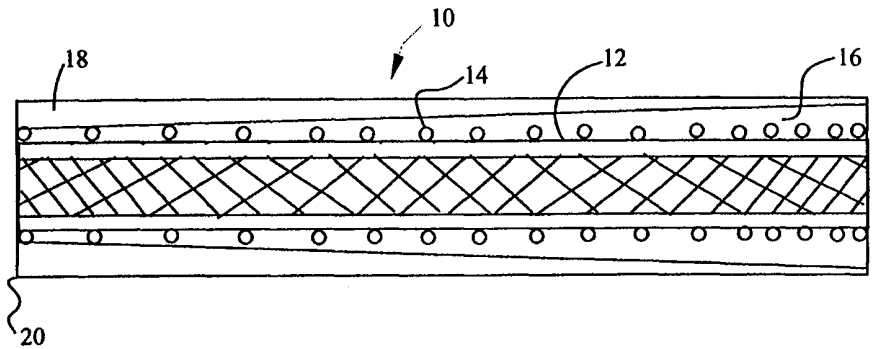




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: REINFORCED VARIABLE STIFFNESS TUBING <div style="text-align: center;">  </div>		
(57) Abstract <p>A multilayered catheter (10) is disclosed which has an inner liner (12) covered with a variable pitch braid (14) which is encapsulated within an interior co-taper (16), and exterior co-taper (18). The current invention utilizes the varying braid patterns encapsulated throughout the catheter to program into the tube either good push ability characteristics or good flexibility characteristics.</p>		

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1 REINFORCED VARIABLE STIFFNESS TUBING

2 BACKGROUND OF THE INVENTION

3 Cross-Reference to Related Application

4 This application claims the benefit of copending provisional
5 patent application, serial number 60/093,035, filed July 16,
6 1998, the disclosure of which is incorporated hereby, by
7 reference, as though recited in full.

8 Field of the Invention

9 The invention discloses reinforced co-
10 tapered, variable stiffness tubing, and more
11 specifically a reinforced tubing using an
12 encapsulated braid.

13 Brief Description of the Prior Art

14 Catheterization procedures are used to diagnose the
15 condition of a patient's body tissue such as arterial
16 passageways or the like. Normally, an incision is made in
17 the patient's body in order to insert the catheter apparatus
18 into the passageways to be diagnosed. The catheter is then
19 inserted through the incision and into the desired
20 passageway. The catheter is fed through the passageway
21 until it is correctly positioned adjacent the desired body
22 organ, such as the heart. The catheter is then precisely
23 rotated and manipulated into the desired body organ, for

1 instance, the right coronary artery. Diagnostic fluid is
2 then injected into the passageway at a predetermined minimum
3 flow rate in order for a separate device, such as an x-ray;
4 to properly record in photograph form the condition of the
5 passageway.

6 Dilatation catheters predominately fall into two
7 categories, over-the-wire catheters that are fed over a
8 guide wire and fixed wire catheters, which serve as their
9 own guide wire. Wireless dilatation balloon catheters have
10 been developed in an attempt to obtain some of the advantage
11 of an over-the-wire catheter. Dilatation catheters must
12 offer flexibility to allow the catheter to maneuver through
13 tight curvatures in the vascular system. The physician must
14 also have the ability to transmit longitudinal force, from
15 the proximal to the distal ends, to push the catheter
16 through the guide catheter and arteries and across the
17 stenosis.

18 Angioplasty is an effective method of opening stenosis
19 in the vascular system. In the most commonly used form of
20 angioplasty, a balloon catheter is guided through the
21 vascular system in position across the stenosis. Once in
22 position, the balloon is inflated, the artery opened and
23 acceptable blood flow reestablished.

1 The above procedures, however, frequently induce trauma
2 to the walls of the patient's passageways. Prior art
3 catheters have sought to reduce this trauma by providing a
4 highly flexible catheter that bends in conformance with the
5 passageways. In order to allow the catheter to be fed
6 through the passageways, the catheter must have sufficient
7 rigidity to provide adequate torque transmission. Without
8 sufficient torque transmission, the catheter cannot be
9 precisely rotated into the desired body organ. Further,
10 poor torque transmission causes buckling, wind-up and
11 whiplash, inducing trauma to the passageways and causing
12 pain and discomfort to the patient.

13 Thus, the medical profession has been faced with a
14 trade-off between a highly flexible catheter apparatus that
15 fails to function adequately when in torsion or a rigid
16 catheter that creates an intolerable amount of trauma.

17 U.S. Patent 5,805,649 issued to Flynn, discloses a
18 Torque Controlled Tube that utilizes the co-tapering of
19 polymeric materials, such as polyamides and polyurethanes,
20 to produce a tube that is variable in stiffness. While this
21 construction produces adequate pushability and kink
22 resistance results for thick walled tubing, it does not
23 address problems inherent in thin-walled tubing. The

1 stiffer material is in higher concentration in the
2 sections(s) of the tube that requires good pushability while
3 the softer material is in higher concentration in the tube
4 sections that require greater flexibility.

5 To address problems associated with thin walled tubing,
6 many angiography and guiding catheters are constructed by
7 encapsulating a braid for added strength and flex
8 properties. Unfortunately, due to the construction methods
9 of these catheters, the braid pattern remains constant
10 throughout the entire length of the catheter, with exception
11 of the tip region, therefore compromising performance
12 characteristics through out the different segments of the
13 catheter.

14 One method of producing a variable stiffness tube,
15 suitable for medical device applications, is disclosed in
16 U.S. Patent Number 5,531,721, Multiple Member Intravascular
17 Guide Catheter. This patent relates to the bonding/joining
18 of multiple tube sections. These tube sections may or may
19 not be reinforced. The difficulty in producing a catheter
20 of this nature is that the transition from a "stiff" section
21 to a "soft" section is not achieved continuously. Rather at
22 each joint, a stress riser may occur that can weaken the

1 tube's structure thereby leading to possible premature
2 kinking when flexed or rupturing when pressurized.

3 Engleson, U.S. Patent Number 5,312,356, discloses a
4 Catheter with Low-Friction Distal Segment that utilizes a
5 variable braided pattern to minimize jamming, stick or
6 locking of the distal end of the catheter or any part of the
7 guide wire against the surface. The braided material is
8 exposed on the inner surface of the tube at the distal tip
9 of this catheter and is not used to provide variable
10 stiffness but rather as a means of preventing the sticking
11 problems mentioned previously.

12 Many other patents have addressed the problem of
13 minimizing body trauma during insertion of a catheter.
14 These include the use of a glass transition material (U.S.
15 5,441,489 to Utsumi et al); a single-lumen shaft for use
16 with either a fixed-wire balloon catheter or an innerless
17 catheter (U.S. 5,533,987 to Pray et al); and a collapsible
18 shaft and guide wire lumen (5,466,222 to Ressemann et al).
19 Muni et al (U.S. 5,569,196) discloses a tractable catheter
20 having two lumens that vary in Shore hardness. In 5,603,705
21 to Berg, an intravascular catheter is constructed with an
22 outer layer and an inner layer that is covered with a
23 support surface, such as a stainless steel wire braid.

1 Another dual lumen catheter that includes a wire braid
2 between the two lumens, is disclosed in 5,078,702 to
3 Pomeranz. In 5,254,107 to Soltesz the plastic catheter shaft
4 has embedded the braid within the outer catheter shaft. In
5 4,764,324 to Burnham also incorporates the reinforcing
6 member into the outer lumen by heating the lumen after
7 molding. U.S. 5,221,270 to Parker discloses the use of
8 tapered ends on the catheter materials to change from a
9 harder Shore to a softer Shore and provide an outer diameter
10 with a uniform, continuous outer layer.

11 U.S. 4,425,919 has sought to overcome the foregoing
12 problems by providing a catheter with a small outside
13 diameter and utilizing a pre-oriented substrate that
14 adequately supports the reinforcing means. A flat braid is
15 used which is maintained in its position around the
16 substrate by a surrounding superstrate.

17 SUMMARY OF THE INVENTION

18 The foregoing prior art examples do not provide
19 solutions to the current problems associated with thin
20 walled catheters that are used for placement of medical
21 devices.

22 Although the prior art illustrates attempts to provide
23 a flexible catheter tubing with a soft tip and stiff body,

1 in order to reduce trauma while allowing for
2 maneuverability, they do not specifically address the
3 current problems associated with thin walled catheters that
4 are used for placement of medical devices. For example, the
5 co-tapering of materials address stiffness and flexibility
6 issues in angiography catheters where thicker walled
7 catheters are acceptable, but do not provide sufficient
8 strength to perform as a guide catheter. One existing
9 problem with current guide catheter technology is that the
10 braid pattern is constant through out the length of the
11 catheter, therefore compromising both push and flex
12 requirements.

13 Another problem that has been addressed in the prior
14 art is that of adhering a "soft" tip to the distal end of
15 the catheter. Many catheters use a heat or gluing process
16 to adhere a low durometer polymeric material to the end of
17 the catheter. Usually, these materials are in the same
18 polymeric family, (i.e. urethanes, ethylenes, etc.) but vary
19 in durometer and do not bond easily to the tube matrix.
20 Pomeranz, U.S. Patent 5,078,702 discloses a Soft Tip
21 Catheter that attempts to address these bonding problems to
22 form a stable joint. Unfortunately, this design limits the

1 | contact surface of the materials being bonded due to the
2 | presence of the inner liner.

3 | The current invention overcomes the foregoing problems
4 | in "stiff" to "soft" transition by providing a continuous
5 | structure that is reinforced while varying in longitudinal
6 | stiffness. Further the utilization of a co-tapered soft tip
7 | reduces body trauma while selecting polymeric materials
8 | matching the contact surface maximize the bonding mechanism
9 | between the tube and the tip.

10 |

11 |

12 |

13 |

BRIEF DESCRIPTION OF THE DRAWINGS

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16 |

The advantages of the instant disclosure will become
apparent when read with the specification and the drawings,
wherein:

17 |

18 |

FIGURE 1 is a longitudinal, cross-sectional view of the
disclosed catheter;

19 |

20 |

FIGURE 2 is a cross-section view of the distal end of
the tube of Figure 1;

21 |

22 |

23 |

FIGURE 3 is a longitudinal, cross-sectional view of the
catheter of Figure 1 with a two layered, co-tapered tip
attached to the distal end; and

1 Figure 4 is a longitudinal cross-sectional view of a
2 three layer co-taper system over a braid.

3 DETAILED DESCRIPTION OF THE
4 PREFERRED EMBODIMENTS OF THE INVENTION

5 Currently variable stiffness catheters comprise an
6 inner most layer that is comprised of a thin fluoropolymer
7 film. This film is then covered with a braid, which is
8 usually metallic but also can be made of a polymer, such as
9 nylon, high density and linear polyolefines, such as
10 polyethylene, or a composite, such as Kevlar. The actual
11 braid design can be single or side-by-side strands,
12 following a traditional braid pattern. The braid is then
13 coated with at least two component co-tapered.

14 The cotapered layers of tubing, extend from the
15 proximal to distal ends. In general, the discrete layers
16 differ in durometer as they advance distally, forming a
17 rigid to soft composite construction. Most advantageously
18 the structure softens in durometer from distal to proximal
19 end.

20 In other applications, a soft tube having a uniform
21 durometer is joined with the braided substrate. A non-
22 braided soft tip is then usually bonded to the distal end.
23 Hubs and strain relief are fitted proximally and the tip is

1 preformed into a specific shape depending on the intended
2 application.

3 In U. S. 5,085,649 issued on February 4, 1992 to
4 Vincent Flynn, a catheter tubing suitable for medical use
5 is disclosed. The tubing is multi-layer and comprises an
6 interior tubular portion, consisting of two layers, and a
7 concentric outer shell. The two interior layers are tapered
8 inversely for a portion of the length of the tube with at
9 least one end of the interior portion extending beyond the
10 concentric outer shell. Although the '649 patent provides
11 an increased torque resistance and pushability suitable for
12 thick walled tubing, the problems inherent with thin wall
13 tubing are not overcome.

14 To enable the tubing of the disclosed invention to
15 overcome the problems inherent with thin wall tubing, a
16 braid is added to the variable stiffness tube to increase
17 the resistance to kinking while maintaining the desired
18 flexibility. The braid further increases the burst
19 pressures and pushability of the catheter. Possibly the
20 most valuable improvement is the increased torque control of
21 the distal tip.

22 The current invention utilizes varying braid patterns
23 encapsulated throughout the catheter to program into the

1 tube either good pushability characteristics or good
2 flexibility characteristics. Typically a "loose" braid
3 pattern promotes column strength in the structure and hence
4 enhances the pushability of the catheter while a "tight"
5 braid pattern promotes radial reinforcement in the structure
6 and enhances the flexibility of the tube. By providing
7 variable patterns within a single length of tubing, a single
8 catheter can be provided with optimum controllability.

9 The advantage of the braid has been recognized in the
10 prior art, such as 5,312,356 to Engelson et al, where the
11 braid is used to minimize jamming, sticking or locking of
12 the distal end of the catheter. The catheter disclosed
13 herein utilizes the advantages provided by the braid and
14 incorporates these with the variable stiffness tube in an
15 easy to manufacture monolithic construction that avoids
16 bursting and reduces body stress and trauma. The extruded
17 construction, which incorporates the braid in a single
18 extrusion operation, greatly reduces manufacturing expenses
19 by providing a single step, fully automated process

20 The catheter tube 10, as illustrated in Figures 1 and 2
21 is constructed by forming an interior liner 12 as the inner
22 most layer. The liner 12 is then covered with a variable
23 pitch braid 14 and then encapsulated within an interior co-

1 taper 16 and exterior co-taper 18 that form the tube wall
2 20. The liner 12 is manufactured from a resin having
3 suitable properties to provide minimal friction between a
4 guide wire/device or fluid and the interior surface of the
5 liner 12. Examples of these materials are a fluoropolymer
6 or high durometer polymers (greater than 63D Shore hardness)
7 such as polyurethane, polyamide, polyimide, peek,
8 polyesters, Pebax, Plexar, polyethylenes, etc. The wall
9 thickness of the liner 12 can vary from .0005 inch to .0030
10 inch depending on the desired performance. The thickness
11 of the liner 12 directly alters the flexibility and
12 subsequently the kink resistance. By varying the thickness
13 of the liner 12 within the catheter length, additional
14 control over flexibility can be achieved.

15 The variable pitch braid 14 can be fabricated from
16 round or profile wire stock. The braid pattern can also be
17 formed using one; two or three wires wound parallel to and
18 touching each other in a diamond or herringbone pattern.
19 Typical materials used in the braid 14 are stainless steel,
20 nickel titanium or any precious metal that could enhance the
21 fluoroscopic visualization of the tube. Typical round wire
22 diameters are .0005 inch to .005 inch with profile wire
23 sizes varying from a width to height ratio of 1:1 to 8:1

1 with the minimum height of .0005 inch to a maximum width of
2 .005 inch. The braid pattern, defined in pics per inch
3 (ppi) will vary depending upon the desired pushability. In
4 regions where pushability is required the pattern will be in
5 the range from about 10 to 40 ppi while in regions where
6 flexibility and kink resistance is essential, the pattern
7 will be in the range of from about 50 to 150 ppi. In
8 addition to changing the ppi, adjusting the diameter of the
9 wire, as well as width to height ratio will further alter
10 the pushability characteristics of the catheter.

11 The interior layer 16 tapers longitudinally along a
12 portion of the tube 10, with the concentration of material
13 increasing from the proximal end to the distal end. The
14 interior co-taper 16 is generally manufactured from a
15 material having a low durometer (80A-40D) and preferably is
16 polymer compatible for thermal bonding to the liner 12. In
17 specialized applications, however, the durometer may be
18 increased and will be evident to those skilled in the art.
19 Typical materials used for the interior co-taper 16 are low
20 durometer polyurethane, polyamide, polyimide, peek,
21 polyesters, pebax, polyethylenes, etc. The percent
22 concentration for the interior co-taper 16 can be as little
23 as 1% of the total tube wall 20 at the proximal end and

1 increase to as much as 99.9% of the total tube wall 20 at
2 the distal end. This concentration can taper linearly
3 through out the length of the catheter or transition from
4 over a length of about 2 inches to about 9 inches. The
5 taper is dependent upon the length of the catheter and end
6 use, and will become apparent to those skilled in the art.

7 The exterior jacket layer 18 tapers longitudinally with
8 decreasing concentrations of material from the proximal to
9 distal ends. The exterior co-taper 18 must be capable of
10 thermal bonding to the interior co-taper 16 and have a high
11 durometer (60D-85D). Again, typically materials used for
12 this layer are high durometer, polyurethane, polyamide,
13 polyimide, peek, polyesters, pebax, polyethylenes, etc. As
14 with the interior co-taper 16, the percent concentration can
15 be as little as 1% or as much as 99.9% of the total tube
16 wall 20.

17 Figure 3 depicts the disclosed tube 10 with a two
18 layer, co-tapered tip 26 attached to the distal end. The
19 inner tip layer 30 tapers longitudinally with an increasing
20 concentration of material from the proximal end to the
21 distal end. The inner tip layer is usually manufactured
22 from a low durometer (80A- 40D) material to minimize trauma
23 to the vessel walls. The polymeric material must be capable

1 of being thermal bonded to the liner 12 as well as to the
2 exterior tip layer 28. Typical materials used for this
3 layer are low durometer polyurethane, polyamide, polyimide,
4 peek, polyesters, pebax, polyethylenes, etc. The
5 concentrations of this material are as little as 1% of the
6 total tip 26 proximally and increase to as much as 99% of
7 the total tip 26 distally. The exterior tip layer 28
8 typically tapers longitudinally with decreasing
9 concentrations of material, from the proximal to distal ends
10 of the tip 26. The high durometer (60D-85D) polymeric
11 material use to manufacture the exterior tip layer 28 must
12 be capable of thermal bonding to the liner 12, the interior
13 co-taper 16, the exterior co-tapered 18 and the exterior tip
14 layer 28. This material can be selected from the group of
15 materials listed heretofore. Usually the materials selected
16 for manufacturing the interior co-taper 16 and the exterior
17 tip layer 28 are identical in polymeric structure and
18 hardness. As an alternate embodiment, grinding the distal
19 end of the tube to expose the softer, interior co-tapered
20 layer is used to create the tip rather than affixing a
21 separate constructed tip.

22 In an alternate embodiment, the tubing 40 can consist
23 of three outer layers over the braid, as illustrated in

1 Figure 4. In this embodiment the central core 50 is covered
2 with the braid 48, interior layer 46 and mid-layer 44.
3 These correspond to the layers set forth in response to
4 Figure 1. The additional exterior layer 42 and has been
5 added to further customize the properties of the catheter;
6 the durometer varying based on the end use.

7 A variation to the polymeric structure is the inclusion
8 of a radiopaque compound into the tip material to enhance
9 fluoroscopic visualization. These radiopaque compounds are
10 usually available in either powder or concentrate form and
11 are made of heavy metal materials such as tungsten, barium
12 sulfate, bismuth trioxide, tantalum, etc.

13 Additional detail for manufacture of the co-tapered
14 tubing can be found in U.S. 5,085,649 issued February 4,
15 1992 to Vincent J. Flynn, which is incorporated herein as
16 though recited in full.

17 The interior diameter of the liner 12 affects the
18 overall interior diameter of the end use catheter and all
19 dimensions must be adjusted accordingly. The addition of the
20 additional layers, either on the interior or exterior, can
21 also be used to produce variable stiffness tube.

22 Each layer within the disclosed tube possesses
23 different physical properties, tailored to satisfy multiple

1 | purposes. By discretely feeding the braided substrate
2 | portion into the co-tapered construction the bonding of soft
3 | tips can be eliminated. This construction eliminates the
4 | multiple joints that are present in many prior art
5 | construction methods. The continuous transition from hard
6 | to soft provides a natural transition, in contrast to prior
7 | art constructions that have abrupt changes at welds,
8 | increasing kinking tendencies when bent.

1 What is claimed is:

- 2 1. A reinforced catheter device having a multilayer
3 structure, and varying in longitudinal stiffness,
4 comprising a continuous interior layer and an
5 outer layer, said outer layer being a braided
6 structure, said braided structure having a braid
7 pattern that varies along the length, whereby the
8 torque control, kink resistance and pushability of
9 said catheter device is varied by the variation in
10 braid pattern.
- 11 2. The reinforced catheter device of claim 1, further
12 comprising a co-tapered soft tip whereby body
13 trauma reduced.
- 14 3. The reinforced catheter of claim 1, wherein two
15 adjacent layers are cotapered.
- 16 4. The reinforced catheter device of claim 3, wherein
17 said braid varies in tightness thereby providing
18 varying radial reinforcement and flexibility.
- 19 5. The reinforced catheter of claim 3, wherein said
20 braid is a precious metal thereby enhancing the
21 fluoroscopic visibility of said catheter.
- 22 6. The reinforced catheter of claim 5, wherein said
23 braid is made from a material selected from the

- 1 group consisting of stainless steel, nickel, and
2 titanium.
- 3 7. The reinforced catheter of claim 3, wherein said
4 braid is made from a composite polymeric material.
- 5 8. The reinforced catheter of claim 3, wherein said
6 braid is made from a material selected from the
7 group consisting of kevlar, dacron, and carbon
8 fiber.
- 9 9. The reinforced catheter of claim 3, wherein said
10 braid is a round wire having a diameter in the
11 range from about .0005 inch to .005 inch.
- 12 10. The reinforced catheter of claim 3, wherein said
13 braid is a wire having a wire profile varying from
14 a width to height ratio of 1:1 to 8:1, and having
15 a minimum height of .0005 inch and a maximum width
16 of .005 inch.
- 17 11. The reinforced catheter of claim 3, wherein said
18 braid pattern has a region of optimized
19 pushability with a braid pattern in the range from
20 about 10 to 40 ppi and a region of optimized
21 flexibility and kink resistance with a braid
22 pattern in the range of from about 50 to 150 ppi.

- 1 12. The reinforced catheter of claim 7, wherein said
2 braid pattern has a region of optimized
3 pushability with a braid pattern in the range from
4 about 10 to 40 ppi and a region of optimized
5 flexibility and kink resistance with a braid
6 pattern in the range of from about 50 to 150 ppi.
- 7 13. The reinforced catheter of claim 3, wherein said
8 catheter has an outer layer, said outer layer
9 encapsulating said braid and being laminated to an
10 inner layer.
- 11 14. The reinforced catheter of claim 3, wherein said
12 catheter further comprises an outer jacket
13 comprising at least two material of different
14 durometers.
- 15 15. The reinforced catheter of claim 11, at least of
16 material braid pattern has a region of optimized
17 pushability with a braid pattern in the range from
18 about 10 to 40 ppi and a region of optimized
19 flexibility and kink resistance with a braid
20 pattern in the range of from about 50 to 150 ppi.
- 21 16. The reinforced catheter of claim 3 wherein said
22 catheter has a low friction interior surface
23 layer, said interior surface layer comprising a

- 1 material selected from the group consisting of a
2 fluoropolymer, polyamide, and polyethylene.
- 3 17. The reinforced catheter of claim 13, wherein said
4 outer layer is an overlay having a durometer of at
5 least 55D.
- 6 18. The reinforced catheter of claim 17, wherein said
7 overlay is a tacky, low durometer material having
8 a durometer of less than 55D.
- 9 19. The reinforced catheter of claim 3, wherein said
10 catheter has an outer layer, said outer layer
11 encapsulating said braid and being laminated to an
12 inner layer, said inner layer having its outer
13 surface modified to promote lamination with said
14 outer layer.
- 15 20. The reinforced catheter of claim 19, wherein said
16 inner layer has its outer surface modified by
17 chemical etching.

1/2

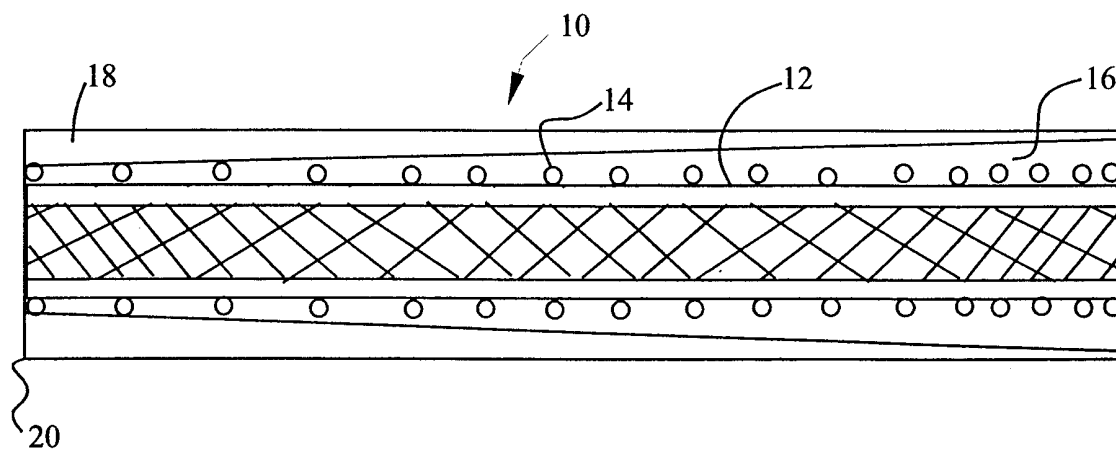


Figure 1

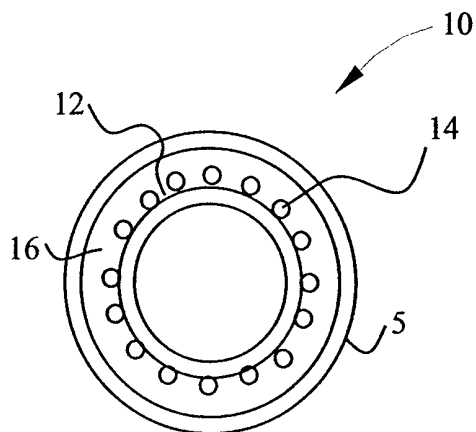


Figure 2

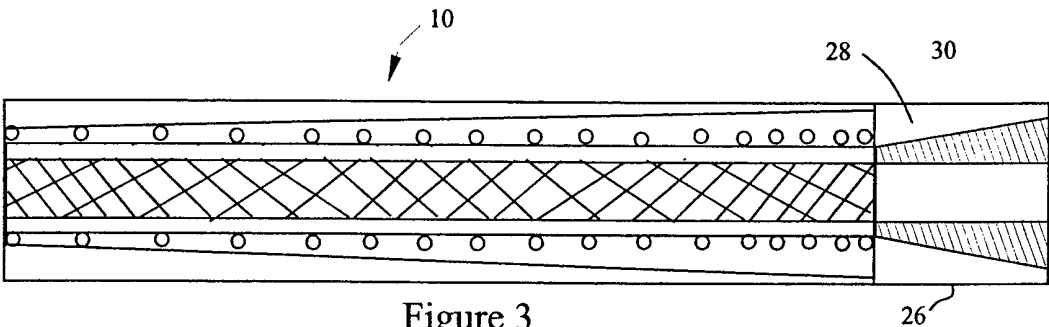


Figure 3

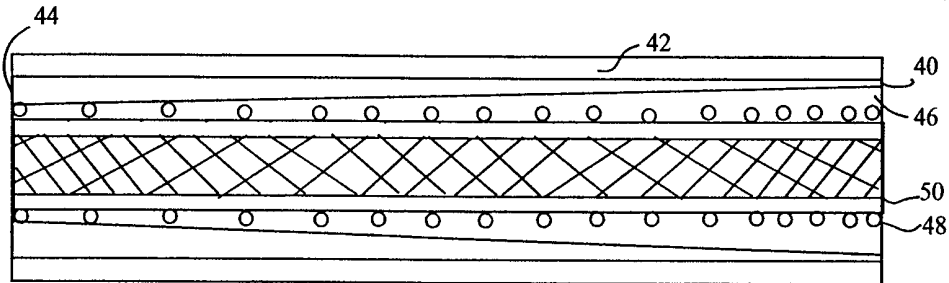


Figure 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/16102

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 25/00

US CL : 604/527

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. : 604/525, 527

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,538,513 A (OKAJIMA) 23 July 1996, entire disclosure.	1-4, 6, 7, 9, 13, 14, 16-18 ----- 5, 8, 10-12, 15, 19-20



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 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
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