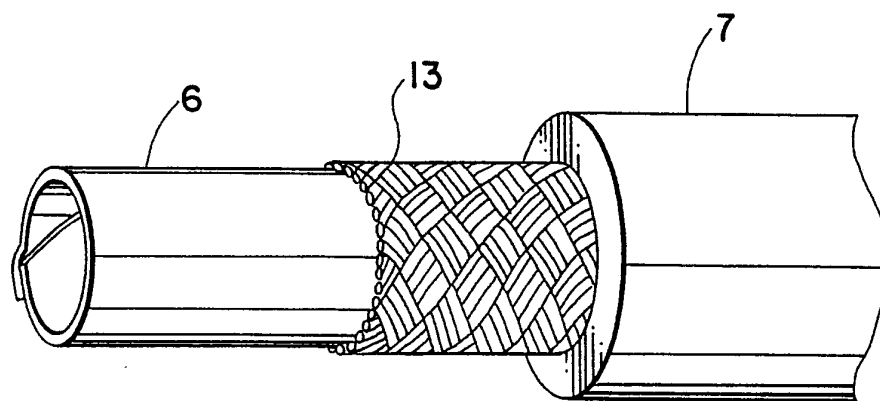




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁵ : A61M 25/00</p>	A1	<p>(11) International Publication Number: WO 91/13648 (43) International Publication Date: 19 September 1991 (19.09.91)</p>
<p>(21) International Application Number: PCT/US91/01771 (22) International Filing Date: 15 March 1991 (15.03.91) (30) Priority data: 494,649 15 March 1990 (15.03.90) US (71) Applicant: W.L. GORE & ASSOCIATES, INC. [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US). (72) Inventors: CRAWLEY, Jerald, Mathew ; 812 West Coy, Flagstaff, AZ 86001 (US). DAVIDSON, Daniel, Francis ; 3923 N. Paradise Road, Flagstaff, AZ 86004 (US). MY- ERS, David, John ; HC75 Box 2476, Camp Verde, AZ 86322 (US).</p>		<p>(74) Agents: SAMUELS, Gary, A. et al.; W.L. Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US). (81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). 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: A CATHETER LINER AND A METHOD OF MAKING THE SAME



(57) Abstract

A fluoropolymeric thinwall catheter liner of tape-wrapped construction is described, as well as a catheter tube comprising said catheter liner and a method of making such a catheter liner. By wrapping a tape of a thin fluoropolymer around a mandrel to form a tube it is possible to produce a fluoropolymeric catheter liner of thinner wall than has been previously possible with tube extrusion techniques. A thinner wall allows an increase in the carrying capacity of any catheter of given outside diameter, thereby increasing the effectiveness of the catheter.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

-1-

A CATHETER LINER AND A METHOD OF MAKING THE SAME

FIELD OF THE INVENTION

This invention relates to a fluoropolymeric thinwall catheter
5 liner of tape-wrapped construction, to catheters incorporating this
liner, and to methods of producing such a fluoropolymeric thinwall
catheter liner and catheters using the liner.

BACKGROUND OF THE INVENTION

Fluoropolymers are preferred materials for medical catheters
10 because they are biocompatible, inert, and lubricious. There is
little risk of adverse biological or chemical reaction with
fluoropolymer catheters. Their lubricious surfaces allow them to be
used effectively as guiding catheters or used in conjunction with
guidewire devices. Fluoropolymer catheters have less than ideal
15 handling and structural characteristics. Relative to other available
catheter materials, fluoropolymers offer relatively poor flexibility
and kink resistance, poor crush resistance, inadequate column strength
to allow the catheter to be pushed through complex passageways without
buckling, and are liable to buckle when subjected to torsional forces.

20 Because of the compromises involved between the mechanical,
biological and chemical requirements for catheter performance, many
available "high performance" catheters are of composite construction
that uses two or more different materials in order to take advantage
of their different desirable properties. For example, a common
25 composite construction involves the use of an outer polymeric jacket
of, for example, polyethylene, an intermediate layer of a structural
fiber such as braided stainless steel wire and an inner surface liner
of a fluoropolymer such as fluorinated ethylene propylene (hereinafter
FEP) or polytetrafluoroethylene (hereinafter PTFE). These composite
30 catheters are able to offer an inert and lubricious inner
fluoropolymeric surface, good column strength, crush resistance and
torque resistance due to the intermediate structural fiber, and

-2-

finally, good flexibility with a smooth outer surface due to the outer polymeric jacket.

One drawback to these composite construction catheters is their overall thickness. The outside diameter of a catheter is limited by
5 the space available within the body passages that it is required to negotiate. The available inside diameter and consequent catheter volume is thus limited by the thickness of the composite construction that makes up the wall of the catheter.

As the purpose of the inner surface liner is to provide an inert
10 and lubricious surface without any structural requirements other than maintaining an uninterrupted surface, the liner may functionally be very thin.

Fluoropolymer liners have heretofore been extruded with wall thickness down to about 0.0015 inches.

15

SUMMARY OF THE INVENTION

The present invention relates to a catheter liner comprised of a fluoropolymer tape wrapped around a mandrel to form a tube. The mandrel is subsequently removed from the inside of the liner. It also relates to catheters incorporating such a liner, and to methods of
20 making the liner and catheters incorporating the liner.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 shows a perspective view of a helically tape-wrapped fluoropolymer catheter liner of the present invention after the manufacturing mandrel has been removed.

25

FIGURE 2 shows a longitudinal section of a helically tape-wrapped fluoropolymer catheter liner of the present invention prior to the application of an outer jacket and prior to the removal of the manufacturing mandrel.

30

FIGURE 3 shows the construction of a finished catheter incorporating a helically tape-wrapped fluoropolymer catheter liner of the present invention, further having a first outer jacket of braided wire adjacent to and surrounding the liner and a second outer jacket

-3-

of polyethylene adjacent to and surrounding the first jacket of braided wire.

FIGURE 4 shows a cross section of a longitudinally applied tape-wrap forming the fluoropolymer catheter liner of the present invention wherein the tape edges are abutted.

FIGURE 5 shows a cross section of a longitudinally applied tape-wrap forming the fluoropolymer catheter liner of the present invention wherein the tape edges are overlapped.

DETAILED DESCRIPTION OF THE INVENTION

By wrapping a fluoropolymer tape around a mandrel to form a tube, it has been found possible to produce a fluoropolymer catheter liner having a thinner wall than previously available extruded fluoropolymer catheter liners. As shown in Figure 1, the catheter liner 6 of the present invention is made by diametrically slicing film rolls of wide, thin fluoropolymer film into rolls of narrow tape and wrapping the tape around a suitable mandrel. The tape may be wrapped around the mandrel either longitudinally, i.e., in cigarette wrap fashion, or helically. The tape edges may be abutted to adjacent tape edges or preferably adjacent tape edges may be overlapped. The wrapped tape is then heat-treated to melt-bond the edges of the tape to the adjacent layer of tape. The covering outer jacket or jackets may then be applied.

Figure 2 describes a longitudinal section of a catheter liner of the present invention prior to the application of an outer jacket and prior to removal of the manufacturing mandrel 10. In this configuration a helically applied tape wrapping is shown wherein half of the width of each tape layer 11 overlaps half of the width of the adjacent tape layer 12. In this fashion the liner is comprised of at least two layers of tape at any cross section and each tape edge is covered by the mid-portion of the width of the adjacent tape layer. It is apparent that more than two layers can be used if deemed necessary. It is also apparent that only one layer can provide a continuous fluoropolymer liner if the adjacent tape edges are sealed together by melt-bonding.

Figure 3 shows one possible catheter construction 7 using the catheter liner of the present invention. The tape-wrapped tubular liner 6 is shown having a braided first surrounding jacket of structural fibers 13, e.g., stainless steel wire or Nylon® fibers, and
5 further having a second surrounding jacket of a polymeric material with a smooth outer surface, e.g., polyethylene.

Figures 4 and 5 present different methods of finishing the tape edges. Figure 4 shows the tape edges 14 abutted while Figure 5 shows one tape edge 15 overlapping the second tape edge 16. Either abutted
10 edges or overlapped edges may be used with helical and longitudinal wrapping techniques. Abutted edges offer the option of minimizing the wall thickness while overlapped edges offer the most secure bond. Melt-bonding together of adjacent edge surfaces is done thermally as previously described.

15 Fluoropolymer tape-wrapped catheter liners can also be made to serve as exterior-surface liners for any desired type of catheter simply by applying the tape to the outer surface of the catheter construction as applied around a mandrel to produce an inner liner.

Fluoropolymer tapes used herein include tapes of
20 polytetrafluoroethylene, fluorinated ethylene propylene copolymer, perfluoro(alkyl vinyl ether) and ethylene/fluoroethylene copolymers.

Such a fluoropolymeric catheter liner can be produced with PTFE film of 0.0005 inch thickness, available in rolls from Norton Performance Plastics, Wayne, New Jersey. A roll may be sliced
25 diametrically using a sharp blade while rotating the roll so that a narrow roll of tape is produced. In constructing the catheter of the following description, a tape of 0.50 inch width can be sliced from the roll of film. Using conventional tape-wrapping techniques, a length of this tape can be helically wrapped around a silver plated
30 copper wire mandrel of 0.082 inch diameter. A slight amount of tension applied to the tape will allow it to lay uniformly and to fit tightly to the surface of the mandrel. The selected pitch results in the application of two layers of film over the surface of the mandrel. With a two-layer covering of film, all film edges are covered with an
35 overlying or underlying layer of film as shown in Figure 2. The tape-wrapped mandrel can then be placed into an oven set at 380°C for a period sufficient to melt-bond the tape edges to the adjacent tape

-5-

surfaces. This heat-treating process will result in the melt-bonding together of adjacent surfaces of the wrapped tape. The heat-treated tube, still on the wire mandrel, can then be immersed in a tank containing TETRA-ETCH® (W. L. Gore & Associates, Flagstaff, Arizona) for a period of about 15 seconds at about 25 degrees C. Residual TETRA-ETCH can then be removed in a rinse of isopropyl alcohol. The etching process will allow the subsequently applied layer of stainless steel wire braid to mechanically grip the outer surface of the tape-wrapped tube. This braid can be applied with a Steeger braiding machine using about 40 gauge stainless steel wire applied at about 30 picks per inch. Following the application of the braid, the assembly can be fed through a one inch screw extruder where an outer jacket of 0.014 inch thick polyethylene can be applied. The catheter tubing comprising the tape-wrapped liner, braided wire jacket and extruded polyethylene outer jacket, all surrounding the wire mandrel, can then be cut into desired lengths (typically 4.5 feet) using a wire cutting tool. The wire mandrel can then be extracted from the lumen of the catheter tubing by stripping about two inches of the liner, braid and jacket from each end, gripping the exposed wire and applying tension to cause the wire to stretch. The stretch can cause a reduction in the diameter of the wire mandrel, freeing it from the surface of the catheter liner and allowing removal of the catheter tubing from the mandrel. Any desired catheter fittings or terminations may then be attached to the catheter tubing by existing techniques (e.g., injection molding or by the use of adhesives).

This process allows the manufacture of very long continuous lengths of catheter tubing which may subsequently be cut into any desired shorter length. The use of certain metallic mandrel surfaces during manufacture may leave toxic residues which must be removed, preferably by flushing the catheter liner surface with an appropriate solvent. Mandrels of other materials may also be used, e.g., polymeric mandrels of FEP or PTFE. The essential requirements of the mandrel are that it has a smooth exterior surface, that it is removable from the catheter liner surface after the catheter has been cut to length, and that any potentially harmful residue mandrel material is easily and entirely removable. The use of inert mandrel

-6-

materials such as fluoropolymers is thus preferred. The mandrel may be of the form of a tube (hollow) or of a rod (solid).

EXAMPLE 1

A 75 foot length of fluoropolymeric catheter liner was made by
5 helically tape-wrapping an FEP tape (from Norton Performance Plastics,
Wayne, New Jersey) of 0.5 inch width and 0.0006 inch thickness about a
mandrel of PTFE tubing (from Teleflex, Jaffrey, New Hampshire) of
0.077 outside diameter and about 75 foot length. The tape was under
tension during tape-wrapping, causing about 3% elongation and thinning
10 of the tape to a thickness of about 0.0005 inches. The tape was
applied with conventional tape-wrapping equipment to give a total wall
thickness of two layers of tape at any cross section of the mandrel.
The tape-wrapped mandrel was heat treated to melt-bond the tape edges
in an oven set at 340°C for about 27 seconds, then etched, rinsed and
15 braided according to the description of Example 1. A 2 foot length of
FEP heat shrink tubing (SPC Technologies, Gaffney, North Carolina) was
placed over a 2 foot length cut from the braided mandrel. The outside
diameter of this tubing before shrinking was .250 inches, with a 0.010
inch thick wall. Heat shrinking was accomplished by pulling the tape-
20 wrapped and braided mandrel with surrounding FEP tubing through a
hollow, heated (340°C) die of 0.140 inch inside diameter and 1.0 inch
length at a rate of about 1 foot per minute. The die was contained
within a six inch long oven set at 340°C that allowed pre-heating of
the tubing before it contacted the die. In this manner the FEP heat
25 shrink tubing formed the outer jacket of the catheter construction.

About two inches of tape-wrapping, braid and jacket was stripped
from each end of the mandrel. One exposed mandrel end was gripped
between the jaws of a vise and tension was applied to the mandrel by
pulling the other exposed mandrel end by hand. The tension caused
30 elongation of the tubular PTFE mandrel, reducing its diameter and
allowing the finished catheter comprised of the FEP tape-wrapped
liner, the braided covering and surrounding outer FEP jacket to be
removed from the mandrel without damage to the catheter.

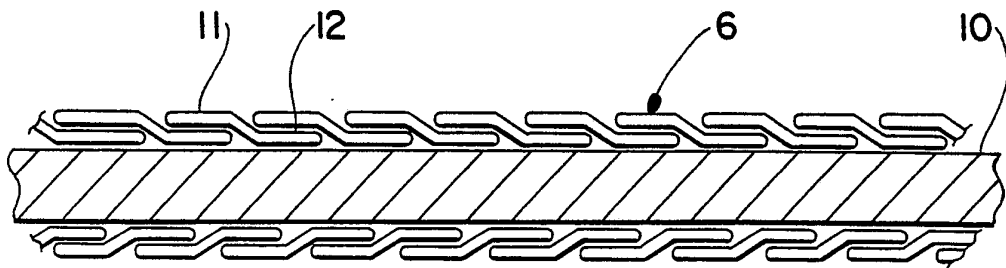
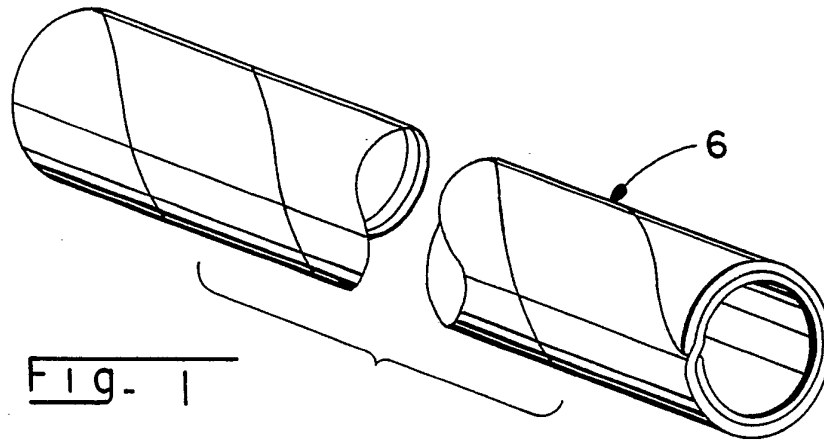
-7-

We Claim:

1. A catheter liner comprised of a fluoropolymer tape wrapped into the form of a tube.
2. A catheter liner according to claim 1 wherein said tape is helically applied.
- 5 3. A catheter liner according to claim 1 wherein said tape is longitudinally applied.
4. A catheter liner according to claim 1 wherein said tape is applied in at least two layers wherein one layer overlaps the other layer.
- 10 5. A catheter liner according to claim 4 wherein said overlapping tape layers are melt-bonded together.
6. A catheter liner according to claim 1 wherein said liner has a wall thickness less than or equal to 0.0015 inches.
- 15 7. A catheter liner according to claim 1 wherein said liner has a wall thickness less than or equal to 0.0010 inches.
8. A catheter tube comprised of a fluoropolymer tape-wrapped tubular liner and at least one outer tubular jacket that concentrically surrounds said tubular liner.
- 20 9. A catheter tube according to claim 8 wherein said outer jacket is comprised of polyethylene.
10. A catheter tube according to claim 8 wherein said outer jacket is comprised of braided stainless steel wire.
11. A catheter liner comprised of a fluoropolymer tube having a spiral seam.
- 25 12. A catheter liner comprising a fluoropolymer tube having a longitudinal seam.
13. A catheter liner according to claim 11 or 12 wherein said tube has a wall thickness less than or equal to 0.0010.
- 30 14. A method of making a fluoropolymeric catheter liner which comprises wrapping a fluoropolymer tape around a mandrel to form a tube.
15. The method of claim 14 wherein the tape is helically wrapped around said mandrel.
- 35 16. The method of claim 14 wherein the tape is longitudinally wrapped around said mandrel.

17. The method of claim 14 wherein said tape is wrapped in overlapping layers, further comprising melt-bonding said overlapping layers together.
18. The method of claim 14 which further comprises removing
5 the mandrel from the catheter liner.

1/2



2 / 2

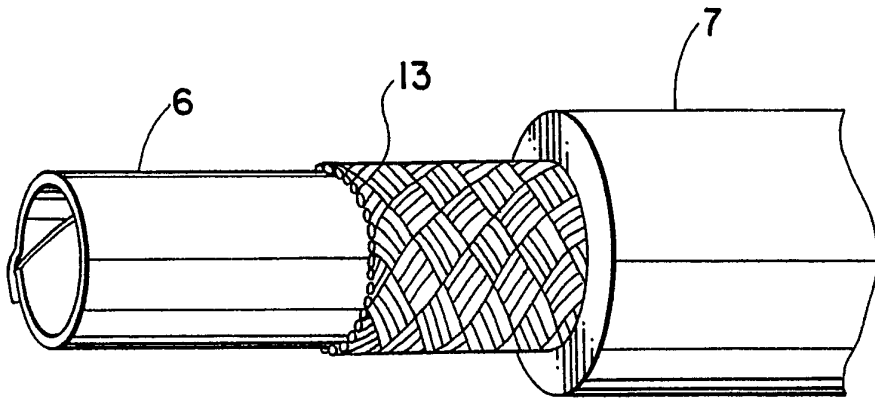


FIG- 3

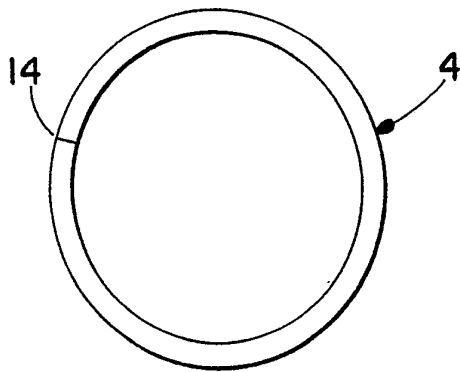


FIG- 4

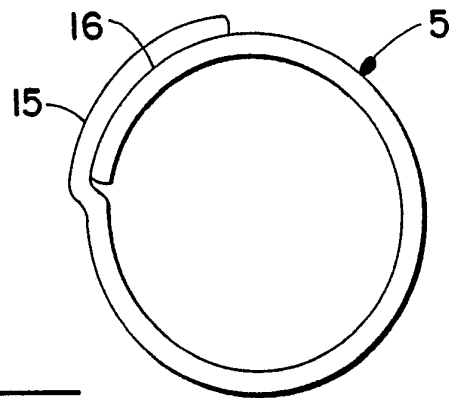
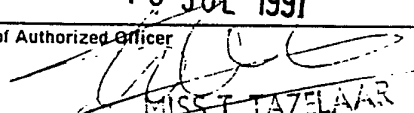


FIG- 5

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/01771

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶				
According to International Patent Classification (IPC) or to both National Classification and IPC				
IPC5: A 61 M 25/00				
II. FIELDS SEARCHED				
Minimum Documentation Searched ⁷				
Classification System	Classification Symbols			
IPC5	A 61 M; F 16 L			
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched ⁸				
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹				
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³		
A	FR, A, 1591251 (OHLER FLEXROHR G.M.B.H.) 5 June 1970, see the whole document --	1,2,4, 11,14, 15,17, 18		
A	SE, B, 315449 (CALUMET & HECLA CORPORATION) 29 September 1969, see the whole document --	1,2,11, 14,15, 18		
A	US, A, 4430083 (GANZ ET AL) 7 February 1984, see e.g. detail 25 and adherent text --	1,2,8, 14,15, 18		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> <p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 50%; border: none; vertical-align: top;"> <p>"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</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p> </td> </tr> </table>			<p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>
<p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>			
IV. CERTIFICATION				
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report			
26th June 1991	18 JUL 1991			
International Searching Authority	Signature of Authorized Officer			
EUROPEAN PATENT OFFICE	 MISS T. TAZELAAR			

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	DE, B2, 1640127 (GENERAL CABLE CORP.) 18 May 1977, see e.g. details 14 and 24 and adherent text --	1,3,4,6, 7,13,16, 17
A	US, A, 4106509 (MCWHORTER) 15 August 1978, see e.g. column 1, line 61 --	1,8
A	US, A, 4280500 (ONO) 28 July 1981, see e.g. column 1, lines 58-59 --	1,8
A	GB, A, 2043201 (SURGIMEDA/S) 1 October 1980, see e.g. p. 2, line 80 and p. 3, line 4 --	9,10
A	Patent Abstracts of Japan, Vol 2, No 98, M 30, abstract of JP 53- 67109, publ 1978-06-15 (NITTO DENKI KOGYO K.K.) -- -----	1,3,4,5, 12,16, 17

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

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

1. Claim numbers....., because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim numbers....., 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. Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

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

- 1) A catheter liner according to claims 1-7 and a method of making the same according to claims 14-18,
 - 2) a catheter tube according to claims 8-10,
 - 3) a second catheter liner according to claims 11 and 13 and
 - 4) a third catheter liner according to claims 12 and 13.
1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
 2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
 3. 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 claim numbers:
 4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
- No protest accompanied the payment of additional search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/US 91/01771**

SA 46029

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 29/05/91. The European Patent office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A- 1591251	05/06/70	NONE	
SE-B- 315449	29/09/69	NONE	
US-A- 4430083	07/02/84	CA-A- 1170137 EP-A- 0063859 JP-A- 57173065	03/07/84 03/11/82 25/10/82
DE-B2- 1640127	18/05/77	SE-B-C- 372839	13/01/75
US-A- 4106509	15/08/78	CA-A- 1099172 DE-A- 2734742 FR-A- 2360319 GB-A- 1525357	14/04/81 09/02/78 03/03/78 20/09/78
US-A- 4280500	28/07/81	NONE	
GB-A- 2043201	01/10/80	DE-A- 3006058 FR-A-B- 2454907 SE-A- 8001287 US-A- 4321226	04/09/80 21/11/80 20/08/80 23/03/82

For more details about this annex : see Official Journal of the European patent Office, No. 12/82