

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W.L. GORE & ASSOCIATES, INC.,

Plaintiff,

v.

C.R. BARD, INC., and BARD
PERIPHERAL VASCULAR, INC.,

Defendants.

C.A. No. 11-515-LPS-CJB

JURY TRIAL REQUESTED

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff W.L. Gore & Associates, Inc. (“Gore” or “Plaintiff”), by its attorneys, Faegre Baker Daniels LLP, for its complaint against C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, “Bard” or “Defendants”) alleges as follows:

Nature of the Action

1. This is an action for infringement of United States Patent Nos. 5,735,892 (the “892 patent”), 5,700,285 (the “285 patent”), and 8,221,487 (the “487 patent”) under 35 U.S.C. § 271, including sections (a) and (g).

The Parties

2. Plaintiff W.L. Gore & Associates, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 555 Paper Mill Road, Newark, Delaware 19711.

3. On information and belief, Defendant C.R. Bard, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 730 Central Avenue, Murray Hill, New Jersey.

4. On information and belief, Defendant Bard Peripheral Vascular, Inc. is a corporation organized and existing under the laws of the State of Arizona, with a principal place of business at 1625 West 3rd Street, Tempe, Arizona.

5. On information and belief, Bard Peripheral Vascular, Inc. is a wholly owned subsidiary of C.R. Bard, Inc.

Jurisdiction and Venue

6. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants transact business, including the sale and offering for sale of their products, including but not limited to the FLUENCY® Plus Tracheobronchial Stent Graft and the FLAIR® Endovascular Stent Graft, in the District of Delaware and have sufficient contacts with this District to subject Defendants to personal jurisdiction. Moreover, Defendant C.R. Bard, Inc. has previously filed at least four separate patent litigations in this district, availing itself of the District of Delaware as a forum to adjudicate its disputes.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). Upon information and belief, Defendants conduct substantial business in this District and have committed and continue to commit acts of infringement in this District.

Background

9. The '892 patent, entitled "Intraluminal Stent Graft," issued on April 7, 1998 to David J. Myers, James D. Lewis, Wayne D. House, and Karl E. Schwarz. A copy of the '892 patent is attached to this complaint as Exhibit A.

10. The '285 patent, entitled "Intraluminal Stent Graft," issued on Dec. 23, 1997 to David J. Myers, James D. Lewis, Wayne D. House, and Karl E. Schwarz. A copy of the '285 patent is attached to this complaint as Exhibit B.

11. The '487 patent, entitled "Intraluminal Stent Graft," issued on July 17, 2012 to David J. Myers, James D. Lewis, and Wayne D. House. A copy of the '487 patent is attached to this complaint as Exhibit C.

12. Defendants have had knowledge of the '892 patent since at least 1999.

13. Defendants have had knowledge of the '285 patent since at least 2007.

14. W.L. Gore & Associates, Inc. is the owner of all right, title, and interest in the '892, '285, and '487 patents, including the right to sue, enforce, and recover all damages, past and future, for all infringements.

15. Gore Enterprise Holdings, Inc. was previously the owner of the '892 and '285 patents and W.L. Gore & Associates, Inc. was the licensee of the '892 and '285 patents with rights to practice those patents in the United States. On January 30, 2012 Gore Enterprise Holdings, Inc. assigned all right, title, and interest in the '892 and '285 patents to W.L. Gore & Associates, Inc., including the right to seek damages for past infringement thereof.

16. Defendants make, use, sell, offer for sale, and/or import the FLUENCY® Plus Tracheobronchial Stent Graft.

17. Defendants make, use, sell, offer for sale, and/or import the FLAIR® Endovascular Stent Graft.

Count I

18. The allegations of paragraphs 1-17 are incorporated as if fully set forth herein.

19. Defendants are infringing the '892 patent by making, using, offering to sell,

selling, and importing at least the FLAIR® Endovascular Stent Graft and the FLUENCY® Plus Tracheobronchial Stent Graft, all to the injury of Gore.

20. Bard's acts of infringement have injured and damaged Gore.

21. Upon information and belief, Defendants' infringement has been willful and will continue to be willful, making this case exceptional and entitling Gore to increased damages and reasonable attorney's fees pursuant to 35 U.S.C. §§ 284 and 285 of the patent statute.

Count II

22. The allegations of paragraphs 1-17 are incorporated as if fully set forth herein.

23. Defendants are infringing the '285 patent by making, using, offering to sell, selling, and importing at least the FLAIR® Endovascular Stent Graft and the FLUENCY® Plus Tracheobronchial Stent Graft and/or inducing or contributing to the completion by others of the method claimed in the '285 patent, all to the injury of Gore.

24. Bard's acts of infringement have injured and damaged Gore.

25. Upon information and belief, Defendants' infringement has been willful and will continue to be willful, making this case exceptional and entitling Gore to increased damages and reasonable attorney's fees pursuant to 35 U.S.C. §§ 284 and 285 of the patent statute.

Count III

26. The allegations of paragraphs 1-17 are incorporated as if fully set forth herein.

27. Defendants are infringing the '487 patent by making, using, offering to sell, selling, and importing at least the FLAIR® Endovascular Stent Graft and the FLUENCY® Plus Tracheobronchial Stent Graft, all to the injury of Gore.

28. Bard's acts of infringement have injured and damaged Gore.

Prayer for Relief

Wherefore, Plaintiff Gore requests the following relief:

- (a) judgment against Bard as to infringement of the '892, '285, and '487 patents;
- (b) a permanent injunction preventing Defendants and their officers, directors, agents, servants, employees, attorneys, licensees, successors, assigns, and customers, and those in active concert or participation with any of them, from making, using, importing, selling, or offering to sell any devices or systems that infringe the '892, '285, and '487 patents;
- (c) judgment against Defendants for money damages sustained as a result of Defendants' infringement of the '892, '285, and '487 patents and an accounting;
- (d) judgment against Defendants for increased money damages pursuant to 35 U.S.C. § 284 sustained as a result of Defendants' willful infringement of the '892 and '285 patents;
- (e) costs and reasonable attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. §285; and
- (f) such other relief as this court finds just and proper.

Jury Demand

Plaintiff Gore requests trial by jury.

Dated: October 18, 2012

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Pilar G. Kraman

Adam Poff (#3990)

Pilar G. Kraman (#5199)

Rodney Square

1000 North King Street

Wilmington, DE 19801

(302) 571-6600

apoff@ycst.com

pkraman@ycst.com

OF COUNSEL

James W. Poradek
Kevin P. Wagner
Christopher J. Burrell
Katherine S. Razavi
Lucas J. Tomsich
FAEGRE BAKER DANIELS LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55419
(612) 766-1600

Attorneys for Plaintiff
W.L. GORE & ASSOCIATES, INC.

01:12662552.1

Exhibit A

US005735892A

United States Patent [19]**Myers et al.**[11] **Patent Number:** **5,735,892**[45] **Date of Patent:** **Apr. 7, 1998**[54] **INTRALUMINAL STENT GRAFT**

[75] **Inventors:** **David J. Myers**, Camp Verde; **James D. Lewis**, Flagstaff; **Wayne D. House**, Flagstaff; **Karl E. Schwarz**, Flagstaff, all of Ariz.

[73] **Assignee:** **W. L. Gore & Associates, Inc.**, Newark, Del.

[21] **Appl. No.:** **109,214**

[22] **Filed:** **Aug. 18, 1993**

[51] **Int. Cl.⁶** **A61F 2/06; A61F 2/04**

[52] **U.S. Cl.** **623/1; 623/12; 606/198**

[58] **Field of Search** **606/198, 191, 606/195; 623/1, 12**

[56] **References Cited****U.S. PATENT DOCUMENTS**

3,657,744 4/1972 Ersek .
 3,868,956 3/1975 Alfidi et al. .
 3,953,566 4/1976 Gore .
 4,130,904 12/1978 Whalen .
 4,140,126 2/1979 Choudury .
 4,190,909 3/1980 Ablaza .
 4,300,244 11/1981 Bokros .
 4,313,231 2/1982 Koyamada .
 4,512,228 4/1985 Balko et al. .
 4,553,545 11/1985 Maass et al. .
 4,562,596 1/1986 Kornberg .
 4,577,631 3/1986 Kreamer .
 4,655,771 4/1987 Wallsten .
 4,681,110 7/1987 Wiktor .
 4,740,207 4/1988 Kreamer .
 4,776,337 10/1988 Palmaz .
 4,787,899 11/1988 Lazarus .
 4,791,966 12/1988 Eilentrapp .
 4,820,298 4/1989 Leveen et al. .
 4,877,030 10/1989 Beck et al. .
 4,878,906 11/1989 Lindemann et al. .
 4,925,710 5/1990 Buck et al. .
 4,954,126 9/1990 Wallsten .
 5,078,726 1/1992 Kreamer .
 5,089,006 2/1992 Stiles .
 5,107,852 4/1992 Davidson et al. .
 5,122,154 6/1992 Rhodes .

5,123,917 6/1992 Lee .
 5,151,105 9/1992 Kwan-Gett .
 5,156,620 10/1992 Pigott .
 5,211,658 5/1993 Clouse .
 5,236,447 8/1993 Kubo et al. .
 5,254,113 10/1993 Wilk 606/195 X
 5,282,823 2/1994 Schwartz et al. .
 5,282,824 2/1994 Gianturco .

FOREIGN PATENT DOCUMENTS

0010293 4/1980 European Pat. Off. .
 461791 12/1991 European Pat. Off. .
 464755 1/1992 European Pat. Off. .
 466518 1/1992 European Pat. Off. .
 480667 4/1992 European Pat. Off. .
 508473 10/1992 European Pat. Off. .
 518704 12/1992 European Pat. Off. .
 528039 2/1993 European Pat. Off. .
 539237 4/1993 European Pat. Off. .
 0551179 7/1993 European Pat. Off. .
 3918736 12/1990 Germany .
 55-36492 5/1976 Japan .
 53-67109 6/1978 Japan .
 60-17230 9/1985 Japan .
 8704935 8/1987 WIPO .
 9112779 9/1991 WIPO .
 9113648 9/1991 WIPO .

OTHER PUBLICATIONS

George P J M et al., Covered expandable metal stent for recurrent tracheal obstruction. The Lancet, Mar. 1990; 335:582-584.

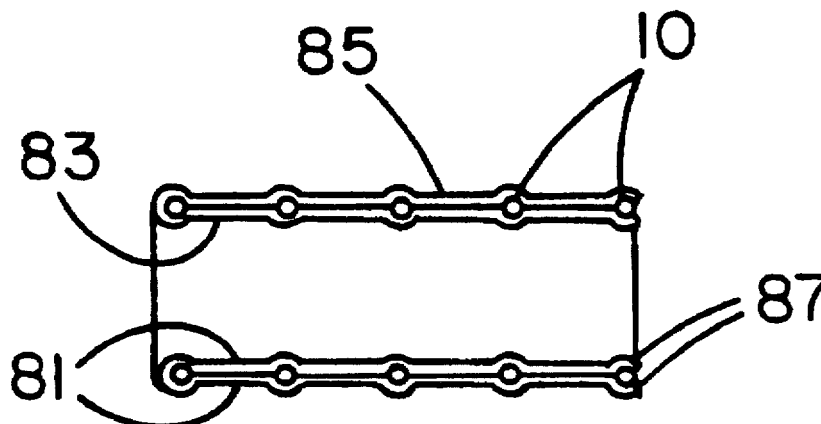
(List continued on next page.)

Primary Examiner—Gary Jackson
Assistant Examiner—Nancy Mulcare
Attorney, Agent, or Firm—Wayne D. House

[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.

48 Claims, 4 Drawing Sheets



5,735,892

Page 2

OTHER PUBLICATIONS

Kato M et al., Development of a chronic endothelialized transcatheter implantable intra-aortic graft. ASAIO Journal 1993; M518-M521.

Lawrence D D et al., Percutaneous Endovascular Graft: Experimental Evaluation. Radiology May 1987; 163(2):357-360.

Yoshioka T et al. Self-Expanding Endovascular Graft: An Experimental Study in Dogs. AJR Oct. 1988; 151:673-676.

Sayers R D et al., Endovascular stenting of abdominal aortic aneurysms. Eur J Vasc Surg 1993; 7:225-227.

Schneck R R and Derman G H. An Intraluminal Silastic Stent for Small Vessel Repair. Orth Clin North Amer. Apr. 1977; 8(2):265-271.

Yoshida H et al., Transcatheter Placement of an Intraluminal Prosthesis for the Thoracic Aorta. A New Approach to Aortic Dissection. ASAIO Transactions 1991;37:M272-M-273.

Balko A et al., Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysm. Jour of Surg Research 1986; 40:305-309.

Chuter T A M et al., Transfemoral Endovascular Aortic Graft Placement. Jour of Vas Surg Aug. 1993; vol. 18(2):185-197.

Cragg A H, Drake M D. Percutaneous Femoropopliteal Graft Placement. Radiology 1993; 187(3):643-648.

Mirich D et al., Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study. Radiology 1989; 170(3):1033-1037.

Parodi J C et al., Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms. Annals of Vascular Surg 1991; vol. 5(6):491-499.

Preminger T J et al., Transluminal vascular stenting using a GORE-TEX covered stent: An experimental study. Presented at the congress of Pediatric Cardiology and Cardiac Surgery Jun. 21-25 1993.

U.S. Patent

Apr. 7, 1998

Sheet 1 of 4

5,735,892

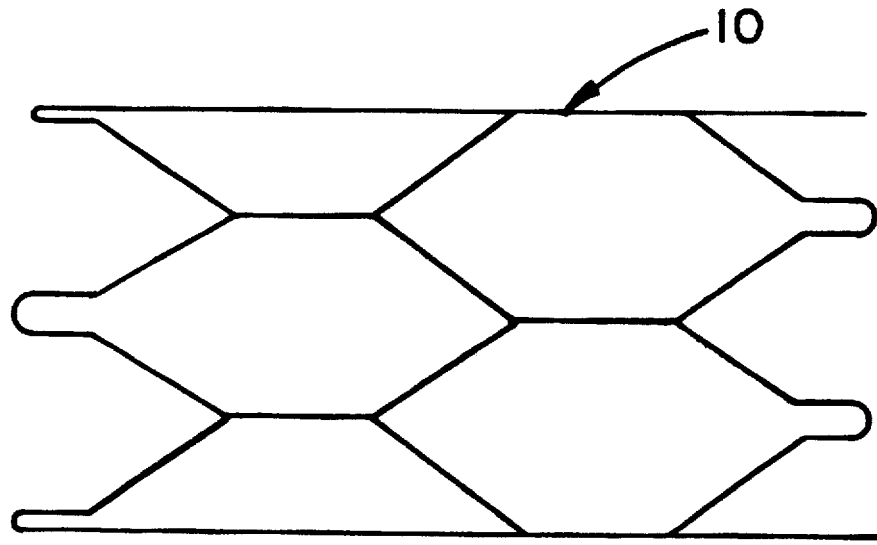


FIG. 1

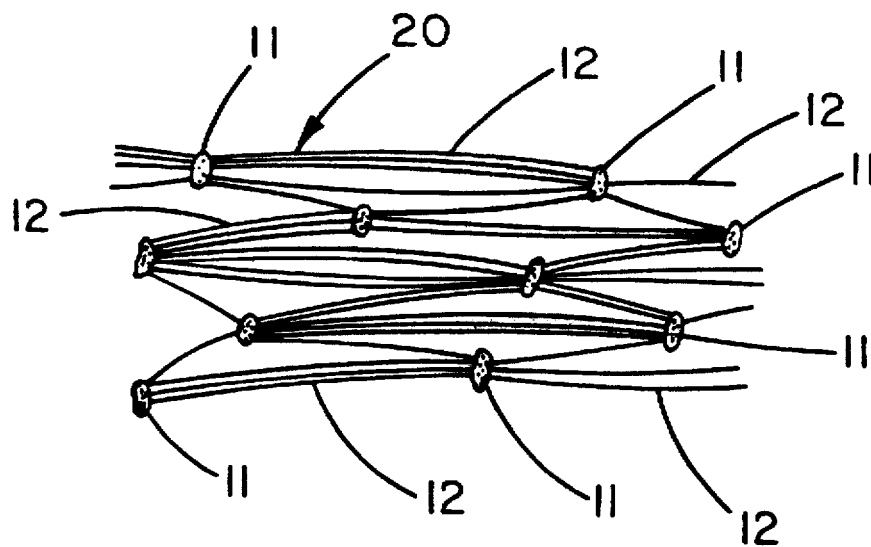


FIG. 2

U.S. Patent

Apr. 7, 1998

Sheet 2 of 4

5,735,892

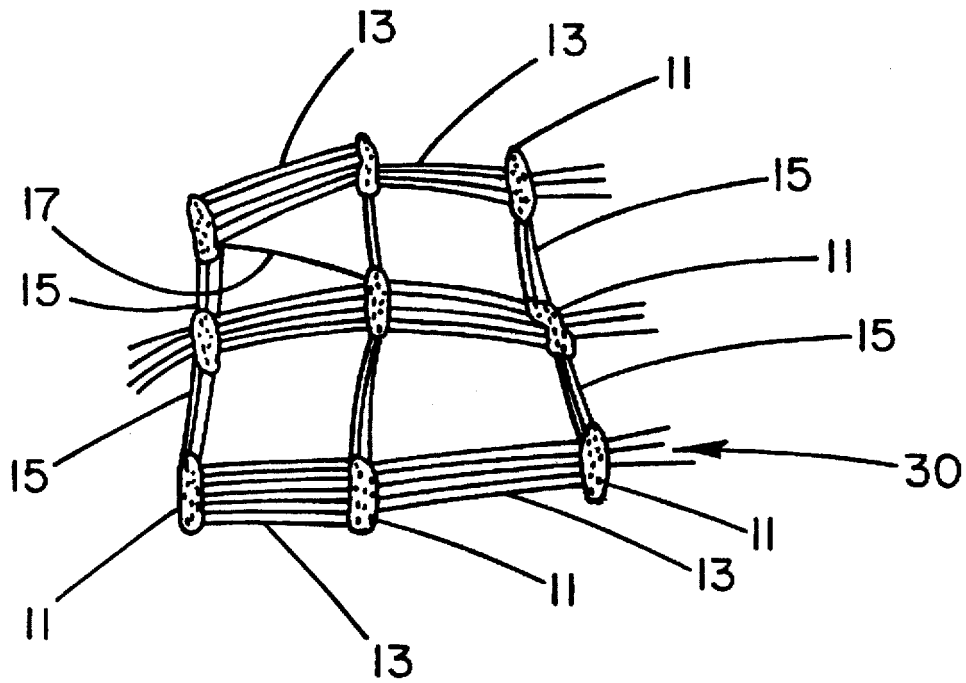


FIG. 3A

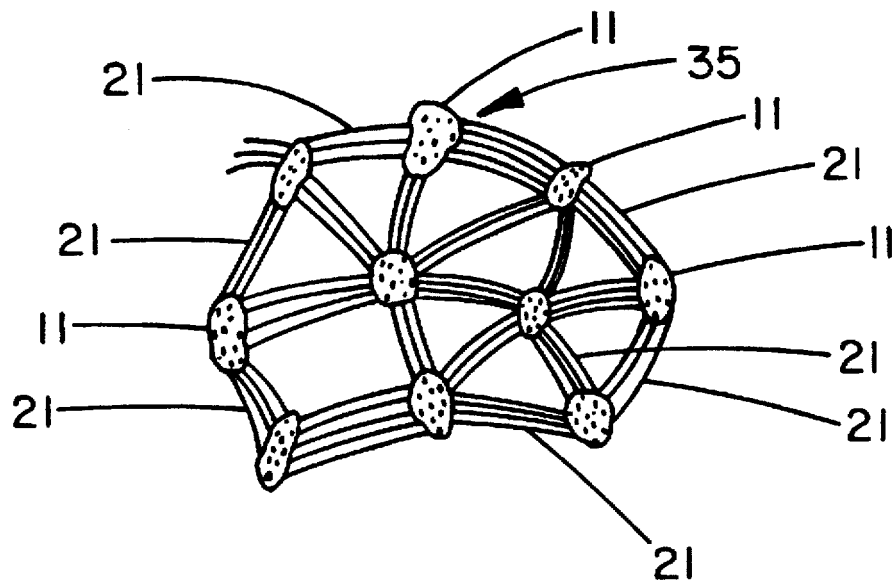


FIG. 3B

U.S. Patent

Apr. 7, 1998

Sheet 3 of 4

5,735,892

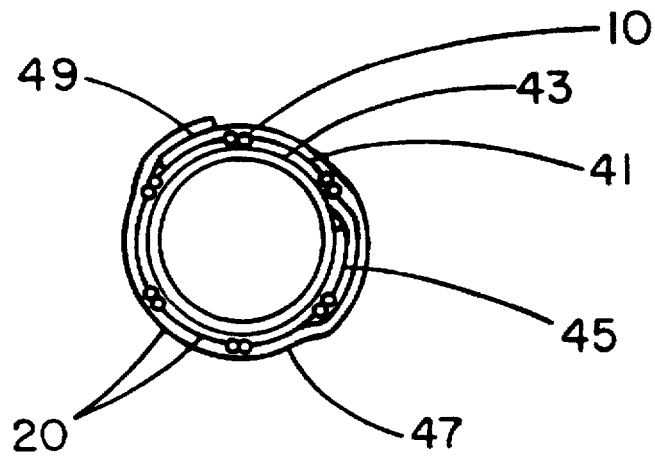


FIG. 4

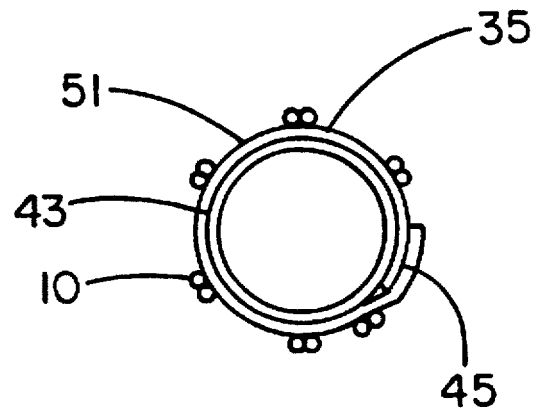


FIG. 5

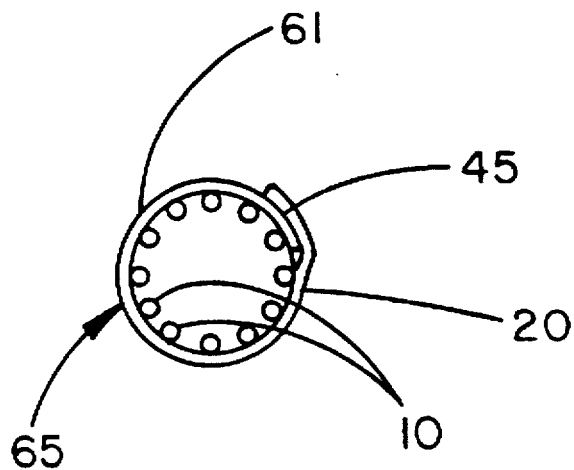


FIG. 6

U.S. Patent

Apr. 7, 1998

Sheet 4 of 4

5,735,892

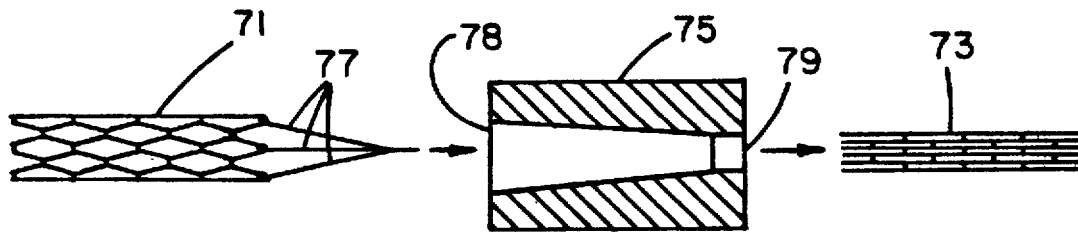


FIG. 7

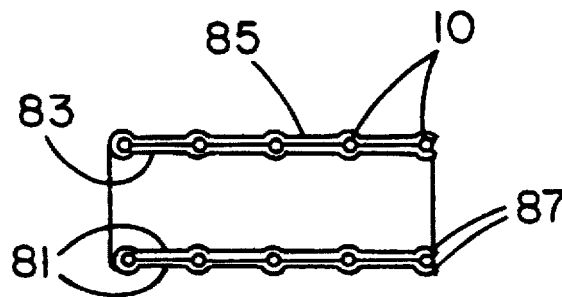


FIG. 8

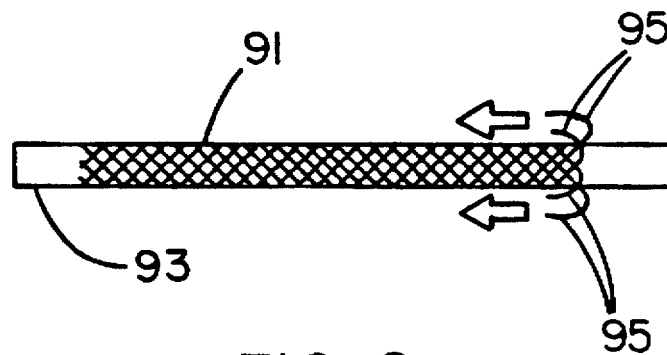


FIG. 9

5,735,892

1

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. Pat. No. 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. Pat. No. 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. Pat. No. 5,122,154 and Lee, U.S. Pat. No. 5,123,917, describe endovascular bypass grafts for intralu-

2

minal 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 Ariz.) or Impra® Graft (Impra, Inc. Tempe Ariz.). 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. Pat. Nos. 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. Pat. No. 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. Pat. No. 4,544,771; and stents of formed wire made as taught by Gianturco, U.S. Pat. No. 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 U.S. Ser. No. 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

5,735,892

3

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

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

FIG. 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.

FIGS. 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.

FIG. 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.

FIG. 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.

FIG. 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.

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

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

FIG. 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

FIG. 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. Pat. No. 4,776,337 to Palmaz and PCT U.S. Ser. No. 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.

FIG. 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. FIGS. 3A and 3B describe

4

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. FIG. 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. FIG. 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 FIG. 3B. The manufacture of these films is taught by U.S. Pat. Nos. 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, Mass.) of the type described by FIG. 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

5,735,892

5

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 FIG. 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.

6

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 FIG. 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 FIG. 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.

5,735,892

7

EXAMPLE 3

A Palmaz stent of the balloon-expandable type (part no. PS30, Johnson & Johnson Interventional Systems, Inc., Warren, N.J.) 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 FIG. 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 FIG. 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 FIG. 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

8

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 FIG. 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 FIG. 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 first tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent and having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface; and
- c) a second tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent, and having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface;

wherein the combined thickness of the first and second tubular coverings is less than about 0.10 mm, thick exclusive of the stent.

2. A tubular intraluminal graft according to claim 1 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering

5,735,892

9

of porous expanded polytetrafluoroethylene film through openings through the wall of the stent.

3. A tubular intraluminal graft according to claim 2 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film by an adhesive.

4. A tubular intraluminal graft according to claim 3 wherein the adhesive is fluorinated ethylene propylene.

5. A tubular intraluminal graft according to claim 1 wherein the first and second tubular coverings of porous expanded polytetrafluoroethylene are affixed by an adhesive.

6. A tubular intraluminal graft according to claim 5 wherein the adhesive is fluorinated ethylene propylene.

7. A tubular intraluminal graft according to claim 1 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.

8. A tubular intraluminal graft according to claim 2 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.

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

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

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

12. 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.

13. A method according to claim 12 wherein the first and second tubular coverings are affixed by an adhesive.

14. A method according to claim 13 wherein the adhesive is fluorinated ethylene propylene.

15. A tubular intraluminal graft comprising:

- a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface, an end edge 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;

10

wherein the tubular covering of porous expanded polytetrafluoroethylene is folded over the end edge of the tubular, diametrically adjustable stent and is affixed to the exterior surface and the luminal surface of the tubular diametrically adjustable stent, and wherein the folded tubular covering has a thickness less than about 0.10 mm thick exclusive of the stent.

16. A tubular intraluminal graft according to claim 15 wherein the tubular covering is affixed by an adhesive.

17. A tubular intraluminal graft according to claim 15 wherein the tubular covering is affixed with sutures.

18. 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 first tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent, and having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface; and
- c) a second tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent, and having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal surface.

19. A tubular intraluminal graft according to claim 18 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.

20. A tubular intraluminal graft according to claim 19 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.

21. A tubular intraluminal graft according to claim 19 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film by an adhesive.

22. A tubular intraluminal graft according to claim 21 wherein the adhesive is fluorinated ethylene propylene.

23. A tubular intraluminal graft according to claim 18 wherein the first and second tubular coverings of porous expanded polytetrafluoroethylene are affixed by an adhesive.

24. A tubular intraluminal graft according to claim 23 wherein the adhesive is fluorinated ethylene propylene.

25. A tubular intraluminal graft according to claim 18 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.

26. A tubular intraluminal graft according to claim 18 wherein the tubular diametrically adjustable stent is a Nitinol stent.

5,735,892

11

27. A tubular intraluminal graft according to claim 18 wherein the stent is a balloon-expandable stent.

28. A tubular intraluminal graft according to claim 18 wherein the stent is a self-expanding stent of braided wire.

29. A tubular intraluminal graft comprising:

a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface, an end edge 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, 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;

wherein the tubular covering of porous expanded polytetrafluoroethylene is folded over the end edge of the tubular, diametrically adjustable stent and is affixed to the exterior surface and the luminal surface of the tubular diametrically adjustable stent.

30. A tubular intraluminal graft according to claim 29 wherein the tubular covering is affixed by an adhesive.

31. A tubular intraluminal graft according to claim 29 wherein the tubular covering is affixed with sutures.

32. 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 first tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent; and

c) a second tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent;

wherein the combined thickness of the first and second tubular coverings is less than about 0.10 mm thick exclusive of the stent.

33. A tubular intraluminal graft according to claim 32 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.

34. A tubular intraluminal graft according to claim 33 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film by an adhesive.

35. A tubular intraluminal graft according to claim 34 wherein the adhesive is fluorinated ethylene propylene.

36. A tubular intraluminal graft according to claim 32 wherein the first and second tubular coverings of porous expanded polytetrafluoroethylene are affixed by an adhesive.

37. A tubular intraluminal graft according to claim 36 wherein the adhesive is fluorinated ethylene propylene.

38. A tubular intraluminal graft according to claim 32 wherein the first tubular covering of porous expanded poly-

12

tetrafluoroethylene 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.

39. A tubular intraluminal graft according to claim 33 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.

40. A tubular intraluminal graft according to claim 32 wherein the tubular diametrically adjustable stent is a Nitinol stent.

41. A tubular intraluminal graft according to claim 32 wherein the stent is a balloon-expandable stent.

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

43. 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.

44. A method according to claim 43 wherein the first and second tubular coverings are affixed by an adhesive.

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

46. 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, 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.

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

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

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

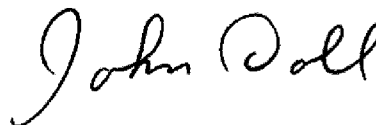
PATENT NO. : 5,735,892
APPLICATION NO. : 08/109214
DATED : April 7, 1998
INVENTOR(S) : David J. Myers et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 4, line 36, replace "804-10" with --2804-10--.

Signed and Sealed this
Seventh Day of April, 2009

A handwritten signature in cursive script that reads "John Doll".

JOHN DOLL
Acting Director of the United States Patent and Trademark Office

Exhibit B

US005700285A

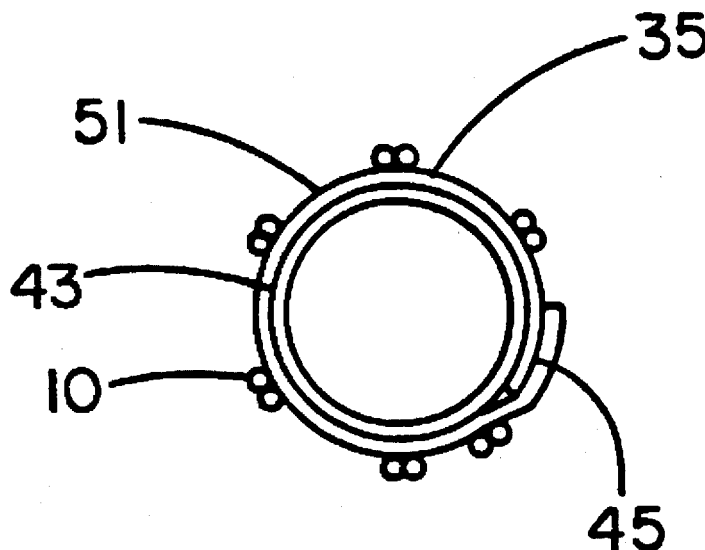
United States Patent [19]**Myers et al.**[11] **Patent Number:** **5,700,285**[45] **Date of Patent:** **Dec. 23, 1997**[54] **INTRALUMINAL STENT GRAFT**[75] **Inventors:** **David J. Myers**, Camp Verde; **James D. Lewis**, Flagstaff; **Wayne D. House**, Flagstaff; **Karl E. Schwarz**, Flagstaff, all of Ariz.[73] **Assignee:** **W. L. Gore & Associates, Inc.**, Newark, Del.[21] **Appl. No.:** **477,051**[22] **Filed:** **Jun. 7, 1995****Related U.S. Application Data**[62] **Division of Ser. No. 109,214**, Aug. 18, 1993, abandoned.[51] **Int. Cl.⁶** **A61F 2/06**; A61F 2/04[52] **U.S. Cl.** **623/1**; 623/12; 606/198[58] **Field of Search** 606/198, 195, 606/191; 623/1, 12[56] **References Cited****U.S. PATENT DOCUMENTS**

4,300,244 11/1981 Bokros .

4,512,228	4/1985	Balko et al. .
4,681,110	7/1987	Wiktor .
4,740,207	4/1988	Kreamer .
4,776,337	10/1988	Palmaz .
4,877,030	10/1989	Beck et al. .
4,954,126	9/1990	Wallsten .
5,107,852	4/1992	Davidson et al. .
5,254,113	10/1993	Wiak .
5,282,823	2/1994	Schwartz et al. .
5,282,824	2/1994	Gianturco .

Primary Examiner—Michael Buiz*Assistant Examiner*—Nancy Connolly Mulcare*Attorney, Agent, or Firm*—Wayne D. House[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.

18 Claims, 4 Drawing Sheets

U.S. Patent

Dec. 23, 1997

Sheet 1 of 4

5,700,285

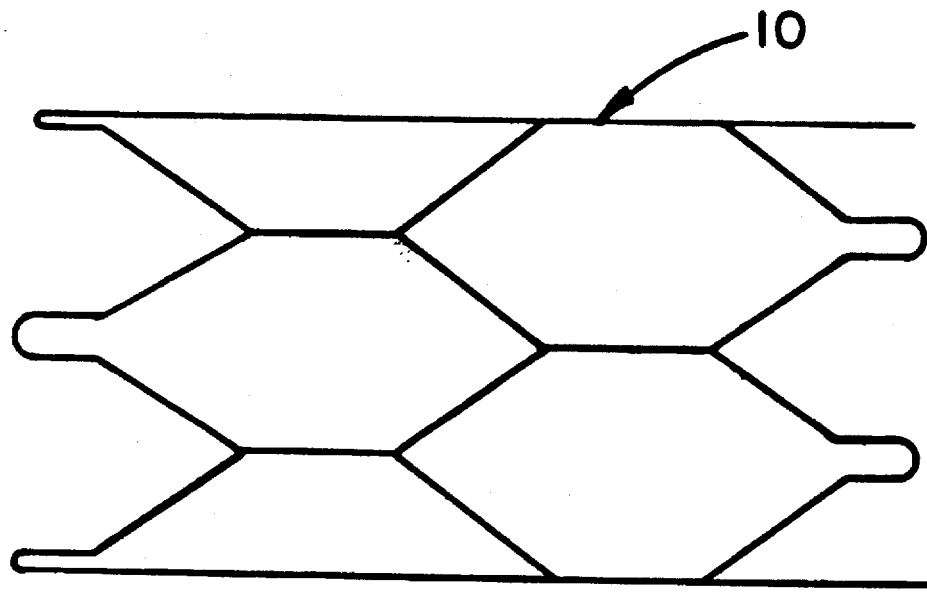


FIG. 1

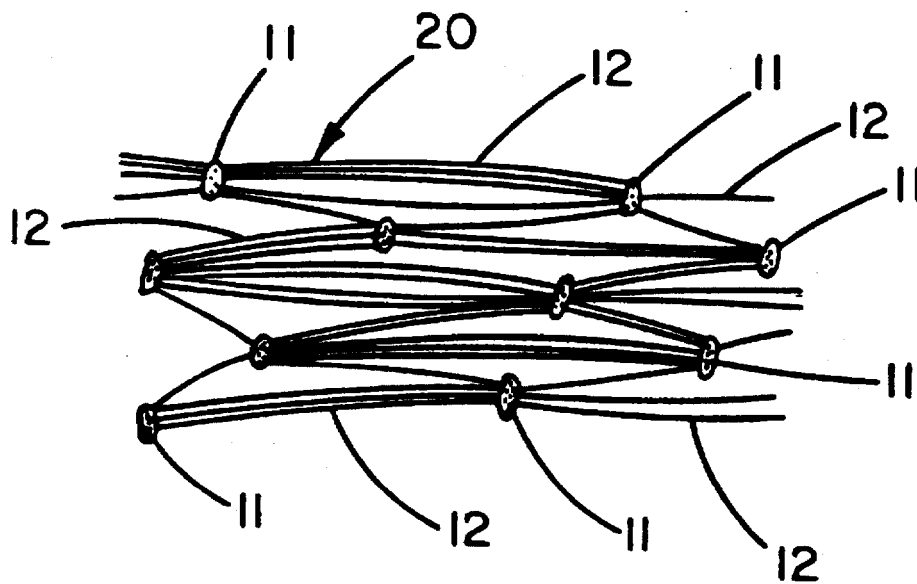


FIG. 2

U.S. Patent

Dec. 23, 1997

Sheet 2 of 4

5,700,285

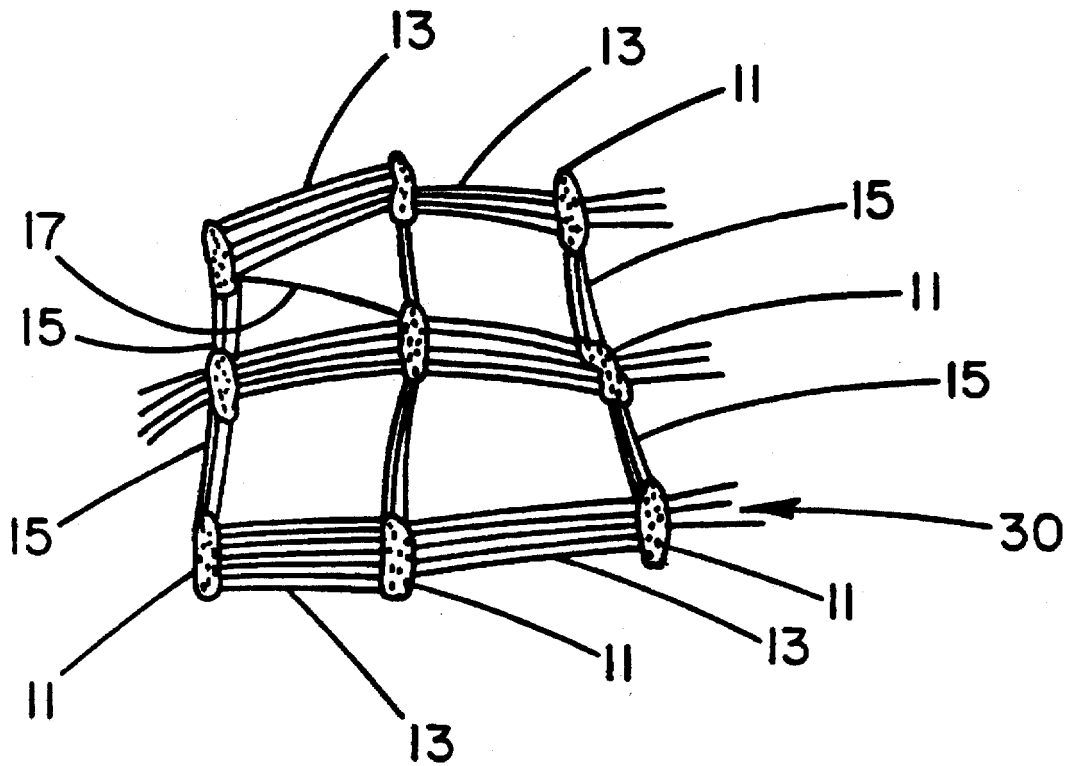


FIG. 3A

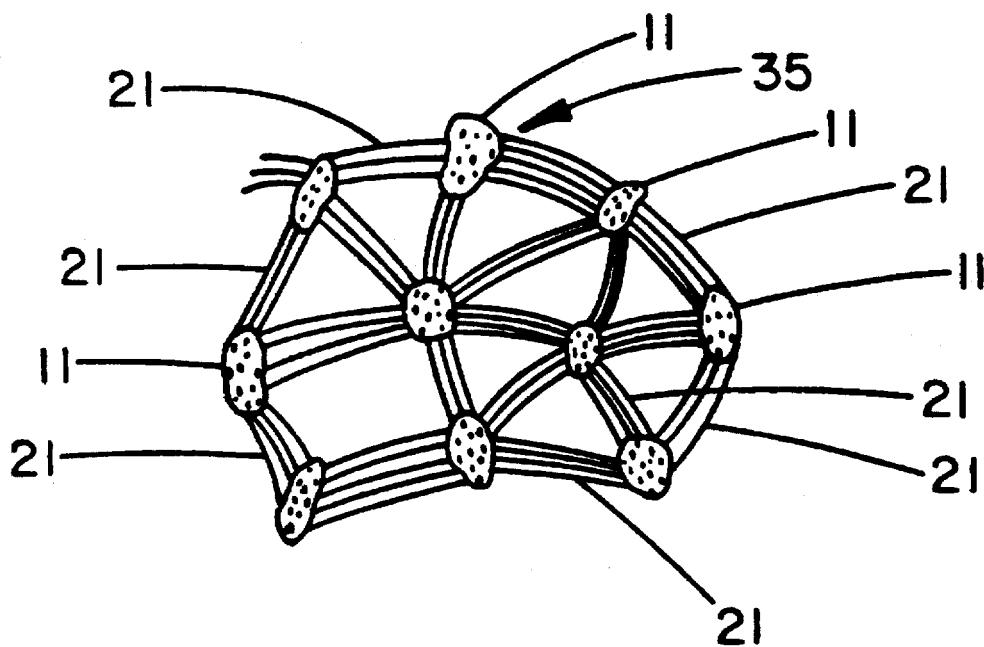


FIG. 3B

U.S. Patent

Dec. 23, 1997

Sheet 3 of 4

5,700,285

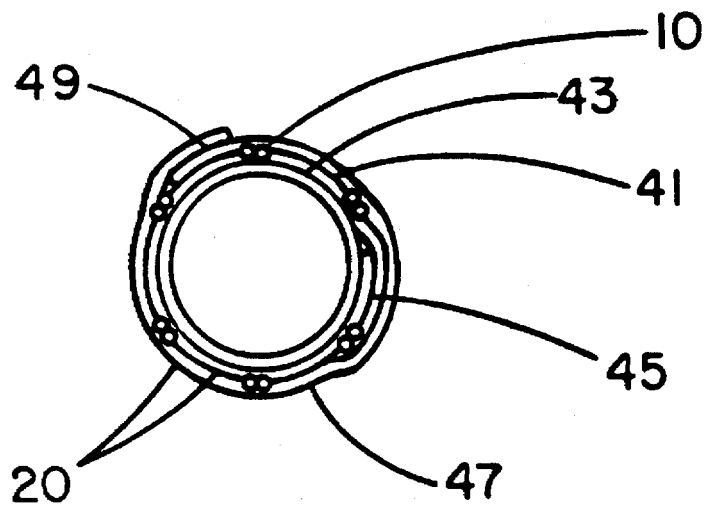


FIG. 4

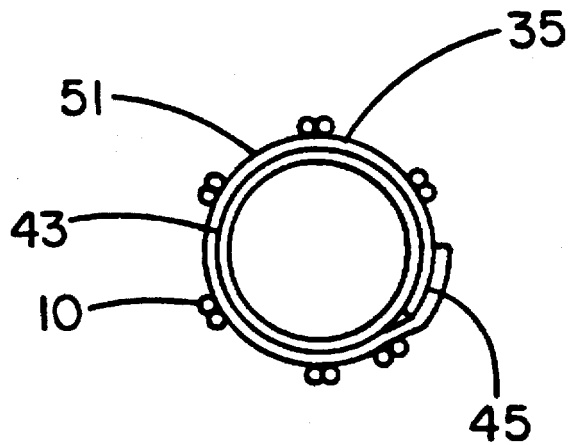


FIG. 5

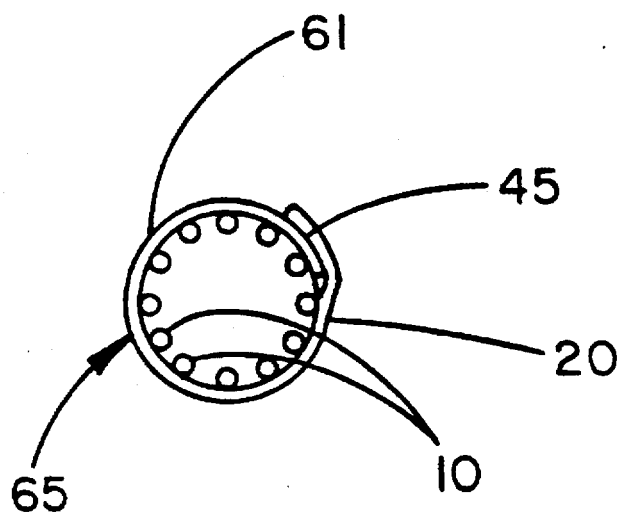


FIG. 6

U.S. Patent

Dec. 23, 1997

Sheet 4 of 4

5,700,285

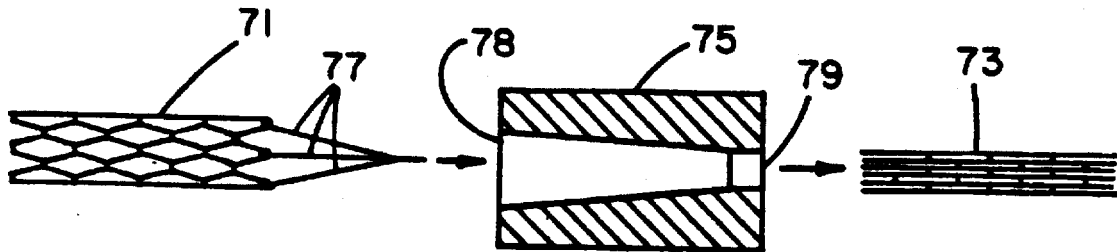


FIG. 7

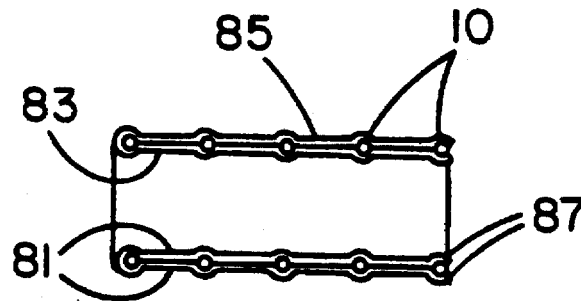


FIG. 8

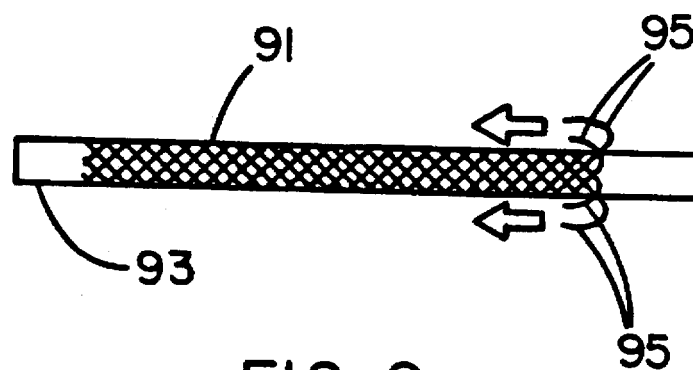


FIG. 9

5,700,285

1

INTRALUMINAL STENT GRAFT

This application is a division of application Ser. No. 08/109,214, filed Aug. 18, 1993 (status:abandoned).

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 ltying 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. Pat. No. 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. Pat. No. 4,140,126, describes a similar method of repairing aortic aneurysms whereby a polyethylene terphthalate vascular graft is fitted at its ends with metal

2

anchoring pins and pleated longitudinally to collapse the graft to a size small enough to allow for distal introduction.

Rhodes, U.S. Pat. No. 5,122,154 and Lee, U.S. Pat. No. 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 Ariz.) or Impra® Graft (Impra, Inc. Tempe Ariz). 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. Pat. Nos. 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. Pat. No. 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. Pat. No. 4,544,771; and stents of formed wire made as taught by Gianturco, U.S. Pat. No. 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.

5,700,285

3

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

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

FIG. 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.

FIGS. 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.

FIG. 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.

FIG. 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.

FIG. 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.

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

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

FIG. 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

FIG. 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. Pat. No. 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.

FIG. 2 describes an enlarged schematic representation of the microstructure of nodes 11 connected by fibrils 12 of a

4

film 20 wherein the uniaxially-oriented fibrils 12 are substantially parallel to each other. FIGS. 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. FIG. 3A describes a microstructure 30 of nodes 11 and fibrils 13 and is 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. FIG. 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 FIG. 3B. The manufacture of these films is taught by U.S. Pat. Nos. 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 m 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, Mass.) of the type described by FIG. 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

5,700,285

5

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 FIG. 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

6

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 FIG. 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 FIG. 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

5,700,285

7

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, N.J.) 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 FIG. 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 FIG. 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 FIG. 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,

8

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 FIG. 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 luminal surface of 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 the luminal surface of the tubular covering; and wherein said intraluminal graft is adapted for implantation in a body conduit.

2. 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 by an adhesive.

3. A tubular intraluminal graft according to claim 2 wherein the adhesive is a thermoplastic adhesive.

4. A tubular intraluminal graft according to claim 3 wherein the thermoplastic adhesive is a thermoplastic fluoropolymer adhesive.

5,700,285

9

5. A tubular intraluminal graft according to claim 4 wherein the thermoplastic fluoropolymer adhesive is fluorinated ethylene propylene.

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

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

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

9. 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.

10. A method according to claim 9 wherein the tubular covering is affixed with an adhesive.

11. A method according to claim 10 wherein the adhesive is fluorinated ethylene propylene.

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

a) selecting at least one a 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

10

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 adjusted to the enlarged diameter;

b) affixing a tubular covering to the luminal surface of the tubular, diametrically adjustable stent; c) collapsing the tubular, diametrically adjustable stent to about the collapsed diameter; and

wherein said intraluminal graft is adapted for implantation in a body conduit.

13. A method according to claim 12 wherein said tubular covering is less than about 0.10 mm thick.

14. A method according to claim 12 wherein said tubular covering is of porous expanded PTFE.

15. A method according to claim 13 wherein said tubular covering is of porous expanded PTFE.

16. A method according to claim 12 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.

17. A method according to claim 14 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.

18. A method according to claim 15 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.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,700,285

DATED : Dec 23, 1997

INVENTOR(S) : David J. Myers, et al

It is certified that error appears in the above-identified patent and that said Letters Patent **is** hereby corrected as shown below:

On title page, in section [62] please delete "abandoned", and insert therefor --Pat .No. 5,735,892--.

At column 9, line 31, please delete "wail" and insert therefor --wall--.

Signed and Sealed this

Fourteenth Day of July, 1998



Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

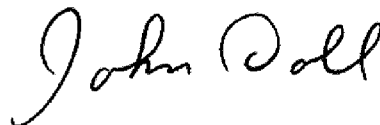
PATENT NO. : 5,700,285
APPLICATION NO. : 08/477051
DATED : December 23, 1997
INVENTOR(S) : David J. Myers et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 4, line 38, replace "804-10" with --2804-10--.

Signed and Sealed this
Fourteenth Day of April, 2009

A handwritten signature in black ink that reads "John Doll". The signature is written in a cursive, flowing style.

JOHN DOLL
Acting Director of the United States Patent and Trademark Office

Exhibit C

(12) **United States Patent**
Lewis et al.

(10) **Patent No.:** **US 8,221,487 B2**
(45) **Date of Patent:** ***Jul. 17, 2012**

(54) **INTRALUMINAL STENT GRAFT**

(75) Inventors: **James D. Lewis**, Flagstaff, AZ (US);
David J. Myers, Camp Verde, AZ (US);
Wayne D. House, Flagstaff, AZ (US)

(73) Assignee: **W. L. Gore & Associates, Inc.**, Newark,
DE (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-
claimer.

(21) Appl. No.: **12/781,358**

(22) Filed: **May 17, 2010**

(65) **Prior Publication Data**

US 2010/0217375 A1 Aug. 26, 2010

Related U.S. Application Data

(60) Continuation of application No. 12/695,247, filed on
Jan. 28, 2010, now Pat. No. 8,080,051, which is a
continuation of application No. 11/237,587, filed on
Sep. 27, 2005, now Pat. No. 7,691,141, which is a
continuation of application No. 10/413,731, filed on
Apr. 14, 2003, now Pat. No. 6,949,119, which is a
continuation of application No. 10/083,461, filed on
Feb. 25, 2002, now Pat. No. 6,547,815, which is a
continuation of application No. 09/306,522, filed on
May 6, 1999, now Pat. No. 6,357,104, which is a
division of application No. 08/872,837, filed on Jun.
11, 1997, now Pat. No. 5,925,075, which is a
continuation of application No. 08/109,214, filed on
Aug. 18, 1993, now Pat. No. 5,735,892.

(51) **Int. Cl.**

A61M 29/00

(2006.01)

(52) **U.S. Cl.** **623/1.13**

(58) **Field of Classification Search** 606/191-198;
623/1.11, 1.13, 1.123, 1.25, 1.36, 1.46
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,657,744 A 4/1972 Ersek
3,868,956 A 3/1975 Alfidi et al.
3,953,566 A 4/1976 Gore
4,130,904 A 12/1978 Whalen
4,140,126 A 2/1979 Choudury
(Continued)

FOREIGN PATENT DOCUMENTS

DE 3918736 12/1990
(Continued)

OTHER PUBLICATIONS

Balko A et al. Transfemoral Placement of Intraluminal Polyurethane
Prosthesis for Abdominal Aortic Aneurysm. J of Surg Research 1986;
40:305-309.

(Continued)

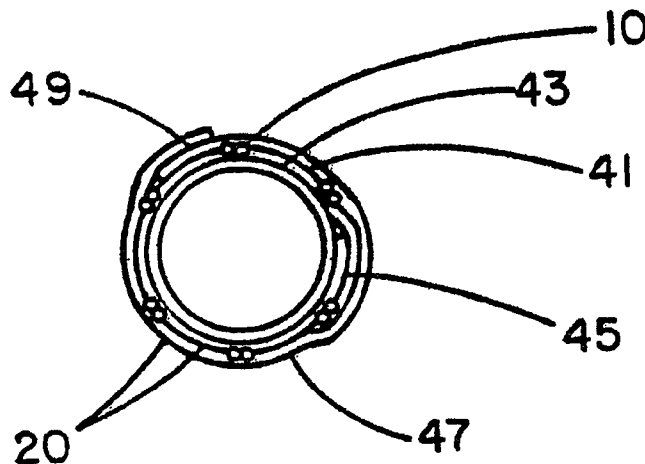
Primary Examiner — Kevin T Truong

(74) *Attorney, Agent, or Firm* — Gilbert R. Gabo

(57) **ABSTRACT**

A method of making an tubular intraluminal graft in the form
of a tubular diametrically adjustable stent having a tubular
covering of porous expanded PTFE 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.

10 Claims, 4 Drawing Sheets



US 8,221,487 B2

Page 2

U.S. PATENT DOCUMENTS

4,190,909	A	3/1980	Ablaza	
4,283,448	A	8/1981	Bowman	
4,300,244	A	11/1981	Bokros	
4,304,010	A	12/1981	Mano	
4,313,231	A	2/1982	Koyamada	
4,385,093	A	5/1983	Hubis	
4,478,898	A	10/1984	Kato	
4,512,338	A	4/1985	Balko et al.	
4,553,545	A	11/1985	Maass et al.	
4,562,596	A	1/1986	Kornberg	
4,577,631	A	3/1986	Kreamer	
4,580,568	A	4/1986	Gianturco	
4,655,771	A	4/1987	Wallsten	
4,681,110	A	7/1987	Wiktor	
4,728,328	A	3/1988	Hughes et al.	
4,740,207	A	4/1988	Kreamer	
4,776,337	A	10/1988	Palmaz	
4,787,899	A	11/1988	Lazarus	
4,791,966	A	12/1988	Eilentrapp	
4,820,298	A	4/1989	Leveen et al.	
4,877,030	A	10/1989	Beck et al.	
4,878,906	A	11/1989	Lindemann et al.	
4,925,710	A	5/1990	Buck et al.	
4,954,126	A	9/1990	Wallsten	
5,078,726	A	1/1992	Kreamer	
5,078,736	A	1/1992	Behl	
5,089,006	A	2/1992	Stiles	
5,107,852	A	4/1992	Davidson et al.	
5,122,154	A	6/1992	Rhodes	
5,123,917	A *	6/1992	Lee	623/22.26
5,147,370	A	9/1992	McNamara et al.	
5,151,105	A	9/1992	Kwan-Gett	
5,156,620	A	10/1992	Pigott	
5,163,955	A	11/1992	Love et al.	
5,211,658	A *	5/1993	Clouse	623/1.14
5,225,131	A	7/1993	Tamaru et al.	
5,236,447	A	8/1993	Kubo et al.	
5,254,113	A	10/1993	Wilk	
5,258,023	A	11/1993	Reger	
5,282,823	A	2/1994	Schwartz et al.	
5,282,824	A	2/1994	Gianturco	
5,344,426	A	9/1994	Lau et al.	
5,405,377	A	4/1995	Cragg	
5,441,515	A	8/1995	Khosravi et al.	
5,443,499	A	8/1995	Schmitt	
5,507,767	A	4/1996	Maeda et al.	
5,556,414	A	9/1996	Turi	
5,637,113	A	6/1997	Tartaglia et al.	
5,645,559	A	7/1997	Hachtman et al.	
5,700,285	A	12/1997	Myers et al.	
5,735,892	A	4/1998	Myers et al.	
5,810,870	A	9/1998	Myers et al.	
5,876,448	A	3/1999	Thompson et al.	
6,165,212	A	12/2000	Dereme et al.	
6,174,329	B1	1/2001	Callol et al.	

FOREIGN PATENT DOCUMENTS

EP	10293	4/1980
EP	461791	12/1991
EP	464755	1/1992
EP	466518	1/1992
EP	480667	4/1992
EP	508473	10/1992
EP	518704	12/1992
EP	528039	2/1993
EP	539237	4/1993
EP	551179	7/1993

EP	814729	9/1995
JP	5536492	5/1976
JP	5367109	6/1978
JP	60172306	9/1985
WO	8704935	8/1987
WO	9112779	9/1991
WO	9113648	9/1991

OTHER PUBLICATIONS

Carrel A Results of the permanent intubation of the thoracic aorta. Surg., Gyn and Ob. 1912;15:245-248.

Chuter TAM, et al. Transfemoral Endovascular Aortic Graft Placement. J Vas Surg 1993; 18(2):185-197.

Cragg AH, Drake MD Percutaneous Femoropopliteal Graft Placement. Radiology 1993; 187(3):643-648.

George PJM et al. Covered expandable metal stent for recurrent tracheal obstruction. The Lancet 1990; 335:582-584.

Kato M et al. Development of a chronic endothelialized transcatheter implantable intra-aortic graft. ASAIO Journal 1993; M518-M521.

Lawrence DD et al. Percutaneous Endovascular Graft: Experimental Evaluation. Radiology 1987; 163.2 :357-360.

Mirich E et al. Percutaneously Placed Endovascular Grafts for Aortic Aneurysms; Feasibility Study. Radiology 1989; 170(3):1033-1037.

Parodi JC et al. Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms. Annals of Vasc Surg 1991; 5(6):491-499.

Preminger TJ et al. Transluminal vascular stenting using a GORE-TEX covered stent: An experimental study. Presented at the congress of Pediatric Cardiology and Cardiac Surgery Jun. 21-25, 1993.

Sayers RD et al. Endovascular stenting of abdominal aortic aneurysms. Eur J Vasc Surg 1993; 7:225-227.

Schenck RR and Derman GH An Intraluminal Silastic Stent for Small Vessel Repair. Orth Clin North Amer 1997; 8(2):265-271.

Yoshida H et al. Transcatheter Placement of an Intraluminal Prosthesis for the Thoracic Aorta, A New Approach to Aortic Dissections. ASAIO Transactions 1991; 37:M272-M273.

The Journal of Teflon, Sep.-Nov. 1971, vol. 12, No. 3, pp. 2-4.

US District Court for Eastern District of Virginia, Norfolk Division; Case No. 2:10-cv-00441-MSD-DEM. Case docket. Jan. 23, 2012; 26 pages.

US District Court for Eastern District of Virginia, Norfolk Division; Case No. 2:10-cv-00441-MSD-DEM. Berry Expert report and exhibits. Jan. 6, 2012; 518 pages.

US District Court for Eastern District of Virginia, Norfolk Division; Case No. 2:10-cv-00441-MSD-DEM. Claim Construction- Opinion and Order. Dec. 14, 2011; 44 pages.

US District Court for Eastern District of Virginia, Norfolk Division; Case No. 2:10-cv-00441-MSD-DEM. Loomis supp report and exhibits. Dec. 23, 2011; 704 pages.

US District Court for Eastern District of Virginia, Norfolk Division; Case No. 2:10-cv-00441-MSD-DEM. Veith Opening report and exhibits. Nov. 21, 2011; 315 pages.

US District Court for Eastern District of Virginia, Norfolk Division; Case No. 2:10-cv-00441-MSD-DEM. Veith rebuttal report. Nov. 21, 2011; 134 pages.

US District Court for Eastern District of Virginia, Norfolk Division; Case No. 2:10-cv-00441-MSD-DEM. Zarins deposition excerpt. Jan. 19, 2012; 38 pages.

US District Court for Eastern District of Virginia, Norfolk Division; Case No. 2:10-cv-00441-MSD-DEM. Zarins report and exhibits. Jan. 6, 2012; 111 pages.

* cited by examiner

U.S. Patent

Jul. 17, 2012

Sheet 1 of 4

US 8,221,487 B2

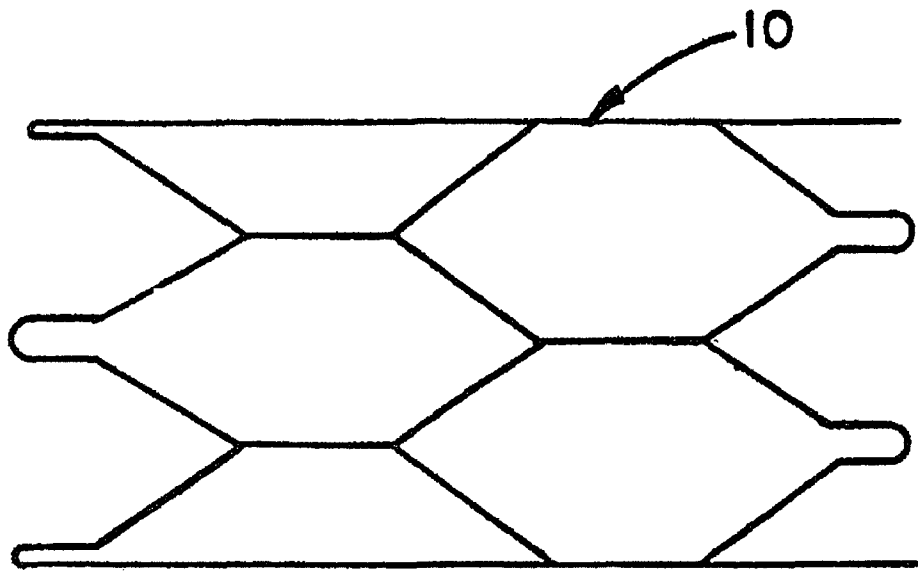


FIG. 1

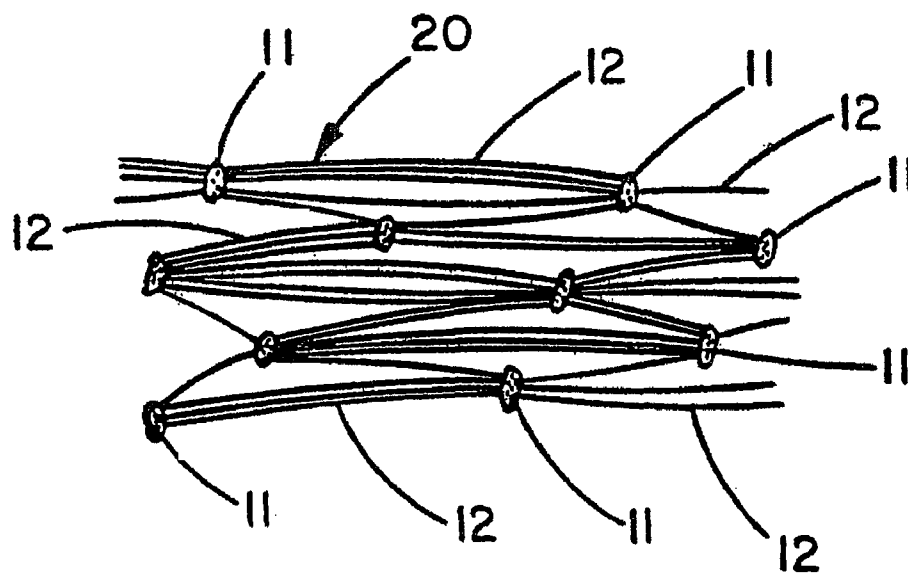


FIG. 2

U.S. Patent

Jul. 17, 2012

Sheet 2 of 4

US 8,221,487 B2

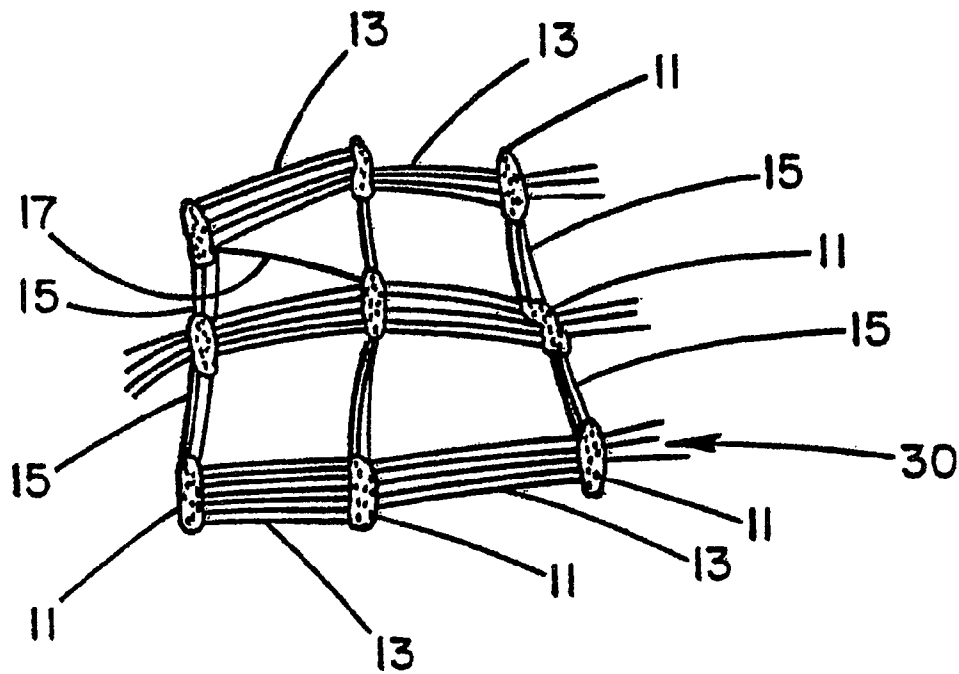


FIG. 3A

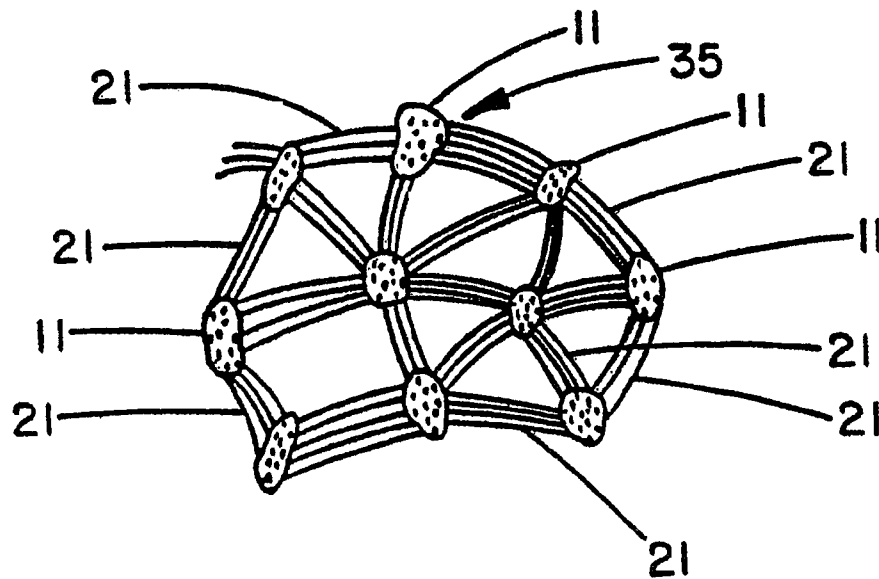


FIG. 3B

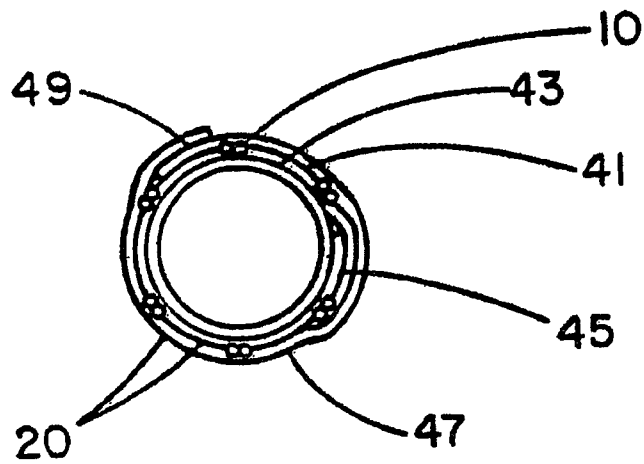


FIG. 4

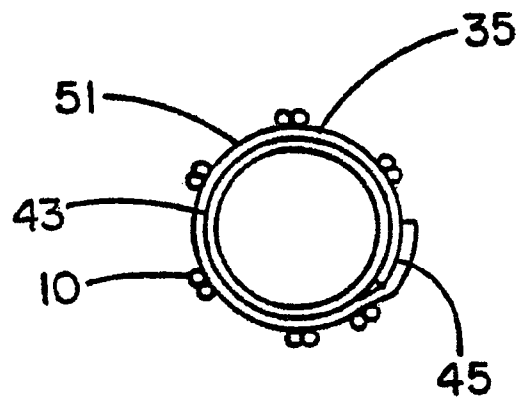


FIG. 5

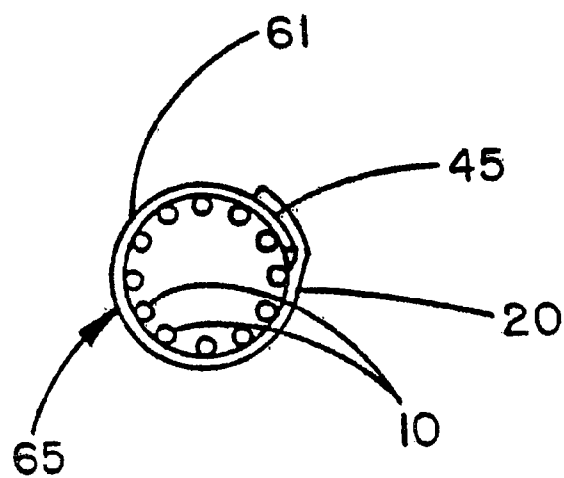


FIG. 6

U.S. Patent

Jul. 17, 2012

Sheet 4 of 4

US 8,221,487 B2

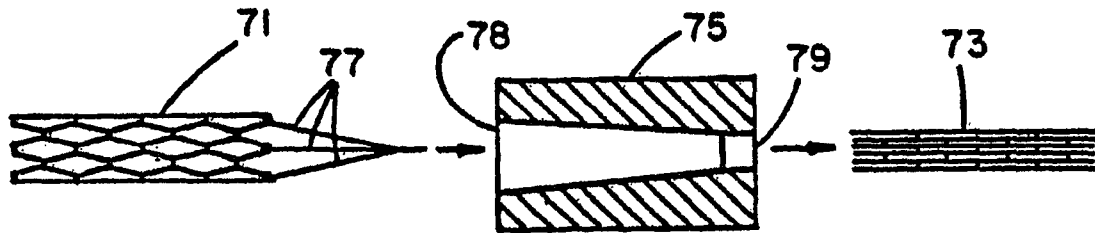


FIG. 7

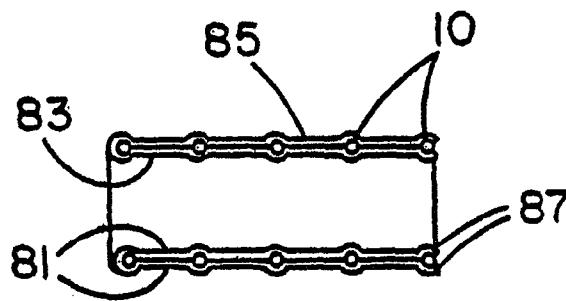


FIG. 8

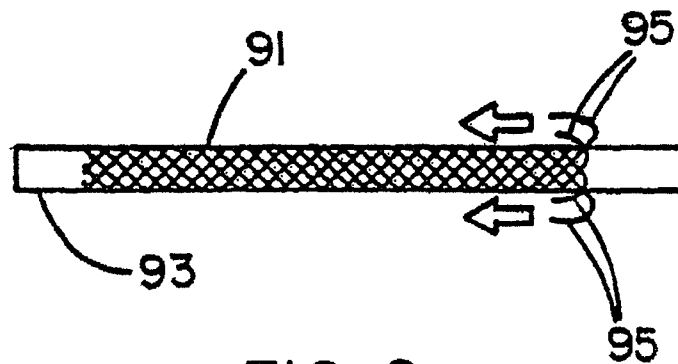


FIG. 9

US 8,221,487 B2

1

INTRALUMINAL STENT GRAFT**CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 12/695,247 filed Jan. 28, 2010, now U.S. Pat. No. 8,080,051, which is a continuation of U.S. application Ser. No. 11/237,587 filed Sep. 27, 2005, now U.S. Pat. No. 7,691,141, which is a continuation of U.S. application Ser. No. 10/413,731, filed Apr. 14, 2003 (U.S. Pat. No. 6,949,119), which is a continuation of U.S. application Ser. No. 10/083,461, filed Feb. 25, 2002 (U.S. Pat. No. 6,547,815), which is a continuation of U.S. application Ser. No. 09/306,522, filed May 6, 1999 (U.S. Pat. No. 6,357,104), which is a division of U.S. application Ser. No. 08/872,837, filed Jun. 11, 1997 (U.S. Pat. No. 5,925,075), which is a continuation of U.S. application Ser. No. 08/109,214, filed Aug. 18, 1993 (U.S. Pat. No. 5,735,892).

FIELD OF THE INVENTION

This invention relates to the field of intraluminal grafts and particularly to a method of making 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

2

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. Pat. No. 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. Pat. No. 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. Pat. No. 5,122,154 and Lee, U.S. Pat. No. 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 Ariz.) or Impra® Graft (Impra, Inc. Tempe Ariz.). 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 method of making 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. Pat. Nos. 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. Pat. No. 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. Pat. No. 4,544,771; and stents of formed wire made as taught by Gianturco, U.S. Pat. No. 4,580,568. Stents of this type expand to a larger diameter after

US 8,221,487 B2

3

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

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

FIG. 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.

FIGS. 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.

FIG. 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.

FIG. 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.

FIG. 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.

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

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

FIG. 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

FIG. 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. Pat. No. 4,776,337 to

4

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.

FIG. 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. FIGS. 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. FIG. 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. FIG. 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 FIG. 3B. The manufacture of these films is taught by U.S. Pat. Nos. 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, Mass.) of the type described by FIG. 1 was provided with both a luminal covering and an exterior covering of

US 8,221,487 B2

5

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 FIG. 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 cir-

6

cumferentially-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 FIG. 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 FIG. 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

US 8,221,487 B2

7

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, N.J.) 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 FIG. 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 FIG. 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

8

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 FIG. 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 FIG. 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 FIG. 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.

The invention claimed is:

1. An intraluminal graft comprising:

- a) a diametrically adjustable stent having an exterior surface, a luminal surface and a wall, the wall having a multiplicity of openings;
- b) a first covering adjacent to the luminal surface of the stent; and
- c) a second covering adjacent to the exterior surface of the stent and affixed to the first covering through the wall of the stent,

US 8,221,487 B2

9

wherein the second covering adjacent to the exterior surface of the stent is affixed to the first covering through the multiplicity of openings through the wall of the stent.

2. The intraluminal graft of claim 1 wherein the second covering is less than about 0.10 mm thick. 5

3. The intraluminal graft of claim 1 wherein the polymer forming the first covering is PTFE.

4. The intraluminal graft of claim 1 wherein the polymer forming the second covering is PTFE. 10

5. The intraluminal graft of claim 1 wherein the diametrically adjustable stent is a self-expanding stent.

6. The intraluminal graft of claim 1, wherein the diametrically adjustable stent is a Nitinol stent.

10

7. The intraluminal graft of claim 1, wherein the first or second covering is of porous expanded PTFE.

8. The intraluminal graft of claim 1, wherein the second covering adjacent to the exterior surface of the stent is affixed to the first covering through the multiplicity of openings through the wall of the stent via adhesive.

9. The intraluminal graft of claim 1, wherein the second covering adjacent to the exterior surface of the stent is affixed to the first covering through the multiplicity of openings through the wall of the stent via sutures.

10. The intraluminal graft of claim 1 wherein the combined thickness of the first and second coverings is less than about 0.05 mm thick.

* * * * *