PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06	A1	(11) International Publication Number: WO 95/05132
		(43) International Publication Date: 23 February 1995 (23.02.95)

(21) International Application Number: PCT/US94/04904

(22) International Filing Date: 4 May 1994 (04.05.94)

(30) Priority Data:
08/109,214 18 August 1993 (18.08.93) US

(71) Applicant: W.L. GORE & ASSOCIATES, INC. [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).

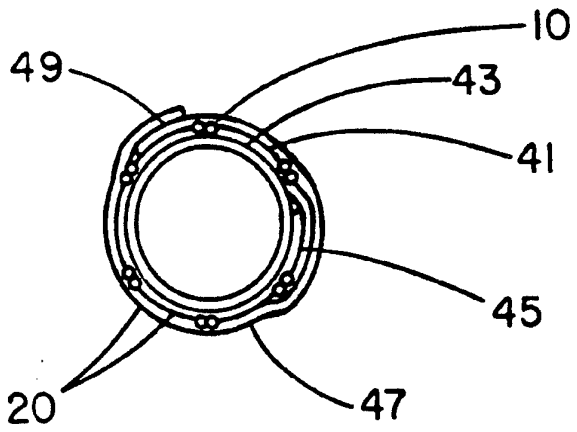
(72) Inventors: MYERS, David, J.; HC75, Box 2476, Camp Verde, AZ 86322 (US). LEWIS, James, D.; Route 4, Box 779, Forest Hills Drive, Flagstaff, AZ 86001 (US). HOUSE, Wayne, D.; 7650 N. Snowbowl Road, Flagstaff, AZ 86001 (US). SCHWARZ, Karl, E.; 2535 Jeffrey Loop, Flagstaff, AZ 86004 (US).

(74) Agents: JOHNS, David, J. et al.; W.L. Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).

(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: AN INTRALUMINAL STENT GRAFT



(57) Abstract

A tubular intraluminal graft in the form of a tubular diametrically adjustable stent having a tubular covering of porous expanded polytetrafluoroethylene which is less than 0.10 mm thick. The covering may be on the exterior surface of the stent, or on the interior surface of the stent, or both. The covering may be affixed to the stent by an adhesive which is preferably fluorinated ethylene propylene.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**GB**	United Kingdom	**MR**	Mauritania
AU	Australia	**GE**	Georgia	**MW**	Malawi
BB	Barbados	**GN**	Guinea	**NE**	Niger
BE	Belgium	**GR**	Greece	**NL**	Netherlands
BF	Burkina Faso	**HU**	Hungary	**NO**	Norway
BG	Bulgaria	**IE**	Ireland	**NZ**	New Zealand
BJ	Benin	**IT**	Italy	**PL**	Poland
BR	Brazil	**JP**	Japan	**PT**	Portugal
BY	Belarus	**KE**	Kenya	**RO**	Romania
CA	Canada	**KG**	Kyrgystan	**RU**	Russian Federation
CF	Central African Republic	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CG	Congo			**SE**	Sweden
CH	Switzerland	**KR**	Republic of Korea	**SI**	Slovenia
CI	Côte d'Ivoire	**KZ**	Kazakhstan	**SK**	Slovakia
CM	Cameroon	**LI**	Liechtenstein	**SN**	Senegal
CN	China	**LK**	Sri Lanka	**TD**	Chad
CS	Czechoslovakia	**LU**	Luxembourg	**TG**	Togo
CZ	Czech Republic	**LV**	Latvia	**TJ**	Tajikistan
DE	Germany	**MC**	Monaco	**TT**	Trinidad and Tobago
DK	Denmark	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**US**	United States of America
FI	Finland	**ML**	Mali	**UZ**	Uzbekistan
FR	France	**MN**	Mongolia	**VN**	Viet Nam
GA	Gabon				

AN INTRALUMINAL STENT GRAFT

FIELD OF THE INVENTION

This invention relates to the field of intraluminal grafts and particularly to thin-wall intraluminal grafts useful as an inner lining for blood vessels or other body conduits.

BACKGROUND OF THE INVENTION

Conventional vascular grafts have long been used for vascular repair in humans and animals. These devices are typically flexible tubes of woven or knitted polyethylene terephthalate or of porous polytetrafluoroethylene (hereinafter PTFE). Grafts of biological origin are also used, these being typically fixed human umbilical or bovine arteries. These conventional vascular grafts usually require invasive surgical methods that expose at least both ends of the segment of vessel to be repaired. Frequently it is necessary to expose the entire length of the vessel segment. These types of repairs consequently cause major trauma to the patient with corresponding lengthy recovery periods and may result in occasional mortality.

Alternative methods have evolved which use intraluminal vascular grafts in the form of adjustable stent structural supports, tubular grafts or a combination of both. These devices are preferably remotely introduced into a body cavity by the use of a catheter type of delivery system. Alternatively they may be directly implanted by invasive surgery. The intent of these methods is to maintain patency after an occluded vessel has been re-opened using balloon angioplasty, laser angioplasty, atherectomy, roto-ablation, invasive surgery, or a combination of these treatments.

Intraluminal vascular grafts can also be used to repair aneurysmal vessels, particularly aortic arteries, by inserting an intraluminal vascular graft within the aneurysmal vessel so that the

prosthetic withstands the blood pressure forces responsible for creating the aneurysm.

Intraluminal vascular grafts provide a new blood contacting surface within the lumen of a diseased living vessel. Intraluminal grafts are not, however, limited to blood vessels; other applications include urinary tracts, biliary ducts, respiratory tracts and the like.

If the intraluminal graft used is of thin enough wall and adequate flexibility, it may be collapsed and inserted into a body conduit at a smaller diameter location remote from the intended repair site. A catheter type of delivery system is then used to move the intraluminal graft into the repair site and then expand its diameter appropriately to conform to the inner surface of the living vessel. Various attachment methods including the use of adjustable stents may be used to secure the intraluminal graft at the desired location without the necessity of invasive surgery.

Intraluminal vascular grafts were suggested as early as 1912 in an article by Alexis Carrel (Results of the permanent intubation of the thoracic aorta. Surg., Gyn and Ob. 1912;15:245-248). U.S. Patent 3,657,744 to Ersek describes a method of using one or more adjustable stents to secure a flexible fabric vascular graft intraluminally, the graft and stent having been introduced distally and delivered to the desired position with a separate delivery system.

Choudhury, U. S. Patent 4,140,126, describes a similar method of repairing aortic aneurysms whereby a polyethylene terephthalate vascular graft is fitted at its ends with metal anchoring pins and pleated longitudinally to collapse the graft to a size small enough to allow for distal introduction.

Rhodes, U.S. Patent 5,122,154 and Lee, U.S. Patent 5,123,917, describe endovascular bypass grafts for intraluminal use which comprise a sleeve having at least two diametrically-expandable stents. Rhodes teaches that the sleeve material is to be made of conventional vascular graft materials such as GORE-TEX® Vascular Graft (W. L. Gore & Associates, Inc., Flagstaff AZ) or Impra® Graft (Impra, Inc. Tempe AZ). Both the GORE-TEX Vascular Graft and Impra Graft are extruded and longitudinally expanded PTFE tubes. Additionally, the GORE-TEX Vascular Graft possesses an exterior helical wrapping of porous

expanded PTFE film. The difficulty with the use of either the GORE-TEX Vascular Graft or the Impra graft as the sleeve component is that the relatively thick, bulky wall of the extruded, longitudinally expanded PTFE tubes limits the ability of the tube to be contracted into a small cross-sectional area for insertion into a blood vessel. For example, the wall thickness of a 6 mm inside diameter Thin Walled GORE-TEX Vascular Graft is typically 0.4 mm. The thinness of the wall is limited by the difficulty of manufacturing an extruded, longitudinally expanded tube having a thin wall of uniform thickness.

SUMMARY OF THE INVENTION

The present invention is a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and further having a tubular covering of porous expanded PTFE film affixed to the stent, said covering being less than about 0.10 mm thick.

Porous expanded PTFE film has a microstructure of nodes interconnected by fibrils and is made as taught by U.S. Patents 3,953,566; 4,187,390 and 4,482,516. As will be described further, the fibrils may be uniaxially oriented, that is, oriented in primarily one direction, or multiaxially oriented, that is, oriented in more than one direction. The term expanded is used herein to refer to porous expanded PTFE. The terms expand, expanding and expandable are used herein to refer to diametrically adjustable intraluminal stents. More specifically, the term balloon-adjustable refers to stents of the Palmaz type as taught by U.S. Patent 4,776,337 which typically require a balloon catheter to increase the diameter of the stent within a blood vessel. The term self-expanding refers to stents which increase in diameter by various other means. Stents of this type include stents of braided wire made as taught by Wallsten, U.S. Patent 4,544,771; and stents of formed wire made as taught by Gianturco, U.S. Patent 4,580,568. Stents of this type expand to a larger diameter after being released from a constraining force which restricts them to a smaller diameter. Self-expanding stents also include stents formed

from Nitinol wire made as taught by PCT US 92/03481. These stents expand in diameter when exposed to a slight increase in temperature.

The tubular covering of porous expanded PTFE film may be affixed to either the exterior surface or the luminal surface of the stent. Alternatively, a first tubular covering of porous expanded PTFE film may be affixed to the exterior surface of the tubular diametrically adjustable stent and a second tubular covering of porous expanded PTFE film may be affixed to the luminal surface of the tubular diametrically adjustable stent. The first and second tubular coverings of porous expanded PTFE film may be affixed to each other through the openings through the wall of the stent.

The porous expanded PTFE film may be affixed to the stent with an adhesive. The adhesive may be a thermoplastic adhesive and more preferably a thermoplastic fluoropolymer adhesive such as fluorinated ethylene propylene (hereinafter FEP) or perfluoroalkoxy (hereinafter PFA). Where first and second tubular coverings of expanded PTFE film are affixed to each other through the multiplicity of openings in the stent wall, the two coverings may be affixed by heating them above the crystalline melt point of the PTFE film adequately to cause them to thermally adhere, or alternatively they may be affixed by an adhesive such as FEP.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of a typical diametrically adjustable stent.

Figure 2 is an enlarged schematic representation of the microstructure of porous expanded PTFE film having a microstructure with uniaxially-oriented fibrils as used to construct Examples 1 and 3.

Figures 3A and 3B describe enlarged schematic representations of the microstructure of porous expanded PTFE film having microstructures of multiaxially-oriented fibrils as used to construct Example 2.

Figure 4 is a transverse cross section of the stent of Example 1 having a luminal layer of porous expanded PTFE film with

longitudinally-oriented fibrils and an exterior layer of porous expanded PTFE film with circumferentially-oriented fibrils.

Figure 5 is a transverse cross section of the stent of Example 2 having a luminal layer of porous expanded PTFE film with biaxially-oriented fibrils.

Figure 6 is a transverse cross section of the stent of Example 3 having an exterior layer of porous expanded PTFE film with circumferentially-oriented fibrils.

Figure 7 describes a method of collapsing a previously outwardly adjusted balloon-expandable stent.

Figure 8 describes the fitting of a single tubular sleeve to both the exterior and luminal surfaces of a stent.

Figure 9 describes the removal a covered, braided wire stent of the self-expanding type from a manufacturing mandrel by everting the braided wire, thereby placing the covering on the luminal surface of the stent.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 is a side view of a typical diametrically adjustable stent. The stent is shown as it would appear implanted into a body conduit with its diameter adjusted beyond the collapsed pre-implantation diameter. While the stent shown is made from metal wire, a perforated sleeve having perforations of suitable shape, size and quantity may also be used. Various suitable stents are described by U. S. Patent 4,776,337 to Palmaz and PCT US 92/03481 to Hess. These stents may be made from implantable metals such as titanium, stainless steel, or Nitinol.

The stent may be provided with an exterior covering of porous expanded PTFE film, or a luminal covering of porous expanded PTFE film, or with both exterior and luminal coverings. Uniaxially-oriented films having a microstructure of uniaxially-oriented fibrils wherein substantially all of the fibrils are oriented parallel to each other may be used. Multiaxially-oriented films having a microstructure of biaxially or multiaxially-oriented fibrils wherein

the fibrils are oriented in at least two directions which are substantially perpendicular to each other may also be used.

Figure 2 describes an enlarged schematic representation of the microstructure of nodes 11 connected by fibrils 12 of a film 20 wherein the uniaxially-oriented fibrils 12 are substantially parallel to each other. Figures 3A and 3B describe enlarged schematic representations of alternative microstructures of porous expanded PTFE films that may also be used for making the present invention. These microstructures have nodes interconnected by fibrils wherein the fibrils are oriented in at least two directions which are substantially perpendicular to each other. Figure 3A describes a microstructure 30 of nodes 11 and fibrils 13 and 15 wherein the fibrils 13 and 15 are biaxially-oriented fibrils which are oriented in two different directions that are substantially perpendicular to each other. Those microstructures may contain some fibrils 17 which are not oriented in the two different directions. Figure 3B describes another alternative microstructure 35 wherein the fibrils 21 are multiaxially-oriented fibrils oriented in virtually all directions within the plane of the sheet material. Either of these films may be made by having been expanded two directions that are perpendicular to each other. The microstructure 30 of multiaxially-oriented fibrils 21 may also have been made by being expanded in more than two directions as shown by Figure 3B. The manufacture of these films is taught by U.S. Patents 3,953,566; 4,198,390 and 4,482,516.

The fibril lengths of the porous expanded PTFE films referred to herein were estimated mean values obtained by examining scanning electron photomicrographs of these films. For multiaxially-oriented films, these estimates included consideration of fibrils oriented in all directions. The mean fibril lengths of the films used to construct the intraluminal grafts of the present invention are preferred to be within the range of about 5 to about 120 microns, although fibril lengths beyond this range may also be useful.

Wall thickness measurements of intraluminal graft stent coverings were determined by cutting away a portion of the covering that covered an opening through the stent wall. The thickness of the sample portion was measured by placing the sample portion between the pads of a Mitutoyo model no. 804-10 snap gauge having a part no. 7300 frame,

and gently easing the pads into contact with the sample portion until the pads were in full contact with the sample portion under the full force of the spring-driven snap gauge pads. Film density measurements were based on the bulk volume of a film sample using the snap-gauge thickness measurement.

The following examples of intraluminal stent grafts are intended to be illustrative only and are not intended to limit the scope of the invention to only the constructions described by these examples.

EXAMPLE 1

A Nitinol wire stent 10 (Nitinol Medical Technologies, Boston, MA) of the type described by Figure 1 was provided with both a luminal covering and an exterior covering of expanded PTFE film. This 3 cm long stent was formed from 0.25 mm diameter Nitinol wire into a tubular shape of interlocking hexagons. The luminal and exterior coverings were both made from a uniaxially-oriented film having fibrils oriented substantially in a single direction wherein the fibrils were all substantially parallel to each other. The luminal covering was provided with the fibrils oriented parallel to the longitudinal axis of the tubular stent; the exterior covering was provided with the fibrils oriented substantially circumferential to the tubular stent. The film used for both the luminal and exterior coverings was a porous expanded PTFE film having a discontinuous, porous coating of FEP applied to one side of the porous expanded PTFE film. Examination of the FEP coated side of the film by scanning electron microscopy revealed FEP on only small portions of the nodes and fibrils at the surface of the film. It was estimated that less than 10% of the available node and fibril surface area exposed at the surface of the film was covered by FEP. The presence of the FEP adhesive thus had little or no adverse effect on the porosity of the porous PTFE film.

The FEP-coated porous expanded PTFE film was made by a process which comprises the steps of:

a) contacting a porous PTFE film with another layer which is preferably a film of FEP or alternatively of another thermoplastic polymer;

b) heating the composition obtained in step a) to a temperature above the melting point of the thermoplastic polymer;

c) stretching the heated composition of step b) while maintaining the temperature above the melting point of the thermoplastic polymer; and

d) cooling the product of step c).

In addition to FEP, other thermoplastic polymers including thermoplastic fluoropolymers may also be used to make this coated film. The adhesive coating on the porous expanded PTFE film may be either continuous (non-porous) or discontinuous (porous) depending primarily on the amount and rate of stretching, the temperature during stretching, and the thickness of the adhesive prior to stretching.

The discontinuously FEP-coated porous expanded PTFE film used to construct this example was of about 0.01 mm thickness and had a density of about 0.3 g/cc. The microstructure of the porous expanded PTFE contained fibrils of about 50 micron mean fibril length.

A 3.0 cm length of film 20 having uniaxially-oriented fibrils was wrapped as a single layer 41 around a hollow, tubular, 1.5 cm outside diameter mandrel 43 of non-porous PTFE to form a seam 45 as described by the cross section of Figure 4. The seam edges 45 overlapped as shown by about 3 mm. The fibrils of the film were oriented parallel to the longitudinal axis of the mandrel; the FEP-coated side of the film faced away from the surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of the mandrel. The 3 cm length of the stent was centered over the 3.0 cm length of film-wrapped mandrel. The stent was then provided with an exterior covering 47 of a 3.0 cm wide tape of the film described above by wrapping the tape circumferentially around the exterior surface of the mandrel so that the edges of the circumferentially-wrapped tape overlapped by about 3 mm to form seam 49. The circumferentially wrapped covering was oriented so that the FEP-coated side of the tape faced inward in contact with the exterior surface of the stent and the outward facing FEP-coated surface of the luminal layer of film exposed through the openings in the stent. Except for the overlapped seam

edges 49, the circumferentially-wrapped covering was only one film layer thick. The uniaxially-oriented fibrils of the microstructure of the circumferentially-wrapped tape were circumferentially-oriented about the exterior stent surface.

The film-wrapped mandrel assembly was placed into an oven set at 360°C for a period of 4 minutes after which the film-wrapped mandrel was removed from the oven and allowed to cool. Following cooling to approximately ambient temperature, the mandrel was removed from the film-wrapped stent. The amount of heat applied was adequate to melt the FEP-coating on the porous expanded PTFE film and thereby cause adjacent layers of film to adhere to each other. Thus the luminal layer of film was adhered to the exterior circumferentially wrapped layer through the openings between the adjacent wires of the stent. The combined thickness of the luminal and exterior coverings was about 0.025 mm.

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40°C water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

EXAMPLE 2

A Nitinol wire stent of the same type used for Example 1 was provided with a luminal covering of a porous expanded PTFE film having a microstructure of biaxially-oriented fibrils as shown by Figure 3A. This was accomplished by wrapping a hollow tubular mandrel of non-porous PTFE with a layer of porous expanded PTFE film having a continuous (non-porous) coating of FEP with the FEP-coated side of the film facing outwardly away from the mandrel surface. This film was about 0.02 mm thick; the porous expanded PTFE had a microstructure of uniaxially-oriented fibrils with the fibrils oriented circumferentially about the exterior surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of

the mandrel. The mandrel assembly was then placed into an oven set at 360°C for four minutes. After removal from the oven and subsequent cooling, the mandrel was removed from the stent leaving the wrapped film adhered to the luminal surface of the stent. This film was then peeled from the luminal stent surface, leaving the FEP-coating and some small shreds of residual porous expanded PTFE adhered to the luminal surface of the stent wires. By removing the film and leaving the FEP adhesive on the luminal stent surface, the film served only as a release substrate for the application of the adhesive to the stent surface.

As shown by Figure 5, the mandrel 43 was then provided with a single layer 51 wrapping of a porous expanded PTFE film 35 having a microstructure of biaxially-oriented fibrils. This film was of about 30 micron fibril length, about 0.08 mm thickness, about 0.3 g/cc density and did not have an FEP coating. The biaxially-oriented fibrils were oriented to be substantially parallel to the longitudinal axis of the mandrel and to the circumference of the mandrel.

The film was overlapped adequately to form a 2 mm wide, longitudinally oriented seamline 45 parallel to the longitudinal axis of the mandrel. A sheet of polyamide film was temporarily placed over the surface of the seam and then contacted with the surface of a hand-held iron set at 400°C to cause the PTFE film seam edges to adhere to each other. Excess material beyond the 2 mm wide seam was trimmed away and discarded. The stent was again carefully fitted over the film-covered mandrel. The resulting assembly was placed into an oven set at 380°C for three minutes and then removed and allowed to cool, after which the mandrel was removed from the stent. The porous expanded PTFE film appeared to be well adhered to the luminal surface of the wire stent by the FEP coating left from the first, previously removed, layer of film. The wall thickness of the PTFE film covering was about 0.08 mm.

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40°C water, thereby increasing the stent diameter

to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

EXAMPLE 3

A Palmaz stent of the balloon-expandable type (part no. PS30, Johnson & Johnson Interventional Systems, Inc., Warren, NJ) was adjusted from its collapsed outside diameter of 3.4 mm to an enlarged outside diameter of 8.0 mm by inserting a tapered stainless steel mandrel followed by a straight 8.0 mm diameter stainless steel mandrel. This stent was then provided with a single layer exterior wrapping of the same discontinuously FEP-coated porous expanded PTFE coating used for the exterior wrapping of the stent of Example 1. This was accomplished by wrapping the film about the exterior surface of the mandrel with the uniaxially-oriented fibrils of the film microstructure oriented parallel to the longitudinal axis of the stent. This exterior covering 61 is described by the transverse cross section of Figure 6. A 2 mm wide seam 45 was formed from the overlapped edges of the porous expanded PTFE film 20 by temporarily placing a thin sheet of polyamide film over these edges and applying heat from a hand-held iron with a surface temperature of about 400°C. The film-wrapped stent 65 was then placed into an oven set at 380 °C for 3 minutes, after which it was removed and allowed to cool. The film appeared to be well adhered to the exterior surface of the stent. The wall thickness of the film covering was about 0.01 mm. The enlarged stent was then collapsed by the following process.

A series of 20 cm long 6-0 sutures were tied individually to each of the closed metal stent openings adjacent to one end of a stent. The film-covered stent was provided with a temporary non-adhered additional wrapping of longitudinally-oriented film without FEP and having a microstructure of uniaxially-oriented fibrils. This temporary wrapping was intended as a dry lubricant. As described by Figure 7 which omits the exterior film covering for clarity, the enlarged stent 71 was then pulled by these sutures 77 through a tapered die 75 of round cross section and 2.5 cm length, the die having a tapered orifice with a 9.5 mm diameter bore at its entrance 78 and a 4.5 mm diameter bore at its exit 79. The result was that the

stent was collapsed back to an outside diameter of 4.5 mm. The lubricity of the temporary covering of porous expanded PTFE film aided in making it possible to pull the stent through the die. This temporary covering was removed after completion of the collapsing process. It is anticipated that the use of a tapered die having an appropriately sized, smaller diameter exit bore would result in collapsing the stent to its original collapsed diameter. The film-covered stent was again enlarged to a diameter of 8 mm using a balloon catheter followed by a tapered stainless steel mandrel. The covering of porous expanded PTFE film appeared to be fully intact after the collapsing and enlarging of the film-covered stent.

Stent coverings may be affixed to a stent surface by variations on this method. For example, a tubular sleeve may be made from a film of porous expanded PTFE and inverted back into itself and fitted over the inner and outer surfaces of a stent as shown by Figure 8. The inner 83 and outer 85 portions of the tubular sleeve 81 may be thermally adhered to each other through the openings in the stent wall, or may be adhered to the stent surfaces by an adhesive such as FEP, or may be affixed to the stent by suturing the open ends 87 of the tube together.

EXAMPLE 4

A long length of 0.07 mm diameter single strand 304 stainless steel wire was provided with a single layer, approximate 1 mm overlap covering of porous expanded PTFE film by helically wrapping the wire with a narrow tape cut from a sheet of porous expanded PTFE film. The tape used was 6 mm wide, 0.01 mm thick, 0.3 g/cc density, and had uniaxially-oriented fibrils of about 50 micron fibril length. This tape-covered wire was then heated by pulling the wire through the 0.14 mm diameter orifice of a 2.5 cm long die heated to 400°C, at a rate of 1.5 meters per minute, thereby adhering the overlapped edges of the tape together and thereby adhering the tape to the wire. This wire was then cut into shorter lengths and spooled onto 16 bobbins. These bobbins were used to supply the wire to a model D-5600 Steeger braider.

A 12 meter length of 1.75 mm diameter non-porous PTFE mandrel was then fed into the braider where a braided covering of the above wire was applied at a density of about 16 picks/cm. An additional covering of tape cut from a sheet of porous expanded PTFE film was then helically wrapped over the surface of the wire-braided PTFE mandrel. The tape used for this helical wrapping was of 0.01 mm thickness, 0.3 g/cc density, about 50 micron fibril length and 12 mm width. Adjacent edges of the helical wrapping were overlapped by approximately 1 mm. The wire-braided Teflon mandrel was then placed into an oven set at 380°C for four minutes, after which it was removed and allowed to cool. As shown by Figure 9, the wire-braided stent 91 with the exterior covering of porous expanded PTFE tape was then removed from the non-porous PTFE mandrel 93 by folding the ends 95 of the braided wires back on themselves and pulling on these everted ends. The exterior covering of porous expanded PTFE film is omitted from Figure 9 for clarity. By applying tension on these everted ends in a direction parallel to the longitudinal axis of the mandrel and from the everted end back toward the opposite, non-everted end, the entire braided construction was everted and simultaneously removed from the mandrel. This everting process of removing the braided assembly from the mandrel resulted in the helical wrapping of film being located on the lumen of the stent. This construction offered good self-expanding characteristics in that when longitudinal tension was placed on the stent, the length of the stent increased and the diameter decreased. Upon release of tension, the stent immediately recovered its previous shorter length and larger diameter. This film-covered stent is therefore expected to be useful as a self-expanding stent.

We Claim:

1. A tubular intraluminal graft comprising:
   a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
   b) a tubular covering of porous expanded polytetrafluoroethylene affixed to the tubular, diametrically adjustable stent, said tubular covering being less than about 0.10 mm thick, and said tubular covering having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.
2. A tubular intraluminal graft according to claim 1 wherein the tubular covering of porous expanded polytetrafluoroethylene is affixed to the exterior surface of the tubular diametrically adjustable stent.
3. A tubular intraluminal graft according to claim 2 wherein the tubular covering of porous expanded polytetrafluoroethylene is affixed to the exterior surface of the tubular diametrically adjustable stent by an adhesive.
4. A tubular intraluminal graft according to claim 3 wherein the adhesive is a thermoplastic adhesive.
5. A tubular intraluminal graft according to claim 4 wherein the thermoplastic adhesive is a thermoplastic fluoropolymer adhesive.
6. A tubular intraluminal graft according to claim 5 wherein the thermoplastic fluoropolymer adhesive is fluorinated ethylene propylene.
7. A tubular intraluminal graft according to claim 1 wherein the tubular covering of porous expanded polytetrafluoroethylene is affixed to the luminal surface of the tubular diametrically adjustable stent.
8. A tubular intraluminal graft according to claim 7 wherein the tubular covering of porous expanded polytetrafluoroethylene is affixed to the luminal surface of the tubular diametrically adjustable stent by an adhesive.
9. A tubular intraluminal graft according to claim 8 wherein the adhesive is a thermoplastic adhesive.

10. A tubular intraluminal graft according to claim 9 wherein the thermoplastic adhesive is a thermoplastic fluoropolymer adhesive.

11. A tubular intraluminal graft according to claim 10 wherein the thermoplastic fluoropolymer adhesive is fluorinated ethylene propylene.

12. A tubular intraluminal graft according to claim 1 wherein the tubular covering comprises a first tubular covering of porous expanded polytetrafluoroethylene is affixed to the exterior surface of the tubular diametrically adjustable stent and a second tubular covering of porous expanded polytetrafluoroethylene film is affixed to the luminal surface of the tubular diametrically adjustable stent.

13. A tubular intraluminal graft according to claim 12 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film through openings through the wall of the stent.

14. A tubular intraluminal graft according to claim 13 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film by an adhesive.

15. A tubular intraluminal graft according to claim 14 wherein the adhesive is fluorinated ethylene propylene.

16. A tubular intraluminal graft according to claim 12 wherein the first and second tubular coverings of porous expanded polytetrafluoroethylene are affixed by an adhesive.

17. A tubular intraluminal graft according to claim 16 wherein the adhesive is fluorinated ethylene propylene.

18. A tubular intraluminal graft according to claim 2 wherein the porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are substantially parallel to each other, said uniaxially-oriented fibrils being oriented circumferentially with respect to the tubular, diametrically adjustable stent.

19. A tubular intraluminal graft according to claim 7 wherein the porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are

substantially parallel to each other, said uniaxially-oriented fibrils being oriented lengthwise with respect to the tubular, diametrically adjustable stent.

20. A tubular intraluminal graft according to claim 2 wherein the porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by fibrils which are oriented in two substantially perpendicular directions, said two substantially perpendicular directions being oriented circumferentially and longitudinally with respect to the tubular diametrically adjustable stent.

21. A tubular intraluminal graft according to claim 12 wherein the first tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented circumferentially with respect to the tubular, diametrically adjustable stent, and wherein the second tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented longitudinally with respect to the tubular, diametrically adjustable stent.

22. A tubular intraluminal graft according to claim 13 wherein the first tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented circumferentially with respect to the tubular, diametrically adjustable stent, and wherein the second tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented longitudinally with respect to the tubular, diametrically adjustable stent.

23. A tubular intraluminal graft according to claim 1 wherein the tubular intraluminal graft comprises a tubular covering affixed to more than one tubular, diametrically adjustable stent.

24. A tubular intraluminal graft according to claim 1 wherein the tubular diametrically adjustable stent is a Nitinol stent.

25. A tubular intraluminal graft according to claim 2 wherein the tubular diametrically adjustable stent is a Nitinol stent.

26. A tubular intraluminal graft according to claim 7 wherein the tubular diametrically adjustable stent is a Nitinol stent.

27. A tubular intraluminal graft according to claim 12 wherein the tubular diametrically adjustable stent is a Nitinol stent.

28. A tubular intraluminal graft according to claim 1 wherein the stent is a balloon-expandable stent.

29. A tubular intraluminal graft according to claim 2 wherein the stent is a balloon-expandable stent.

30. A tubular intraluminal graft according to claim 7 wherein the stent is a balloon-expandable stent.

31. A tubular intraluminal graft according to claim 12 wherein the stent is a balloon-expandable stent.

32. A tubular intraluminal graft according to claim 1 wherein the stent is a self-expanding stent of braided wire.

33. A tubular intraluminal graft according to claim 2 wherein the stent is a self-expanding stent of braided wire.

34. A tubular intraluminal graft according to claim 7 wherein the stent is a self-expanding stent of braided wire.

35. A tubular intraluminal graft according to claim 12 wherein the stent is a self-expanding stent of braided wire.

36. A tubular intraluminal graft according to claim 1 wherein the tubular covering of porous expanded polytetrafluoroethylene is affixed to the exterior surface and the luminal surface of the tubular diametrically adjustable stent.

37. A tubular intraluminal graft according to claim 36 wherein the tubular covering is affixed by an adhesive.

38. A tubular intraluminal graft according to claim 36 wherein the tubular covering is affixed with sutures.

39. A method of making a tubular intraluminal graft comprising:

a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;

b) affixing a tubular covering to the exterior surface of the tubular, diametrically adjustable stent, said covering being less than 0.10 mm thick and said tubular covering having an exterior surface, a luminal surface and a seam extending

from the exterior surface through to the luminal surface of the tubular covering.

40. A method according to claim 39 wherein the tubular covering is affixed with an adhesive.

41. A method according to claim 40 wherein the adhesive is fluorinated ethylene propylene.

42. A method of making a tubular intraluminal graft comprising:

a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;

b) affixing a tubular covering to the luminal surface of the tubular, diametrically adjustable stent, said covering being less than about 0.10 mm thick and said tubular covering having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

43. A method according to claim 42 wherein the tubular covering is affixed with an adhesive.

44. A method according to claim 43 wherein the adhesive is fluorinated ethylene propylene.

45. A method of making a tubular intraluminal graft comprising:

a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;

b) affixing a first tubular covering to the exterior surface and a second tubular covering to the luminal surface, said first and second tubular coverings being in combination less than about 0.10 mm thick and said first and second tubular coverings having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

46. A method according to claim 45 wherein the first and second tubular coverings are affixed by an adhesive.

47. A method according to claim 46 wherein the adhesive is fluorinated ethylene propylene.

48. A method of making a tubular intraluminal graft comprising:
    a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall, said tubular, diametrically adjustable stent having a collapsed diameter and an enlarged diameter wherein said enlarged diameter is at least 1.5 times the collapsed diameter, wherein said tubular, diametrically adjustable stent has been diametrically adjusted to the enlarged diameter;
    b) affixing a tubular covering to the tubular, diametrically adjustable stent; and
    c) collapsing the tubular, diametrically adjustable stent to about the collapsed diameter.

49. A method according to claim 48 wherein the step of collapsing the tubular, diametrically adjustable stent to about the collapsed diameter is accomplished by pulling the tubular, diametrically adjustable stent through an orifice, said orifice having an entrance diameter and an exit diameter wherein said entrance diameter is larger than said exit diameter, and wherein said orifice is tapered between the entrance and exit diameters.

50. A method according to claim 48 wherein the tubular covering is affixed to the exterior surface of the tubular, diametrically adjustable stent.

51. A method according to claim 48 wherein the tubular covering is affixed to the luminal surface of the tubular, diametrically adjustable stent.

52. A method according to claim 48 wherein said tubular covering is less than about 0.10 mm thick.

53. A method according to claim 50 wherein said tubular covering is less than about 0.10 mm thick.

54. A method according to claim 51 wherein said tubular covering is less than about 0.10 mm thick.

55. A method according to claim 48 wherein said tubular covering is of porous expanded PTFE

56. A method according to claim 49 wherein said tubular covering is of porous expanded PTFE.

57. A method according to claim 50 wherein said tubular covering is of porous expanded PTFE.

58. A method according to claim 51 wherein said tubular covering is of porous expanded PTFE

59. A method according to claim 52 wherein said tubular covering is of porous expanded PTFE.

60. A method according to claim 53 wherein said tubular covering is of porous expanded PTFE.

61. A method according to claim 54 wherein said tubular covering is of porous expanded PTFE.

62. A method according to claim 51 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

63. A method according to claim 52 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

64. A method according to claim 53 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

65. A method according to claim 57 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

66. A method according to claim 58 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

67. A method according to claim 59 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

68. A method according to claim 60 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

69. A method according to claim 61 wherein said tubular covering has an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface of the tubular covering.

70. A method of making a tubular intraluminal graft, comprising

a) braiding a length of wire to form a braided wire;

b) helically wrapping an exterior covering of porous expanded polytetrafluoroethylene tape around the braided wire;

c) everting the braided wire wherein the exterior covering of porous expanded polytetrafluoroethylene tape becomes a luminal covering.

71. A method according to claim 70 wherein the length of wire has a covering of polytetrafluoroethylene prior to braiding the length of wire to form a braided wire.

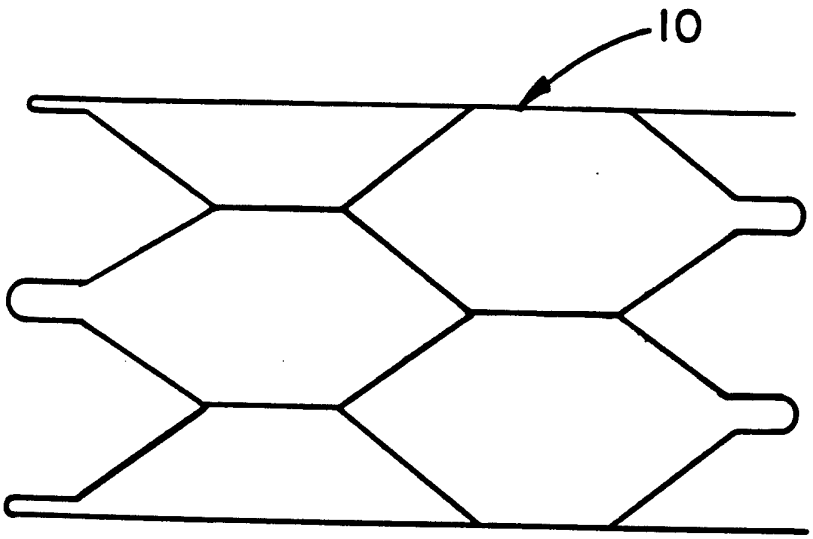


FIG. 1

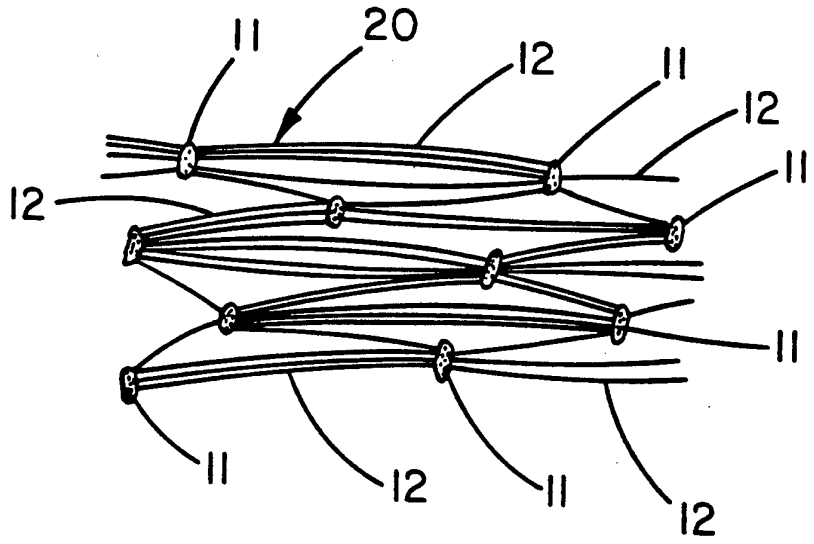


FIG. 2

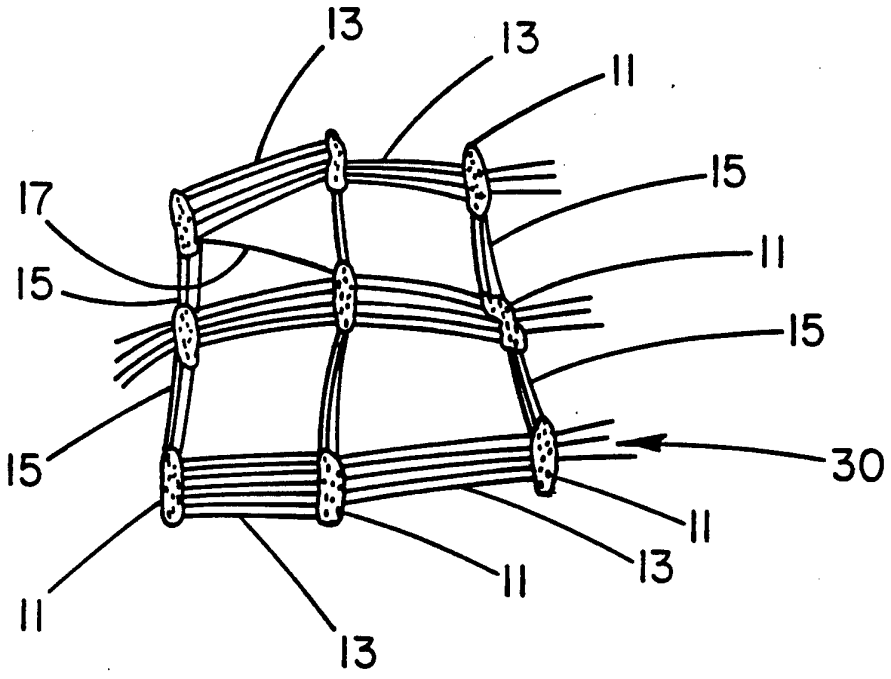

13
13
11
15
17
11
15
15
15
30
11
13
11
11
13

FIG. 3A

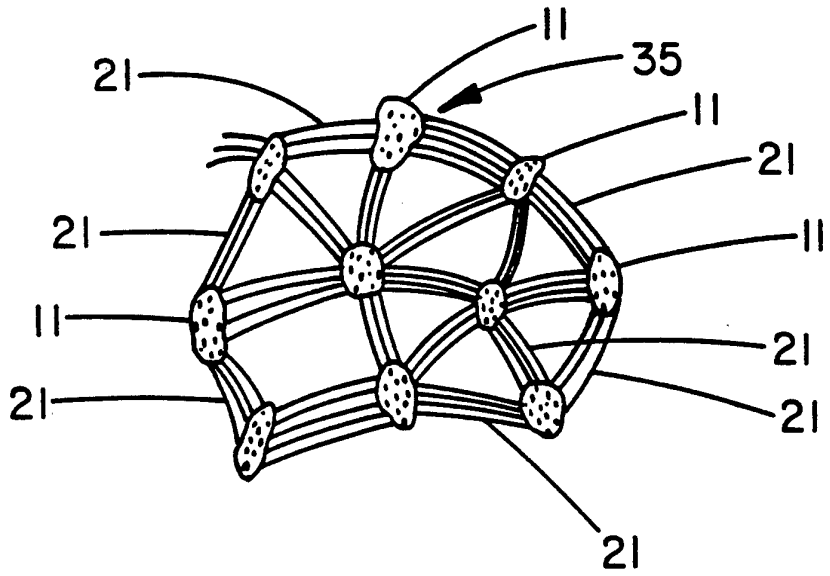

11
21
35
11
21
21
11
11
21
21
21
21

FIG. 3B

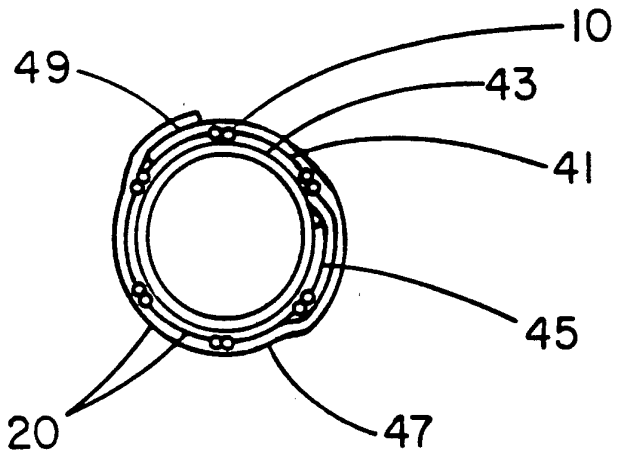


FIG. 4

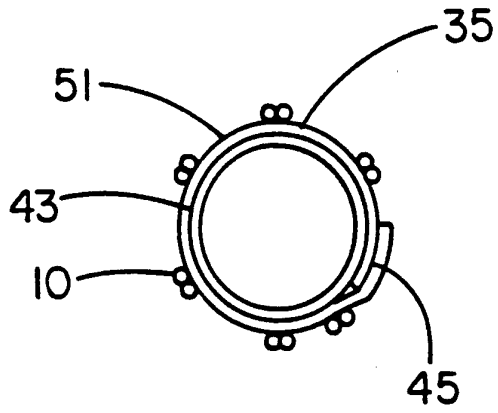


FIG. 5

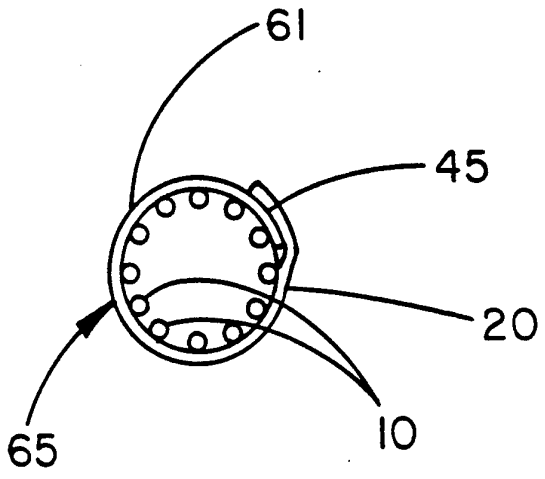


FIG. 6

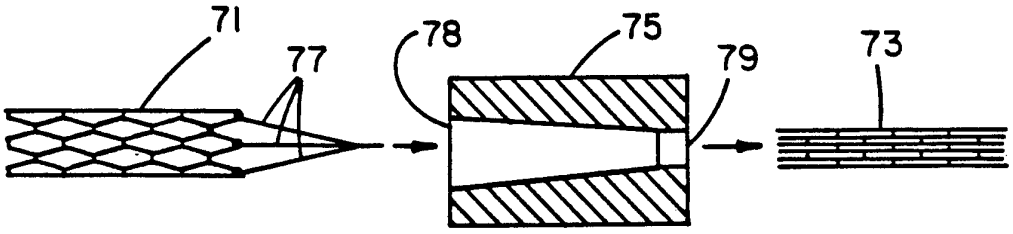


FIG. 7

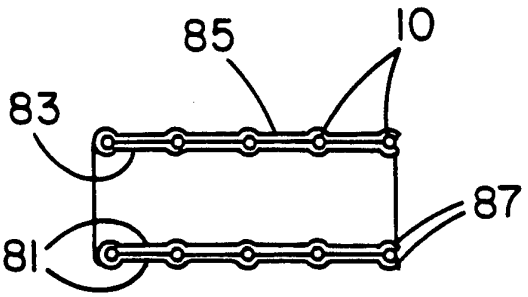


FIG. 8

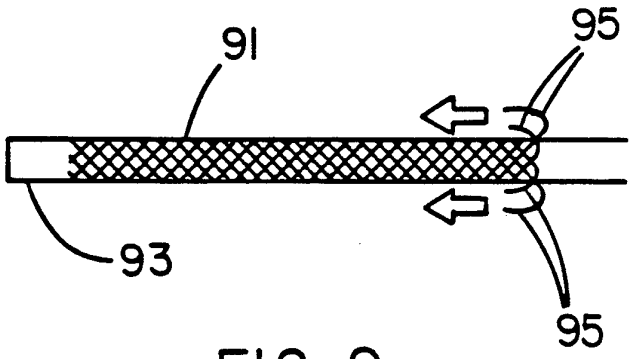


FIG. 9

INTERNATIONAL SEARCH REPORT

Inten. 1 Application No
PCT/US 94/04904

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 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 6 A61F B29C

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.
X	US,A,5 123 917 (LEE) 23 June 1992 cited in the application	1-4,7,8, 12-14, 18,19, 21,22, 28-31
Y	especially see column 4, line 42 - column 5, line 61	5,6,9, 10, 15-17, 20,24-27
A	see the whole document ---	39-71
X	EP,A,0 551 179 (EXPANDABLE GRAFTS PARTNERSHIP) 14 July 1993 see column 11, line 57 - column 13, line 7; figures --- -/--	1,2,7, 12,13, 23, 28-31,38

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 September 1994	16.09.94
Name and mailing address of the ISA 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	Authorized officer Sánchez y Sánchez, J

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,87 04935 (FISCHELL ET AL.) 27 August 1987 see page 6, line 6 - page 10, line 30; figures	1
Y	EP,A,0 010 293 (UNASCO PTY) 30 April 1980 see abstract	5,6,9, 10,15-17
Y	US,A,3 953 566 (GORE) 27 April 1976 cited in the application see example 3; table 3	20
Y	US,A,4 820 298 (LEVEEN ET AL.) 11 April 1989 see claims 1,8,9	24-27
A	US,A,5 156 620 (PIGOTT) 20 October 1992 see column 4, line 4 - line 29; figures 1-3,9,10	1
A	US,A,4 740 207 (KREAMER) 26 April 1988 see column 2, line 20 - line 32; figures	1
A	DE,A,39 18 736 (VALLBRACHT) 13 December 1990 see column 3	1
A	US,A,5 089 006 (STILES) 18 February 1992	
A	US,A,4 300 244 (BOKROS) 17 November 1981	

INTERNATIONAL SEARCH REPORT

...formation on patent family members

Intern. Application No
PCT/US 94/04904

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5123917	23-06-92	NONE		
EP-A-0551179	14-07-93	US-A-	5316023	31-05-94
		AU-A-	3108793	29-07-93
		CA-A-	2085918	09-07-93
		JP-A-	5344989	27-12-93
WO-A-8704935	27-08-87	DE-A-	3786721	02-09-93
		EP-A,B	0257091	02-03-88
		EP-A-	0556940	25-08-93
		US-A-	4768507	06-09-88
EP-A-0010293	30-04-80	AT-T-	9487	15-10-84
		AU-A-	5179879	24-04-80
		CA-A-	1171991	31-07-84
		JP-A-	55065282	16-05-80
		US-A-	4548960	22-10-85
US-A-3953566	27-04-76	US-A-	4096227	20-06-78
		BE-A-	767423	18-10-71
		CA-A-	962021	04-02-75
		CH-A-	555377	31-10-74
		DE-A,B	2123316	02-12-71
		FR-A-	2090775	14-01-72
		GB-A-	1355373	05-06-74
		JP-C-	1216843	17-07-84
		JP-A-	51030277	15-03-76
		JP-B-	56017216	21-04-81
		JP-A-	50138387	04-11-75
		JP-B-	55026567	14-07-80
		NL-A-	7107000	23-11-71
		SE-B-	392582	04-04-77
		US-A-	3962153	08-06-76
		US-A-	4187390	05-02-80
US-A-4820298	11-04-89	NONE		
US-A-5156620	20-10-92	NONE		
US-A-4740207	26-04-88	US-E-	RE34327	27-07-93

INTERNATIONAL SEARCH REPORT

...mation on patent family members

Intern. Application No
PCT/US 94/04904

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A-3918736	13-12-90	NONE	
US-A-5089006	18-02-92	CA-A- 2030196	30-05-91
US-A-4300244	17-11-81	NONE	