



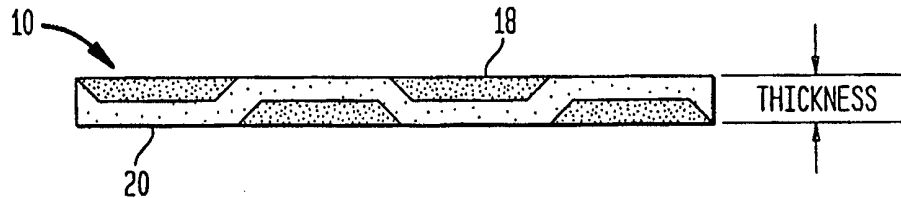
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<p>(21) International Application Number: PCT/US00/02404 (22) International Filing Date: 31 January 2000 (31.01.00) (30) Priority Data: 60/123,111 5 March 1999 (05.03.99) US 09/420,038 18 October 1999 (18.10.99) US (71) Applicant: DATASCOPE INVESTMENT CORP. [US/US]; 14 Philips Parkway, Montvale, NJ 07645 (US). (72) Inventor: DU, George, W.; 4142 La Salle Drive, Palm Harbor, FL 34685 (US). (74) Agent: RONAI, Abraham; Datascope Corp., 14 Philips Parkway, Montvale, NJ 07645 (US).</p>	<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	

(54) Title: ULTRA-THIN LOW POROSITY ENDOVASCULAR GRAFT

(57) Abstract

An ultra-thin endovascular graft having a low rate of water permeation. The woven graft fabric (10) comprises untwisted non-slashed multifilament warp yarns (18) and fill yarns (20) capable of fluttering upon weaving.



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5 **TITLE: ULTRA-THIN LOW POROSITY ENDOVASCULAR GRAFT**

BACKGROUND OF THE INVENTION

1. Field of the Invention

10 The invention relates to a woven fabric for an endovascular application. More particularly, the invention relates to an ultra-thin low porosity woven fabric for use in endovascular grafts.

15 2. Description of the Prior Art

An abdominal aortic aneurysm (AAA) is a sac caused by an abnormal dilatation of the wall of the aorta as it passes through the abdomen. The aorta is the main artery of the body, supplying blood to all organs and parts of the body except the lungs. It arises from the left ventricle of the heart, passes upward, bends over and passes down through the thorax and through the abdomen, and finally divides into the iliac arteries which supply blood to the pelvis and lower extremities.

25 The AAA ordinarily occurs in the portion of the aorta below the kidneys. When left untreated, the aneurysm will eventually cause the sac to rupture with ensuing fatal hemorrhaging in a very short time. The repair of abdominal aortic aneurysms has typically required major abdominal surgery in which the diseased and aneurysmal segment of the aorta is bridged with a prosthetic device, such as a synthetic graft.

35 As with all major surgeries, there are many disadvantages to the above mentioned surgical technique, the foremost of which is the high mortality and morbidity rate associated with

5 surgical intervention of this magnitude. Other disadvantages
of conventional surgical repair include the extensive recovery
period associated with such surgery; difficulties in suturing
the graft to the aorta; the unsuitability of the surgery for
many patients, particularly older patients exhibiting comorbid
10 conditions; and the problems associated with performing the
surgical procedure on an emergency basis after the aneurysm
has already ruptured.

In view of the above mentioned disadvantages of
conventional surgical repair techniques, techniques have been
15 developed for repairing AAAs by intraluminally delivering an
aortic graft to the aneurysm site through the use of a
catheter based delivery system, and securing the graft within
the aorta using an expandable stent. Since the first
documented clinical application of this technique was reported
20 by Parodi et al. in the Annals of Vascular Surgery, Volume 5,
pages 491-499 (1991), the technique has gained more widespread
recognition and is being used more commonly.

Use of the stent/graft deployment catheter eliminates the
problem of suturing the graft to the aorta associated with
25 surgical repair techniques. However, use of the catheter
still requires a cut-down surgery to locate and expose the
blood vessel, and thus, the patient recovery time is still
quite long. Therefore, the need exists for a stent/graft
deployment catheter and a stent/graft which are small enough
30 to be inserted percutaneously into the blood vessel of the
patient. The term stent/graft, as herein used, refers to a
stent and graft assembly, a stent alone, or a graft alone. A
percutaneous procedure would avoid the surgery necessary to
locate the blood vessel and thereby decrease patient recovery
35 time significantly. The presence of such a catheter and

5 stent/graft on the market may finally allow for the full
transition from the currently used surgical cut-down method of
stent/graft insertion to the much preferred percutaneous
insertion method. As of yet, such a catheter has not appeared
on the market because of the difficulty inherent in designing
10 a catheter and stent/graft small enough to be inserted
percutaneously. The present invention discloses a graft
material which is greater than 50% thinner than prior art
graft materials, and thus, given the existence of an
appropriately sized stent/graft deployment catheter, capable
15 of percutaneous insertion.

Various synthetic vascular grafts have been proposed to
replace, bypass or reinforce, diseased or damaged sections of
a vein or artery. Commonly, tubular grafts have been formed
from knitted or woven continuous filament polyester fiber
20 (Dacron Registered TM) and from expanded
polytetrafluoroethylene (PTFE).

The performance of a vascular graft is influenced by a
variety of characteristics such as strength, permeability,
tissue ingrowth, and ease of handling. A graft should be
25 sufficiently strong: (a) to prevent the sidewalls from bursting
when blood is flowing through the device even at high blood
pressures; and (b) to maintain the patency of the vessel
lumen. Furthermore, a graft sidewall must be sufficiently
impervious to blood to prevent hemorrhaging as blood flows
30 through the graft.

Expanded grafts are inherently leak resistant. Woven and
knitted grafts, on the other hand, may require sealing of the
openings between adjacent interlacings to prevent blood
leakage. Sealing of said openings may be accomplished through
35 a pre-clotting procedure. Pre-clotting involves immersing a

5 woven or knitted graft in the patient's blood and then
allowing the graft to dry until the interstices in the graft
fabric become filled with the clotted blood. Another common
technique for sealing the above mentioned openings is to coat
10 the graft with an impervious material such as albumin,
collagen or gelatin. Tissue ingrowth through the interstices
of the graft is believed to nourish and organize a thin
neointima lining on the inner surface of a graft, preventing
clotting of blood within the lumen of the graft which could
occlude the graft. A velour surface may be provided on the
15 outer surface of a woven or a knitted graft to encourage
tissue infiltration. The pore size of a graft also influences
tissue ingrowth. Although larger openings facilitate tissue
penetration, pre-clotting or coating of the graft may be
adversely affected as pore size increases.

20 Ease of handling is another important feature of an
vascular graft. A flexible and conformable graft facilitates
placement of the prosthesis by the surgeon. Increased
elasticity, particularly of woven grafts has been achieved by
crimping the graft. Crimping also improves resistance to
25 kinking when the graft is bent or twisted. Woven and knitted
grafts generally have been formed from continuous filament
polyester yarns which typically are textured prior to
fabrication to impart bulk and stretch to the vascular graft
fabric. A technique known as false twist texturizing has been
30 employed which involves the steps of twisting, heat setting
and then untwisting the continuous multifilament yarns,
providing substantially parallel, wavy filaments.

Graft selection for a particular application has
therefore involved trade-offs and compromises between one or
35 more of the above properties. Expanded PTFE grafts provide

5 strong structures which are non-porous and impervious to blood leakage. The absence of pores, however, precludes tissue ingrowth. Expanded PTFE grafts also may be stiff and nonconforming which detrimentally affects handleability. Knitted grafts have attractive tissue ingrowth and
10 handleability features. The porous structure of knitted grafts, however, requires that the graft be pre-clotted or coated to prevent hemorrhaging. Woven grafts are less porous than knitted grafts and may not require pre-clotting or coating. The tightly compacted weave structure, however, may
15 provide a stiff prosthetic which is not as conformable or as easily handled as is a knitted graft.

The major constraints involved in designing a percutaneously insertable woven endovascular graft, the focus of the present invention, are thickness and porosity/water
20 permeability. It is convenient to refer to the rate of water permeation through the graft fabric as a standard measure. The rate of water permeation is defined here as the amount (ml/minute) of water permeating through one square centimeter of the surface of a graft under 120 mm Hg of pressure. To
25 prevent blood leakage into a graft the rate of water permeation should be below 500 ml/min/cm². Conventional woven vascular grafts require a woven fabric thickness of thicker than 0.25 mm in order to achieve a rate of water permeation of lower than 500 ml/min/cm². Although this limitation is
30 acceptable for bypass vascular grafts where the bulkiness of the fabric is not critical, it imposes a significant problem with respect to using woven fabrics for endovascular stent/grfts. In order to load a stent/grft device onto a percutaneous delivery system, the woven graft fabric used must
35 be in the order of thinner than 0.1 mm, which is on average 3

5 to 6 times thinner than that of conventional bypass vascular grafts. Currently, the weaving technology for making such a thin fabric (<0.1 mm) with low porosity (water permeability lower than 500 ml/min/cm²) is not available.

10 The present invention accomplishes a dramatic reduction in graft woven fabric thickness through the use of non-slashed untwisted yarn. For practical purposes most textiles are generally woven from twisted yarns. Grafts are generally manufactured with at least the warp yarn twisted. Twisting of the yarns acts to bond all the filaments, making up the yarn,
15 together. Bonding of the filaments is important because it assures that if a portion of one filament breaks along its length it does not simply fall out or hang loose from the woven fabric. It is important for most fabrics that surface abrasion, whether during the weaving process itself or during
20 actual use of the fabric, does not cause the woven fabric to easily fall apart.

Attempts have been made to increase the flexibility of grafts, while still maintaining a rate of water permeation of less than 500 ml/min/cm², by forming the prosthesis from very
25 thin fibers having less than one denier per filament ("micro-denier"). Use of these thin fibers results in an overall thinner graft. Representative are U.S. Pat. Nos. 4,695,280 and 4,743,250 which disclose artificial vascular grafts which have been formed from a combination of
30 micro-denier filament yarns and larger yarns. Use of microfilament yarns may achieve graft thickness of less than 0.1 mm, however the water permeability of such grafts is significantly greater than 500 ml/min/cm², and the grafts may chemically degrade over a long period of time. Presently,
35 there is no reliable clinical data available to support the

5 use of filaments with linear density of 1.0 denier or less.
All commercially available textile vascular grafts are made of
polyester yarns having a minimum filament linear density of
approximately 1.5 denier, such as 40/27 Dacron (40/27 is
shorthand for a 40 denier yarn having 27 filaments of 1.48
10 denier each).

While the micro-filament artificial vascular grafts may
be suitable for the particular purpose employed, or for
general use, they would not be as suitable for the purposes of
the present invention as disclosed hereafter.

15

SUMMARY OF THE INVENTION

Accordingly, it is an object of the invention to produce
an ultra-thin endovascular graft appropriate for percutaneous
20 insertion.

It is another object of the invention to produce a graft
fabric having a low porosity, and thus, a low rate of water
permeation.

The invention is an ultra-thin endovascular graft having
25 a low rate of water permeation. The woven graft fabric
comprises untwisted non-slashed multifilament yarns capable of
flattening upon weaving.

To the accomplishment of the above and related objects
the invention may be embodied in the form illustrated in the
30 accompanying drawings. Attention is called to the fact,
however, that the drawings are illustrative only. Variations
are contemplated as being part of the invention, limited only
by the scope of the claims.

35

BRIEF DESCRIPTION OF THE DRAWINGS

5

In the drawings, like elements are depicted by like reference numerals. The drawings are briefly described as follows.

10 FIG 1 is a plan view of a prior art graft fabric woven with twisted yarns.

FIG 1A is a cross section view of the fabric illustrated in FIG 1 taken along lines 1A-1A.

15 FIG 2 is a plan view of an improved graft fabric woven with non-twisted yarns.

FIG 2A is a cross sectional view of the fabric illustrated in FIG 2 taken along lines 2A-2A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20

In conventional woven graft design, textile yarns with a substantial level of twist, at least in the warp direction, are used to construct the graft fabric. Due to the existence of twist, the cross sectional shape of woven yarns is either
25 round or ellipse, depending on the level of twist and the compacting motion the yarns are subjected to during and after weaving.

FIG 1 illustrates a plan view of a prior art woven graft fabric, designated generally 10, comprising a plurality of
30 twisted warp yarns 12 and twisted fill yarns 14 woven together in a conventional 1/1 plain weave.

FIG 1A illustrates a cross section of the woven fabric 10 taken along lines 1A-1A. It can be seen in FIG 1A that the thickness of the woven fabric 10, labeled Thickness, equals
35 approximately the sum of both the twisted warp yarn 12 and the

5 twisted fill yarn 14 thicknesses. The presence of twist on
the yarns makes them generally rigid and incompressible.
Therefore, upon weaving, the twisted incompressible yarns
maintain their round-ellipse cross sectional shape rather than
flattening out. The presence of twist on yarns 12 and 14, and
10 the resultant round-ellipse cross sectional shape of yarns 12
and 14, aside from preventing flattening, also results in the
introduction of unnecessary large interstices 16 between the
yarns 12 and 14, as shown in Figure 1.

Based on the Kozeny-Carmen flow model, water permeability
15 has the following expression:

$$WP \propto \frac{d^2}{\sqrt{t}} \cdot \frac{\varepsilon^3}{(1-\varepsilon)^2} \quad (1)$$

20 Equation (1) indicates that the effect of both fabric porosity
(ε) and filament diameter (d) on water permeability (WP) is
significantly greater than that of fabric thickness (t).
Accordingly, the large yarn interstices 16, which are present
25 due to the twist on the yarns 12 and 14, significantly raises
the water permeability of the graft fabric 10 by increasing
the level of fabric porosity.

In order to assure that the water permeability level
remains below 500 ml/min/cm², grafts are usually made with a
30 thickness greater than 0.1 mm. In clinical practice, surgical
grafts thicker than 0.1 mm are not problematic and in most
cases are necessary for required strength. However, grafts
thicker than 0.1 mm are considered too bulky for endovascular
applications. Use of microfilament yarns in a twisted format,
35 such as 30/30 (30 denier with 30 filaments of 1.0 denier each)

5 polyester yarns, may achieve graft thickness of less than 0.1
mm. However, the water permeability of such a graft is
significantly greater than 500 ml/min/cm², and the graft may
chemically degrade over a long period of time. Presently,
there is no reliable clinical data available to support the
10 use of filaments with linear density of 1.0 denier or less.
All commercially available textile vascular grafts are made of
polyester yarns having a minimum filament linear density of
approximately 1.5 denier, such as 40/27 Dacron.

As discussed above, the best solution to the problem of
15 reducing the fabric thickness (t) while maintaining (or even
lowering) the level of water permeability (WP) and the linear
density of polyester filaments is to lower the fabric porosity
(e). The most efficient method in eliminating the void
content of the graft fabric 10 is to reduce the dimension of
20 the yarn interstices 16, as explained above. This invention
provides a unique method to make woven vascular grafts thinner
(≤ 0.1 mm) and less porous (water permeability lower than
500 ml/min/cm²) than current commercially available vascular
grafts.

25 FIG 2 illustrates a plan view of an improved ultra-thin
graft fabric 10. The graft fabric 10 comprises a plurality of
non-twisted warp yarns 18 and a plurality of non-twisted fill
yarns 20 woven together in a conventional 1/1 plain weave.
Both the warp yarns 18 and the fill yarns 20 used to weave the
30 graft fabric 10 are multifilament polymeric yarns, textured or
flat, non-twisted or only slightly twisted, with a surface
twist angle of less than approximately 5 degrees, but
preferably non-twisted. The linear densities for the warp
yarns 18 and fill yarns 20 may be different or identical,
35 depending on the weavability and design of woven construction.

5 The number of filaments within the yarns 18 and 20 should be sufficient, preferably more than 20 filaments per yarn, for the yarns 18 and 20 to change their cross-sectional shapes, i.e. flatten, during and after weaving. The yarns 18 and 20 are capable of changing their shape during and after weaving
10 because they are non-twisted and non-slashed, i.e. have not gone through the slashing process. The filaments of non-slashed yarn are not bound together by an adhesive, and therefore, can change shape during and after weaving. The weave pattern can be plain, twill, satin or sateen, but
15 preferably 1/1 plain weave because it has the highest degree of interlacing. The surface of a graft, made from the graft fabric 10, can be smooth or a single or double velour, but preferably smooth because the presently disclosed graft fabric 10 is intended for an endovascular application. Constructing
20 and arranging the graft fabric 10 into a tubular configuration, having a lumen for conveying blood therethrough, is well known in the art. In order to achieve optimal fabrication results sufficient yarn tensions should be applied during the weaving process, followed by compacting and
25 heat-setting the graft fabric 10 on appropriate mandrels at a raised temperature above the glass transition temperature and below the melting temperature. Note that use of non-twisted yarn in only one of the directions in the graft fabric 10, warp or fill, is also anticipated.

30 The non-existence of yarn twists (or the presence of a small amount of twist) and the large number of filaments allows the yarns 18 and 20 to form desirable cross-sections close to an idealized equilateral trapezoidal shape, which practically eliminates the interstices 16 between the yarns 18
35 and 20, as illustrated in FIG 2. As depicted in FIG 2A, the

5 flattened yarn cross-section, which has an idealized
 Equilateral Trapezoidal shape, not only eliminates the yarn
 interstices 16, but also results in a significantly thinner
 woven structure. The following example provides a strong
 evidence for all the claims detailed above. It is to be
 10 understood, however, that the examples are included for
 illustrative purposes only and are not intended to limit the
 scope of the invention as set forth in the accompanying
 claims. Design I uses a conventional approach in which
 twisted warp and twisted fill yarns are used. The objective
 15 of Design II is to reduce the graft thickness to half, while
 maintaining or even lowering the water permeability by using
 non-twisted yarns as suggested by this invention.

	<u>Design I</u>	<u>Design II</u>
	<u>(Conventional)</u>	<u>(This Invention)</u>
20	Warp/Filling Yarns	40 denier/27 fila.
		40 denier/27 fila.
25		Dacron 56
	Dacron 56	
	Yarn Twist	7.5 tpi
		0.0 tpi (non-twisted)
	Warp Density	316 ends/inch
		128 ends/inch
30	Filling Density	88 picks/inch
		128 picks/inch
	Area Density	404 yarns/square inch
		256 yarns/square inch
	Weave Pattern	1/1 plain
		1/1 plain
	Graft Diameter	24 mm
		24 mm
	Graft Thickness	0.145 mm
35	(measured)	0.070 mm
	Water Permeability	523 ml/min/cm ²
	(measured)	319 ml/min/cm ²

5 As shown in the above Table, despite the fact that the Design
I graft has an area density (404 yarns/square inch)
approximately 60% higher than that of the Design II graft (256
yarns/square inch), and a thickness (0.145 mm) of over 200%
the thickness of the Design II graft (0.070 mm), its water
10 permeability is measured to be above 60% higher. This example
demonstrates that by using the approach based on this
invention, it is possible to make woven endovascular grafts
much thinner than 0.1 mm with a water permeability lower than
500 ml/min/cm².

15 As many apparently widely different embodiments of the
present invention can be made without departing from the
spirit and scope thereof, it is to be understood that the
invention is not limited to the specific embodiments thereof
except as defined in the appended claims.

20

5

CLAIMS

What is claimed is:

1.A woven graft comprising substantially non-twisted yarns in both the warp and fill directions.

10

2.The graft as claimed in claim 1 wherein the graft is a woven vascular graft.

3.The woven vascular graft as claimed in claim 2 wherein the non-twisted yarns are polymeric, non-slashed, and have at least ten filaments per yarn.

15

4.A woven graft comprising twisted fill yarns and substantially non-twisted warp yarns.

5.The graft as claimed in claim 4 wherein the graft is a woven vascular graft.

20

6.The woven vascular graft as claimed in claim 5 wherein the non-twisted warp yarns are polymeric, non-slashed, and have at least ten filaments per yarn.

7.A woven graft comprising warp yarns and fill yarns each having a surface twist angle of less than about 5 degrees.

8.The graft as claimed in claim 7 wherein the graft is a woven vascular graft.

9.The woven vascular graft as claimed in claim 7 wherein the warp yarns and the fill yarns are polymeric, non-slashed, and have at least ten filaments per yarn.

10.A woven graft comprising warp yarns and fill yarns, said warp yarns having a surface twist angle of less than about 5 degrees.

11.The graft as claimed in claim 10 wherein the graft is a woven vascular graft.

12.The woven vascular graft as claimed in claim 11 wherein the warp yarns are polymeric, non-slashed, and have at least ten filaments per yarn.

13. A woven graft comprising at least two non-twisted interwoven yarns.
14. The graft as claimed in claim 13 wherein the graft is a woven vascular graft.
15. The graft as claimed in claim 13 wherein at least one of the yarns is polymeric, non-slashed, and has at least ten filaments per yarn.
16. The graft as claimed in claims 1, 4, 7, 10, 13, and 14 wherein the graft has a thickness of less than approximately 0.14 mm.
17. The graft as claimed in claim 1, 4, 7, 10, 13, and 14 wherein the graft has a thickness of less than approximately 0.070 mm.
18. The graft as claimed in claim 1, 4, 7, 10, 13, and 14 wherein the warp and fill yarns each being 40 denier and having 27 filaments.
19. The graft as claimed in claim 1, 4, 7, 10, 13, and 14 having a water permeability of less than about 523 ml/min/cm².

FIG. 1
(PRIOR ART)

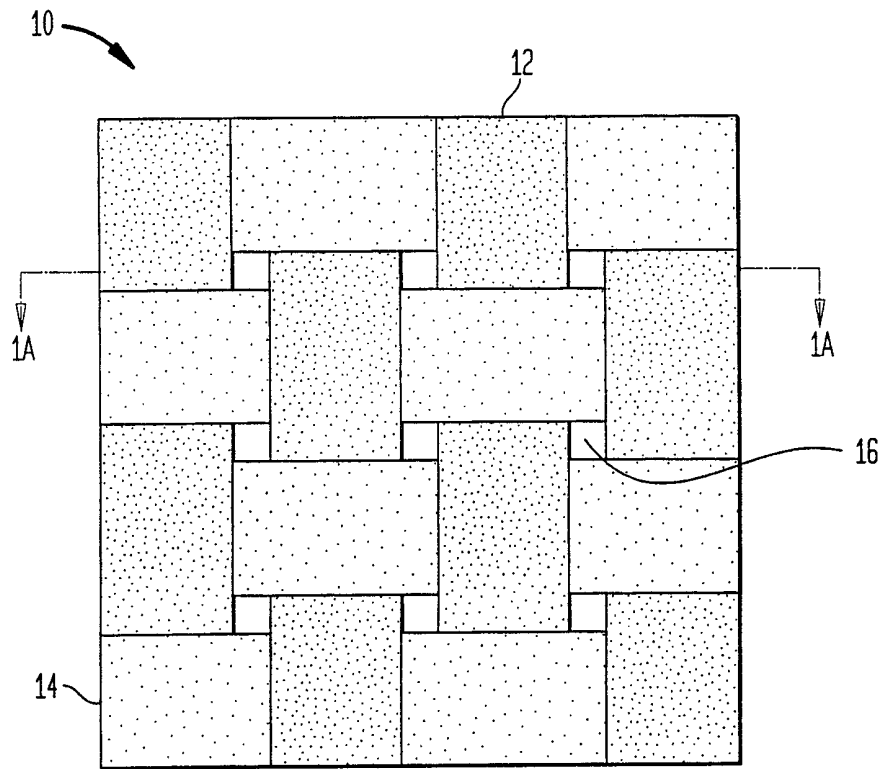


FIG. 1A
(PRIOR ART)

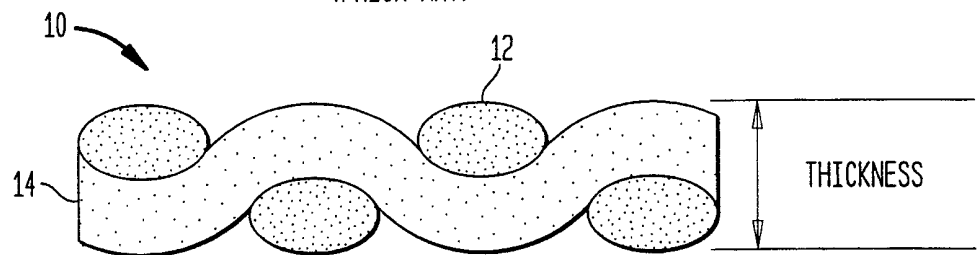


FIG. 2

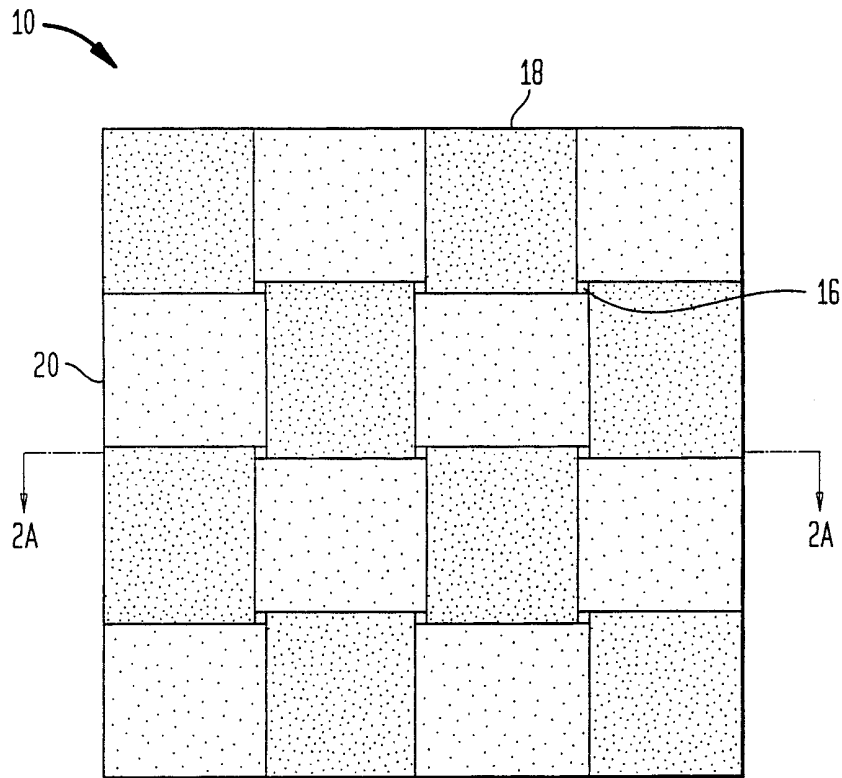
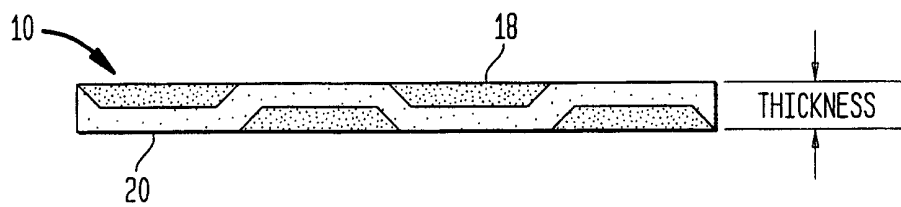


FIG. 2A



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/02404

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

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

B. FIELDS SEARCHED

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

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 191 218 A (CLARK RICHARD E ET AL) 4 March 1980 (1980-03-04) claims 8,10; figures 9,10 column 1, line 17 - line 23 column 3, line 16 - line 32 column 7, line 4 - line 44	1-3,7-17
A	---	4-6,18
X	GB 1 173 811 A (WILLIAM JOHN LIEBIG) 10 December 1969 (1969-12-10) claims 1,6; figures 1,4 page 5, line 35 - line 94	1-3, 7-15,19
A	---	4-6,18
	-/--	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search

Date of mailing of the international search report

29 June 2000

07/07/2000

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INTERNATIONAL SEARCH REPORT

I. International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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