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Notice Of Entitlement

I, John David O'Connor, of 31 Market Street, Sydney, New South Wales, 2000, Australia, Patent Attorney for the Applicant/Nominated Person in respect of Application No. 78609/94, state the following:-

The Applicant/Nominated Person has entitlement from the actual inventors as follows:

The Applicant/Nominated Person is the assignee of the actual inventors.

The Applicant/Nominated Person is entitled to rely on the application listed in the Declaration under Article 8 of the PCT as follows:

The Applicant/Nominated Person is the assignee of the basic applicants.

The basic application listed on the Declaration under Article 8 of the PCT is the first application made in a Convention country in respect of the invention.

DATED 6 June 1996

John David O'Connor

IRN: 339571

Instructor Code: 060033

[N:\LIBT]01720:MER

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GUIDING CATHETER

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(71) Applicant(s)
SCHNEIDER (USA) INC.

(72) Inventor(s)
NUSAYR AAZAM; JOHN B LOGAN; BRAD J WESSMAN; WILLIAM R PRIEDEMAN

(74) Attorney or Agent
SPRUSON & FERGUSON , GPO Box 3898, SYDNEY NSW 2001

(56) Prior Art Documents
EP 520692
EP 473045
US 4425919

(57) In addition, the use of a PVDF/HFP copolymer for inner liner 21 allows guiding catheter to be gamma sterilized. Other prior catheters that use a polytetrafluoroethylene (PTFE/Teflon) inner liner cannot be gamma sterilized because PTFE is not gamma stable.

CLAIM

1. A catheter comprising:

an elongate tube having a proximal end and a distal end defining an inner lumen and a wall with an annular cross section of a substantially uniform thickness between the distal end and the proximal end and with an exposed innermost liner formed from a material including a copolymer of polyvinylidene fluoride and hexafluoropropylene and an outer polymeric jacket;

wherein the catheter is stable upon exposure to gamma radiation.

CORRECTED VERSION*

PCT

ANNOUNCEMENT OF THE LATER PUBLICATION OF INTERNATIONAL SEARCH REPORTS

78609/94

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(71) Applicant: SCHNEIDER (USA) INC. [US/US]; 5905 Nathan Lane, Plymouth, MN 55442-1656 (US).

(72) Inventors: AZAM, Nusayr; Apartment No. 4220, 12500 Marion Lane W., Minneapolis, MN 55305 (US). LOGAN, John, B.; 11614 Sunset Trail, Plymouth, MN 55441 (US). WESSMAN, Brad, J.; 1121 Trailwood Street, Hopkins, MN 55343 (US). PRIEDEMAN, William, R.; 1906 Deer Hill Drive, Wayzata, MN 55391 (US).

(74) Agents: SPIEGEL, Allen, J. et al.; Pfizer Inc., 235 East 42nd Street, New York, NY 10017 (US).

(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

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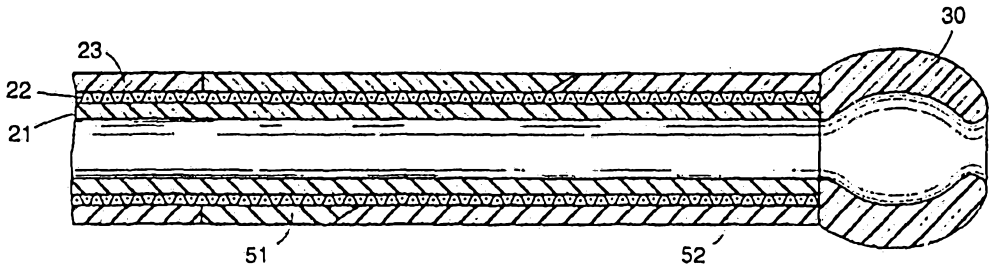
(54) Title: GUIDING CATHETER



(57) Abstract

A catheter (10) is disclosed having a proximal shaft formed from an inner liner (21) formed from a copolymer of polyvinylidene fluoride and hexafluoropropylene, an outer jacket (23) formed from a blend of nylon and polyether block amide or polyether block amide alone, and a soft flexible tip (30) affixed to the distal end of the proximal shaft formed from polyether block amide. A stem (50) may be located between the proximal shaft and the soft flexible tip (30). The stem (50) has an outer jacket formed from a proximal stem transition sleeve (51) with a tapered distal end and a distal stem sleeve (52) with a complementary tapered proximal end connected to the tapered distal end of the proximal stem transition sleeve (51). The stem transition sleeve (51) and the stem sleeve (52) are both formed from polyether block amide alone or a blend of polyether block amide and nylon. The outer jacket (23) may be the same hardness as or harder than the stem transition sleeve (51) which in turn is harder than the stem sleeve (52) and the soft flexible tip (30). An intermediate wire mesh braid extends through the proximal shaft and, if desired, through the stem.

GUIDING CATHETER

Background of the Invention

Guiding catheters are commonly used during coronary angioplasty procedures to aid in delivering a balloon catheter or other interventional medical device to a treatment site in a coronary vessel. In a routine coronary angioplasty procedure, a guiding catheter is introduced into a peripheral artery and advanced over a guidewire through the aorta until the distal end of the guiding catheter is engaged with the appropriate coronary ostium. Next a balloon dilatation catheter is introduced over the guidewire and through the guiding catheter. The guidewire is advanced past the distal end of the guiding catheter within the lumen of the diseased vessel and manipulated across the region of the stenosis. The balloon dilatation catheter is then advanced past the distal end of the guiding catheter over the guidewire until the balloon is positioned across the stenotic lesion. After the balloon is inflated to dilate the blood vessel in the region of the stenotic lesion, the guidewire, balloon dilatation catheter and guiding catheter are withdrawn.

Guiding catheters typically have preformed bends formed along their distal portion to facilitate placement of the distal end of the guiding catheter into the ostium of a particular coronary artery of a patient. In order to function efficiently, guiding catheters should have a relatively stiff main body portion and soft distal tip. This stiffness has been provided in the past by using a reinforced construction or by using certain relatively stiff polymeric materials. The stiff main body portion gives the guiding catheter sufficient "pushability"

and "torqueability" to allow the guiding catheter to be inserted percutaneously into a peripheral artery, moved and rotated in the vasculature to position the distal end of the catheter at the desired site adjacent to a particular coronary artery. However, the distal portion should have sufficient flexibility so that it can track over a guidewire and be maneuvered through a tortuous path to the treatment site. In addition, a soft distal tip at the very distal end of the catheter should be used to minimize the risk of causing trauma to a blood vessel or even puncturing the vessel wall while the guiding catheter is being moved through the vasculature to the proper position. Such a soft tip is described in U.S. Patent No. 4,531,943. In addition, the inner surface of the guiding catheter should be lubricous to facilitate movement of guidewires, balloon catheters and other interventional medical devices therethrough.

Guiding catheters currently on the market attempt to achieve these goals with varying degrees of success. However, none of the previous or current designs have heretofore provided an optimum combination of features that yield a catheter with a stiff main body portion, a flexible distal portion and a soft distal tip that can be successfully used in coronary angioplasty procedures.

~~Therefore it would be desirable to provide a~~ guiding catheter that has sufficient ~~rigidity~~ along its proximal portion for ~~enhanced~~ pushability and torqueability, ~~yet~~ has a flexible distal portion and ~~soft~~ tip to provide enhanced trackability and ~~minimize trauma to the vessel wall.~~

Summary of the Invention

It is an object of the current invention to provide an improved catheter.

There is disclosed herein a catheter comprising:

an elongate tube having a proximal end and a distal end defining an inner lumen and a wall with an annular cross section of a substantially uniform thickness between the distal end and the proximal end and with an exposed innermost liner formed from a material including a copolymer of polyvinylidene fluoride and hexafluoropropylene and an outer polymeric jacket;

wherein the catheter is stable upon exposure to gamma radiation.

The guiding catheter of this invention can also include a stem. The stem is comprised of a stem transition sleeve and a stem sleeve that fits over the inner liner along a distal portion of the bodystock. The stem transition sleeve has a tapered distal portion. The stem sleeve has a tapered proximal portion that complements the taper of the stem transition sleeve. The outer jacket of the bodystock along this distal portion may be removed to allow the stem transition sleeve and stem sleeve to be fitted thereon. In addition, the stem may have a braided reinforcement therein.

Brief Description of the Drawings

The above and other objects and advantages of this invention will be apparent upon consideration of

the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout and in which:

FIG. 1 is a plan view of one embodiment of the guiding catheter of this invention with a portion of the catheter removed to show the construction of the bodystock;

FIG. 2 is a longitudinal sectional view of the distal portion of one embodiment of the guiding catheter of this invention prior to the attachment of the stem and tip;

FIG. 3 is a longitudinal sectional view of the stem transition sleeve and stem sleeve prior to assembly of the guiding catheter of this invention;

FIG. 4 is a longitudinal sectional view of the distal portion of one embodiment of the guiding catheter of this invention; and

FIG. 5 is a plan view of the distal portion of the guiding catheter of this invention showing the stem transition sleeve, stem sleeve and soft tip.

Detailed Description of the Invention

One embodiment of the invention is a guiding catheter 10 which has a tubular bodystock 20 and a soft tip 30 attached to the distal end of bodystock 20. Guiding catheter 10 can have any desired inner diameter and outer diameter. Typical dimensions are an inner diameter of between about 0.050 inches to about 0.130 inches (0.127 cm to 0.330 cm) and an outer diameter of about 0.070 inches to about 0.150 inches (0.178 cm to 0.381 cm). A conventional polycarbonate hub 40 is attached to the proximal end of bodystock 20. In addition, an injection molded strain relief tube 50 is connected to hub 40 and the

proximal portion of bodystock 20. Strain relief tube 50 preferably has a tapered design as shown in FIG. 1. However, a constant outside diameter construction could also be used. The material used to produce strain relief tube 50 is a polyether block amide (PEBA) having a hardness of 25D to 63D. The PEBA may be mixed with up to 50% nylon, preferably nylon-12, 15% to 36% barium sulfate for radiopacity and either 4% titanium dioxide or 0.5% organic pigment as a colorant.

Bodystock 20 is formed from an inner liner 21, an intermediate wire mesh braid 22 and an outer jacket 23. Inner liner 21 is formed from a copolymer of polyvinylidene fluoride (PVDF) and hexafluoropropylene (HFP). HFP is used to enhance the ability of inner liner 21 to be plasma etched to facilitate the attachment of outer jacket 23 thereto. Preferably 10% HFP is used. Suitable PVDF/HFP copolymer can be obtained from Solvay under the designation Solef. The PVDF/HFP copolymer preferably has a thickness of between about 0.0010 inches (0.0025 cm) and about 0.0050 inches (0.0127 cm).

Inner liner 21 when formed from a PVDF/HFP copolymer provides a lubricous surface facing the lumen of guiding catheter 10. This facilitates the passage of other medical devices therethrough. In addition, the use of a PVDF/HFP copolymer for inner liner 21 allows guiding catheter to be gamma sterilized. Other prior catheters that use a polytetrafluoroethylene (PTFE/Teflon) inner liner cannot be gamma sterilized because PTFE is not gamma stable. If gamma sterilization will not be used, PVDF could be combined with another polymer such as PTFE. In addition, the PVDF/HFP copolymer can be

extruded continuously. This contributes to the ease of manufacture of the resulting product.

Intermediate wire mesh braid 22 is formed from stainless steel wires braided over inner liner 21. Although stainless steel wire is preferred, other suitable materials such as Kevlar, or various polymer filaments could also be used. The stainless steel wire has a circular cross-section with a diameter of between about 0.0010 inches (0.0025 cm) and about 0.0030 inches (0.0076 cm). Alternatively, a flat wire could be used. Any suitable braid pattern can be used for intermediate wire mesh braid 22. Preferably a 16 wire stagger braid pattern is used. In this pattern each wire is helically wound around inner liner 21 in a two over and two under braided manner. The braid angle, as measured from the plane perpendicular to the longitudinal axis of guiding catheter 10, can be between about 15 degrees and about 60 degrees with 30 degrees being preferred.

Outer jacket 23 is formed from PEBA alone or from a blend of PEBA and nylon. Suitable PEBA can be obtained from Atochem under the designation Pebax. Suitable nylon can be obtained from Huls, America under the designation Vestamid. Outer jacket 23 preferably has a durometer of between about 63D and about 72D. When a blend of nylon and PEBA is used for outer jacket 23, preferably up to 50% nylon-12 is used. The use of PEBA alone or blended with nylon provides a bodystock material that is sufficiently stiff so that guiding catheter 10 has a proximal portion with enhanced "pushability" and "torqueability".

Optionally the PEBA or nylon and PEBA blend for outer jacket 23 can be mixed with a radiopaque

material. Suitable materials are barium sulfate, bismuth subcarbonate, bismuth trioxide and bismuth oxychloride. Preferably a 36% by weight loading of barium sulfate is used. Lesser or greater amounts of barium sulfate can be used to make outer jacket 23 less radiopaque or more radiopaque as the case may be. A pigment can also be used to color outer jacket 23. If such a pigment is used, preferably 0.5% by weight is used. Lesser or greater amounts of the pigment can be used depending on the color desired.

Soft tip 30 constitutes the most distal end of guiding catheter 10. It is formed from PEBA such as the PEBA used for outer jacket 23. Preferably soft tip 30 has a durometer of between about 25D and about 40D. This gives soft tip 30 a softness that is sufficient to minimize the chances of damage to the inner surface of a blood vessel through which guiding catheter 10 may pass. In addition, it is hard enough to maintain an opening therethrough to allow the passage of a guidewire, balloon catheter or other interventional medical device to pass out of the distal end of soft tip 30. Soft tip 30 can be made radiopaque by mixing 15% by weight barium sulfate with the PEBA. Of course greater or lesser amounts of barium sulfate or other radiopaque filler can be used. A 4% by weight loading of titanium dioxide can be used to color soft tip 30. Again greater or lesser amounts of titanium dioxide can be used. Preferably soft tip 30 has a length of between about 0.060 inches (0.15 cm) to about 0.20 (0.51 cm) inches.

Preferably guiding catheter 10 has a stem 50 located between bodystock 20 and soft tip 30. Stem 50 is composed of stem transition sleeve 51 and a

stem sleeve 52. Stem transition sleeve 51 is formed from 40D to 70D PEBA blended with up to 50% nylon by weight. In addition, 36% barium sulfate by weight and 0.5% by weight of an organic pigment can be used. Again greater or lesser amounts of barium sulfate and the pigment can be used. Stem sleeve 52 is formed from 25D to 40D PEBA with up to 50% by weight of nylon. In addition, 15% to 36% by weight of barium sulfate can be used. Finally, 4% by weight of titanium dioxide or 0.5% by weight of an organic pigment can be used to provide color to stem sleeve 52. Again greater or lesser amounts of barium sulfate and the pigment can be used.

Stem transition sleeve 51 has a taper along the distal portion. Preferably this taper is 20 degrees but can be from about 10 degrees to about 30 degrees. Stem sleeve 52 has a complementary taper along its proximal portion to provide a smooth transition between stem transition sleeve 51 and stem sleeve 52. The length of stem sleeve 52 can vary depending on the length of the distal portion of guiding catheter 10 that is desired to be flexible. Preferably stem sleeve 52 can be from about 0.45 inches (1.14 cm) to about 2.1 inches (5.33 cm) as measured from its most distal end to the most proximal end of the taper. In addition, stem 50 can have a total length of between about 0.5 inches (1.27 cm) to about 6 inches (15.24 cm).

Stem transition sleeve 51 and stem sleeve 52 fit over the distal portion of bodystock 20 where outer jacket 23 and, if desired, braid 22 have been removed. This configuration provides a smooth transition in the flexibility of guiding catheter 10 from its proximal end to its distal end. This smooth

transition from the high hardness/stiffness of bodystock 20 to the high softness of soft tip 30 eliminates stress concentration at the stem to bodystock joint. High stress concentrations at this joint would promote kinking and failure of guiding catheter 10.

Guiding catheter 10 can be manufactured according to the following process. A thin layer of PVDF/HFP copolymer is extruded over a silicone impregnated acetal core rod to form inner liner 21. The PVDF/HFP copolymer is plasma etched in an argon/oxygen atmosphere. Other atmospheres, such as an ammonia atmosphere, could also be used. Preferably a molar ratio of 70 to 30 argon to oxygen is excited by an electrical current of 550 watts in a vacuum of 200 millitorr. The residence time of inner jacket 21 is six minutes. This gas plasma chemically modifies the surface of the copolymer as it passes through the plasma field. This surface modification leaves active molecular bonding sites free to attach to the polymer molecules in the second jacket. Of course this surface modification could be achieved by chemically etching the copolymer with, for example, butyl amine. The plasma etching step can occur either before or after the braiding step. A plurality of stainless steel wires are braided around the PVDF/HFP inner liner 21. The number of wires used is a function of the diameter of the catheter to be formed and the desired rigidity for the catheter. The PEBA or nylon/PEBA blend outer jacket 23 is extruded over wire mesh braid 22. For the stemless embodiment, the distal end of the resulting assembly is ground and soft tip 30 is injection molded thereto.

In the stemmed embodiment, a distal portion of outer jacket 23 and, if desired, a corresponding length of braid 22 is removed. Then a pre-extruded stem transition sleeve 51 and a pre-extruded stem sleeve 52 are slipped over the distal portion and RF welded in place. Soft tip 30 is injection molded to the distal end of this assembly.

Thus it is seen that a guiding catheter is provided that has a lubricous inner surface and is sufficiently rigid along its proximal length to provide "pushability" and "torqueability" yet is flexible along its distal portion and has a distal soft tip to provide enhanced trackability and to minimize trauma to the vessel wall. One skilled in the art will appreciate that the described embodiments are presented for purposes of illustration and not of limitation and the present invention is only limited by the claims which follow.

The claims defining the invention are as follows:

1. A catheter comprising:

an elongate tube having a proximal end and a distal end defining an inner lumen and a wall with an annular cross section of a substantially uniform thickness between the distal end and the proximal end and with an exposed innermost liner formed from a material including a copolymer of polyvinylidene fluoride and hexafluoropropylene and an outer polymeric jacket;

wherein the catheter is stable upon exposure to gamma radiation.

2. The catheter of claim 1 wherein the outer polymeric jacket comprises a blend of nylon and polyether block amide or polyether block amide alone.

3. The catheter of claim 1 further comprising an intermediate reinforcing layer.

4. The catheter of claim 1 further comprising a soft flexible tip formed from a material including polyether block amide affixed to the distal end of the elongate tube.

5. The catheter of claim 1 wherein the exposed innermost liner is plasma etched.

6. The catheter of claim 4 wherein the material forming the outer jacket is harder than the material forming the soft flexible tip.

7. The catheter of claim 4 wherein the material forming the outer polymeric jacket has a hardness in the range of about 63D to about 72D and the material forming the soft flexible tip has a hardness in the range of about 25D to about 40D.

8. The catheter of claim 3 wherein the intermediate reinforcing layer is a wire mesh braid.

9. The catheter of claim 1 further comprising a stem transition sleeve having a proximal end and a tapered distal end with its proximal end connected to the distal end of the elongate tube; and a stem sleeve with a complementary tapered proximal portion bonded to the tapered distal end of the stem transition sleeve.

10. The catheter of claim 9 wherein the innermost liner is formed from a material including a copolymer of polyvinylidene fluoride and hexafluoropropylene extends through the stem transition sleeve and stem sleeve in coaxial fashion.

11. The catheter of claim 9 further including a soft flexible tip formed from a material including polyether block amide affixed to the distal end of the stem sleeve.

12. The catheter of claim 11 wherein the stem transition sleeve has a hardness in the range of about 40D to about 70D and the stem sleeve and the soft tip both have a hardness in the range of about 25D to about 40D.

13. The catheter of claim 9 wherein the stem transition sleeve and the stem sleeve are both formed from a material including polyether block amide alone or a blend of polyether block amide and nylon.

14. The catheter of claim 9 further comprising a wire mesh intermediate reinforcing layer.

15. A catheter substantially as hereinbefore described with reference to the accompanying drawings.

Dated 7 February, 1997
Schneider (USA) Inc.

Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

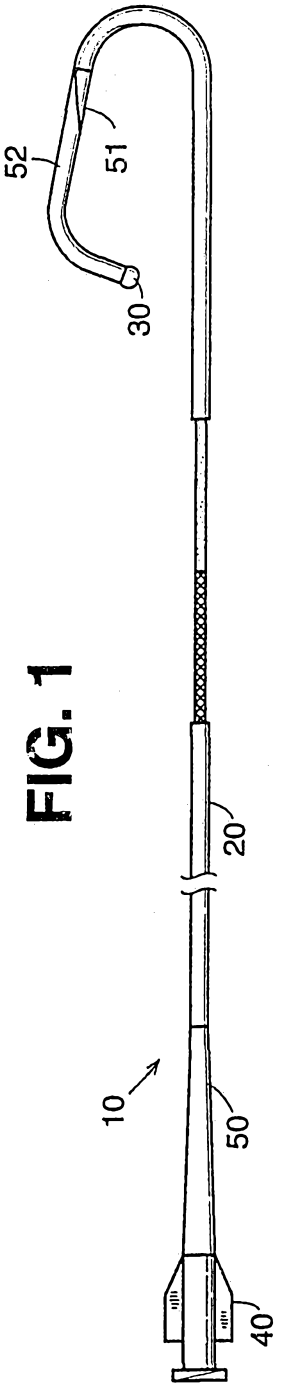


FIG. 1

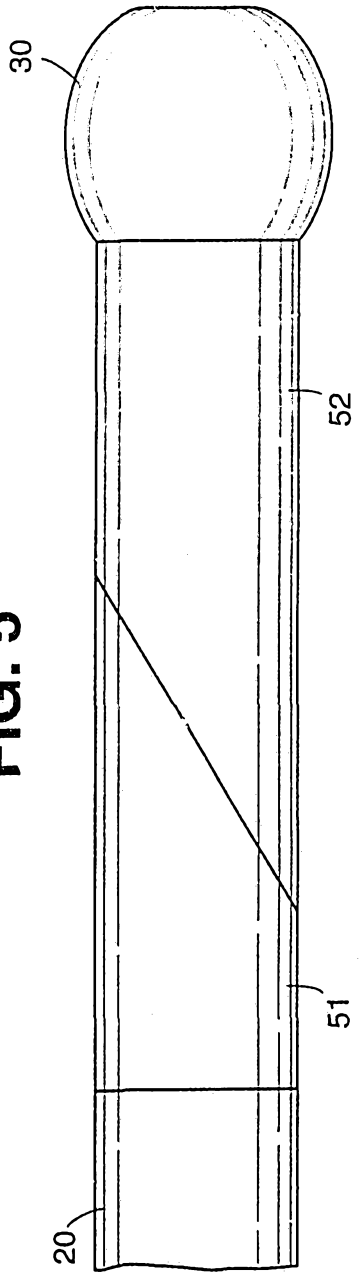
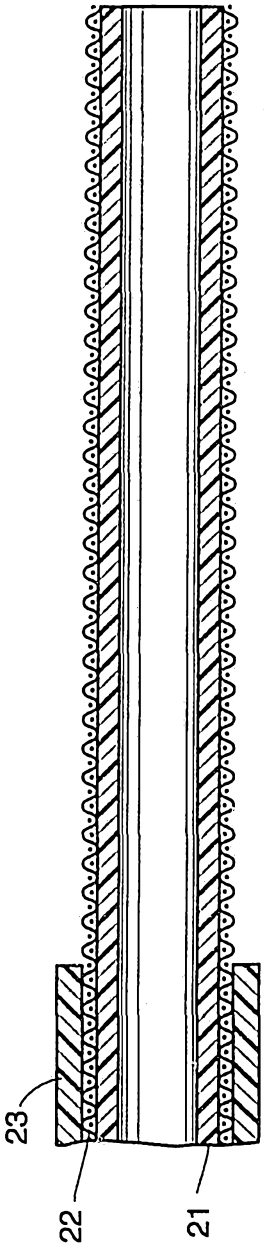


FIG. 5

78609/94

FIG. 2



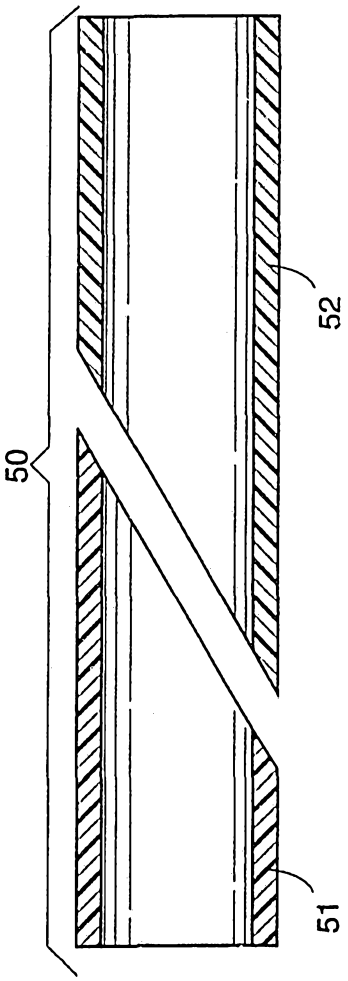


FIG. 3

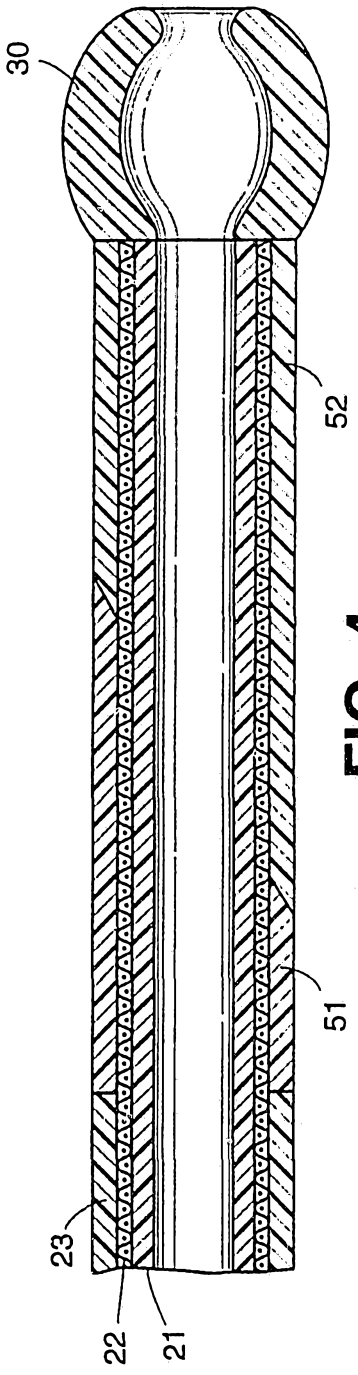


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 94/00336

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 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 6 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 520 692 (PARKER) 30 December 1992 see column 3, line 13 - line 41; figure 1 see column 5, line 10 - line 12	1-4
Y	US,A,4 425 919 (ALSTON) 17 January 1984 see column 3, line 10 - line 16; figure 1 see column 4, line 7 - line 29 see column 5, line 12 - line 15	1-4
A	WO,A,91 13648 (CRAWLEY) 19 September 1991 see page 1, line 20 - line 29; figure 3 see page 4, line 19 - line 21	1-4
A	EP,A,0 473 045 (IKEDA) 4 March 1992 see column 2, line 30 - line 38; figure 1	1

☐ 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

"E" earlier document but published on or after the international filing date

"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)

"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

"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

"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

"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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 July 1995	01. 08. 95

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	Germano, A

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

INTERNATIONAL SEARCH REPORT

national application No.
PCT/IB 94/ 00336

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims: 1-4

2. Claims: 5-23

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-4

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 94/00336

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0520692	30-12-92	US-A-	5221270	22-06-93
		AU-B-	652254	18-08-94
		AU-A-	1833492	07-01-93
		CA-A-	2069807	29-12-92
		CA-A-	2078201	29-12-92
		JP-A-	7008563	13-01-95
US-A-4425919	17-01-84	NONE		
WO-A-9113648	19-09-91	DE-D-	69103264	08-09-94
		DE-T-	69103264	24-11-94
		EP-A-	0530201	10-03-93
EP-A-0473045	04-03-92	NONE		