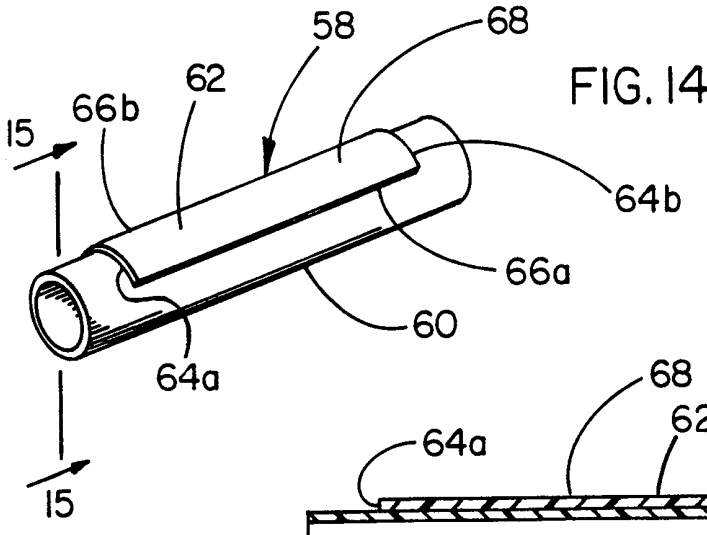


FIG. 14

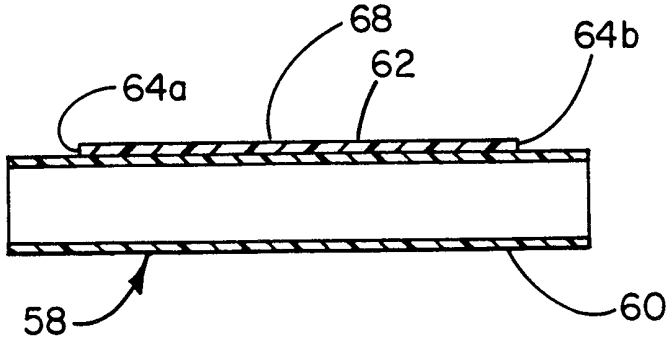


FIG. 15

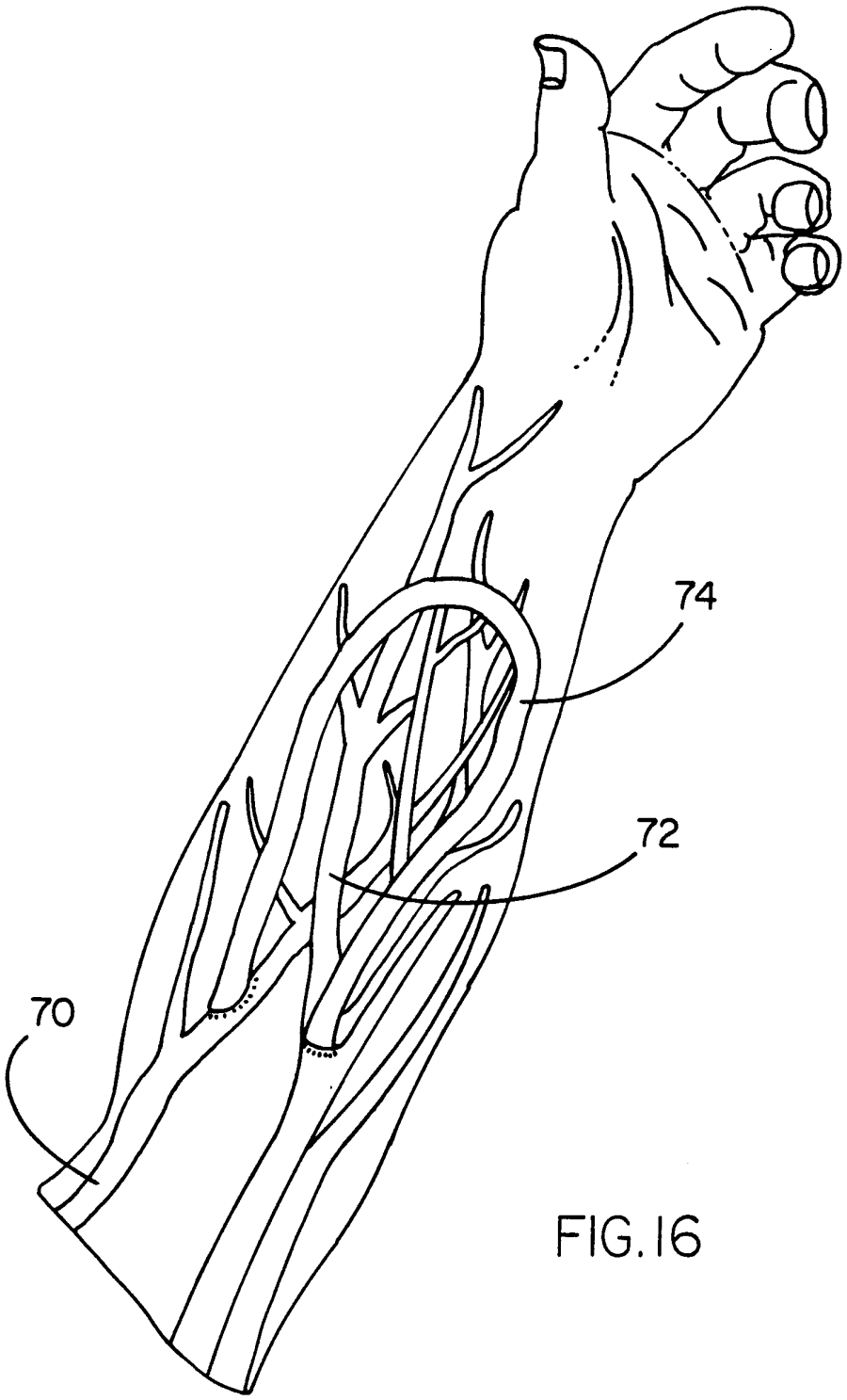


FIG. 16

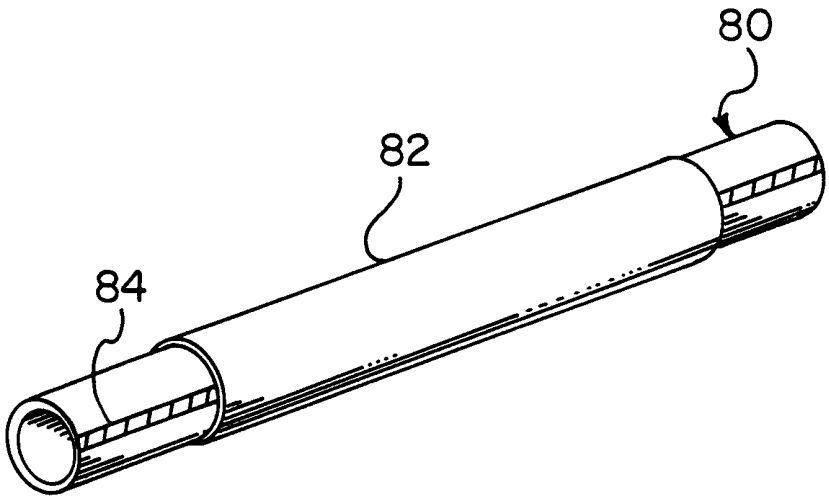


FIG. 17

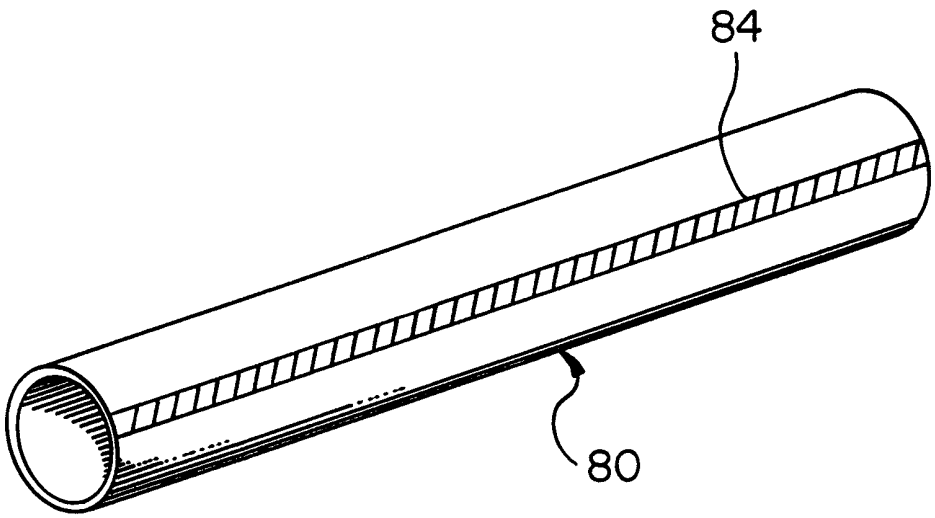


FIG. 18

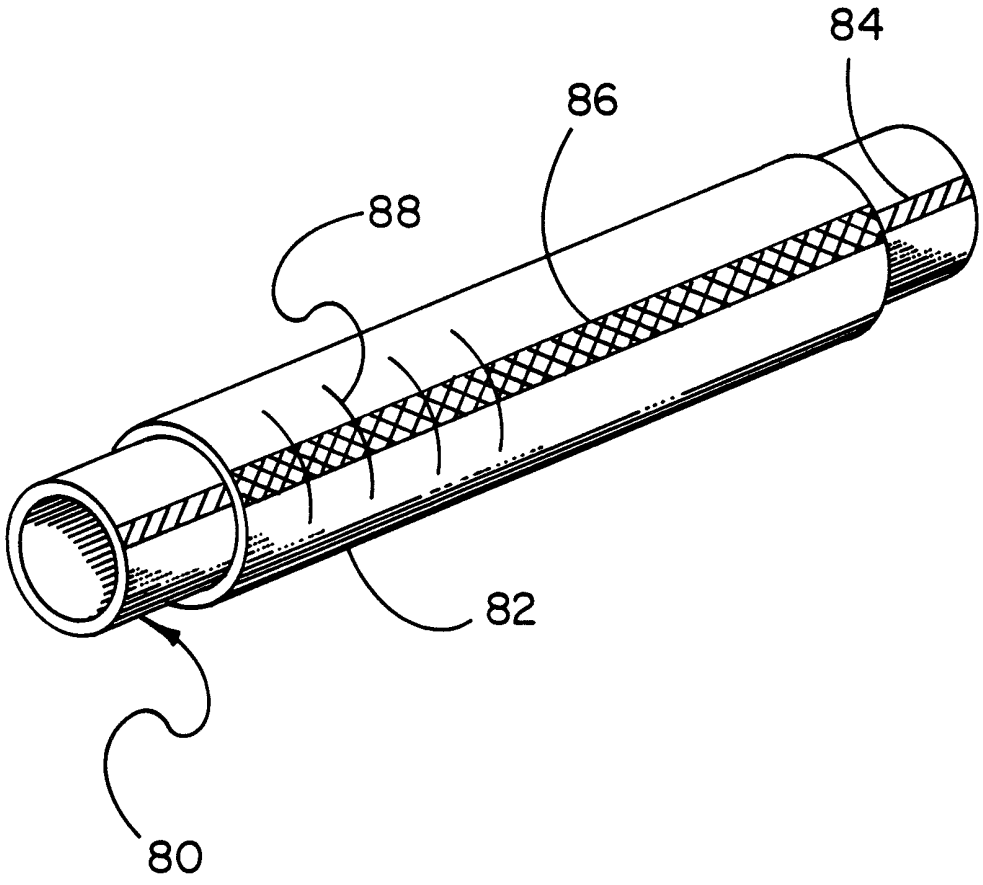


FIG. 19

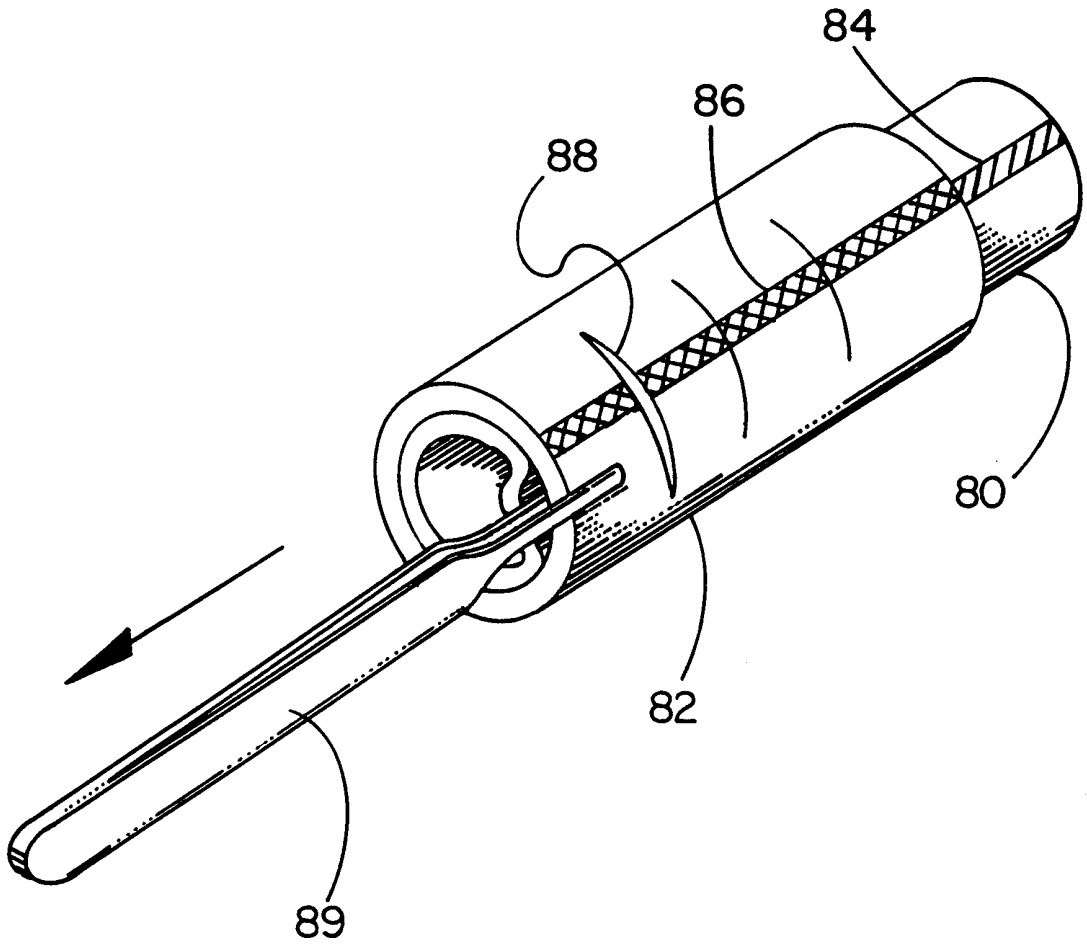


FIG. 20

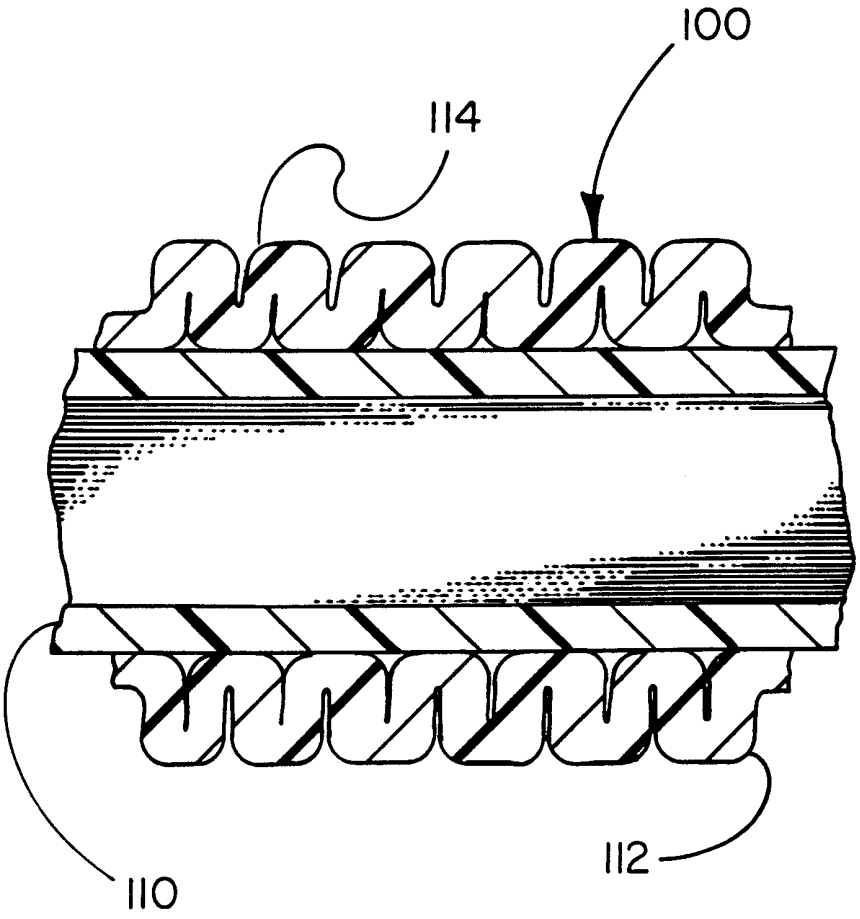


FIG. 21

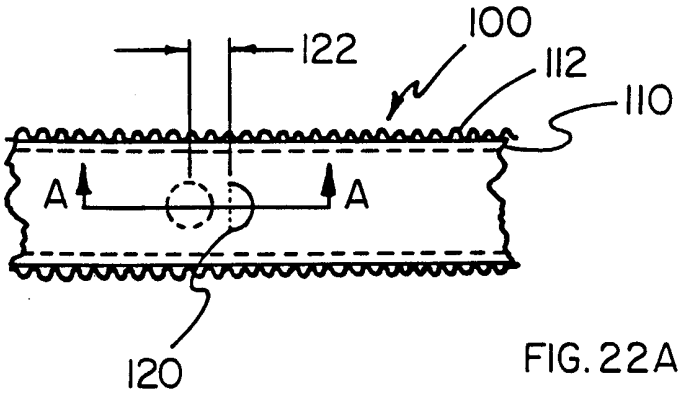


FIG. 22A

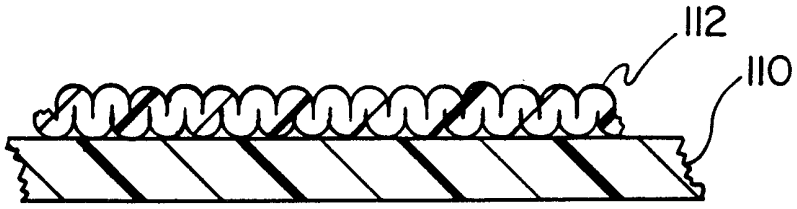


FIG. 22B

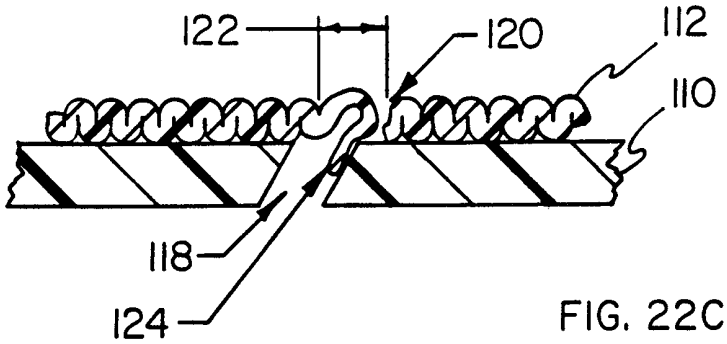


FIG. 22C

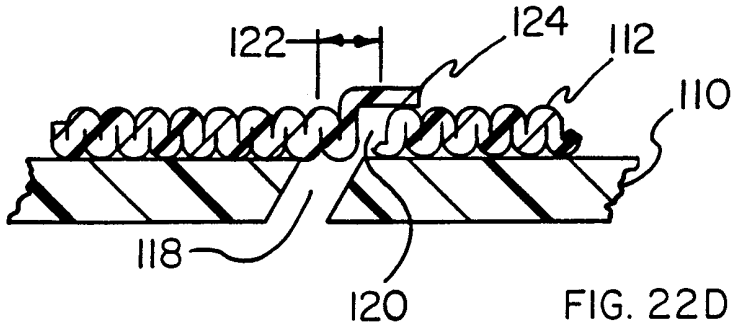


FIG. 22D

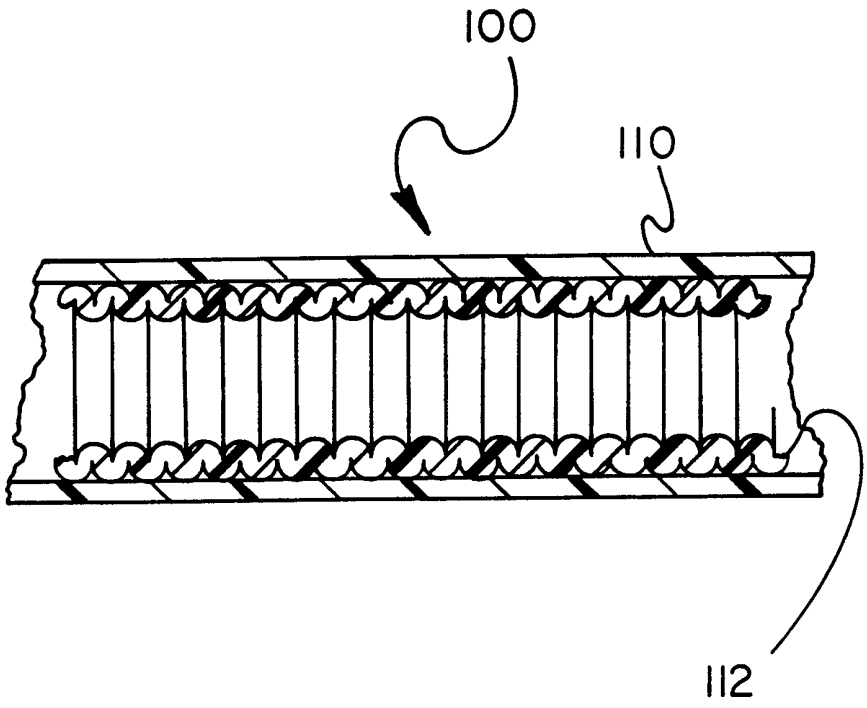


FIG. 22E

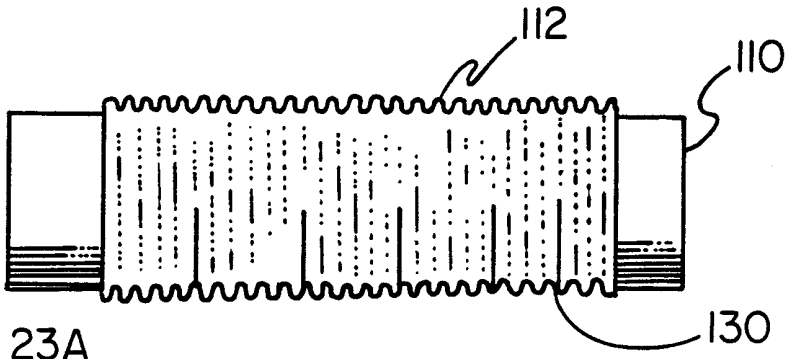


FIG. 23A

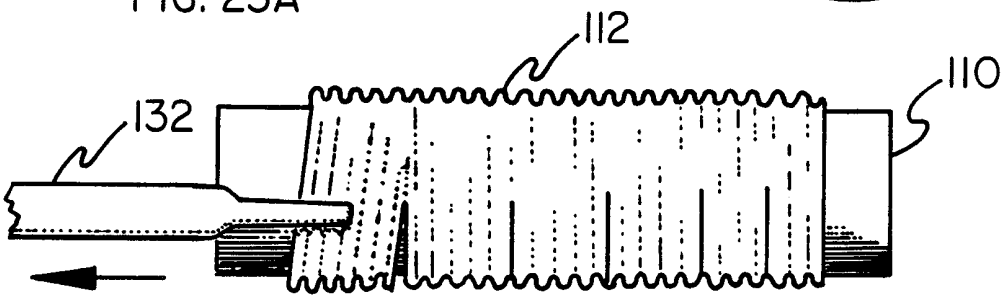


FIG. 23B

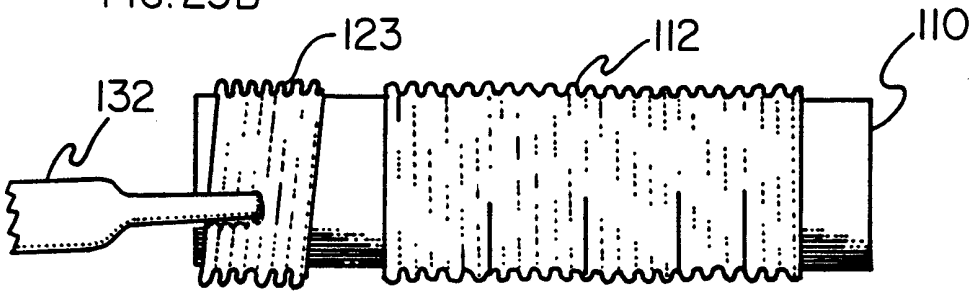


FIG. 23C

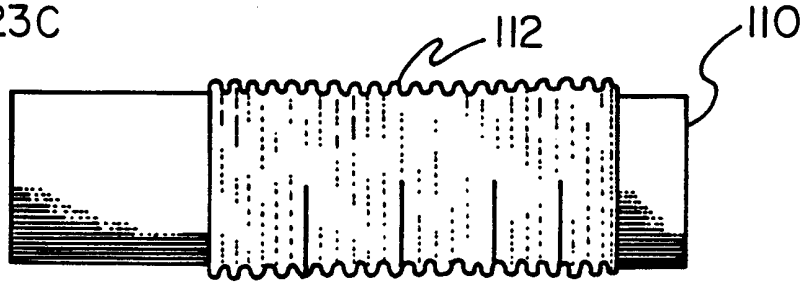


FIG. 23D

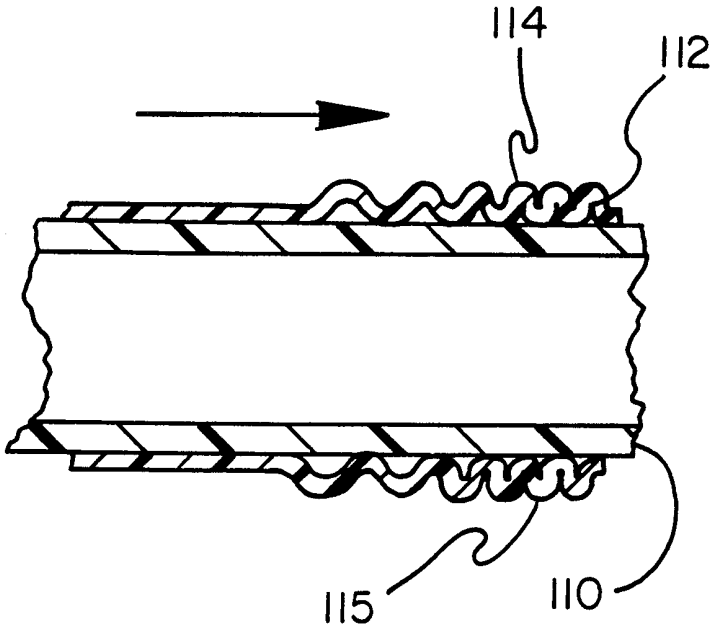
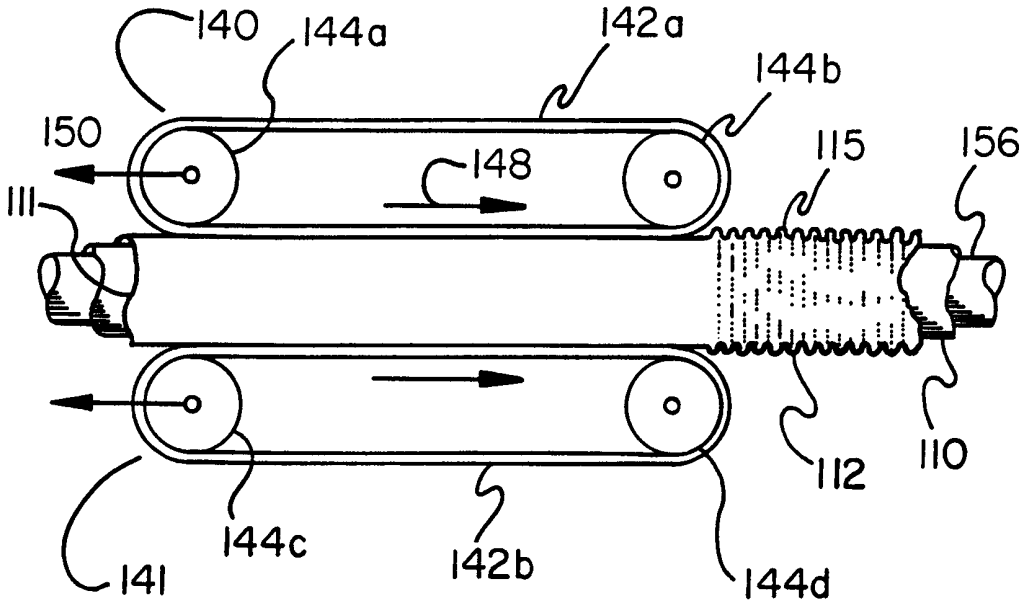


FIG. 24


140
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144c
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144d
141

FIG. 25

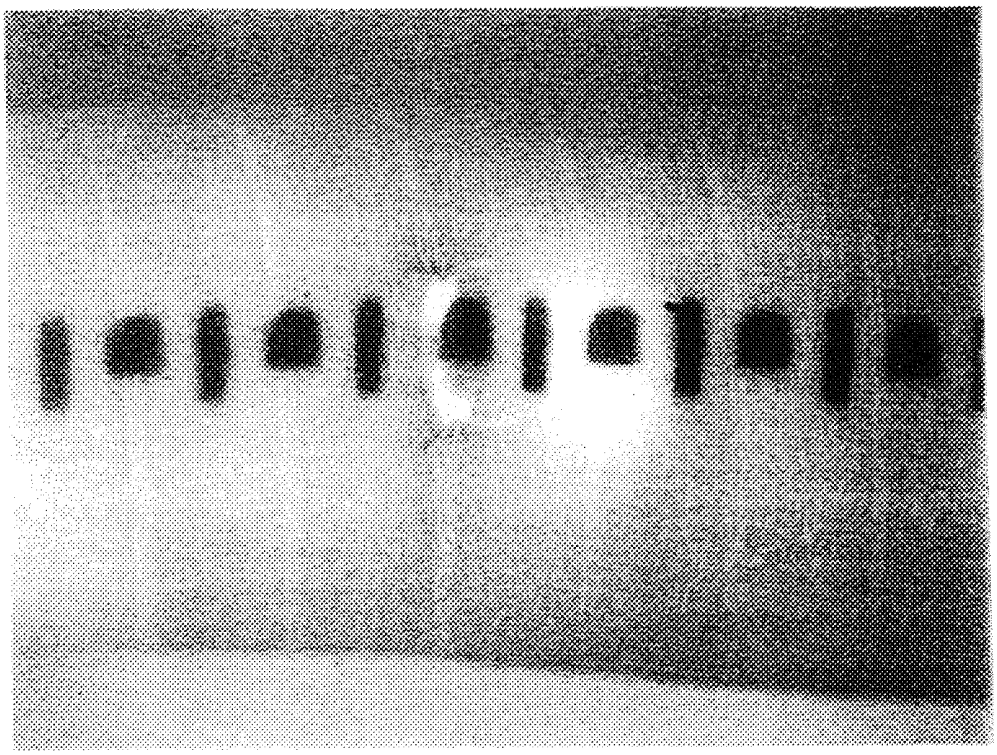

FIG. 26

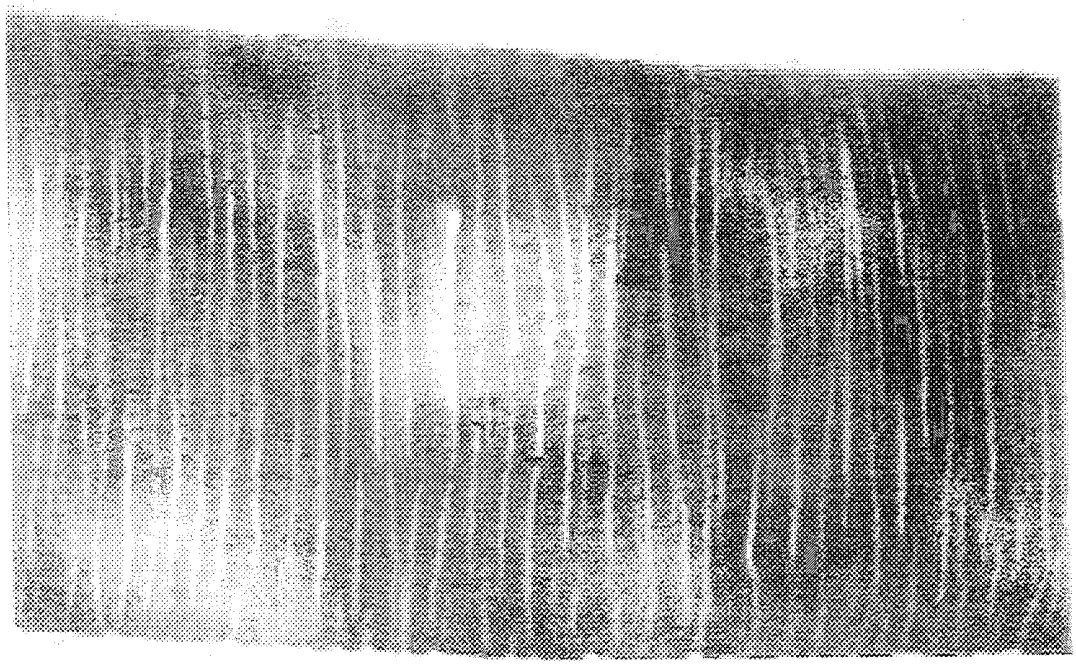

FIG. 27

FIG. 28

FIG. 29

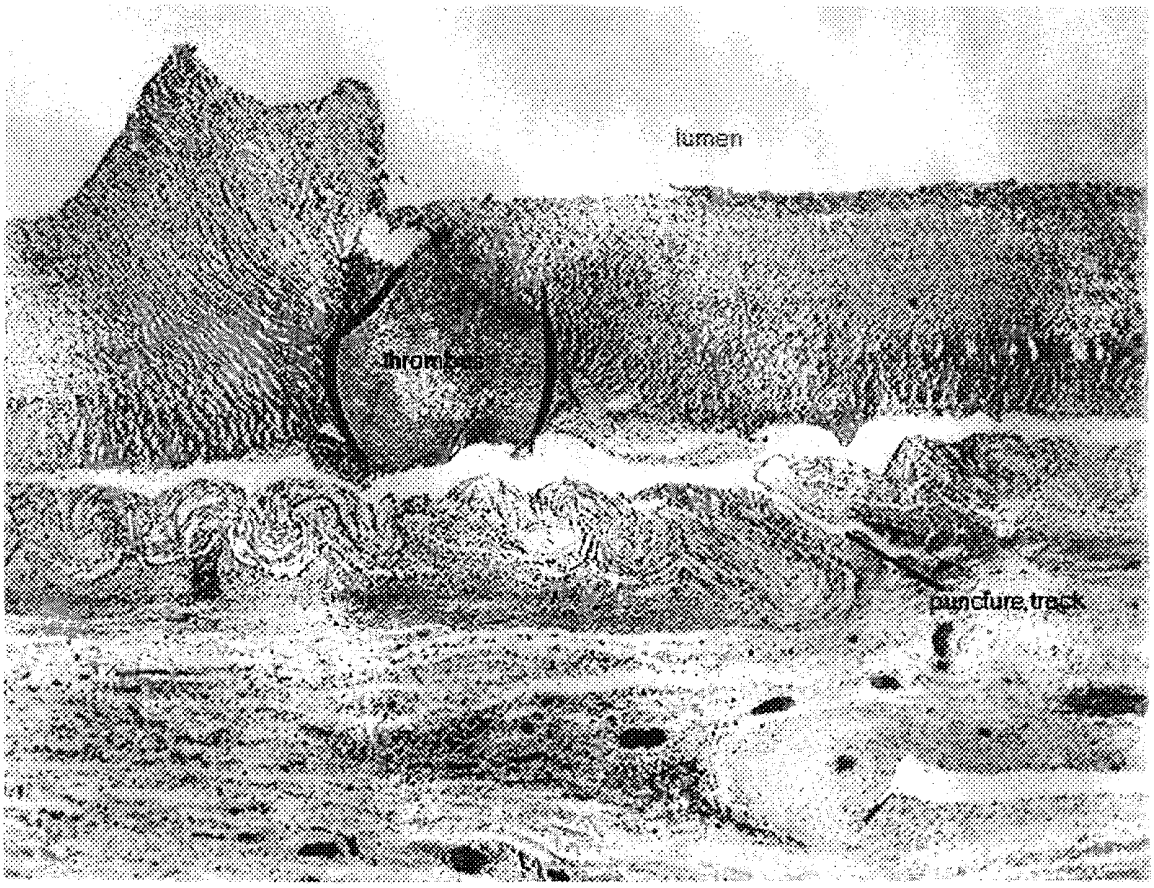

FIG. 30

INTERNATIONAL SEARCH REPORT

Interr ·'ional Application No
PCT, US 99/02997

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M39/10 A61M39/04 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F F16L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 095, no. 003, 28 April 1995 (1995-04-28) & JP 06 343688 A (SUMITOMO ELECTRIC IND LTD), 20 December 1994 (1994-12-20) abstract	1,12
A	US 3 814 137 A (MARTINEZ F) 4 June 1974 (1974-06-04) abstract; figures 1-3	1,12
A	DE 26 16 833 A (MEADOX MEDICALS INC) 16 June 1977 (1977-06-16) figures 1-10	1,12
A	US 4 086 665 A (POIRIER VICTOR L) 2 May 1978 (1978-05-02) abstract; figures 1,2	1,12

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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Date of the actual completion of the international search	Date of mailing of the international search report
8 September 1999	15/09/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jameson, P

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INTERNATIONAL SEARCH REPORT

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Intern ional Application No
PCT, US 99/02997

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