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(71) Applicant *(for all designated States except US)*: **MICRO THERAPEUTICS, INC.** [US/US]; 2 Goodyear, Irvine, CA 92618 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **KIM, James, H.** [US/US]; 12671 Flower Street #7, Garden Grove, CA 92840 (US). **STRAUSS, Brian, M.** [US/US]; 20592 Porter Ranch Road, Trabuco Canyon, CA 92692 (US). **SLEE, Earl, H.** [US/US]; 7 Whitesail, Laguna Niguel, CA 92677 (US).

(74) Agents: **KREBS, Robert, E.** et al.; Burns, Doane, Swecker & Mathis, LLP, P.O. Box 1404, Alexandria, VA 22313-1404 (US).

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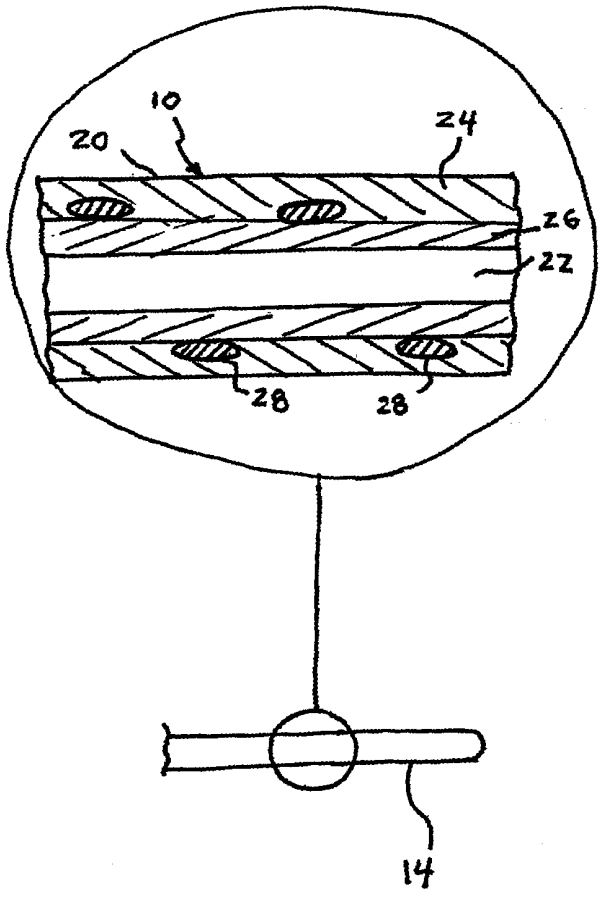
(54) Title: ELLIPTICAL WIRE-REINFORCED CATHETER



(57) Abstract: A catheter for insertion into the body of a patient is formed of an elongate structure defining a main lumen. The elongate structure is provided with an elliptical or oval reinforcing wire wound at least partially around the main lumen. According to one embodiment, the elongate structure comprises a single material, with the wire being embedded in the material. According to another embodiment, the elongate structure comprises inner and outer layers of the same or different materials, with the wire being wound over the inner material and under the outer material. Various winding configurations and pitches can be used depending on the desired catheter characteristics.

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ELLIPTICAL WIRE-REINFORCED CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §§119 and/or 365 to Provisional U.S. Patent Application no. 60/167,613 filed in the U.S. Patent and Trademark Office on November 26, 1999, the entire content of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to wire-reinforced catheters used for detection and/or delivery of material to and from remote locations within the body of a patient.

2. Description of Related Art

Wire-reinforced catheters are well known in the art. Generally, these consist of an elongated, flexible tubular body defining a central lumen extending from one end of the body to the other end. The lumen communicates with the exterior of the body at the ends. In this manner, when a distal end of the catheter is implanted in the body of a patient, the lumen provides a conduit for delivery of material to or from the body, or for transfer of sensor information from within the interior of the body.

Structurally, the tubular body of the catheter is formed of a polymeric or other material, typically formed in layers. One arrangement, of particular interest here, contemplates a structure in which an inner layer is surrounded by a wound reinforcing wire. Atop this reinforcing wire is overlaid an outer layer,

such that the reinforcing wire is sandwiched between the inner and outer layers. The winding pitch of the reinforcing wire can be varied along the length of the catheter to achieve a desired flexibility profile. One or more wires can be used, spirally wound in the same or opposite directions, extending partially or completely along the length of the catheter. Multiple, counter-woven strands thus used can be considered as forming a reinforcing wire mesh between the inner and outer layers of the catheter. In cross section, the wires deployed in the prior art are either round or rectangular.

One prior art device is the subject of U.S. Pat. No. 3,924,632 to Cook, disclosing a catheter 10 having inner (30) and outer (35) layers of plastic material such as polyethylene. A mesh of woven fiber glass bands 40, 41, 42, 43, 48, 49, 50 and 51 is disposed between these layers, the mesh comprising counter-rotated strands spirally wound around the exterior of inner layer 30. The strands are of 0.0005-inch thickness. Layers 30 and 35 are heat bound to each other through the interstices of the fiber glass mesh. To provide maximal flexibility at the tip of catheter 10, the distalmost portion comprises a meshless tube 52 bonded to the end.

U.S. Patent No. 4,516,972 to Samson teaches the use of a ribbon reinforcement layer 16 disposed between an inner liner 12 and an outer layer 26 of a catheter 11. The ribbon is wound around inner liner 12 at varying pitches in order to achieve a specific flexibility profile in which proximal end portion 12a, intermediate portion 12b, and distal portion 12c each exhibit different flexibility. The ribbon is omitted altogether from a tip portion of the catheter 11 for maximum flexibility. One or two layers (17, 18) of ribbon can be used, counter rotated, with the second layer overlying the first layer. The ribbon material is preferably Kevlar.

U.S. Patent No. 4,425,919 to Alston, Jr. et al. discloses a catheter 10 which is provided with a flat wire braid 14 disposed between an inner layer 12 and an outer layer 16. The inner layer 12 is made from a stretched, pre-oriented polyvinylidene fluoride or nylon 12. Outer layer 16 materials can be polyolefin

polymers or ethyl vinyl acetate or polyurethane, adapted for sterilization by radiation. A flexible tip is provided by extending the outer layer beyond the inner layer and wire braid, so that the outer layer alone forms the tip and results in a more flexible structure.

U.S. Patent No. 5,037,404 to Gold, et al. shows a catheter 10 having an inner layer 12 made from polyethylene, nylon, PVC, polyurethane or silicon rubber. Layer 12 is surrounded by a helically wound wire sheath 16 having a pair of counter rotated wires 18, 20 whose relative angle (i.e., pitch) can be varied to achieve desired torsional and longitudinal stiffness characteristics in different sections. The number of sections may be two or more, depending on the application, and the possibility of three sections is discussed. The wires 18, 20 can be braided, or they can be configured such that one overlies the other. Any desired wire cross-section may be used, and possible wire materials include stainless steel, nylon, and memory alloys such as Nitinol.

U.S. Patent No. 5,069,674 to Fearnot, et al. shows the use of a spirally wound wire 105 to reinforce a catheter 100 comprised of an outer sheath 104 and an inner tube 401 (see Fig. 4). The coils of the wire 105 are loosely wound at the distal end of the catheter in order to achieve a more flexible structure at that end. The material of the wire 105 is hardened stainless steel "or other metals or alloys", while the material of the outer sheath 104 can be polyamide, fluoropolymers, TEFLON™ or other copolymer plastics.

U.S. Patent No. 5,279,596 to Castaneda, et al. shows a catheter 10 having a distal portion 22 which is more flexible than a proximal portion 14. In both portions a support wire is embedded. Wire 28 of the distal portion is preferably of rectangular cross-section and is made of stainless steel. Structurally, wire 28 coaxially surrounds an inner layer 26 and is embedded in an overlaying outer layer 24 (see Fig. 4). Inner layer 26 is formed of PTFE, while outer layer 24 is formed of nylon. The relative difference in flexibility between distal portion 22 and proximal portion 14 is achieved using appropriate materials selection, particularly, by selecting for the outer layer of the distal portion a material with a

lower Shore D durometer rating (a rating of 40 is mentioned in col. 3, ll. 63-64) than that of the outer portion of the proximal portion.

U.S. Patent No. 5,176,660 to Truckai, et al., discusses the Gold, et al. patent (see above) and its teachings are specifically held out as an extension of the concepts of the Gold, et al. patent. In Truckai, a catheter 10 is provided with an inner layer 12 made of polyethylene, nylon, PVC, polyurethane, or silicon rubber. A tubular braided wire sheath 16 is formed over inner layer 12. The braided wire sheath 16 comprises a pair of counter rotating helical strands 18,20 of flat wire made from spring steel. Nitinol is also discussed, in col. 4, l. 40. Over the braided wire sheath 16 and bonded with the inner layer 12 via the interstices of the sheath is an outer layer 22, made of the same material as the inner layer, as seen from Fig. 5. The angle strands 18 and 20 make with each other can be varied in different segments of the catheter 10 to achieve varying physical characteristics, as discussed in col. 3, ll. 17-19 and col. 4, ll. 21-23. These characteristics include stiffness/flexibility.

U.S. Patents Nos. 5,454,795, 5,695,483 and 5,876,386 to Samson describe a catheter in which one or more stiffener ribbons (274) are used to reinforce the tubular body (270) of the catheter and control flexibility. The stiffener ribbons are selectively applied in varying pitches and turn directions ("handedness") in order to tailor the catheter flexibility profile to specific applications. The catheter is constructed to have the stiffener ribbons sandwiched between inner and outer tubular polymer layers, referred to respectively as an inner tubular liner (272) and outer tubular cover (276). The ribbons are described as rectangular in cross section, having dimensions of between 0.75 mil and 1.5 mil in thickness and between 2.5 mil and 8.0 mil in width. Alternatively, depending on the ribbon material, thickness and width dimensions of 0.5 mil and 1.0 mil, respectively, are mentioned. The tubular polymer layers comprise compatible materials designed to adhere to each other with or without the aid of a suitable adhesive.

The above-described prior art references are herein incorporated by reference in their entirety.

The prior art has been found to suffer from shortcomings due to the cross-sectional shape of the reinforcing wires used. Specifically, the use of round wire fails to provide the desired stiffness control, and requires wires whose thickness is dimensionally incompatible with the design and size requirements for many applications. Rectangular cross section wires, on the other hand, have sharp edges which can cause damage to the tubular body of the catheter during manufacture and/or use.

BRIEF SUMMARY OF THE INVENTION

To overcome the deficiencies of the prior art, the present invention provides a catheter having a reinforcing wire whose cross sectional shape is oval or elliptical. In this manner, the potentially problematic sharp edges of the rectangular reinforcing wire of the prior art are avoided. Moreover, the wire is not round in cross section, thus providing improved functional and dimensional performance over the known prior art.

In accordance with the present invention, a catheter having a substantially tubular body in which a main lumen is formed is provided with a helically wound reinforcing wire in at least a portion thereof. This portion may be the distalmost, implantable portion of the catheter, or it may be a different portion or the entirety of the catheter. The tubular body comprises inner and outer layers of identical or different materials between which the reinforcing wire is helically wound. The reinforcing wire is selected to have an oval or elliptical cross section, thereby reducing the potential for damage to the inner and outer layers of the catheter due to the presence of sharp edges. Additionally, the oval or elliptical cross sectional shape affords the advantages of a smaller profile and improved performance, compared to bulkier and less suitable conventional round wire devices.

The winding configuration selected in the catheter of the present invention is a function of the desired catheter flexibility profile, with a higher winding pitch being used to impart greater flexibility. Additionally, flexibility can be controlled through judicious selection of the materials for the reinforcing wire and the inner and outer layers.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. 1 is a diagrammatical view of a catheter in accordance with the invention;

FIG. 1A is a sectional view of a segment of the catheter of FIG. 1;

FIG. 2 is a schematic view showing a first reinforcing wire winding configuration;

FIG. 2A is a sectional view of an alternative embodiment of a segment of the catheter of FIG. 1;

FIG. 3 is a schematic view showing a second reinforcing wire winding configuration;

FIG. 4 is a schematic view showing a third reinforcing wire winding configuration;

FIG. 5 is a schematic view showing a fourth reinforcing wire winding configuration;

FIG. 6 is a cross-sectional view depicting a first exemplary reinforcing wire shape in accordance with the invention; and

FIG. 7 is a cross-sectional view depicting a second exemplary reinforcing wire shape in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows diagrammatically a catheter 10 in accordance with the present invention. Catheter 10 is an elongate, generally tubular structure having a proximal portion 12 and a distal portion 14. A fitting, designated generally as 16, is disposed at proximal portion 12 and serves to interface the catheter 10 with various support and delivery devices, depending on the contemplated application of the catheter. Catheter 10 in operation is introduced into the body of a patient (not shown) such that the distal portion 14 is guided, using for instance a guidewire (not shown), to a target site within the body for performance of a needed procedure, such as localized delivery of medicament to the site. Proximal portion 12 remains exterior to the patient and provides access, via a main lumen (as described below), to the site within the patient's body.

FIG. 1A is a partial sectional view of a segment 20 of catheter 10 in accordance with the invention. Segment 20 is an exemplary portion of the catheter 10, such that the structure of segment 20 as described can be specific to a prescribed portion of the catheter, such as distal portion 14, or can be illustrative of the construction of the entire length of the catheter. Segment 20 comprises a main lumen 22 extending longitudinally along the segment length and defined by an inner layer 26 and an outer layer 24. Main lumen 22 extends substantially the entire length of catheter 10, from proximal portion 12 to distal portion 14, and is in communication with the exterior of the catheter at least at these portions and/or in their vicinity. Lumen 22 serves to convey materials between proximal portion 12 and distal portion 14 of catheter 10, which materials include but are not limited to nutrition, medicaments, contrast media, liquid embolizing agents, blood, guidewires and other devices such as sensors and sensor information-

carrying conductors. Layers 24 and 26 are generally tubular in shape, resulting in a generally tubular segment 20 and catheter 10.

Numeral 28 represents a reinforcing wire overlying inner layer 26 and covered by outer layer 24. Wire 28 is preferably disposed in a helical pattern, illustrated diagrammatically in FIG. 2. Other patterns are also possible, as illustrated in FIGS. 3-5. In FIG. 3, two wire strands are used, one overlying the other. Specifically, in FIG. 3, wire 28 is wrapped around inner layer 26 and around a second, inner wire 30. Wires 28 and 30 can be wound in the opposite directions, as depicted in FIG. 3, or they can be wound in the same direction and offset such that one wire is disposed between the other wire to provide a denser weave pattern—that is, a higher pitch (not shown). In FIG. 4, the two wires 28 and 30 are wound in opposite directions and interwoven, to effectively form a reinforcing mesh over inner layer 26. In FIG. 5, segment 20 is shown as divided into two segments, 32 and 34, each having the wire 28 wound at a different pitch over inner layer 26. Different pitches are used to selectively control flexibility of different portions of catheter 10. Moreover, in some constructions combinations of the above patterns can be used, in different segments or within the same segment, depending on the desired characteristics.

It is also contemplated that the catheter 10 can be constructed of a single layer 36. In such a construction, reinforcing wire 28 is embedded in layer 36 using standard manufacturing techniques. FIG. 2A depicts such an arrangement.

An important feature of the present invention is the cross-sectional shape of the wires 28 and 30. In order to eliminate sharp edges while reducing the profile of the wire, an elliptical or oval shape is selected. FIGS. 6 and 7 depict such shapes. It will appreciated that adherence to strict definitions of elliptical—that is, in the conic curve sense—is not intended, and some deviation is contemplated. It will also be appreciated that the term "wire" is not intended to designate an electrically conductive material or a metallic material, although the latter construction is in fact preferred. For purposes of completion, however, it

will appreciated that a suitable polymeric material or other non-metallic materials fall within the purview of the present invention.

Dimensionally, it is contemplated that the wire have a thickness **t** of between about 0.0005 inches to about 0.005 inches, and a width **w** of between about 0.0015 inches to about 0.015 inches. Other dimensional combinations for the wire can be a thickness of about 0.0005 inches and a width of about 0.0015 inches, a thickness of about 0.001 inches and a width of about 0.003 inches, a thickness of about 0.002 inches and a width of about 0.006 inches, or a thickness of about 0.005 inches and a width of about 0.015 inches. Other dimensional combinations are also contemplated and it is not intended that the invention be limited to those enumerated above.

Catheter 10 is constructed from materials which are well known in the art and which are governed by the particular application with a view to for example the flexibility and torquability requirements, along with the particular procedure to be performed on the patient, patient size and condition, and the materials to be delivered to the target site in the patient's body. It is preferred that the catheter be constructed to meet certain minimal physical criteria. Specifically, for many applications it is preferred that the distal portion of the catheter adhere to a critical bend diameter constraint of no more than about 1.50 mm and exhibit a lateral stiffness of greater than about 8,500° deflection/in-lb measured by a Tinius-Olsen Stiffness Tester at 20°-30° of deflection.

The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to those of ordinary skill in the art that modifications thereto can be made without departure from the spirit and scope of the invention.

CLAIMS

1. A catheter comprising:

a substantially elongate structure having a proximal portion and a distal portion and defining a main lumen extending between the proximal and distal portions, the main lumen being in communication with the exterior of the elongate structure at least at said proximal and distal portions; and

an oval reinforcing wire surrounding the main lumen along at least a segment of the substantially elongate structure.

2. The catheter of Claim 1, wherein the substantially elongate structure comprises:

an inner layer defining the main lumen; and

an outer layer surrounding the inner layer,

wherein the oval reinforcing wire is disposed between the inner and outer layers.

3. The catheter of Claim 1, wherein the substantially elongate structure comprises a single layer in which the oval reinforcing wire is embedded.

4. The catheter of Claim 1, wherein the oval reinforcing wire has a thickness **t** of about 0.0005 inches to about 0.005 inches, and a width **w** of about 0.0015 inches to about 0.015 inches.

5. The catheter of Claim 1, wherein the oval reinforcing wire is helically wound around the main lumen along the segment.

6. The catheter of Claim 1, wherein the helical winding is of varying pitches.

7. The catheter of Claim 1, wherein the oval reinforcing wire comprises two wires.

8. The catheter of Claim 5, wherein the two wires are wound in opposite directions around the main lumen along the segment.

9. The catheter of Claim 6, wherein the two wires are interwoven.

10. The catheter of Claim 1, wherein the distal portion of the catheter exhibits a critical bend diameter of no more than about 1.50 mm.

11. The catheter of Claim 1, wherein the distal portion of the catheter exhibits a lateral stiffness of greater than about 8,500° deflection/in-lb measured by a Tinius-Olsen Stiffness Tester at 20°-30° of deflection.

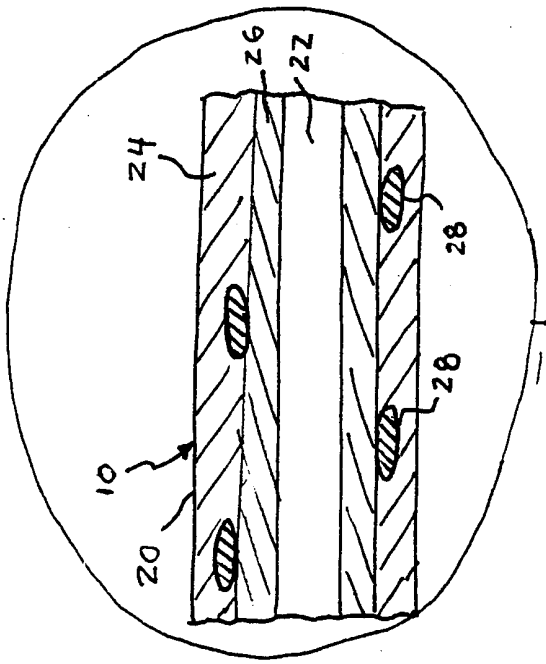

FIG. 1A

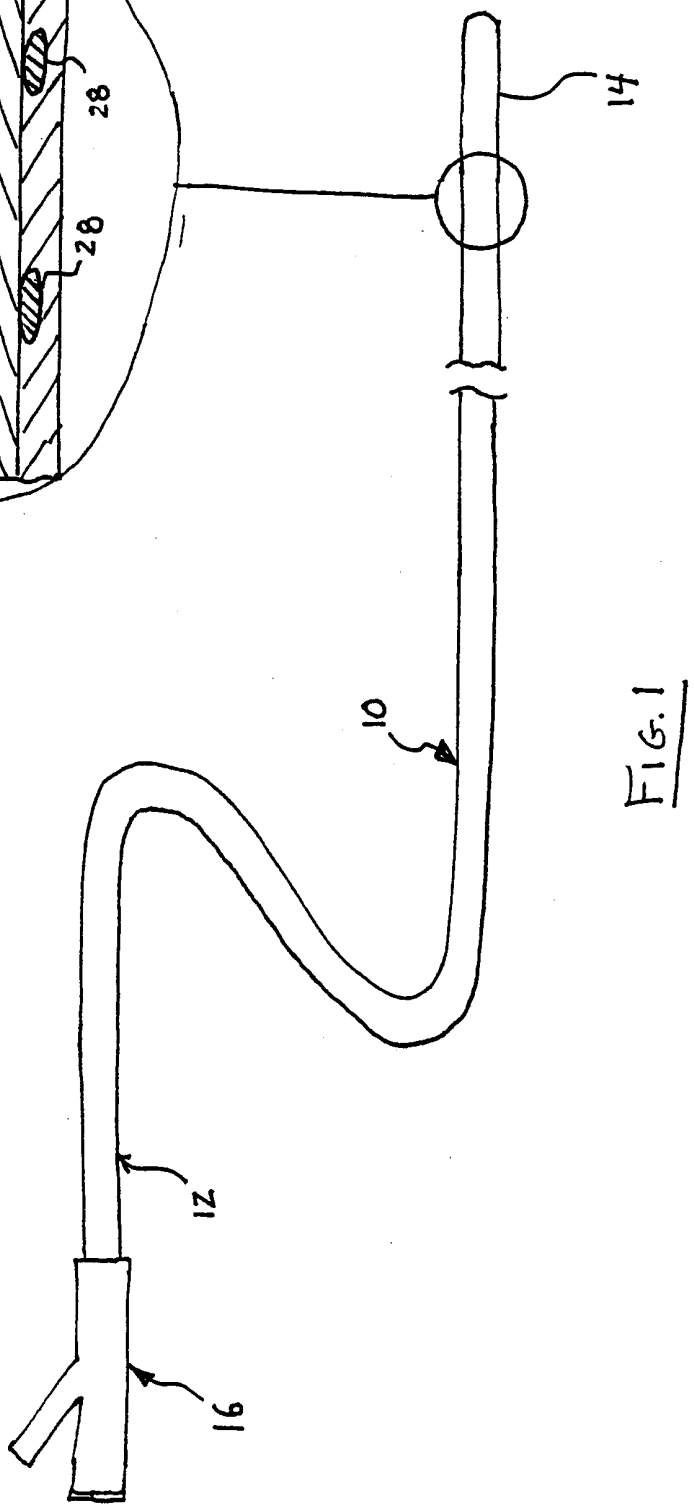

FIG. 1

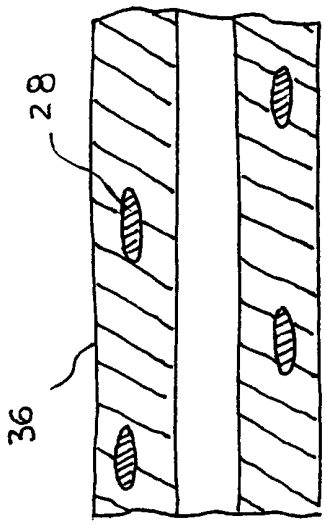

FIG. 1B

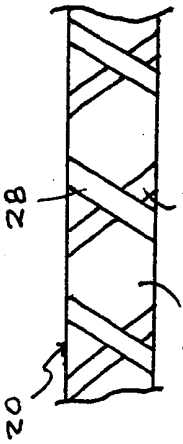

FIG. 3

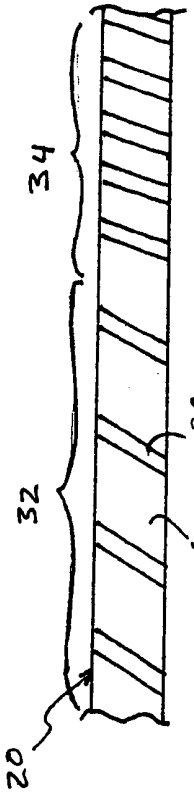

FIG. 5

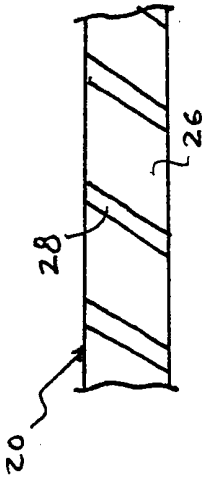

FIG. 2

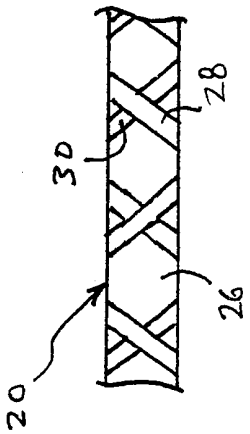

FIG. 4

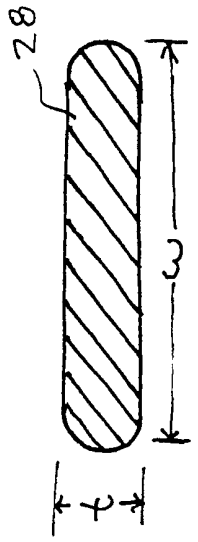

FIG. 7

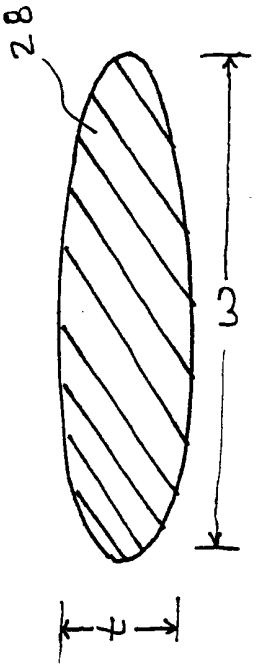

FIG. 6

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 00/30157

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00

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 A61M

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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 951 539 A (SAMSON GENE ET AL) 14 September 1999 (1999-09-14) column 12, line 6 - line 19 column 15, line 39 - line 44; figures	1-11
X	US 5 964 971 A (LUNN PETER A) 12 October 1999 (1999-10-12) column 3, line 9 - line 24; figures	1,3-5, 7-9
X	US 5 704 926 A (SUTTON GREGG S) 6 January 1998 (1998-01-06) column 5, line 6 - line 20; figures	1-6
X	US 5 713 867 A (MORRIS MARY M) 3 February 1998 (1998-02-03) column 6, line 30 - line 47; figures	1,3,5,8

☐ 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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"O" document referring to an oral disclosure, use, exhibition or other means

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Date of the actual completion of the international search	Date of mailing of the international search report
21 March 2001	28/03/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. .ional Application No
PCT/US 00/30157

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