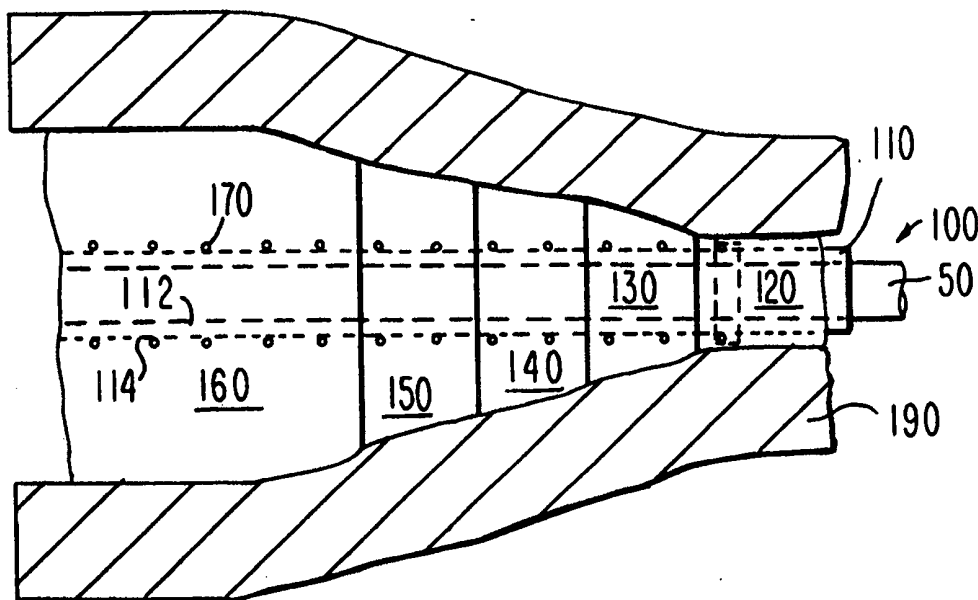




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(54) Title: MICRO-CATHETERS AND METHODS OF THEIR MANUFACTURE



(57) Abstract

A micro-catheter including an inner primary liner and a plurality of concatenated tubular sections is provided. The primary liner extends substantially from the proximal end to the distal end of the catheter. Each of the tubular sections has a respective inner surface that is fused to the outer surface of the primary liner. The outer diameter of any section is equal to or greater than the outer diameter of any other more distally located section. Each of the tubular sections may have different physical properties and dimensions for making customized micro-catheter profiles.

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MICRO-CATHETERS AND
METHODS OF THEIR MANUFACTURE

Background of the Invention

This invention relates to medical catheters
5 for accessing vascular target sites for diagnostic or
intervention purposes. In particular, this invention
relates to micro-catheters capable of navigating
through extremely small diameter vessels.

Goldsteen et al. U.S. patent application
10 No. 08/745,618, filed November 7, 1996 (which is hereby
incorporated by reference herein), shows medical
procedures and instrumentation for installing tubular
grafts in a patient (e.g., for providing a bypass
15 conduit around a blockage in the patient's circulatory
system). A key aspect of that invention involves using
flexible catheters that are inserted into a patient's
body through remote entry ports. These catheters must
be capable of traveling relatively long distances,
sometimes through circuitous, small diameter vessels
20 (less than 2 millimeters), such as peripheral
vasculature of the brain and heart. This environment,
however, may cause a guide wire located in the micro-
catheter to bind, or cause the micro-catheter itself to
kink or buckle, which may prevent the catheter from
25 reaching a target site in a patient.

In addition to guiding wires, micro-catheters
may be used to inject viscous fluids, including drugs,

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to target sites in the patient. However, due to the viscous nature of some fluids and the small diameter of the lumen of the catheter, the fluid may be injected through the lumen at very high pressures, sometimes as high as 400 psi. Such pressures may cause the wall of the micro-catheter to rupture, or burst, which may harm the patient. Also, these fluids may be reactive with the inner surface of the flexible micro-catheter, which may cause rapid degradation of the catheter wall, thereby increasing the susceptibility of the wall to bursting.

In view of the foregoing, it is an object of this invention to provide a micro-catheter to access vascular target sites for diagnostic and interventional purposes.

It is another object of the invention to provide a micro-catheter with improved kinking and buckling resistance.

It is still another object of the invention to provide a flexible micro-catheter with high burst strength and relatively low reactivity with reactive fluids.

It is a further object of the invention to provide a flexible micro-catheter with a high degree of steerability.

It is yet another object of the invention to provide methods of manufacturing a micro-catheter that has variable flexibility and profile along its length.

Summary of the Invention

These and other objects of the invention are accomplished in accordance with the principles of the invention by providing a micro-catheter that includes a tubular primary liner that extends substantially along the entire length of the catheter and a plurality of concatenated tubular sections having inner surfaces

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that are fused to the outer surface of the primary liner. The outer diameter of any section is equal to or greater than the outer diameter of any other more distally located section. In a preferred embodiment of
5 the present invention, a structural section, which extends substantially the entire length of the primary liner, is embedded between the primary liner and the tubular sections.

A method for making a micro-catheter in
10 accordance with the principles of this invention is also provided. In a first step, a primary mandrel is covered with a tubular primary liner having an outer surface. Subsequently, a plurality of tubular sections are placed over the primary liner to form a
15 concatenated chain of sections. Next, the outer surface of the primary liner is fused to the inner surfaces of the tubular sections and axially adjacent sections are fused to each other. Finally, the primary mandrel is removed from the primary liner to form a
20 primary lumen. When a structural section is desired to improve the torque response, kink resistance, and burst resistance of the catheter, that structural section is preferably inserted between the primary liner and the tubular sections.

25 Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments.

Brief Description of the Drawings

30 FIG. 1A is a simplified longitudinal view, partly in section, of a representative portion of an illustrative micro-catheter before being fused in accordance with this invention. In FIG. 1A and several other FIGS., catheter width is greatly exaggerated

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compared to length to better reveal the construction of various catheter components.

FIG. 1B is another view similar to FIG. 1A showing the same illustrative micro-catheter after
5 being fused in accordance with this invention.

FIG. 2 is a longitudinal elevational view of a portion of another illustrative micro-catheter having a curved section in accordance with this invention.

FIG. 3 is a longitudinal elevational view of
10 a portion of another illustrative micro-catheter having several curved sections in accordance with this invention.

FIG. 4A is a longitudinal view of two adjacent sections, with roughened ends, of still
15 another illustrative micro-catheter in accordance with this invention.

FIG. 4B is a longitudinal view of two adjacent sections, with shaped ends, of yet another illustrative micro-catheter in accordance with this
20 invention.

FIG. 5 is a flow chart of an illustrative embodiment of the procedure for manufacturing a micro-catheter according to this invention.

Detailed Description of the Preferred Embodiments

25 According to the present invention, a micro-catheter and methods for the manufacture and use of such a catheter are provided. The micro-catheter includes at least a primary liner and a plurality of concatenated tubular sections fused to the primary
30 liner. A micro-catheter constructed in accordance with this invention may, for example, be used to guide instruments or fluids, or it may stand alone, for accessing particular vascular sites.

As used herein, a micro-catheter is a
35 catheter for intra-vascular use, including coronary

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vessels, neuro-vessels, and/or neuro-vasculature. In contrast to a micro-catheter, a guiding catheter is not for intra-vascular use. A guiding catheter is larger than a micro-catheter and normally serves as a conduit
5 for delivery of an interventional device, such as a micro-catheter, a guiding wire, or a balloon catheter, to targeted vasculature.

FIGS. 1A and 1B show micro-catheter 100 before and after fusing, respectively. Catheter 100
10 includes at least primary liner 110 and concatenated tubular sections 120, 130, 140, 150, and 160. Primary liner 110 extends substantially from the proximal end (not shown) of catheter 100 to distal end 102 of catheter 100 and has inner surface 112 and outer
15 surface 114. Each of concatenated tubular sections 120, 130, 140, 150, and 160 has an inner surface 122, 132, 142, 152, and 162, respectively, that is fused to outer surface 114 of primary liner 110. The outer diameter of any section is equal to or
20 greater than the outer diameter of any other more distally located section. In other words, given any pair of two sections, including a distal section and a proximal section (such as sections 120 and 130 and sections 120 and 160), the distal section has an outer
25 diameter that does not exceed the outer diameter of the proximal section. The outer diameter of the distal section, however, should be equal to or less than the outer diameter of the proximal section of the pair. Micro-catheter 100, as shown in FIG. 1A, has five
30 tubular sections 120, 130, 140, 150, and 160, but may, in accordance with this invention, have more or less sections, as required.

Primary liner 110 preferably has a substantially cylindrical shape. Primary liner 110 can
35 be made from any flexible material, including many polymers. Polymers that may be used in accordance with

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this invention include polytetrafluoroethylene and (such as that sold under the trademark TEFLON® by E. I. du Pont de Nemours & Company, of Wilmington, Delaware), polyetheramide (such as that sold under the trademark PEBAX®, by Ato Chemie, of Courbevoie, France), polyamide, polyimide, and any combination thereof.

The magnitude of inner diameter 116 of primary liner 110 depends on the particular application for which catheter 100 is used. However, inner diameter 116 can certainly range between about 0.010 inches and about 0.160 inches, preferably less than about 0.020 inches. Primary liner 110 preferably has a wall thickness 118 of between about 0.00075 inches and about 0.003 inches, but could be more or less as needed. Outer surface 114 of primary liner 110 is preferably roughened before being fused to inner surfaces 122, 132, 142, 152, and 162 to improve adhesion. Outer surface 114 may be roughened by etching it mechanically or chemically, but any roughening technique may be used. One type of chemical etching technique involves exposing surface 114 to tetrafluoroethylene (such as that sold under the trademark TETRA-ETCH®, by W.L. Gore & Associates, Inc., of Newark, Delaware).

Sections 120, 130, 140, 150, and 160 may be made from any polymer capable of being molded when subject to elevated temperatures during fusing, including polytetrafluoroethylene, polyamide, polyimide, and preferably, polyetheramide.

As shown in FIG. 1A, micro-catheter 100 may further include structural section 170 disposed on outer surface 114 of primary liner 110 and substantially between outer surface 114 of primary liner 110 and sections 120, 130, 140, 150, and 160. Structural section 170 provides improved torque

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response, kink resistance, and burst resistance. Structural section 170 also provides a certain amount of rigidity to catheter to prevent collapse at sharp turns. Preferably, structural section 170 does not
5 extend to distal end 102 of catheter 100 to form tip portion 123 without structural section 170 disposed thereunder. In this way, tip portion 123 remains very flexible. Although tip portion 123 may have any axial length, lengths between about 3 millimeters and
10 about 10 millimeters have been found to work particularly well for many micro-catheter applications. Tip section 123 may have any useful outer diameter, and is preferably less than about 0.030 inches.

Structural section 170 may also have any
15 appropriate wall thickness, but for many micro-catheter applications that thickness is preferably between about 0.001 inches and about 0.003 inches. In order to ensure proper fusing between outer surface 114 of primary liner 110 and the inner surfaces of the tubular
20 sections, intervening structural section 170 should not prevent those surfaces from contacting with each other during fusing. Therefore, porous structural materials that provide contact between the layers and the liner during fusing, such as metal braid, coil, or ribbon,
25 are appropriate structural materials. Structural section 170 may also be embedded directly in primary liner 110 before primary liner fused to the tubular sections.

A micro-catheter in accordance with this
30 invention may further include an electromagnetically opaque material for determining the catheter position with electromagnetic radiation during use of the catheter. Preferably, electromagnetically opaque material is substantially opaque to electromagnetic
35 radiation having a frequency in the x-ray portion of the electromagnetic spectrum. Examples of

electromagnetically opaque materials include bismuth carbonate, tungsten, barium sulfate, and mixtures thereof.

In one embodiment of the present invention,
5 the opaque material is a powder dispersed in at least one of the tubular sections. When the opaque material has a different concentration in each of the sections, the resulting opacity can be used to identify the exact positions of those sections during use. The
10 electromagnetically opaque material may also be in the form of a solid marker attached to a known position on catheter 100. For example, as shown in FIG. 1A, marker 180 is placed on, or embedded in, section 120. Marker 180 may indicate the outer diameter of
15 section 120 to prevent inserting a catheter too far. A plurality of markers can also be positioned along the catheter to identify multiple sections of the catheter during an operation.

Sections 120, 130, 140, 150, and 160 are made
20 from flexible materials, preferably flexible polymers that are capable of being molded when subject to elevated temperatures during fusing, such as polytetrafluoroethylene, polyamide, polyimide, and polyetheramide. Polyetheramide is a preferred polymer
25 because its physical characteristics, including hardness, tensile strength, and flexural modulus, can be engineered by choosing the proper ratio of (1) regular and linear chains of rigid polyamides to (2) flexible polyethers. For example, in order to obtain a
30 micro-catheter having a flexibility that increases distally, the polyamide-polyether concentration ratio should decrease distally. In other words, the concentration ratio of any proximal section should not be less than the concentration ratio for any other more
35 distal section.

In a similar fashion, other physical properties of the micro-catheter can be varied axially. For example, if the hardness of a catheter should decrease distally, the hardness of any distal section
5 should not exceed the hardness for any other more proximal section. Of course, a single section can have a hardness that decreases distally as well, either in a step-wise fashion or continuously. In addition to hardness, the flexural modulus of the catheter will
10 decrease distally when the flexural modulus of any distal section does not exceed the flexural modulus of any other more proximal section. And, like hardness, a single section can have a flexural modulus that varies (especially decreases) distally, either in a step-wise
15 fashion or continuously, if originally formed that way. Furthermore, as shown clearly in FIG. 2, the length of each successive section may decrease (or increase) in a distal direction.

The following table describes some physical
20 properties of the illustrative example according to the present invention shown in FIGS. 1A and 1B:

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EXAMPLE

Section No.	Flexural Modulus Range(kpsi)	Hardness (D)	Radial Dimensions (inner x outer diameter (inches))	Length (cm)
120	2-3	40	0.023 x 0.026	1
130	3-13	55	0.023 x 0.028	3
140	13-29	63	0.023 x 0.031	7
150	29-50	67	0.023 x 0.033	20
160	> 50	70-80	0.023 x 0.039	94

In order to improve the steerability of a micro-catheter according to this invention, at least one of the tubular sections may be curved. The curvature improves steerability because when catheter is rotated in a vessel, for example, the catheter tip can be pointed in any desired angular direction. For example, FIG. 2 shows micro-catheter 200, including sections 220, 230, 240, 250, and 260, of which section 260 is curved. FIG. 3 shows micro-catheter 300, including 320, 330, and 340, of which sections 330 and 340 are curved. The curved sections are formed by heating the micro-catheter around a curved mandrel. Curvature may be accomplished by inserting a curved mandrel into a prefused catheter and applying heat to reshape the catheter. Alternatively, the catheter may be formed during the initial fusing process with a curved primary mandrel. Furthermore, a catheter that is curved and braided provides steerability and torque such that a guide wire is not always required.

In addition to the primary mandrel, one or more secondary mandrels may be used to form respective integrated secondary lumen, as described more fully in Berg et al. U.S. application No. 08/____,____, filed _____ (Docket No. 293/032), which is hereby

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incorporated by reference herein. A secondary lumen may be integrated into one or more contiguous sections and form an opening at any position along the length of the catheter.

5 FIG. 5 shows an illustrative sequence of steps 500 for manufacturing a catheter in accordance with this invention, such as micro-catheters 100, 200, and 300, shown in FIGS. 1B, 2, and 3, respectively. These steps include covering a primary mandrel with a
10 tubular lining in step 510, placing or sliding a plurality of tubular sections over said primary liner in step 520, fusing the primary lining and tubular sections in step 530, and removing the primary mandrel from the primary liner to form a primary lumen therein
15 in step 540. To some extent these steps have already been mentioned, so the discussion of them here may be some what abbreviated.

In step 510, a primary mandrel is covered with a tubular primary liner. Primary mandrel 50 may
20 be cylindrical and have any outer diameter. However, preferred embodiments of the invention are formed using a primary mandrel with an outer diameter of up to about 0.020 inches. The primary mandrel may be covered by vapor deposition or sliding the primary liner onto
25 the primary mandrel. In order to improve the fused bond between the inner surface of the tubular sections and the outer surface of the primary liner during fusing, in step 530, the outer surface of the primary liner may be roughened, such as by etching, by any
30 conventional mechanical or chemical technique.

In step 520, a plurality of tubular sections are placed over the primary liner to form a concatenated chain of sections. Each of the sections has an inner surface and an outer diameter.
35 Furthermore, given any two sections, including a distal section and a proximal section, the distal section has

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an outer diameter that does not exceed the outer diameter of the proximal section. The outer diameter of the distal section, however, may be equal to or less than the outer diameter of the more proximal section.

5 The axial ends of each tubular section may be shaped or roughened to improve the fused bond between adjacent sections. For example, FIG. 4A shows an illustrative embodiment according to this invention in which contacting surfaces 412 and 422 of adjacent
10 sections 410 and 420 are roughened before fusing. FIG. 4B shows another illustrative embodiment in which portions of contacting surfaces 432 and 434 of respective sections 430 and 440 are shaped to axially overlap. This overlap increases the surface area,
15 which may improve the fused bond therebetween.

 In step 515, the primary liner may optionally be covered with a porous structural section that permits contact during fusing between the outer surface of the primary liner and the inner surfaces of the
20 tubular sections. As described in some detail above, the structural section provides improved torque response, kink resistance, and burst resistance.

 In step 518, a secondary mandrel may optionally be inserted between the primary liner and
25 the tubular sections before being fused together to form an integrated secondary lumen upon removal of the secondary mandrel in step 550. Preferably, the secondary mandrel is first coated with a secondary liner, which may be made from the same material as the
30 primary liner. Inserting a secondary mandrel in step 518 preferably includes placing the distal end of the secondary mandrel at a surface of the catheter to form a secondary lumen opening. That opening may be at a tubular section outer surface (such as outer
35 surface 154 of section 150), a tubular section distal surface (such as distal surface 145 of section 140), a

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primary liner inner surface (such as inner surface 112), or a primary liner distal surface (such as distal surface 111). The secondary lumen opening may also be formed at the intersection between any two adjacent section outer surfaces (such as at point 155 between sections 140 and 150). As described more fully in the above-mentioned Berg et al. reference, an inflatable balloon may be formed at an outer surface opening by bonding with an elastic sheet over that opening.

In step 530, the inner surfaces of the tubular sections are fused to the outer surface of the primary liner and axially adjacent sections are fused to each other. Step 530 may include (1) placing heat shrink tubing over the chain of concatenated sections, (2) heating the heat shrink tubing so that it squeezes together the primary liner (and any secondary liners) and the tubular sections, and (3) removing the heat shrink tubing after the heating step. Fusing may further include heating the primary liner via the primary mandrel. Finally, in step 540, the primary mandrel is removed from the primary liner to form a primary lumen.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the number of sections, as well as the material properties and physical dimensions, may be selected as needed.

The Invention Claimed Is

1. A micro-catheter having a proximal end and a distal end, said micro-catheter comprising:
a tubular primary liner that substantially extends from said proximal end to said distal end, said primary liner having an inner surface and an outer surface; and
a plurality of concatenated tubular sections having respective inner surfaces fused to said primary liner outer surface, such that any pair of said sections comprises a proximal section having an outer diameter and a distal section having an outer diameter that does not exceed outer diameter of said proximal section.
2. The micro-catheter of claim 1 wherein said primary liner comprises a material selected from a group consisting of polytetrafluoroethylene, polyamide, polyimide, polyetheramide, and any combination thereof.
3. The micro-catheter of claim 1 wherein said primary liner has an inner diameter of less than about 0.020 inches.
4. The micro-catheter of claim 1 wherein said primary liner has a wall thickness of between about 0.00075 inches and about 0.003 inches.
5. The micro-catheter of claim 1 wherein said primary liner outer surface is roughened.
6. The micro-catheter of claim 1 further comprising a structural section disposed on said outer surface of said primary liner for providing torque

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response, kink resistance, and burst resistance to said catheter.

7. The micro-catheter of claim 6 wherein a distal most section has a distally located tip portion, said structural section being disposed on said primary liner up to a proximal end of said tip portion so that said tip portion has a desired stiffness.

8. The micro-catheter of claim 7 wherein said tip portion has an axial length of between about 3 millimeters and about 10 millimeters.

9. The micro-catheter of claim 6 wherein said structural section is substantially between said outer surface of said primary liner and said sections.

10. The micro-catheter of claim 6 wherein said structural section has a wall thickness of between about 0.001 inches and about 0.003 inches.

11. The micro-catheter of claim 6 wherein said structural section comprises a structural material.

12. The micro-catheter of claim 11 wherein said structural material is metal.

13. The micro-catheter of claim 12 wherein said structural material is selected from a group consisting of braided, coiled, and ribboned materials.

14. The micro-catheter of claim 1 further comprising an electromagnetically opaque material for

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determining a position of said catheter with electromagnetic radiation during catheter use.

15. The micro-catheter of claim 14 wherein said electromagnetically opaque material is substantially opaque to electromagnetic radiation having a frequency in the x-ray portion of the electromagnetic spectrum.

16. The micro-catheter of claim 15 wherein said electromagnetically opaque material is selected from a group consisting of bismuth carbonate, tungsten, barium sulfate, and mixtures thereof.

17. The micro-catheter of claim 15 wherein said opaque material is a powder dispersed in at least one of said sections.

18. The micro-catheter of claim 17 wherein said opaque material has a different concentration in each of said at least one sections for identification purposes during use of said catheter.

19. The micro-catheter of claim 15 wherein said opaque material is a solid marker attached to a known position of said catheter.

20. The micro-catheter of claim 1 wherein each of said sections comprises a polymer.

21. The micro-catheter of claim 20 wherein said polymer comprises polyetheramide having a polyether concentration and an polyamide concentration at a polyether-polyamide ratio, wherein said ratio for said proximal section is not less than said ratio for said distal section.

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22. The micro-catheter of claim 20 wherein each of said sections has a hardness, said distal section hardness not exceeding said proximal section hardness.

23. The micro-catheter of claim 22 wherein at least one of said sections has a hardness that decreases distally.

24. The micro-catheter of claim 23 wherein said at least one of said sections has a hardness that continuously decreases distally.

25. The micro-catheter of claim 1 wherein each of said sections has a length, said distal section length not substantially exceeding said proximal section length.

26. The micro-catheter of claim 1 wherein each of said sections has a flexural modulus, said distal section flexural modulus not exceeding said proximal section flexural modulus.

27. The micro-catheter of claim 1 wherein at least one of said sections has a flexural modulus that decreases distally.

28. The micro-catheter of claim 27 wherein said at least one of said sections has a flexural modulus that continuously decreases distally.

29. The micro-catheter of claim 26 wherein said sections include a tip section, said tip section being closest to said distal end of said catheter, said tip section outer diameter being less than about 0.030 inches.

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30. The micro-catheter of claim 29 wherein at least one of said sections has an outer diameter that decreases distally.

31. The micro-catheter of claim 30 wherein said at least one of said sections has an outer diameter that continuously decreases distally.

32. The micro-catheter of claim 1 wherein at least one of said plurality of tubular sections is curved to improve steerability.

33. The micro-catheter of claim 1 wherein said catheter has an integrated secondary lumen.

34. The micro-catheter of claim 33 wherein said secondary lumen is at least partially formed in one of said sections.

35. The micro-catheter of claim 34 wherein at least two of said adjacent sections at least partially overlap.

36. A method for making a micro-catheter having a proximal end and a distal end, said method comprising:

covering a primary mandrel with a tubular primary liner having an outer surface;
placing a plurality of tubular sections over said primary liner to form a concatenated chain of sections, each of said sections having an inner surface and an outer diameter, any pair of said sections including a proximal section and a distal section, said distal section outer diameter not exceeding said proximal section outer diameter;

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fusing said outer surface of said primary liner to said inner surfaces of said sections and axially adjacent sections to each other; and removing said primary mandrel from said primary liner to form a primary lumen.

37. The method of claim 36 wherein said covering comprises covering a primary mandrel that has an outer diameter of up to about 0.020 inches.

38. The method of claim 36 wherein said covering comprises covering with a primary liner having a thickness of between about 0.001 inches and about 0.003 inches.

39. The method of claim 36 wherein said covering comprises covering with a polymer.

40. The method of claim 39 wherein said covering comprises covering with a polymer comprising a material selected from a group consisting of polytetrafluoroethylene, polyamide, polyimide, polyetheramide, and any combination thereof.

41. The method of claim 39 wherein said covering comprises depositing by condensation of vapor.

42. The method of claim 39 wherein said covering comprises sliding said primary liner onto said primary mandrel.

43. The method of claim 36 further comprising roughening said outer surface of said first layer to improve said fusing to said inner surfaces of said sections.

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44. The method of claim 36 wherein said placing comprises placing at least two adjacent sections that have axially overlapping portions.

45. The method of claim 36 further comprising covering said primary liner with a porous structural section, said structural section providing physical contact between said outer surface of said primary liner and said inner surfaces of said tubular sections during said fusing.

46. The method of claim 45 further comprising placing a secondary mandrel adjacent an outer surface of said structural section before said fusing.

47. The method of claim 36 further comprising inserting a secondary mandrel between said primary liner and said sections before fusing for forming a respective secondary lumen.

48. The method of claim 47 wherein said inserting comprises inserting a secondary mandrel coated with a secondary liner.

49. The method of claim 47 wherein said secondary liner comprises a material selected from a group consisting of polytetrafluoroethylene, polyamide, polyimide, polyetheramide, and any combination thereof.

50. The method of claim 47 wherein said inserting comprises inserting said secondary mandrel so that a distal end of said secondary mandrel forms an opening at a surface of said catheter, said surface being selected from a group consisting of a tubular section outer surface, a tubular section distal

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surface, a primary liner inner surface, a primary liner distal surface, and an intersection between any two adjacent section outer surfaces.

51. The method of claim 50 further comprising bonding an elastic sheet around said opening to form an inflatable balloon.

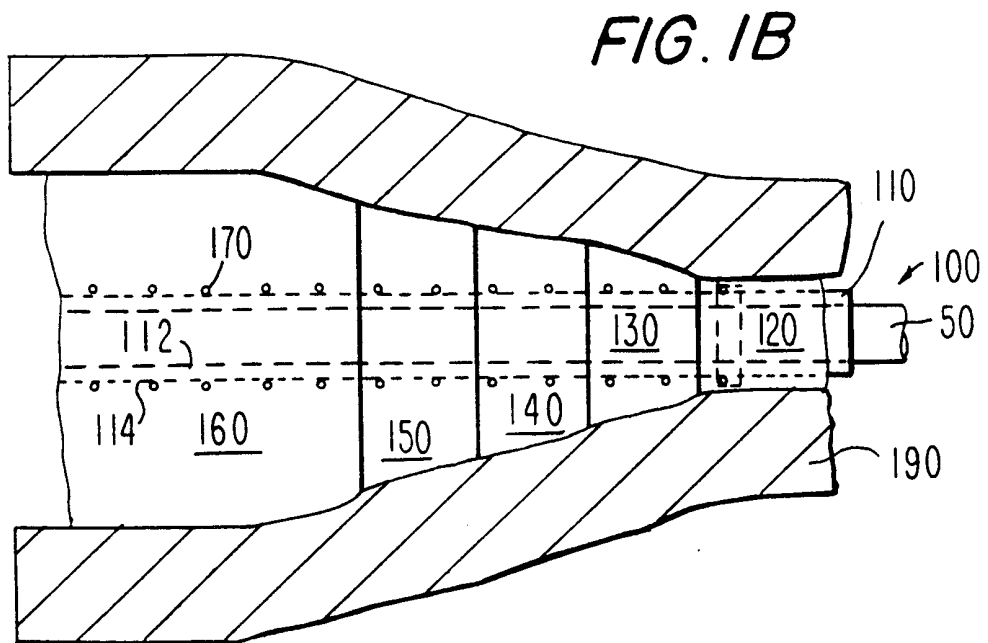
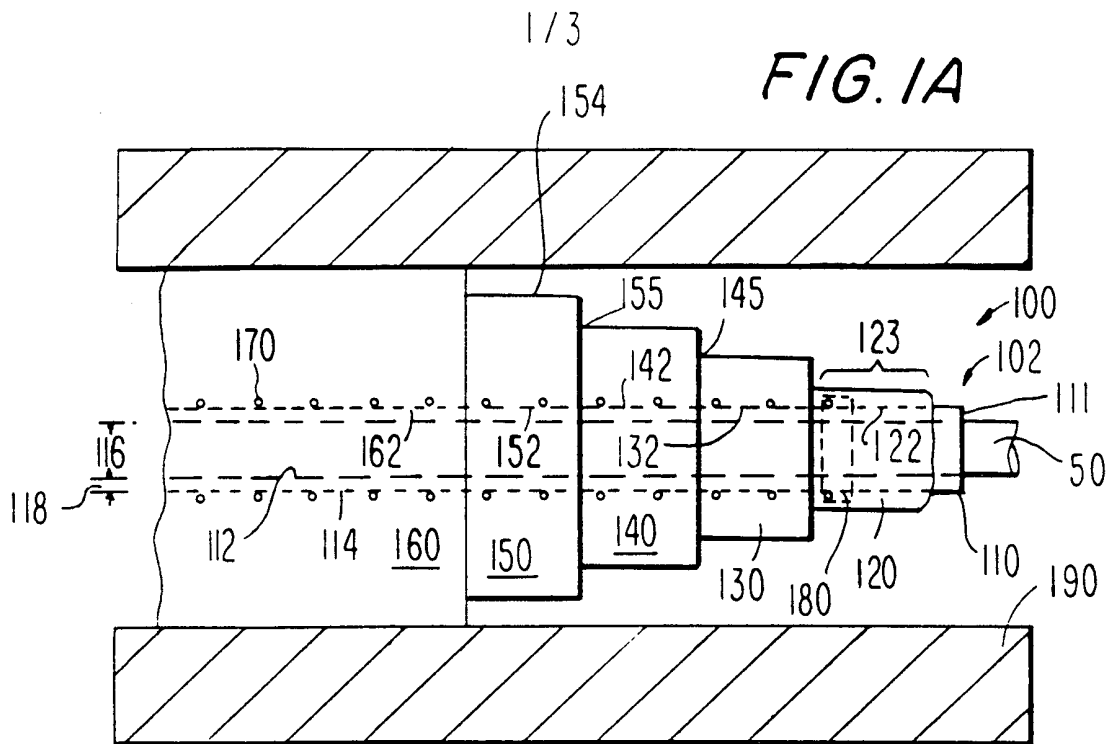
52. The method of claim 36 wherein said fusing comprises:

placing heat shrink tubing over said sections;

heating said heat shrink tubing so that it squeezes said liner and sections together, thereby causing said outer surface of said primary liner to fuse to said inner surfaces of said sections and said axially adjacent sections to fuse to each other; and

removing said heat shrink tubing after said heating.

53. The method of claim 36 wherein said fusing comprises applying heat to said primary liner by heating said primary mandrel.



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FIG. 2

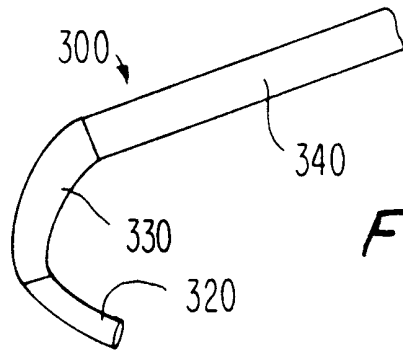
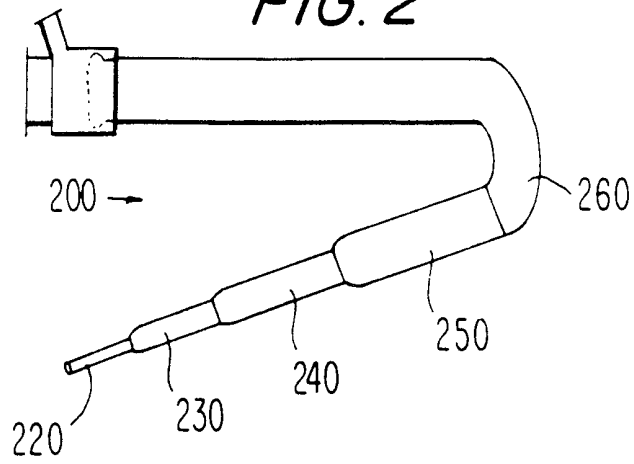


FIG. 3

FIG. 4A

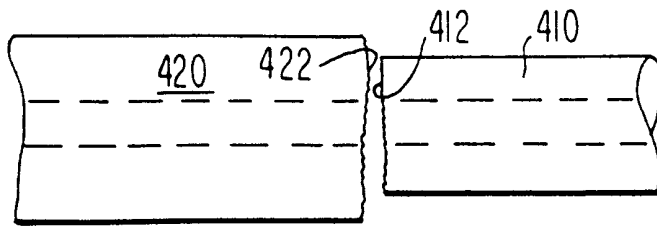
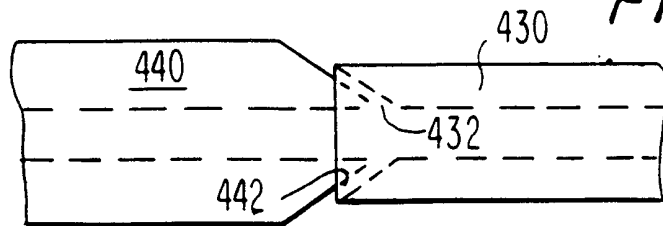
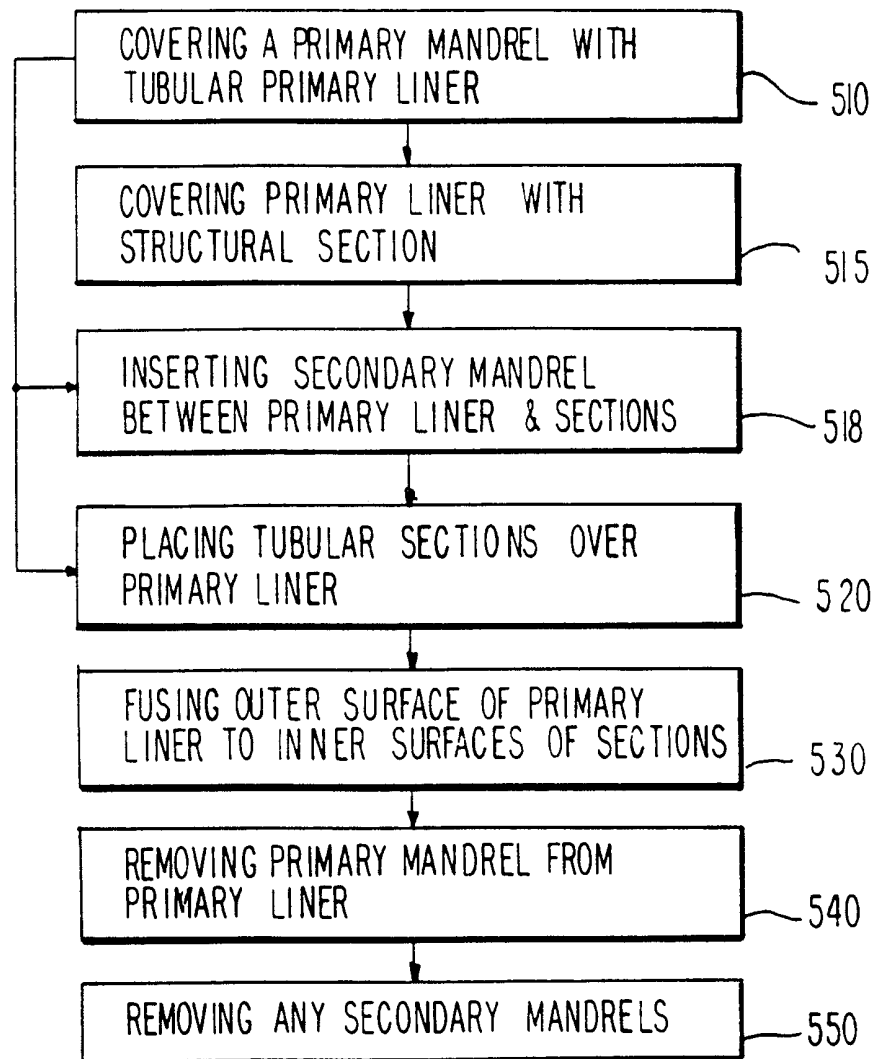


FIG. 4B



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FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/26737

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.
X	WO 96 20750 A (MEDTRONIC) 11 July 1996 see page 5, line 16 - page 8, line 8; figures --- -/--	1, 2, 6-9, 11-13, 22-24, 26-28, 36, 39, 40, 42, 45, 52, 53
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		
<input checked="" type="checkbox"/> 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	"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	
"E" earlier document but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
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Date of the actual completion of the international search <p style="text-align: center; font-weight: bold;">28 May 1999</p>	Date of mailing of the international search report <p style="text-align: center; font-weight: bold;">09/06/1999</p>	
Name and mailing address of the ISA 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	Authorized officer <p style="text-align: center; font-weight: bold;">Kousouretas, I</p>	

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/26737

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 5 254 107 A (SOLTESZ) 19 October 1993</p> <p>see column 4, line 34 - column 5, line 62; figures</p> <p style="text-align: center;">---</p>	<p>1,2,5-7, 9,11, 13-15, 20-24, 26-28, 36,39, 40,42, 43,45</p>
A	<p>US 5 676 659 A (MCGURK) 14 October 1997</p> <p>see column 4, line 48 - column 7, line 67; figures</p> <p style="text-align: center;">---</p>	<p>1-3,6,7, 9-13,21, 36,39, 40,42, 45,52,53</p>
A	<p>US 4 495 134 A (OUCHI) 22 January 1985</p> <p>see column 6, line 45 - column 7, line 55; figures</p> <p style="text-align: center;">-----</p>	<p>1,20,22, 30,31,36</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

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