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[Continued on next page]

(54) Title: HIGH PRESSURE INFUSION CATHETER

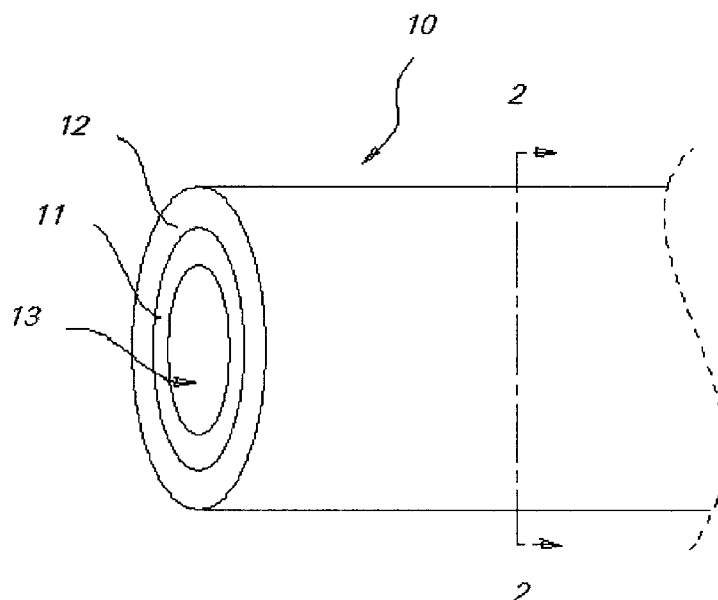


FIG. 1

(57) Abstract: A catheter (10) having an outer tubular layer (42) defining a lumen (13) and a thin-walled liner (11) on an inner surface of an outer tubular layer is disclosed. In the presently preferred embodiment, the material of the liner is PTFE which has a thickness of ≤ 0.0015 inches. The outer tubular layer is composed of a nylon, polyurethane, or PEBAX material. The flex modulus of this material is under 60,000 psi so that the catheter retains some flexibility. Although the liner by itself is fairly rigid and kinkable, the PTFE liner provides excellent strength in preventing ruptures. The traits change, however, when the outer tubular layer is applied. The combination of the two materials results in a flexible shaft with excellent flow rate capacity.



Published:

— *with international search report (Art. 21(3))*

HIGH PRESSURE INFUSION CATHETER

FIELD OF THE INVENTION

[0001] The present invention generally relates to a catheter, and in particular, to an infusion catheter with a high flow rate capacity.

BACKGROUND OF THE INVENTION

[0002] A peripherally inserted central catheter (PICC) is a form of intravenous access that can be used for a prolonged period of time, e.g. for extended chemotherapy regimens, long duration antibiotic therapy or total parenteral nutrition. Accordingly, peripherally inserted central catheters have several requirements that are necessitated by these and related procedures.

[0003] First, they need to have high flow rates to deliver large quantities of fluid media to the blood stream. In particular, the catheters need to be able to handle large volumes of therapeutic agents. However, high flow rates may generate relatively high pressure and cause the formation of aneurisms, which may result in a potential rupture to the veins.

[0004] Second, these catheters need to be fairly flexible. This is because increased flexibility of catheters may reduce potential trauma to the veins caused by catheters remaining in the body for several weeks. In addition, increased flexibility may also reduce the potential kinking of catheters. Kinking often occurs as the catheter is introduced and advanced into the patient, particularly when advanced along a tortuous pathway or past luminal strictures.

[0005] Therefore, a catheter is needed that may provide sufficient strength to withstand the high pressure generated by high flow rates as well as high degree of flexibility to reduce potential trauma and kinking.

SUMMARY OF THE INVENTION

[0006] The present invention is directed to a catheter having an outer tubular layer defining a lumen and a thin-walled liner disposed on the inner surface of the outer tubular layer.

[0007] In one embodiment of the invention, the outer tubular layer is composed of a nylon, polyurethane, or polyether block amide (PEBAX) material. The flex modulus of this material is under 60,000 psi, which allows the catheter to retain some degree of flexibility. The thin-walled liner disposed on the inner surface of the outer tubular layer comprises polytetrafluoroethylene (PTFE) having a thickness of ≤ 0.0015 inches. The thin-walled PTFE

liner provides high degree of strength that is sufficient to withstand the relatively high pressure that is typically generated by high flow rates and is therefore resistant to rupturing. However, the liner material by itself is fairly rigid and kinkable. When the outer tubular layer is applied there over, these traits of rigidity and kinking are modified. The combination of the two materials results in a flexible shaft with excellent flow rate capacity.

[0008] In another embodiment of the invention, the liner on inner surface of the outer tubular layer of the catheter includes a thin-walled polyolefin or PEBAX heat shrink material. Due to the greater strength of this material, the burst pressure of the device increases, while minimally affecting the flexibility.

[0009] In a third embodiment of the invention, the catheter comprises multiple lumens. Each lumen is PTFE-lined. These lumens may be round or oval in shape, which minimizes their profiles and maximizes their flow rates. Ovaling of lumens can be accomplished by inserting undersized mandrels into the liners prior to applying the outer tubular layer of polymer or heat shrink material. The compressive forces applied during processing will naturally oval out the liner. The PTFE liner may also comprise a heat shrinkable form that can be shrunk over on an oval shaped mandrel, over which the outer tubular layer material can then be applied.

[0010] In a fourth embodiment of the invention, a nylon, polyurethane or PEBAX material is sandwiched between the outer heat shrink material and the thin-walled liner. The flex modulus is varied along the length of the shaft to provide variable flexibility along the length thereof. This can also fill in the voids that are present with the multilumen variants. The material may also be selectively filled with radio-opaque material for fluoro imaging.

[0011] These and other advantages, as well as the invention itself, will become apparent in the details of construction and operation as more fully described below. Moreover, it should be appreciated that several aspects of the invention can be used with other types of catheters or elongate medical devices utilized for delivering a fluid or therapeutic agent to a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings, in which:

FIG. 1 is a perspective view of the first embodiment of the invention;

FIG. 2 is a cross-sectional view taken along line 2-2 of FIG. 1;

FIG. 3 is a cross-sectional view of the third embodiment of the invention; and

FIG. 4 is a cross-sectional view of the fourth embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0013] The invention is described with reference to the drawings in which like elements are referred to by like numerals. The relationship and functioning of the various elements of this invention are better understood by the following detailed description. However, the embodiments of this invention as described below are by way of example only, and the invention is not limited to the embodiments illustrated in the drawings. It should also be understood that the drawings are not to scale and in certain instances details have been omitted, which are not necessary for an understanding of the present invention, such as conventional details of fabrication and assembly.

[0014] FIGS. 1-2 illustrate an exemplary embodiment. The catheter 10 has an outer tubular layer 12 which forms a lumen 13. The thin-walled liner 11 is disposed on the inner surface of the outer tubular layer 12. The material of the thin-walled liner 11 on the inner surface of the outer tubular layer 12 is PTFE, which has a thickness of ≤ 0.0015 inches. The outer tubular layer 12 is composed of a nylon, polyurethane, or PEBAX material. The flex modulus of the outer material is under 60,000 psi so that the catheter 10 retains some overall flexibility. The liner 11 by itself is fairly rigid and tends to kink. Nevertheless, it provides excellent strength and can accommodate the relatively high pressure that is typically generated by high flow rates, which prevents rupturing of the catheter 10. When the outer tubular layer 12 is applied to and disposed over the inner layer 11, however, the inner layer's traits of rigidity and tendency to kink are modified. The combination of the two materials results in a flexible shaft with excellent flow rate capacity.

[0015] In a second embodiment, the liner 11 on the inner surface of the outer tubular layer 12 of the catheter 10 includes the use of thin-walled polyolefin or PEBAX heat shrink material. This increases the burst pressure of the device due to the higher relative strength of this material while minimally affecting the flexibility.

[0016] FIG. 3 illustrates a third embodiment. The catheter 10 forms multiple lumens 13. Each lumen 13 is PTFE-lined. These lumens 13 are preferably rounded or oval in shape, which minimizes their profiles and maximizes their flow rates. However, other cross-sectional shapes can be employed depending on the size, number and arrangement of the lumens 13. In the particular embodiment illustrated, the lumens 13 each have a rounded "D"-shape. Rounding or ovaling of the lumens 13 can be accomplished by inserting undersized mandrels into the liners 11 prior to applying the outer tubular layer 12 of polymer or heat

shrink material. The compressive forces applied during processing will naturally oval out the liner 11. The PTFE liner 11 may also comprise a heat shrinkable form that can be shrunk on an ovaled mandrel, over which the outer tubular layer 12 material can then be applied.

[0017] FIG. 4 illustrates a fourth embodiment. A nylon, polyurethane or PEBAX material 12 is sandwiched between the outer heat shrink material 14 and the thin-walled liner 11. The flex modulus of the heat shrink material 14 may be varied along the length of the shaft to provide a variable flexibility to the shaft. For example, in some embodiments the distal portion of the shaft may be made more flexible than the proximal portion of the shaft to provide a shaft that is both flexible and pushable. The heat shrinkable material 14 can also fill in any voids that may be present within the middle layer 12 of the multilumen variants. Selective portions of the heat shrink material 14 may also be filled with a radio-opaque material for fluoro imaging.

[0018] While there have been described what are presently believed to be the preferred embodiments of the invention, those skilled in the art will realize that changes and modifications may be made thereto without departing from the spirit of the invention. It is to be understood that the invention can be carried out by specifically different apparatus and methods of use, and that various modifications, both as to the apparatus details and use thereof, can be accomplished without departing from the scope of the invention itself.

CLAIMS:

1. A medical catheter comprising an elongate shaft, the shaft comprising:
an outer tubular layer defining a lumen; and
a thin-walled liner disposed on an inner surface of the outer tubular layer, the liner comprising a PTFE material and having a thickness of equal to or less than about 0.0015 inches.
2. The catheter of Claim 1, wherein the liner material is selected from the group consisting of polyolefin and PEBAX.
3. The catheter of Claim 2, wherein the outer tubular layer is selected from the group consisting of nylon, polyurethane and PEBAX.
4. The catheter of Claim 3, wherein the outer tubular layer material has a flex modulus of less than 60,000 psi.
5. The catheter according to any of the preceding claims, wherein the lumen comprises a plurality of sub-lumens separated by the PTFE liner material.
6. The catheter of Claim 5, wherein the sub-lumens each have a rounded or oval cross-sectional shape.
7. The catheter according to any of the preceding layers, wherein a heat shrinkable material is disposed over an outer surface of the outer tubular layer.

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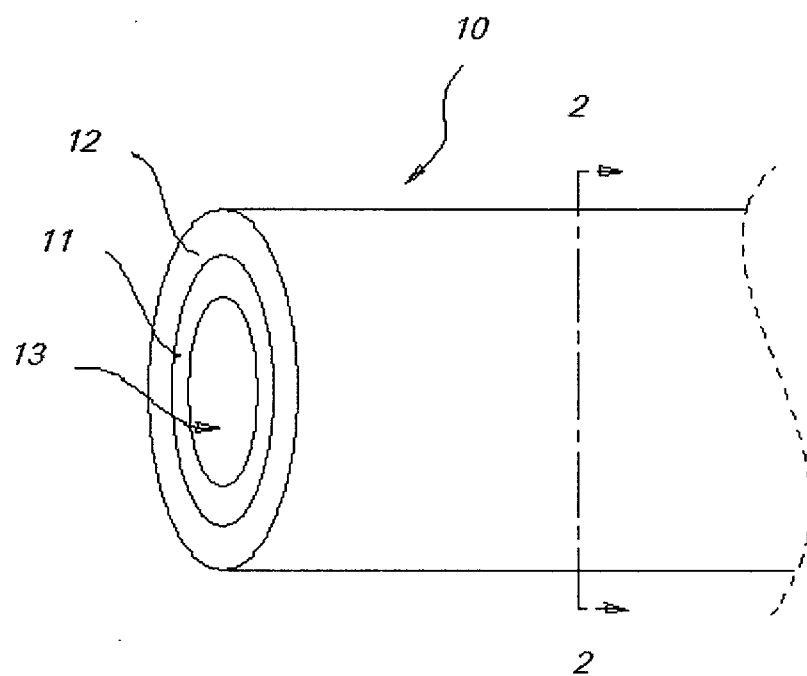


FIG. 1

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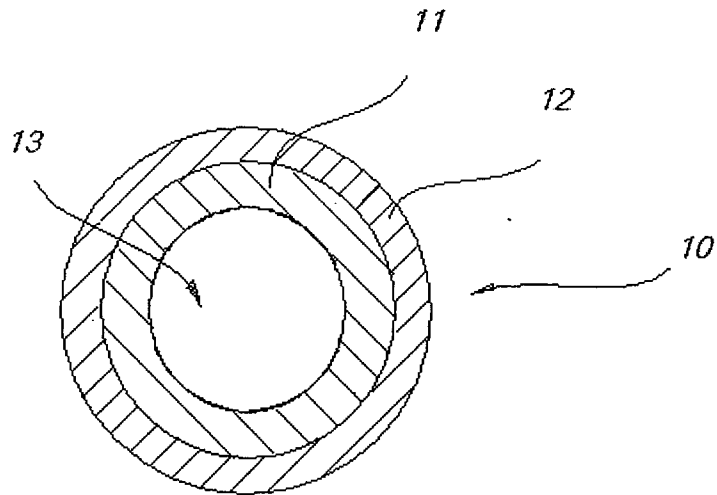


FIG. 2

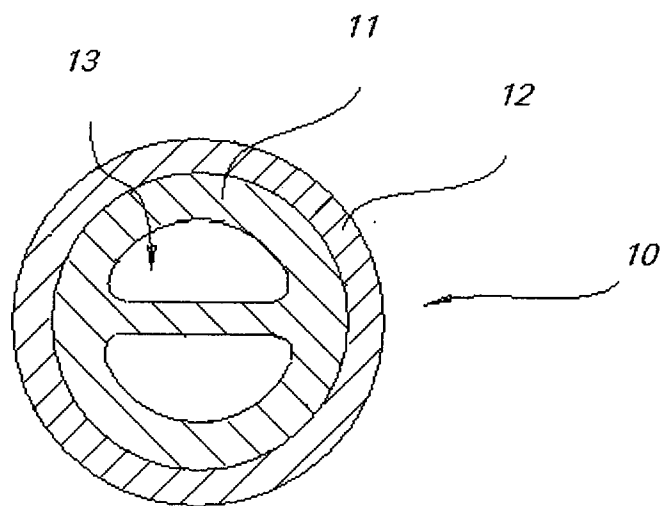


FIG. 3

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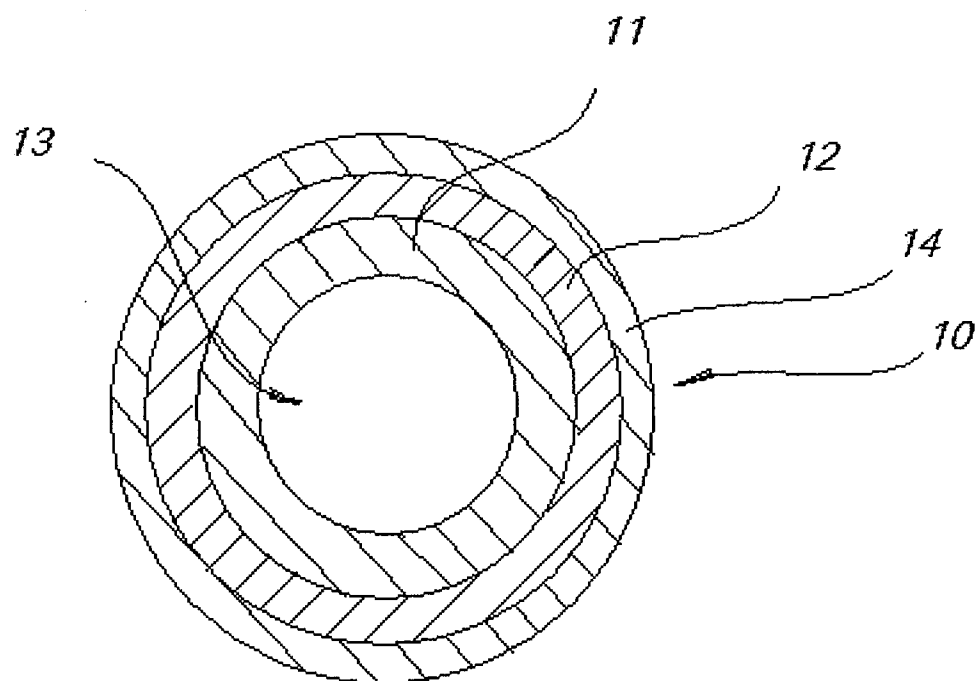


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/068935

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00 A61L29/14 A61L29/08

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)
A61M A61L

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 186 986 B1 (BERG TODD ALLEN [US] ET AL) 13 February 2001 (2001-02-13) column 2, line 63 - column 6, line 54; figures 1a-5	1,3-4,7
X	US 2007/169877 A1 (LEEFLANG STEPHEN A [US] ET AL) 26 July 2007 (2007-07-26) paragraph [0003] - paragraph [0005] paragraph [0061] - paragraph [0083]; figures 1a-3d paragraph [0106] - paragraph [0108]; figure 7	1,3,5-7
X	WO 91/13648 A1 (GORE & ASS [US]) 19 September 1991 (1991-09-19) the whole document	1,3,7
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family 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

11 March 2010

Date of mailing of the international search report

22/03/2010

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/068935

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/65557 A2 (SCIMED LIFE SYSTEMS INC [US] BOSTON SCIENT LTD [BB]) 23 December 1999 (1999-12-23) page 7, line 13 - page 10, line 30; figures 2-4 -----	1,3,5-6
X	EP 1 068 876 A2 (TERUMO CORP [JP]) 17 January 2001 (2001-01-17) paragraph [0036] - paragraph [0063]; figures 1-7 paragraph [0066] - paragraph [0081] paragraph [0140] - paragraph [0143] -----	1,3-4
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X	WO 01/07101 A1 (TFX MEDICAL EXTRUSION PRODUCTS [US]) 1 February 2001 (2001-02-01) page 5, line 25 - page 11, line 28; figures 1-5 -----	1,3,5-7
X	EP 0 729 766 A1 (CORDIS EUROP [NL]) 4 September 1996 (1996-09-04) column 2, lines 5-36; figure 1 column 2, line 58 - column 3, line 10; figure 3 column 3, lines 25-32 -----	1
A	US 5 702 372 A (NELSON TIMOTHY S [US]) 30 December 1997 (1997-12-30) column 3, line 18 - column 4, line 63; figure 2 -----	1,3

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 2(completely); 3-4(partially)

The independent claim 1 defines the liner comprising a PTFE material, and claim 2 states that the liner material is selected from the group consisting of polyolefin and PEBAX (which does not include PTFE). Dependent claims 3 and 4 have been searched as claims dependent on claim 1 alone.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/068935

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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.: 2(completely); 3-4(partially)
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:
see FURTHER INFORMATION sheet PCT/ISA/210
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 No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

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 searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
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.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/068935

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