AU9467139

(12) PATENT ABRIDGMENT (11) Document No. AU-B-67139/94
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 670198

(54) Title
SOLID WOVEN TUBULAR PROSTHESIS

International Patent Classification(s)
(51)[5] **A61F 002/04** **A61F 002/06**

(21) Application No. : **67139/94** (22) Application Date : **25.04.94**

(87) PCT Publication Number : **WO94/24960**

(30) Priority Data

(31) Number	(32) Date	(33) Country
052657	**26.04.93**	**US UNITED STATES OF AMERICA**

(43) Publication Date : **21.11.94**

(44) Publication Date of Accepted Application : **04.07.96**

(71) Applicant(s)
MEADOX MEDICALS, INC.

(72) Inventor(s)
PETER J. SCHMITT

(74) Attorney or Agent
DAVIES COLLISON CAVE , 1 Little Collins Street, MELBOURNE VIC 3000

(56) Prior Art Documents
WO 92/16166
WO 91/10766
US 4923470

(57) Claim

1. A tubular prosthesis for implantation in a patient's body comprising:

a woven fabric having a plurality of superposed plies including an outer ply and an inner ply, each of said plies including a plurality of circumferentially extending fill yarns and a plurality of longitudinally extending warp yarns, and wherein each of the yarns extending in one direction continuously passes through at least two adjacent plies, and wherein said plies have a porosity sufficient to allow ingrowth of tissue while limiting leakage of fluid therefrom, and wherein at least one of said plies includes a fusible material to aid in ravel resistance.

OPI DATE 21/11/94 APPLN. ID 67139/94
AOJP DATE 05/01/9 PCT NUMBER PCT/US94/04606

AU9467139

IN

(51) International Patent Classification 5 :
A61F 2/04, 2/06

A1

(11) International Publication Number: WO 94/24960

(43) International Publication Date: 10 November 1994 (10.11.94)

(21) International Application Number: PCT/US94/04606

(22) International Filing Date: 25 April 1994 (25.04.94)

(30) Priority Data:
08/052,657 26 April 1993 (26.04.93) US

(71) Applicant: MEADOX MEDICALS, INC. [US/US]; 112 Bauer Drive, Oakland, NJ 07436 (US).

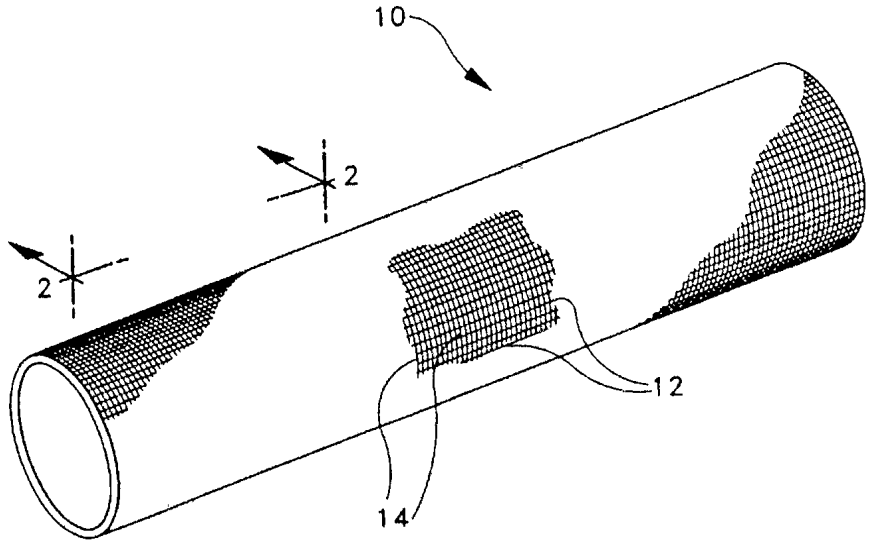
(72) Inventor: SCHMITT, Peter, J.; 2 Bubenko Drive, Garnerville, NY 10923 (US).

(74) Agents: HOFFMANN, Charles, R. et al.; Hoffmann & Baron, 350 Jericho Turnpike, Jericho, NY 11753 (US).

(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: SOLID WOVEN TUBULAR PROSTHESIS



(57) Abstract

A solid woven tubular prosthesis (10) having sufficient inherent wall stiffness so as to be radially self-supporting. The solid woven prosthesis (10) is capable of being formed with a smooth, continuous inner wall that improves the hemodynamic flow with respect to conventional woven prosthesis, thereby facilitating the flow of fluid therethrough.

SOLID WOVEN TUBULAR PROSTHESIS

BACKGROUND OF THE INVENTION

The present invention relates to tubular prostheses, and, more particularly, to woven tubular prostheses having increased wall stiffness.

In the past, tubular prostheses have commonly been manufactured by, for example, weaving a plurality of warp yarns and a plurality of fill yarns into a tubular fabric. Such products, however, typically lack sufficient radial stiffness to maintain an open lumen, i.e., if unsupported, they will radially collapse. The tendency to radially collapse or kink is particularly problematic to a surgeon during implantation of the prosthesis.

Conventional weaves used for vascular grafts and other medical devices are known as simple weaves, i.e., one-ply weaves. These types of constructions are inherently strong with respect to burst pressure, but suffer from the above-mentioned kinking and collapsing tendencies, as well as the tendency to ravel at the ends, making it difficult to properly hold sutures. Additionally, the one-ply structure has inherent limitations as to the properties which can be engineered into the final woven product. For example, simple weaves do not stretch well radially or longitudinally and, further, possess only a simple pore structure due to the single layer.

To overcome these characteristics, prior art prostheses are typically crimped at equidistant lengths along their longitudinal axis. The crimping is believed to provide the prosthesis with sufficient radial stiffness to maintain an open lumen. The crimping additionally provides a degree of longitudinal compliance to the prosthesis.

Crimping, however, is not without its disadvantages. For example, the crimps create a plurality of irregularities along the inner wall of the prosthesis that may create blood flow disturbances. These blood flow disturbances become more pronounced and consequently less acceptable as the diameter of the prosthesis is reduced. In addition, thrombi can accumulate in the valleys of the crimps, tending to form hyperplastic pockets.

An alternative prior art technique for providing radial stiffness to a woven prosthesis involves the use of a stiffening component. Specifically, the fabric is woven around a suitable stiffener or, alternatively, such a stiffener is secured to either the interior or exterior of the prosthesis following weaving. The use of a stiffener, however, creates its own drawbacks. For example, tissue ingrowth may be hindered by the stiffener, the porosity of the prosthesis may be affected by the stiffener and, finally, the ability to suture the prosthesis to the host vessel may be hindered by the stiffener.

It would therefore be desirable to provide a woven tubular prosthesis that contains sufficient inherent wall stiffness so as to be radially self-supporting. Such a graft would not require crimping or the use of stiffening components, thereby providing a smooth, continuous inner wall that better simulates the natural hemodynamics of the connecting vessels, even with respect to those prostheses having a relatively small diameter, e.g., down to about 4 mm. Additionally, the same prosthesis would be less prone to pinching, kinking or other collapsing tendencies when subjected to bending forces, as well as being resistant to ravelling when cut to size during surgery. The prosthesis would also have the ability to hold sutures well. Finally, the pore structure would be more tortuous,

thereby providing better hemostasis at the time of implantation and the ability to support long term healing and tissue incorporation.

SUMMARY OF THE INVENTION

The present invention relates to implantable multi-ply woven tubular prostheses, such as vascular grafts, intraluminal devices, such as endoprostheses, and the like.

According to one aspect the present invention provides a tubular prosthesis for implantation in a patient's body comprising:

a woven fabric having a plurality of superposed plies including an outer ply and an inner ply, each of said plies including a plurality of circumferentially extending fill yarns and a plurality of longitudinally extending warp yarns, and wherein each of the yarns extending in one direction continuously passes through at least two adjacent plies, and wherein said plies have a porosity sufficient to allow ingrowth of tissue while limiting leakage of fluid therefrom, and wherein at least one of said plies includes a fusible material to aid in ravel resistance.

Due to the potential for using materials having different characteristics for each ply, a variety of structural and property gradients can be achieved. For example, a porosity gradient from the innermost to the outermost ply can be incorporated into the prosthesis, thereby reducing blood loss yet, at the same time, encouraging tissue ingrowth and assimilation of the prosthesis into the body. Similarly, different types of yarns may be used in the interlocking plies to achieve a gradient of properties such as stiffness, compliance, texture, ravel resistance and fray resistance. This can be achieved by using, for example, different yarns or by subjecting the same or different yarns to different

AUSTRALIAN PATENT OFFICE

treatments prior to incorporation into the fabric. In one embodiment, elastomeric yarns are incorporated, in an elongated state, into the prosthesis in the warp direction such that subsequent to the weaving process the fabric will retract longitudinally, thereby providing longitudinal compliance. Other means of providing longitudinal compliance, such as heat-setting techniques, are also contemplated.

The implantable prosthetic devices of the present invention may be used in a variety of locations in the body, such as intraluminal applications in the vascular system, pulmonary system or gastrointestinal track. Of particular usefulness, however, are vascular grafts that are implanted surgically or by endoscopic means.

One embodiment of a prosthesis and a method in accordance with the invention will now be described by way of example only with reference to the accompanying drawings in which:

Fig. 1 is a perspective view of a solid woven tubular prosthesis;

Fig. 2 is a cross-sectional view taken along lines 2-2 of Fig. 1;

Fig. 3 is a cross-sectional view similar to Fig. 2 wherein each of the outermost warp yarns float over three fill yarns;

Fig. 3a depicts the prostheses of Fig. 3 after a heat-setting process in which the outermost warp yarns form a raised filamentous velour surface;

Fig. 4 is a cross-sectional view similar to Fig. 2 wherein a pair of elastomeric warp yarns have been

AUSTRALIAN PATENT OFFICE

incorporated into the prostheses; and

Fig. 4a depicts the prostheses of Fig. 4 after a heat-setting process wherein the outermost warp yarns form a raised filamentous velour surface.

DETAILED DESCRIPTION OF THE INVENTION

As mentioned above, weaving is commonly employed to fabricate tubular prostheses. Woven prostheses are ideal in that they provide strong, pressure-resistant vessels. These same grafts, however, typically require radial support through mechanical treatment, such as crimping, or through the incorporation of radial stiffening yarns.

Referring to Fig. 1, a woven tubular prosthesis 10 is shown including longitudinally-extending warp yarns 12 and circumferentially-extending fill yarns 14.

The use of several plies advantageously allows certain preferable characteristics to be designed into the prostheses. Specifically, different yarns can be used in the different plies. For example, depending on the chosen materials, a porosity gradient can be created in the wall of the prosthesis. Such a gradient resists leaking of fluid from the inner wall, yet still allows ingrowth of natural tissue into the outer wall. Moreover, because the prosthesis is a solid woven unitary structure, the discretely-designed plies are interconnected in such a fashion that the plies become inseparable and also, at the same time, may provide sufficient inherent wall stiffness to the prostheses to allow it to be radially self-supporting.

AUSTRALIAN PATENT OFFICE 13

The solid woven prosthesis of the present invention can best be understood by reference to Fig. 2, which depicts a prosthesis having three plies. Referring to Fig. 2, fill yarn 14a is located in the outermost ply, fill yarn 14b is located in the intermediate ply and fill yarn 14c is located in the innermost ply. A plurality of warp yarns 12 are solidly woven throughout these fill yarns.

Specifically, by definition each warp yarn (or fill yarn) in a solid woven prosthesis must pass continuously through, and therefore be part of, at least two adjacent plies. Of course, the design of the prosthesis may require that each warp yarn pass continuously through each and every ply. In such a case, all of the plies will have warp yarns in common to form a unitary solid structure.

In a preferred embodiment (as best shown in Fig. 2), the prosthesis is fabricated with three plies. The outermost ply preferably contains textured or filamentous materials for enhanced tissue attachment. The intermediate ply preferably contains a fusible material to aid in ravel resistance. Finally, the innermost ply preferably contains a bioresorbable material to aid in healing, long term patency and zero preclotting. Such designs, i.e., those having different properties and property gradients, cannot be created with simple, single-ply weaves as found in the prior art and conventionally employed in medical devices of this sort.

The solid woven prosthesis of the present invention may have a wall thickness greater than that of the typical prior art device, thereby providing a degree of radial support. For example, wall thicknesses may range from 0.50 mm to 1.25 mm, whereas a conventional wall thickness ranges from 0.25 mm to 0.50 mm. Moreover, the solid woven design provides greater wall stiffness and resistance to kinking

AUSTRALIAN PATENT OFFICE

or pinching, as compared to single-ply grafts due to the increased wall thickness. Notwithstanding the increased wall thickness of the multi-ply unitary construction, excellent longitudinal or axial flexibility for handling is retained. Specifically, tubular products made from this weave structure may be ~~are~~ sufficiently flexible and compliant to meet the requirements of a prosthetic implant or graft.

Because the solid woven prosthesis is radially self-supporting, crimping or the use of stiffeners is not required. As a result, the inner wall of the prosthesis can be fabricated as a smooth, continuous surface. In contrast, the inner wall of a conventional crimped one-ply prosthesis includes a plurality of irregularities or corrugations that disturb the flow of fluid therethrough, e.g., the flow of blood through an artery. This is additionally problematic because debris may collect in these irregularities causing further complications in patients with arterial disease. In larger-sized prostheses, these disturbances have little effect on the flow of fluid. However, as the diameter of the prostheses decreases, the acceptability of the disturbances decreases. The present invention, by providing a prostheses which may have ~~having~~ a smooth, continuous inner wall, overcomes this disadvantage associated with the prior art and, as a result in certain aspects, is capable of being employed to fabricate relatively small-sized prostheses.

As described below in Example 3, a solid woven texturized graft having raised velour loops can be fabricated in accordance with the present invention. Specifically, with reference to Fig. 3, prosthesis 10' is woven such that the warp yarns located at the outer-most surface pass externally over at least two fill yarns. For example, warp yarn 12' passes over fill yarns $14a_1$, $14a_2$ and $14a_3$. The "loose" surface weave allows these

AUSTRALIAN PATENT OFFICE

warp yarns to rise from the surface following heat-setting, thereby forming a filamentous velour surface as shown in Fig. 3a.

In an additional embodiment, as described below in Example 4, at least one elastomeric warp yarn 16 is incorporated into the fabric. Prosthesis 10" is woven with the elastomeric warp yarns in a stretched state such that subsequent to weaving the fabric will longitudinally retract, thereby providing a degree of longitudinal compliance. Longitudinal compliance assists the surgeon in sizing the length of the prosthesis for implantation and also provides a degree of flexibility to the prosthesis following implantation.

Following manufacture and treatment, the prosthesis is sealed in a package. The package, along with the prosthesis contained therein, is then subjected to a sterilization procedure, e.g., a radiation procedure, a heat procedure, etc. Alternately, the prosthesis may be sterilized prior to being sealed in its packaging or may be sterilized by the physician performing the implant operation at the time of such surgery.

EXAMPLES

Examples of polymeric materials useful in the present invention include, without limitation, yarns made from polyester, polypropylene, polytetrafluoroethylene, polyethylene, polyurethane and resorbable polymers.

The following examples serve to provide further appreciation of the invention but are not meant in any way to restrict the effective scope of the invention.

EXAMPLE 1 - 3 PLY SOLID WOVEN

The following specifications are used to fabricate a solid woven prosthesis of the present invention.

Weave	-	3 Ply Solid Woven (Triple Plain), tubular
Warp Yarn	-	Textured 50 denier/48 filament polyester
Fill Yarn	-	2 ply/textured 50 denier/48 filament polyester
Ends per inch	-	160
Picks per inch	-	200

Subsequent to weaving the prosthesis, the material is scoured in a basic solution of warm water (e.g., 150°F) and cleaning detergent. It is then rinsed to remove the cleaning agents. Next, the prosthesis is heat-set on mandrels of the final desired inside diameter. Typically, the outside diameter of the mandrel is approximately equal to the diameter of the final prosthesis. The woven tubing is woven to be 5-15% oversize so that it can be mounted onto a mandrel and shrink fitted to an exact diameter. Heat-setting can take place in a steam heated autoclave at about 250°F for about 5-10 minutes or in a convection oven at 250-400°F for about 10-30 minutes.

EXAMPLE 2 - 3 PLY SOLID WOVEN WITH LONGITUDINAL COMPLIANCE

The following specifications are used to fabricate a solid woven prosthesis of the present invention.

Weave	-	3 Ply Solid Woven (Triple Plain), tubular
Warp Yarn	-	Textured 50 denier/48 filament polyester
Fill Yarn	-	2 ply/textured 50 denier/48 filament polyester
Ends per inch	-	160
Picks per inch	-	160

Subsequent to weaving the prosthesis, the material is scoured in a basic solution of warm water (e.g., 150°F) and cleaning detergent. It is then rinsed to remove the cleaning agents. Next, the prosthesis is heat-set on mandrels of the final desired inside diameter. Typically, the outside diameter of the mandrel is equal to the diameter of the final prosthesis. The woven tubing is woven to be 5-15% oversize so that it can be mounted onto a mandrel and shrink fitted to an exact diameter.

Heat-setting can take place in a steam heated autoclave at about 250°F for about 5-10 minutes or in a convection oven at 250-400°F for about 10-30 minutes. The

heat-setting can be done in a two-step process. The first step involves heat-setting the prosthesis in its fully extended state to shrink fit the prosthesis snugly to the mandrel. The second heat-setting step entails compressing the prosthesis longitudinally. The compression is on the order of 25-50%. The prosthesis is then heat-set a second time using at least the same conditions as in the first heat-setting cycle.

As a result of the heat-setting, the warp yarns buckle and crimp. The heat locks the yarns in this geometry to build in "spring like" or elastomeric properties.

EXAMPLE 3 - 3 PLY SOLID WOVEN WITH LONGITUDINAL COMPLIANCE AND EXTERNAL VELOUR

The following specifications are used to fabricate a solid woven prosthesis of the present invention.

Weave	-	3 Ply Solid Woven, Tubular with 3 filling floats on outer ply
Warp Yarn	-	Textured 50 denier/48 filament polyester
Fill Yarn	-	2 ply/textured 50 denier/48 filament polyester
Ends per inch	-	160
Picks per inch	-	160

Subsequent to weaving the prosthesis, the material is scoured in a basic solution of warm water (e.g., 150°F) and cleaning detergent. It is then rinsed to remove the cleaning agents. Next, the prosthesis is heat-set on mandrels of the final desired inside diameter. Typically, the outside diameter of the mandrel is equal to the diameter of the final prosthesis. The woven tubing is woven to be 5-15% oversize so that it can be mounted onto a mandrel and shrink fitted to an exact diameter.

Heat-setting can take place in a steam heated autoclave at about 250°F for about 5-10 minutes or in a convection oven at 250-400° for about 10-30 minutes. The heat-setting can be done in a two-step process. The first step involves heat-setting the prosthesis in its fully extended state to shrink fit the prosthesis snugly to the mandrel. The second heat-setting step entails compressing the prosthesis longitudinally. The compression is on the order of 25-50%. The prosthesis is then heat-set a second time using at least the same conditions as in the first heat-setting cycle.

As a result of the heat-setting, the warp yarns buckle and crimp. The heat locks the yarns in this geometry to build in "spring like" properties. The warp yarns in the outer ply which are floating over 3 picks, would raise from the fabric, forming a filamentous velour surface.

EXAMPLE 4 - 3 PLY SOLID WOVEN WITH ELASTOMERIC COMPONENTS TO PROVIDE LONGITUDINAL COMPLIANCE

The following specifications are used to fabricate a solid woven prosthesis of the present invention.

Weave	-	3 Ply Solid Woven, Tubular with 3 filling floats on outer ply
Warp Yarn	-	Textured 50 denier/48 filament polyester & 140 denier Lycra Spandex
Fill Yarn	-	2 ply/textured 50 denier/48 filament polyester
Ends per inch	-	160 of polyester, 20 of spandex
Picks per inch	-	160

The tubing is woven to include an elastomeric yarn in the warp direction, such as Lycra Spandex from DuPont. The elastomeric yarn is woven into the fabric by inserting it between the first and second plies. The elastomeric yarn is woven in a stretched state, so that after weaving the fabric will retract longitudinally. The elastomeric yarn provides the longitudinal compliance to the graft.

Subsequent to weaving the prosthesis, the material is scoured in a basic solution of warm water (e.g., 150°F) and cleaning detergent. It is then rinsed to remove the cleaning agents. The scouring process allows the woven tubing to fully retract by relieving the stress induced by weaving the elastomeric warp yarns in a stressed state.

The prosthesis is heat-set on mandrels of the final desired inside diameter. Typically, the outside diameter of the mandrel is equal to the diameter of the final prostheses. The tubing is woven to be 5-15% over-size so that it can be mounted onto a mandrel and shrink fitted to an exact diameter. Heat-setting can take place in a steam heated autoclave at about 250°F for about 5-10 minutes or in a convection oven at 250-400°F for about 10-30 minutes.

The warp yarns in the outer ply which are floating over 3 picks, are raised from the fabric, forming a filamentous velour surface. Longitudinal compliance on the order of 25-50% can be achieved by this method.

Thus, while there have been described what are presently believed to be the preferred embodiments of the invention, those skilled in the art will realize that various changes and modifications may be made to the invention without departing from the spirit of the invention, and it is intended to claim all such changes and modifications which fall within the scope of the invention.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

AUSTRALIAN PATENT OFFICE

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A tubular prosthesis for implantation in a patient's body comprising:

a woven fabric having a plurality of superposed plies including an outer ply and an inner ply, each of said plies including a plurality of circumferentially extending fill yarns and a plurality of longitudinally extending warp yarns, and wherein each of the yarns extending in one direction continuously passes through at least two adjacent plies, and wherein said plies have a porosity sufficient to allow ingrowth of tissue while limiting leakage of fluid therefrom, and wherein at least one of said plies includes a fusible material to aid in ravel resistance.

2. A prosthesis according to Claim 1, wherein said woven fabric has a thickness of about 0.5mm to about 1.25mm.

3. A prosthesis according to Claim 1 or Claim 2, wherein said woven fabric is heat-set whereby said woven fabric undergoes a period of controlled shrinkage.

4. A prosthesis according to Claim 3, wherein said woven fabric is heat-set in an elastically compressed position to provide said woven fabric with longitudinal compliance.

5. A prosthesis according to any one of Claims 1 to 4, wherein said plies are formed from non-homogeneous materials whereby physical properties of said outer ply differ from physical properties of said inner ply.

6. A prosthesis according to Claim 5, wherein said plurality of plies create a porosity gradient between said outer ply and said inner ply.

7. A prosthesis according to Claim 6, wherein the

AUSTRALIAN PATENT OFFICE

porosity of said woven fabric at said outer ply is greater than the porosity of said woven fabric at said inner ply.

8. A prosthesis according to Claim 5, wherein said outer ply is formed from a textured material to facilitate tissue attachment.

9. A prosthesis according to Claim 8, wherein said warp yarns in said outer ply form a filamentous velour surface.

10. A prosthesis according to Claim 5, wherein at least one of said warp yarns is an elastomeric polymer.

11. A prosthesis according to Claim 1, further comprising a middle ply, and wherein said outer ply is formed from a filamentous material for enhanced tissue attachment, said middle ply is formed from said fusible material, and said inner ply is formed from a bioresorbable material to aid in healing.

12. A prosthesis according to Claim 1, wherein said prosthesis is formed with a smooth continuous inner surface to facilitate flow of fluid therethrough.

13. A prosthesis substantially as hereinbefore described with reference to the drawings and/or Examples.

Dated this 6th day of May, 1996.
MEADOX MEDICALS, INC.
by its Patent Attorneys
DAVIES COLLISON CAVE

AUSTRALIAN PATENT OFFICE 13

6713 9/14

FIG-1

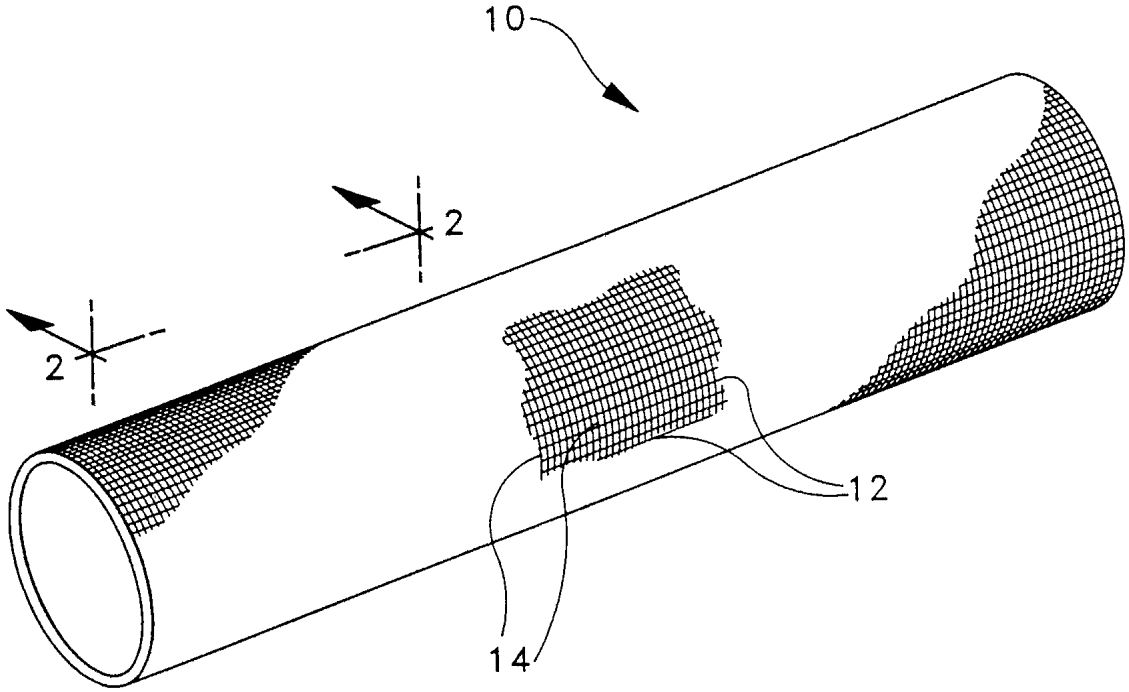


FIG-2

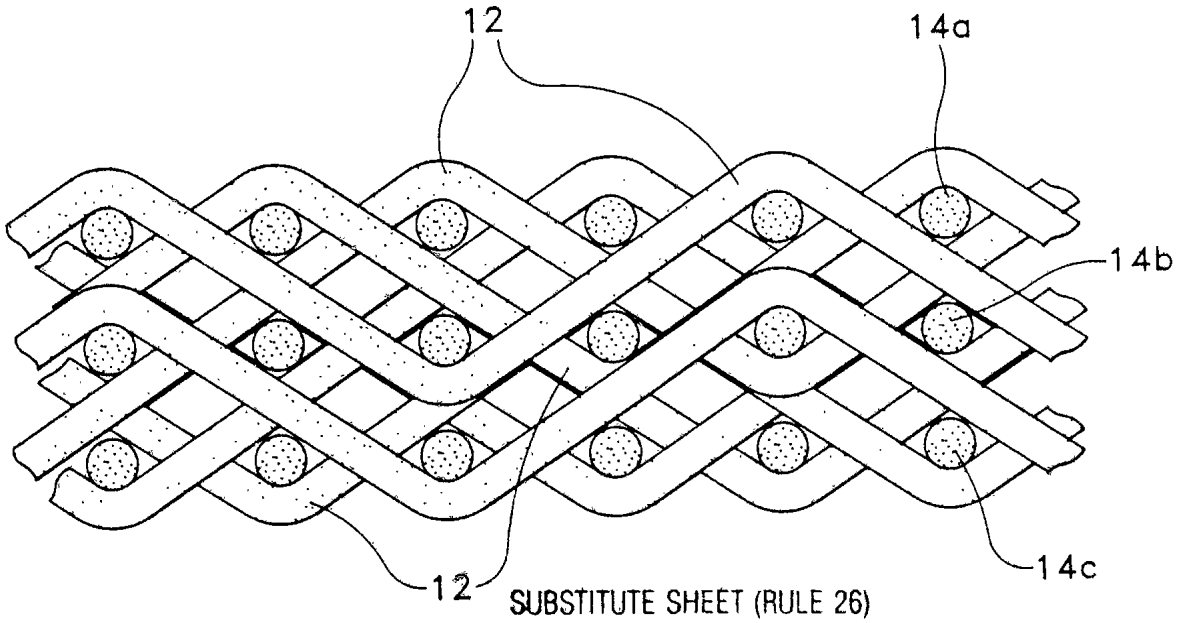


FIG-3

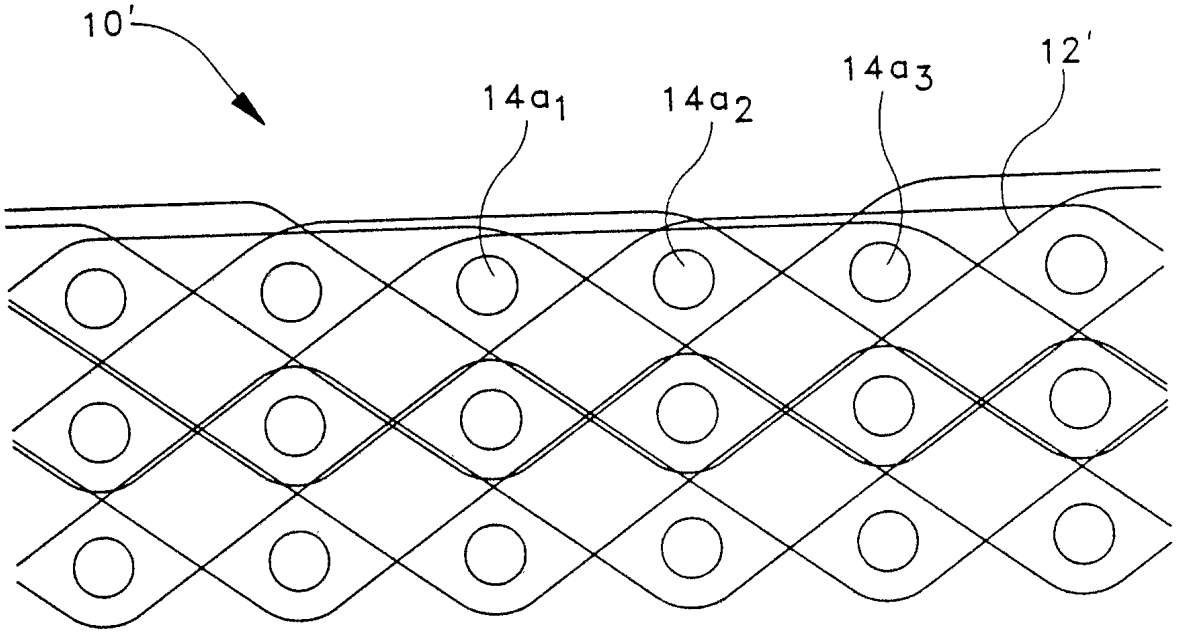


FIG-3a

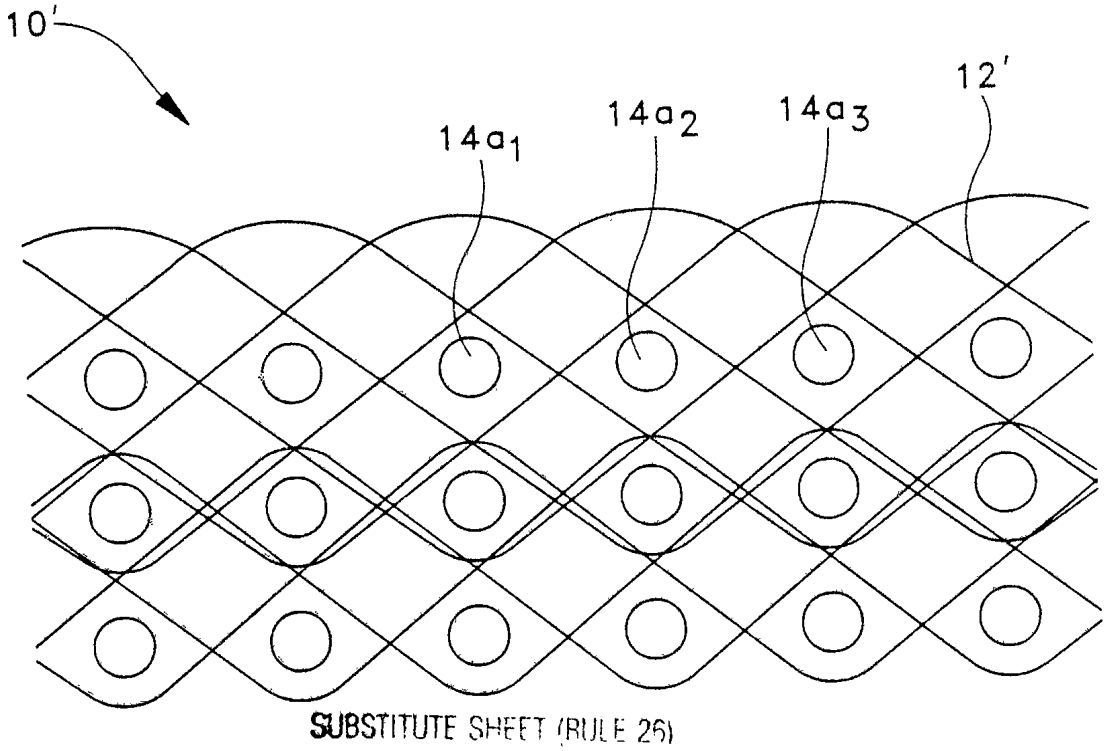


FIG-4

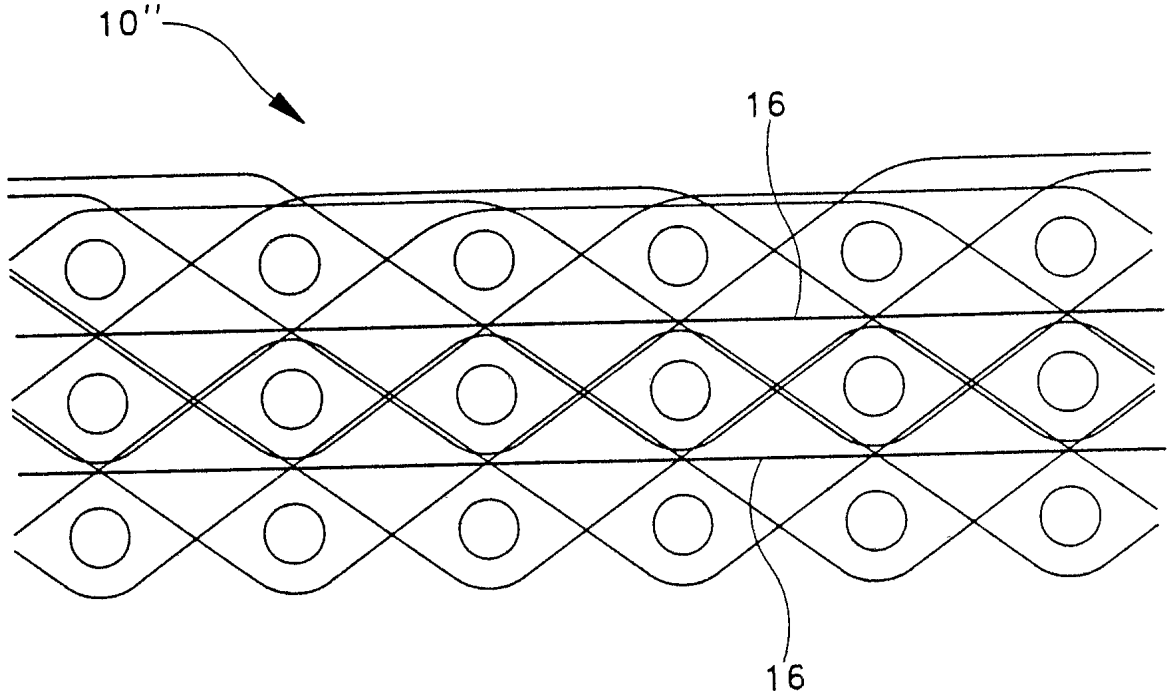
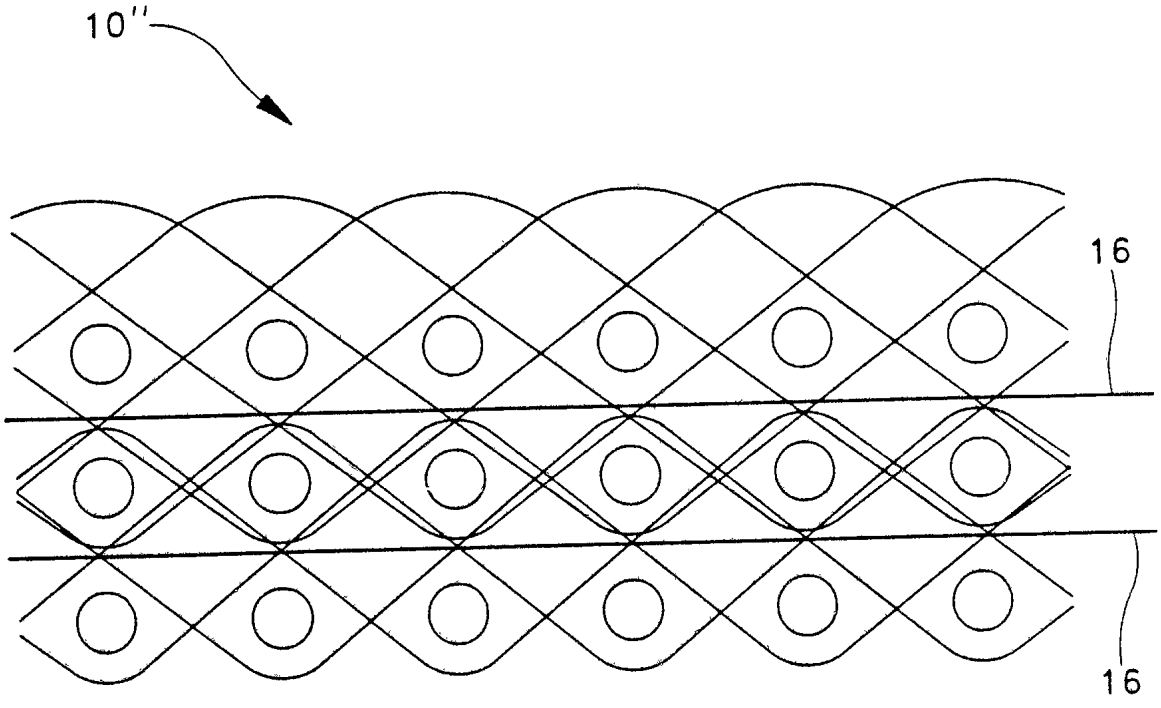


FIG-4a



INTERNATIONAL SEARCH REPORT

In. ational application No.
PCT/US94/04606

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 2/04, 2/06
US CL :600/36; 623/1, 12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/36; 606/192-200; 623/1, 11, 12

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

NONE

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

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO, A, 92/16166, (BROOKSTEIN ET AL.), 01 October 1992.	1-24
A	WO, A, 91/10766, (BROOKSTEIN ET AL.), 25 July 1991.	1-24
A	US, A, 4,923,470, (DUMICAN), 08 May 1990.	1-24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 26 MAY 1994	Date of mailing of the international search report 27 JUL 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FOR DEBRA S. BRITTINGHAM Telephone No. (703) 308-3401

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