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<p>(21) International Application Number: PCT/US96/15845</p> <p>(22) International Filing Date: 2 October 1996 (02.10.96)</p> <p>(30) Priority Data: 08/543,992 17 October 1995 (17.10.95) US</p> <p>(60) Parent Application or Grant (63) Related by Continuation US 08/543,992 (CON) Filed on 17 October 1995 (17.10.95)</p> <p>(71) Applicant (for all designated States except US): MEDTRONIC, INC. [US/US]; 7000 Central Avenue Northeast, Minneapolis, MN 55432 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): BRIN, David, S. [US/US]; 14 Sawmill Brook Road, West Newbury, MA 01950 (US). MACDONALD, Stuart, R. [US/US]; 4 Greenleaf Drive, Danvers, MA 01923 (US). DUNFEE, Albert, H. [US/US]; 65 Pearson Drive, Byfield, MA 01922 (US).</p>	<p>(74) Agents: PLUNKETT, Dianne, M., F. et al.; Medtronic, Inc. MS301, 7000 Central Avenue Northeast, Minneapolis, MN 55432 (US).</p> <p>(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>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>	
<p>(54) Title: GUIDE CATHETER WITH SOFT DISTAL SEGMENT</p>		
<p>(57) Abstract</p> <p>A multi-layer guiding catheter for use in PTCA procedures is disclosed. The catheter exhibits a flexural stiffness gradation along the length of the catheter by connecting elongated segments of progressively lower flexural stiffness from the proximal to the distal end of the catheter. The elongated segments are connected together with preferably four tongue-in-groove interlocks at each junction of the elongated segments. The interlocks are bonded together with a transition segment which occupies the interstices of the tongue and the groove of each interlock.</p>		

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GUIDE CATHETER WITH SOFT DISTAL SEGMENT**FIELD OF THE INVENTION**

5 The present invention relates to catheters, and more particularly, to a catheter which exhibits differential flexibility along the length of the catheter. Such a catheter can be used in PTCA procedures such as balloon angioplasty, atherectomy, stent implantation procedures, or radiology procedures.

BACKGROUND OF THE INVENTION

10 One of the therapeutic procedures applicable to the present invention is known as percutaneous transluminal coronary angioplasty (PTCA). This procedure can be used, for example, to reduce arterial build-up of cholesterol fats or atherosclerotic plaque. Typically, a guidewire is steered through the vascular system to the lesion site of therapeutic interest. A dilatation catheter is inserted over the guidewire and is tracked along the guidewire to the lesion where the catheter is inflated to dilate the
15 lesion. A guiding catheter acts as a support conduit for both the guidewire and the dilatation catheter. The considerations in guiding catheter design include torsional stiffness, bending stiffness, and kink resistance.

20 United States patent number 5,254,107, issued to Soltesz, discloses at column 2, lines 6-23, a catheter which "carries an embedded fibrous, tubular reinforcement member, with the catheter shaft defining a first section which comprises a first plastic material and a second section abutting the first section which comprises a second plastic material having different physical properties from the first plastic material. The tubular reinforcement member comprises integral fibers that extend between, and are embedded in, the plastic of both the first and second sections of the catheter shaft.
25 Thus, the connection between the first and second sections of the catheter shaft does not entirely depend upon a plastic bond between them, but rather the first and second catheter sections are also held together because of their embedded relation with the fibrous reinforcement member, which has the integral fibers extending between and embedded in the plastic of both of the first and second sections."

30 United States patent number 4,899,787, issued to Ouchi et al, discloses at column 2, lines 47-54 "an endoscope tube having flexibility which varies in a step-wise

manner from one end of the tube to the other is obtained by integrally bonding two or more thermoplastic synthetic resin tube sections formed of respective resin materials having different hardnesses to the outer surface of the tubular core structure to form a coating layer in an analogous manner.”

5 United States patent number 5,234,416, issued to MacCauley et al, discloses at column 2, lines 7-13 “an elongated tubular shaft having proximal and distal ends, an inner lumen extending therein and a flexible nontraumatic distal tip which is significantly softer than the catheter shaft to which it is secured. The nontraumatic distal tip has at least two, relatively short elastomeric or rubber-like tubular elements
10 which are coaxially secured to the distal end of the tubular shaft.”

SUMMARY OF THE INVENTION

It is an object of the invention to provide a guiding catheter which exhibits differential flexural stiffness along the length of the catheter to allow sufficient flexibility in the distal end for atraumatic positioning of the distal end within the coronary vasculature while allowing for sufficient columnar strength in the proximal
15 region to facilitate moving the catheter through the tortuous ilio-femoral vasculature of the patient. Further, the guiding catheter must possess the requisite torsional stiffness to facilitate the positioning and rotation of the catheter within the vasculature. Moreover, the catheter must be able to be aggressively manipulated in axial,
20 compressive, bending, and torsional modes without kinking or buckling of the cross-section of the catheter.

In accordance with the object of the invention, the present invention relates to a guiding catheter which comprises an elongated shaft of a relatively high bending stiffness, a first elongated segment of a relatively intermediate bending stiffness, and a
25 second elongated segment, of a relatively low bending stiffness. A first junction comprising a plurality of tongue-in-groove interlocks is used to bond the elongated shaft to the first elongated segment and a second junction comprising a plurality of tongue-in-groove interlocks is used to bond the first elongated segment to the second elongated segment. A soft tip is bonded to the distal end of the second elongated
30 segment.

In an alternative embodiment, the invention relates to a guiding catheter which comprises an elongated shaft of a relatively high bending stiffness, and a first elongated segment of a relatively low bending stiffness. A first junction comprising a plurality of tongue-in-groove interlocks is used to bond the elongated shaft to the first elongated segment. A soft tip is bonded to the distal end of the first elongated segment.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 depicts applicants' preferred embodiment of a guiding catheter;

Figure 2 depicts a cross-sectional view of applicants' preferred embodiment of a guiding catheter along section line 2-2 of Figure 1;

Figure 3 depicts the preferred embodiment of applicants' guiding catheter in a cross-section along section line 3-3 in Figure 1;

Figure 4 depicts the preferred embodiment of applicants' guiding catheter in a cross-section along section line 4-4 in Figure 1;

Figure 5 depicts a plan view of applicants' alternative embodiment of a guiding catheter; and

Figure 6 depicts applicants' guiding catheter in a cross-section of the alternative embodiment along section line 6-6 in Figure 5.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figure 1, the preferred embodiment of the applicants' guiding catheter 10 is shown. The catheter is shown in the commonly-used "Amplatz" curve shape, the Amplatz shape being first suggested by pioneer interventionalist Dr. Kurt Amplatz. The guiding catheter 10 preferably includes an inner lumen of 0.086 inches, an outer diameter of 0.104 inches, and a length of approximately 100 cm. In the preferred embodiment, a first transition segment 12 is bonded to the elongated shaft 11 and to the first elongated segment 13. The first elongated segment 13 is approximately 5 cm in length. The first transition segment 12 is preferably comprised of a 63D PEBAX® which is injection molded or otherwise bonded by heat and pressure to the elongated shaft 11 and to the first elongated segment 13. The first transition segment 12 is preferably of a unitary polymer construction, without any additional means for reinforcement. The elongated shaft 11, the first transition segment 12, and the first elongated segment 13 are connected to form the first

junction 14. It is critical that the first junction 14 exhibit acceptable kink resistance. Acceptable kink resistance for a catheter with an outside diameter of 0.104 inches and an inside diameter of 0.086 inches is defined as 60 degrees to 80 degrees of angular deflection, as measured by the ASTM D684 testing method. To achieve acceptable flexural and torsional kink resistance, the geometry of the first junction 14 is selected so that a gradual stiffness transition is achieved across these respective structural elements. Because the first transition segment 12 is preferably of unitary polymer construction, the first junction 14 will be prone to flexural kinking at the first transition segment 12 unless the ratio of the length to the wall thickness of the first transition segment 12 is less than approximately 10. For a wall thickness of the preferred embodiment of 0.009 inches (wall thickness = $(0.104 - 0.086)/2 = 0.009$ inches), the length of the first transition segment 12 must be less than 0.090 inches. Further, the first junction 14 will be prone to torsional kinking at the first transition segment unless the ratio of the circumference to the wall thickness of the first transition segment 12 is less than approximately 10. For a wall thickness of the preferred embodiment of 0.009 inches, the circumference of the first transition segment must be less than 0.090 inches. The circumference of the preferred embodiment, however, is approximately 0.327 inches (circumference = $3.14159 * 0.104$ inches = 0.327). Thus, to prevent flexural and torsional kinking in the first junction 14 at the first transition segment 12, the first transition segment 12 can have a length and a circumference of not greater than 0.090 inches without an additional means for reinforcement to prevent torsional kinking.

To accommodate the above geometric constraints on the first transition segment 12, the first junction 14 is characterized by preferably four "tongue-in-groove" interlocks 15 between the elongated shaft 11 and the first elongated segment 13. The interlocks 15 are spaced at 90 degree intervals about the circumference of the first junction 14. The 90 degree intervals of the interlocks 15 limit the circumference of the first transition segment 12 to less than 0.090 inches (0.327 inches/ $(360$ degrees/ 90 degrees/ $interlock = 0.082$ inches), with the interlocks 15 of the elongated shaft 11 and the first elongated segment 13 providing the additional means for reinforcement (to be discussed below) to prevent torsional kinking. The first transition segment 12 occupies the interstices of the interlocks 15 between the elongated shaft

11 and the first elongated segment 13 and has a "zigzag" shape about the circumference of the first junction 14. The length of the first transition segment 12 is approximately 0.078 inches to achieve a gradual stiffness transition while allowing for acceptable flexural kink resistance across the first junction 14. Alternatively, one to three tongue-in-groove interlocks 15 between the elongated shaft 11 and the first elongated segment 13 may be used. In the case of one tongue-in-groove interlock 15, a slight improvement in manufacturability is obtained over the 4 interlocks 15, but the one interlock is less torsionally and flexurally kink resistant. In the case of two interlocks 15, the interlocks 15 are spaced at 180 degree intervals about the circumference of the first junction 14. Similarly, in the case of three interlocks 15, the interlocks 15 are spaced at 120 degree intervals about the circumference of the first junction 14.

A second transition segment 16 is bonded to the first elongated segment 13 and to the second elongated segment 17. The second elongated segment 17 is approximately 2 cm in length. The second transition segment 16, which is of unitary polymer construction, is preferably comprised of a 63D PEBAX® which is injection molded or otherwise bonded by heat and pressure to the first elongated segment 13 and to the second elongated segment 17. The first elongated segment 13, the second transition segment 16, and the second elongated segment 17 are connected to form the second junction 18. The geometry of the second junction 18 is selected so that a gradual durometer transition is achieved across these respective structural elements. The second junction 18 is characterized by preferably four tongue-in-groove interlocks 15 between the first elongated segment 13 and the second elongated segment 17. The geometric constraints applied to the first junction 14 and the first transition segment 12 apply to the second junction 18 and second transition segment 16, respectively. The second transition segment 16 occupies the interstices of the interlocks 15 between the first elongated segment 13 and the second elongated segment 17. A soft tip 19 is bonded using heat and pressure to the distal end of the second elongated segment 17. Preferred materials for the soft tip 19 include the Shore durometer 40D grade of PEBAX®.

Referring to Figure 2, applicants' guiding catheter 10 is shown depicted in a cross-section of the elongated shaft 11 along section line 2-2 of Figure 1. The elongated shaft 11 is constructed of a relatively stiff composite, and is preferably a heat and pressure lamination of a thermoplastic elastomeric inner tube 20 and a composite outer tube 21, the composite outer tube 21 consisting of a stainless steel wire braid 22 and a thermoplastic elastomeric outer tube 23. The stainless steel wire braid 22 is preferably a 16 strand weave at a preferred density of 40-50 pixels per inch. The stainless steel wire braid 22 acts as a means for reinforcement for the thermoplastic elastomeric outer tube 23 which increases flexural and torsional kink resistance of the composite outer tube 21. The materials for the elongated shaft 11 are selected so that the desired bending stiffness and torsional stiffness is achieved. A principal indicator of bending stiffness is the flexural modulus of the material. Further, the torsional stiffness of the elongated shaft 10 is enhanced where the thermoplastic elastomeric inner tube 20 and the thermoplastic elastomeric outer tube 23 are of compatible melt temperatures and melt viscosities. Preferred thermoplastic elastomers which possess the desired flexural moduli and melt compatibility include the tradename PEBA[®], a polyether block amide copolymer obtainable from the Elf Atochem Corporation, Philadelphia, PA. The preferred PEBA[®] grades include the Shore durometer 70D grade for both the thermoplastic elastomeric inner tube 20 and the thermoplastic elastomeric outer tube 23.

Referring to Figure 3, the applicants' guiding catheter 10 is shown depicted in a cross-section of the preferred embodiment along section line 3-3 of Figure 1. Preferably, the first elongated segment 13 has a bending stiffness which is approximately 20 to 50 % less than the elongated shaft 11. The first elongated segment 13 is preferably a heat and pressure lamination of a thermoplastic elastomeric inner tube 30 and a composite outer tube 31, the composite outer tube 31 consisting of a stainless steel wire braid 32 and a thermoplastic elastomeric outer tube 33. The materials for first elongated segment 13 are selected so that the desired bending stiffness is achieved. Further, torsional stiffness of the first elongated segment 13 is enhanced where the thermoplastic elastomeric inner tube 30 and the thermoplastic elastomeric outer tube 33 are of compatible melt temperatures and melt viscosities.

Preferred materials for the thermoplastic elastomeric inner tube 30 include the Shore durometer 70D grade of PEBAX® while the preferred materials for the thermoplastic elastomeric outer tube 33 include the Shore durometer 55D grade of PEBAX®. Alternatively, Shore durometer 63D PEBAX® may be used for the thermoplastic elastomeric outer tube 33.

Referring to Figure 4, the applicants' guiding catheter 10 is shown depicted in a cross-section along section line 4-4 of Figure 1. Preferably, the second elongated segment 17 has a bending stiffness which is approximately 20 to 50 % less than the first elongated segment 13. The second elongated segment 17 is preferably a heat and pressure lamination of a thermoplastic elastomeric inner tube 40 and a composite outer tube 41, the composite outer tube 41 consisting of a stainless steel wire braid 42 and a thermoplastic elastomeric outer tube 43. The materials for second elongated segment 17 are selected so that the desired bending stiffness is achieved. Further, torsional stiffness of the second elongated segment 17 is enhanced where the thermoplastic elastomeric inner tube 40 and the thermoplastic elastomeric outer tube 43 are of compatible melt temperatures and melt viscosities. Preferred materials for the thermoplastic elastomeric inner tube 40 include the Shore durometer 70D grade of PEBAX® while the preferred materials for the thermoplastic elastomeric outer tube 43 include the Shore durometer 40D grade of PEBAX®.

Referring to Figure 5, an alternative embodiment of the applicants' guiding catheter 50 is shown. In the alternative embodiment, a first transition segment 52 is bonded to the elongated shaft 51 and to the first elongated segment 53. The first elongated segment 53 is approximately 2 cm in length. The first transition segment 52 is of a unitary polymer construction and is preferably comprised of a 63D PEBAX® which is injection molded or otherwise bonded by heat and pressure to the elongated shaft 51 and to the first elongated segment 53. The elongated shaft 51, the first transition segment 52, and the first elongated segment 53 are connected to form the first junction 54. It is critical that the first junction 54 exhibit acceptable kink resistance. Acceptable kink resistance for a catheter with a preferred outside diameter of 0.078 inches and an inside diameter of 0.064 inches is defined as 60 degrees to 80 degrees of angular deflection, as measured by the ASTM D684 testing method. To

achieve acceptable kink resistance, the geometry of the first junction 54 is selected so that a gradual durometer transition is achieved across these respective structural elements. The first junction 54 is characterized by preferably four tongue-in-groove interlocks 55 between the elongated shaft 51 and the first elongated segment 53. The first transition segment 52 occupies the interstices of the interlocks 55 between the elongated shaft 51 and the first elongated segment 53. Further, the first transition segment 52 is fused to both the elongated shaft 51 and to the first elongated segment 53. A soft tip 56 is bonded to the distal end of the first elongated segment 53. Preferred materials for the soft tip 56 include the Shore durometer 40D grade of PEBAX®.

Referring to Figure 6, the applicants' guiding catheter 50 is shown depicted in a cross-section along section line 6-6 of Figure 5. Preferably, the first elongated segment 53 has a bending stiffness which is approximately 20 to 50 % less than the elongated shaft 51. The first elongated segment 53 is preferably a heat and pressure lamination of a thermoplastic elastomeric inner tube 60 and a composite outer tube 61, the composite outer tube 61 consisting of a stainless steel wire braid 62 and a thermoplastic elastomeric outer tube 63. The materials for first elongated segment 53 are selected so that the desired bending stiffness is achieved. Further, torsional stiffness of the first elongated segment 53 is enhanced where the thermoplastic elastomeric inner tube 60 and the thermoplastic elastomeric outer tube 63 are of compatible melt temperatures and melt viscosities. Preferred materials for the thermoplastic elastomeric inner tube 60 include the Shore durometer 70D grade of PEBAX® while the preferred materials for the thermoplastic elastomeric outer tube 63 include the Shore durometer 40D grade of PEBAX®.

The preceding embodiments are illustrative of the invention and modifications may be made to these embodiments without departing from the scope and breadth of the invention.

What is claimed is:

1. A catheter defining at least one continuous lumen, comprising:

an elongated shaft having a proximal end and a distal end and defining at least one lumen;

5 a first transition segment having a proximal end and a distal end and defining at least one lumen, the proximal end of the first transition segment being connected to the distal end of the elongated shaft;

a first elongated segment having a proximal end and a distal end and defining at least one lumen, the proximal end of the first elongated segment being connected to
10 the distal end of the first transition segment;

the distal end of the elongated shaft and the proximal end of the first elongated segment having a plurality of tongue-in-groove interlocks, one of each of the interlocks having a tongue on one of the distal end of the elongated shaft and the proximal end of the first elongated segment, one of each of the interlocks having a groove on the other
15 of the distal end of the elongated shaft and the proximal end of the first elongated segment, one of each of the interlocks having the tongue mating with the groove, the first transition segment being bonded between the tongue and the groove of one of each of the interlocks.

2. The catheter according to claim 1, further comprising:

20 a second transition segment having a proximal end and a distal end and defining at least one lumen, the proximal end of the second transition segment being connected to the distal end of the first elongated segment;

a second elongated segment having a proximal end and a distal end and defining at least one lumen, the proximal end of the second elongated segment being
25 connected to distal end of the second transition segment;

the distal end of the first elongated segment and the proximal end of the second elongated segment having a plurality of tongue-in-groove interlocks, one of each of the interlocks having a tongue on one of the distal end of the first elongated segment and the proximal end of the second elongated segment, one of each of the interlocks having
30 a groove on the other of the distal end of the first elongated segment and the proximal end of the second elongated segment, one of each of the interlocks having the tongue

mating with the groove, the second transition segment being bonded between the tongue and the groove of one of each of the interlocks; and

a soft tip having a proximal end and defining at least one lumen, the proximal end of the soft tip being connected to the distal end of the second elongated segment.

- 5 3. The catheter according to claim 1 wherein the elongated shaft is comprised of a thermoplastic elastomer and braided wire.
4. The catheter according to claim 3 wherein the thermoplastic elastomer comprises a Shore 70D durometer polyether block amide copolymer.
5. The catheter according to claim 1 wherein the first transition segment
10 comprises a thermoplastic elastomer.
6. The catheter according to claim 5 wherein the thermoplastic elastomer comprises a Shore 63D durometer polyether block amide copolymer.
7. The catheter according to claim 1 wherein the first elongated segment is comprised of a thermoplastic elastomer and braided wire.
- 15 8. The catheter according to claim 7 wherein the thermoplastic elastomer comprises one of a Shore 55D and a Shore 63D durometer polyether block amide copolymer.
9. The catheter according to claim 2 wherein the second transition segment comprises a thermoplastic elastomer.
- 20 10. The catheter according to claim 9 wherein the thermoplastic elastomer comprises a Shore 63D durometer polyether block amide copolymer.
11. The catheter according to claim 2 wherein the second elongated segment comprises a thermoplastic elastomer and braided wire.
12. The catheter according to claim 11 wherein the thermoplastic elastomer
25 comprises a Shore 40D durometer polyether block amide copolymer.
13. The catheter according to claim 2 wherein the soft tip is comprised of a thermoplastic elastomer.
14. The catheter according to claim 13 wherein the thermoplastic elastomer comprises a Shore 40D durometer polyether block amide copolymer.
- 30 15. The catheter according to claim 1, wherein

the elongated shaft has a polymer inner tube and a composite outer tube, the composite outer tube of the elongated shaft being disposed over and fused at least partially to the polymer inner tube of the elongated shaft;

the first transition segment is of unitary polymer construction; and

5

the first elongated segment has a polymer inner tube and a composite outer tube, the composite outer tube of the first elongated segment being disposed over and fused at least partially to the polymer inner tube of the first elongated segment.

16. The catheter according to claim 2, wherein:

the second transition segment is of unitary polymer construction;

10

the second elongated segment has a polymer inner tube and a composite outer tube, the composite outer tube of the second elongated segment being disposed over and fused at least partially to the polymer inner tube of the second elongated segment.

17. The catheter according to claim 15 wherein the polymer inner tube of the elongated shaft is comprised of a thermoplastic elastomer.

15

18. The catheter according to claim 17 wherein the thermoplastic elastomer comprises a Shore 70D durometer polyether block amide copolymer.

19. The catheter according to claim 15 wherein the composite outer tube of the elongated shaft comprises a thermoplastic elastomer and braided wire.

20. The catheter according to claim 19 wherein the thermoplastic elastomer comprises a Shore 70D durometer polyether block amide copolymer.

20

21. The catheter according to claim 15 wherein the first transition segment comprises a thermoplastic elastomer.

22. The catheter according to claim 21 wherein the thermoplastic elastomer comprises a Shore 63D durometer polyether block amide copolymer.

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23. The catheter according to claim 15 wherein the polymer inner tube of the first elongated segment is comprised of a thermoplastic elastomer.

24. The catheter according to claim 23 wherein the thermoplastic elastomer comprises a Shore 70D durometer polyether block amide copolymer.

25. The catheter according to claim 15 wherein the composite outer tube of the first elongated segment comprises a thermoplastic elastomer and braided wire.

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26. The catheter according to claim 25 wherein the thermoplastic elastomer comprises one of a Shore 55D and a Shore 63D durometer polyether block amide copolymer.
27. The catheter according to claim 16 wherein the second transition segment
5 comprises a thermoplastic elastomer.
28. The catheter according to claim 27 wherein the thermoplastic elastomer comprises a Shore 63D durometer polyether block amide copolymer.
29. The catheter according to claim 16 wherein the polymer inner tube of the second elongated segment is comprised of a thermoplastic elastomer.
- 10 30. The catheter according to claim 29 wherein the thermoplastic elastomer comprises a Shore 70D durometer polyether block amide copolymer.
31. The catheter according to claim 16 wherein the composite outer tube of the second elongated segment comprises a thermoplastic elastomer and braided wire.
32. The catheter according to claim 31 wherein the thermoplastic elastomer
15 comprises a Shore 40D durometer polyether block amide copolymer.
33. The catheter according to claim 2 wherein the soft tip is comprised of a thermoplastic elastomer.
34. The catheter according to claim 33 wherein the thermoplastic elastomer comprises a Shore 40D durometer polyether block amide copolymer.

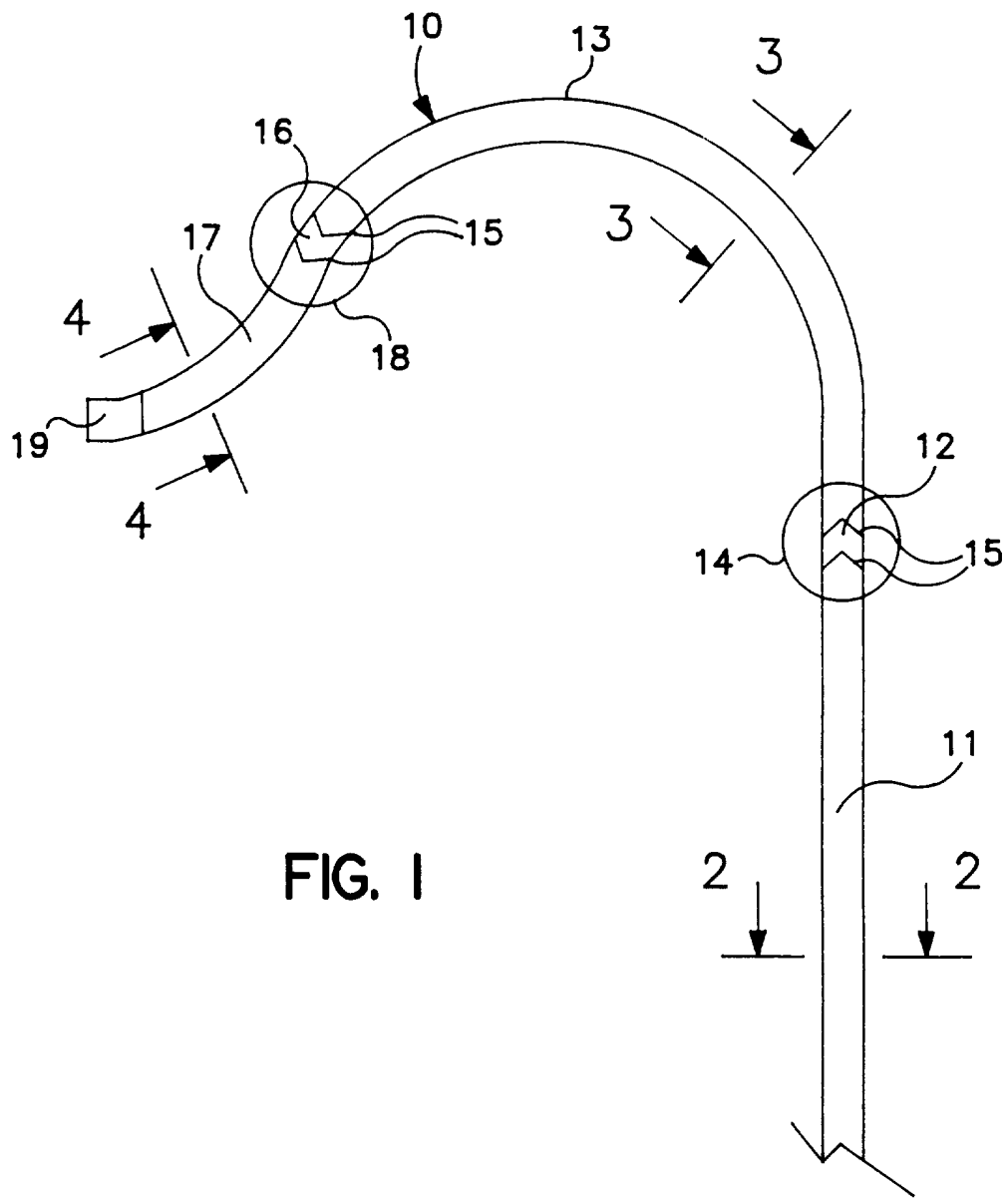


FIG. 1

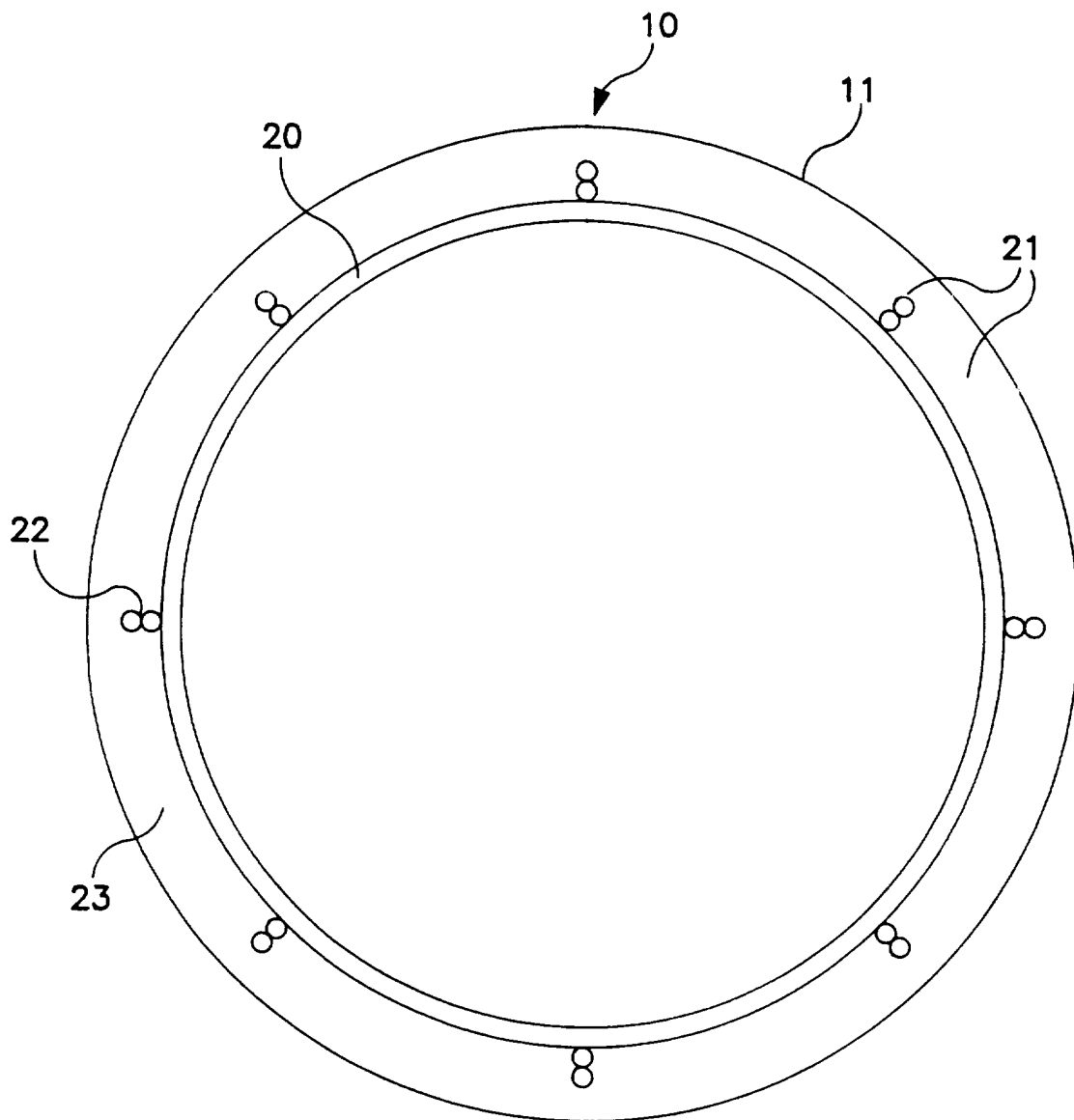


FIG. 2

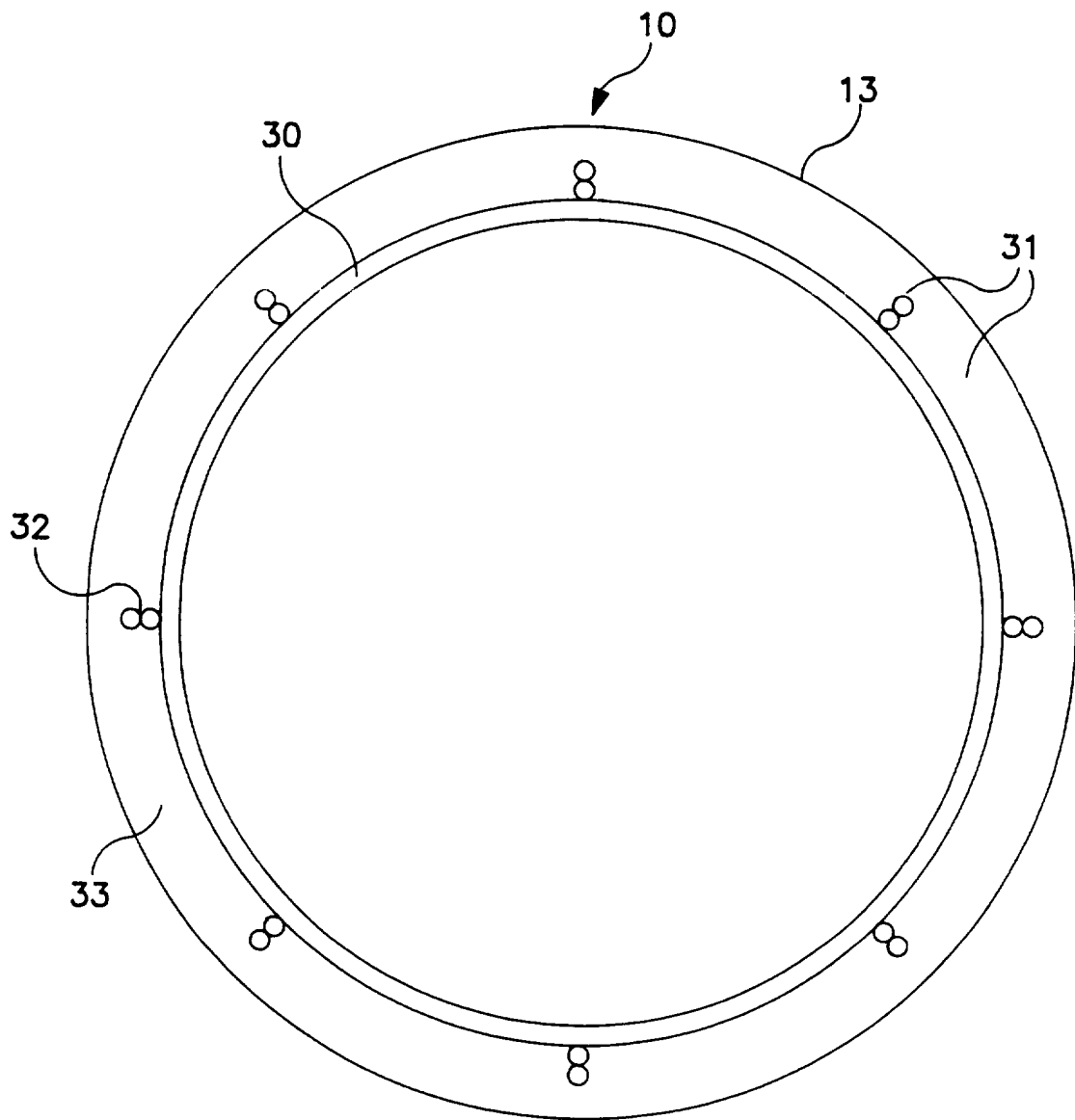


FIG. 3

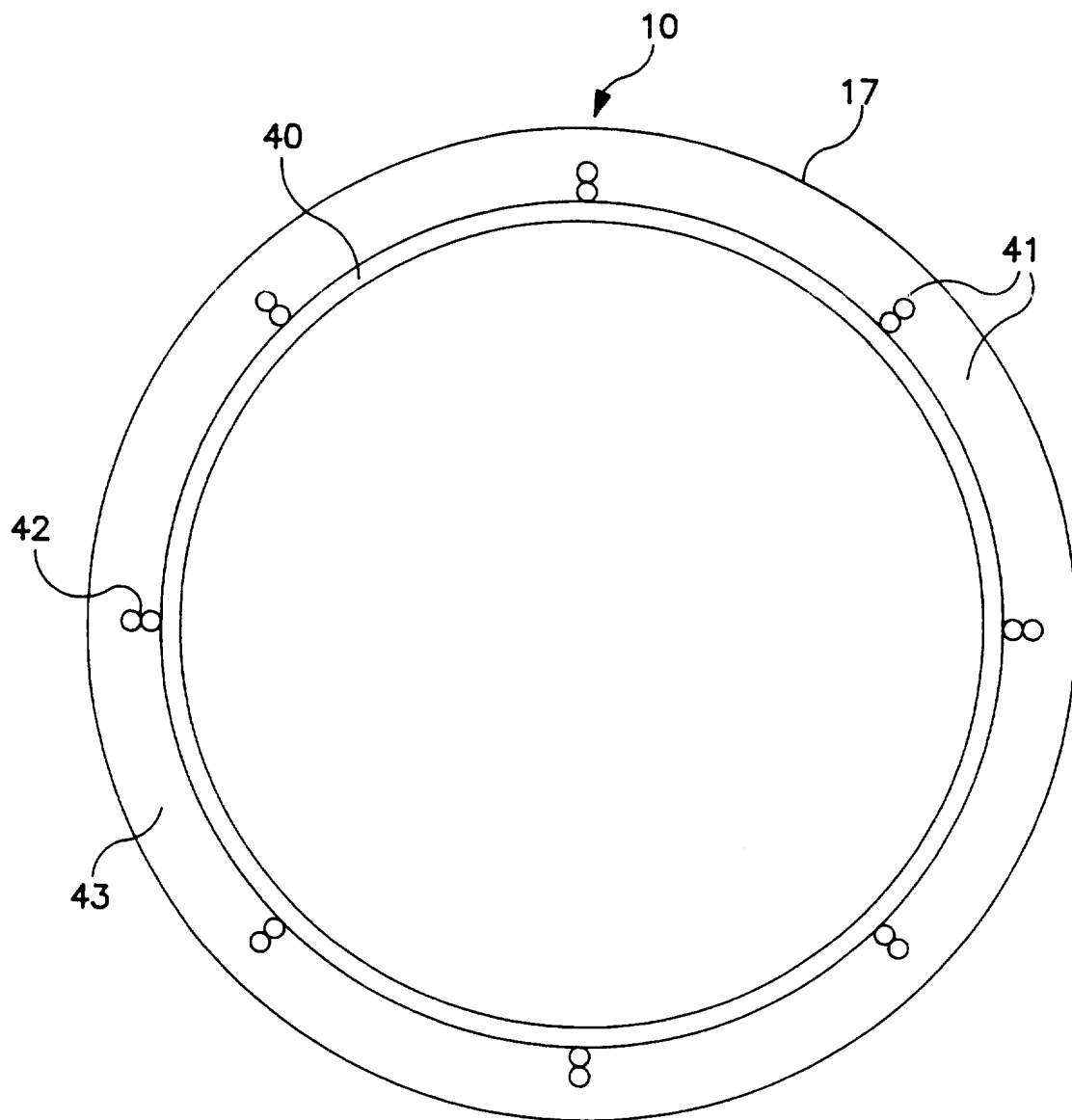


FIG. 4

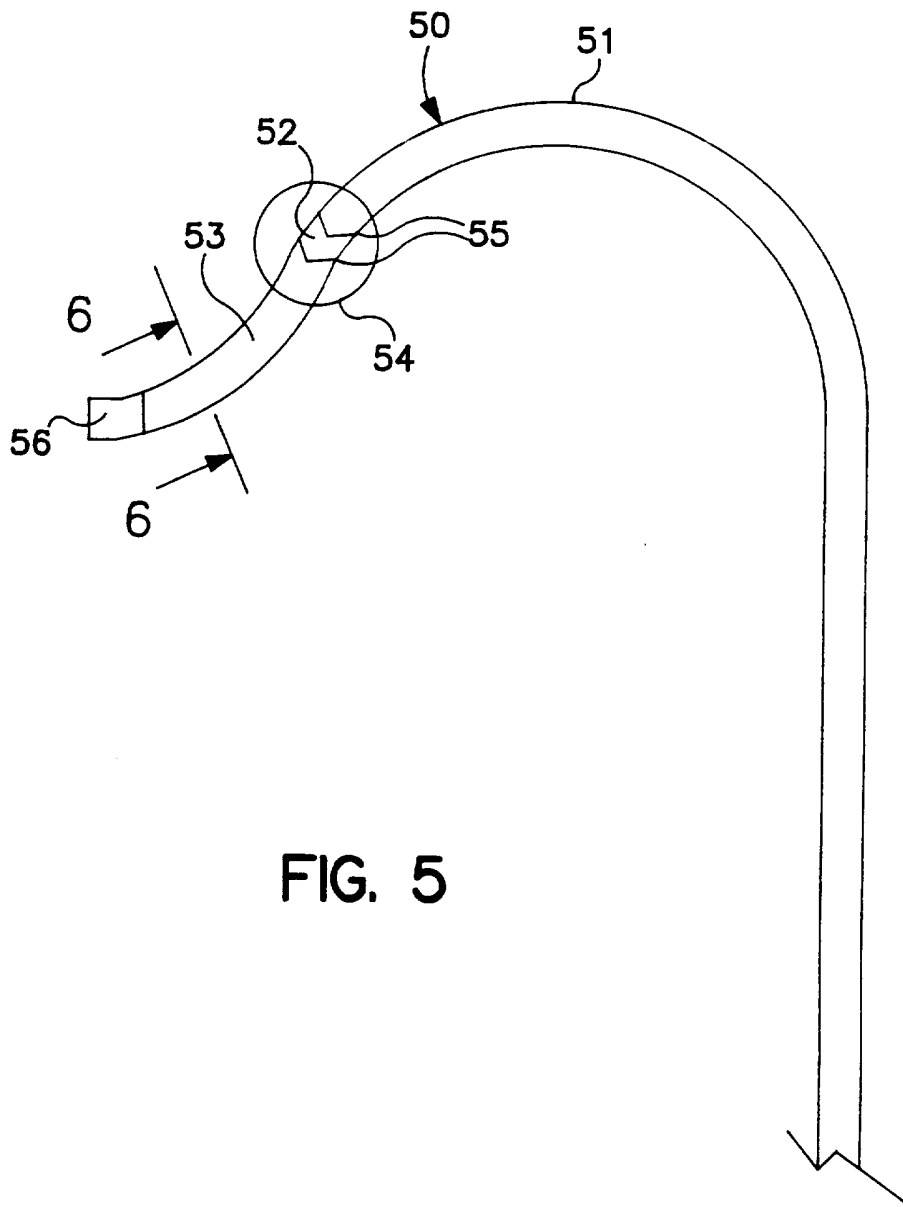


FIG. 5

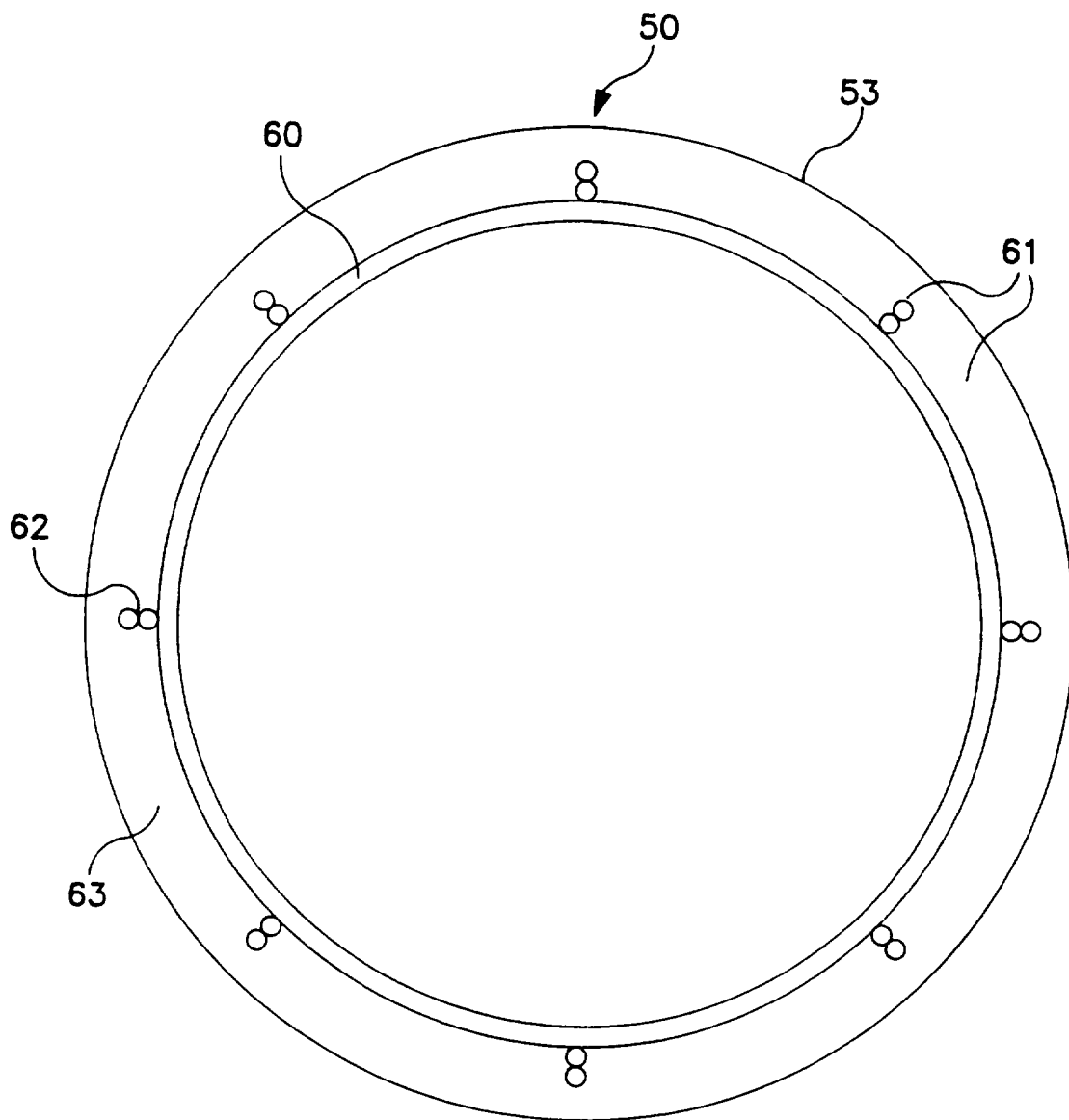


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/15845

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.
A	WO 95 21640 A (SCIMED LIFE SYSTEMS) 17 August 1995 see the whole document ---	1-34
A	EP 0 383 914 A (TERUMO KABUSHIKI KAISHA) 29 August 1990 see page 16, line 23 - page 17, line 12; figures 1,2 ---	1
A	EP 0 542 246 A (BECTON DICKINSON) 19 May 1993 see abstract; figure 3 ---	1
A	US 5 092 848 A (DECIUTIIS) 3 March 1992 see abstract; figures ---	1
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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	
24 February 1997	10.03.97	
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 Kousouretas, I	

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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information on patent family members

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