



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61L 29/00, C08J 7/04</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 97/49437</b> <b>(43) International Publication Date:</b> 31 December 1997 (31.12.97)
<b>(21) International Application Number:</b> PCT/SE97/01121 <b>(22) International Filing Date:</b> 19 June 1997 (19.06.97)  <b>(30) Priority Data:</b> 9602529-1                      26 June 1996 (26.06.96)                      SE  <b>(71) Applicant (for all designated States except US):</b> ASTRA AKTIEBOLAG [SE/SE]; S-151 84 Södertälje (SE).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> ISRAELSSON, Anette [SE/SE]; Mejerigatan 16, S-412 76 Göteborg (SE). UTAS, Jan [SE/SE]; Sparvvägen 9, S-434 96 Kungälv (SE).  <b>(74) Agent:</b> ASTRA AKTIEBOLAG; Patent Department, S-151 85 Södertälje (SE).		<b>(81) Designated States:</b> AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, FI (Utility model), GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), 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).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> MEDICAL DEVICE  <b>(57) Abstract</b>  Method for the manufacture of a medical device which presents a hydrophilic surface coated elongate shaft for insertion into a body passageway comprising the steps of having the elongate shaft formed from a thermoplastic elastomer material selected from the group consisting of a polyether block amide and a styrene block copolymer and forming the hydrophilic coating on the elongate shaft by applying sequentially to the surface of the elongate shaft a solution comprising between 0.05 to 40 % (weight to volume) of an isocyanate compound and a solution containing between 0.5 % and 50 % (weight to volume) of polyvinylpyrrolidone and curing at an elevated temperature.		

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## MEDICAL DEVICE

The present invention relates to medical devices which present an elongate shaft having an outer surface coating for insertion into a passageway in a human or animal body and is principally, but not exclusively, concerned with surface coated catheters.

Many medical devices incorporate elongate shafts such as tubes which are intended for insertion into and through passageways of a living body such as those of the urethral tract and the cardiovascular system. The most common type of this general grouping of medical devices are known as catheters. Exemplary catheters include those designated for urological, angioplasty and valvuloplasty uses, that is, adapted respectively for insertion into the urethra, the lumen of a blood vessel and heart passageway of a living body, normally a human body.

Because of the intended use of such medical devices certain parameters need to be satisfied by the material from which the elongate shaft is manufactured. The material must fulfil such requirements as softness, good kink resistance, good dimensional stability, processability, for example ease to form and glue, and the possibility to be sterilised by radiation, steam, ethylene oxide or other means. There is further the need for the material to accept a surface treatment which will impart desired surface properties to the medical device such as lubricity, hydrophilicity and blood compatibility. To this latter end, the chemistry of the substrate material is critical since this affects the possibility to coat the substrate.

For many years now polyvinyl chloride (PVC) has been used to manufacture medical devices having elongate shafts for insertion into a body passageway such as catheters due to PVC fulfilling the requirements mentioned in the preceding paragraph.

For instance, prior European patent application publication No. 0093093 (Astra Meditec AB) makes known a process for manufacturing a PVC urinary catheter having a hydrophilic outer surface coating which exhibits a low coefficient of friction when wetted. The process involves forming a hydrophilic surface coating on the PVC catheter by sequentially applying

a solution containing between 0.05-40% (weight/volume, that is, kg/l) of an isocyanate compound and a solution of polyvinylpyrrolidone (PVP) containing between 0.5-50% (weight/volume) to the outer surface of the catheter, for example by dipping, and then curing the hydrophilic coating at an elevated temperature advantageously in the presence of  
5 a water-containing gas such as ambient air.

The suitability of PVC for medical devices such as catheters, however, is now being questioned on environmental grounds and further because of the toxicity of the plasticisers added to PVC. Moreover, coating PVC catheters by, for example, the process of European  
10 patent application publication No. 0093093 results in an appreciable shrinkage of the PVC catheters in the longitudinal direction, typically 6-7% of the original length, due to the operating temperatures used in the coating process. The obvious disadvantage of such appreciable shrinkage is the wastage of material in the sense that PVC catheters of longer length than finally required have to be used to account for the shrinkage. In addition,  
15 quality control of the coating process is made more complicated than would be ideal by this marked degree of shrinkage.

There is therefore a need for a medical device which presents a hydrophilic surface coated non-PVC elongate shaft for insertion into a body passageway which experiences no  
20 appreciable shrinkage on application of the hydrophilic surface coating.

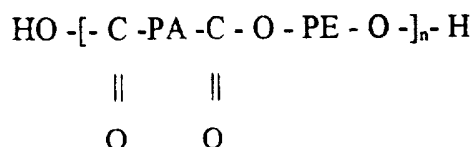
To this end, the present invention provides a method for the manufacture of a medical device which presents a hydrophilic surface coated elongate shaft for insertion into a body passageway comprising the steps of having the elongate shaft formed from a thermoplastic  
25 elastomer material selected from the group consisting of a polyether block amide and a styrene block copolymer and forming the hydrophilic coating on the elongate shaft by applying sequentially to the surface of the elongate shaft a solution comprising between 0.05 to 40% (weight to volume) of an isocyanate compound and a solution containing between 0.5 and 50% (weight to volume) of polyvinylpyrrolidone and curing at an elevated  
30 temperature.

The use of a polyether block amide or a styrene block copolymer results in an elongate shaft which undergoes substantially no shrinkage in the longitudinal direction as compared to PVC on application of the hydrophilic coating as well as providing an elongate shaft with the normal properties required for insertion thereof into a body passageway. The present invention therefore enables a catheter to be provided which addresses the aforementioned disadvantages of PVC based catheters leading to *inter alia* less wastage of starting materials and the possibility to use TV monitors for quality control.

While the background section of prior European patent application publication No. 0566755 (Cordis Corp.) makes it known that the use of a polyether block amide in the manufacture of medical device tubing intended for insertion into a body passageway is known *per se*, European patent application publication No. 0566755 goes on to teach that undesirable blooming develops in such tubing material after it has been stored for a length of time which can interfere with the adherence of a coating thereto, for example a coating for imparting lubricity to the tubing. The solution to the blooming problem according to European patent application publication No. 0566755 is to blend the polyether block amide with a polyetheramide component having substantially no ester linkages.

No such problem with adherence of the hydrophilic coating to a polyether block amide manifests itself when the method according to the present invention is followed despite the fact that blooming is sometimes observed after some months storage. This can be attributed to the manner in which the hydrophilic coating is applied to the elongate shaft in the method according to the invention.

The polyether block amide used in the invention is believed to have a structure as follows:



wherein PA is a polyamide, PE is a polyether and n is an integer greater than 1 which represents the number of blocks of copolymer molecular repeating units within the molecular formula of the copolymer. Representative polyether block amide materials include the Pebax<sup>®</sup> polymers (Elf Atochem S. A.).

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In an embodiment of the invention the styrene block copolymer is a styrene-ethylene/butylene-styrene block copolymer, for example Evoprene<sup>®</sup> G (Evode Plastics Ltd.).

10 Application of the isocyanate solution to the elongate shaft surface results in a coating having unreacted isocyanate groups being formed on the elongate shaft surface. Application of the polyvinylpyrrolidone solution to the elongate shaft surface then results in a hydrophilic polyvinylpyrrolidone-polyurea interpolymer coating being formed on the elongate shaft surface. Curing of this hydrophilic coating binds the isocyanate compounds  
15 together to form a stable non-reactive network that binds the hydrophilic polyvinylpyrrolidone. To advantage, curing takes place in the presence of a water-containing gas, for example ambient air, to enable the isocyanate groups to react with the water to yield an amine which rapidly reacts with other isocyanate groups to form a urea cross-link.

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In an embodiment of the invention the method further comprises the steps of evaporating the solvent of the isocyanate solution prior to application of the polyvinylpyrrolidone solution and evaporating the solvent of the polyvinylpyrrolidone solution prior to curing of the hydrophilic coating. This may for example be done by air drying.

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In an embodiment of the invention the isocyanate compound comprises at least two unreacted isocyanate groups per molecule. The isocyanate may be selected from 2,4-toluene diisocyanate and 4,4'-diphenylmethane diisocyanate, or a pentamer of hexamethylene diisocyanate and toluene diisocyanate of cyanurate type, or trimerized  
30 hexamethylene diisocyanate biuret or mixtures thereof.

The solvent for the isocyanate compound is preferably one which does not react with isocyanate groups. The preferred solvent is methylene chloride but it is also possible to use ethyl acetate, acetone, chloroform, methyl ethyl ketone and ethylene dichloride, for  
5 example.

The isocyanate solution may advantageously contain between 0.5 to 10% (weight to volume) of the isocyanate compound, and may preferably contain between 1 to 6% (weight to volume) of the isocyanate compound. Generally, the isocyanate solution only needs to be  
10 in contact with the surface briefly, for example 5 to 60 sec.

To enhance adherence of the hydrophilic coating to the elongate shaft surface the elongate shaft may be swelled beforehand in a suitable solvent. Another way is to choose a solvent for the isocyanate solution which has the ability to swell or dissolve the elongate shaft  
15 surface which is to be coated.

In order to shorten the necessary reaction times and curing times suitable catalysts for isocyanate curing may be added. These catalysts may be dissolved in either the isocyanate solution or the polyvinylpyrrolidone solution but are preferably dissolved in the latter.  
20 Different types of amines are especially useful, for example diamines, but also for example triethylenediamine. Preferably, an aliphatic amine is employed which is volatisable at the drying and curing temperatures used for the coating, and which furthermore is non-toxic. Examples of suitable amines are N, N' diethylethylenediamine, hexamethylenediamine, ethylenediamine, paradiaminobenzene, 1,3-propandiol-para-aminobenzoic acid diester and  
25 diaminobicyclo-octane.

Where the catalyst is in the polyvinylpyrrolidone solution, the proportion of catalyst in the solution is suitably between 0.1 to 50% by weight of the amount of polyvinylpyrrolidone, preferably between 0.1 to 10% by weight. Some of the above-mentioned amines,  
30 particularly the diamines, can also react with isocyanate and thereby contribute to the cross-

linking of the isocyanate compounds that give the desired strong adherence between the hydrophilic coating and the polymer surface.

The polyvinylpyrrolidone used preferably has a mean molecular weight of between  $10^4$  to  $10^7$  with the most preferred mean molecular weight being about  $10^5$ . Polyvinylpyrrolidone having such a molecular weight is commercially available, for example under the trademark Kollidon<sup>®</sup> (BASF). Examples of suitable solvents for polyvinylpyrrolidone that may be used are methylene chloride (preferred), ethyl acetate, acetone, chloroform, methyl ethyl ketone and ethylene dichloride. The proportion of polyvinylpyrrolidone in the solution is preferably between 0.5 to 10% (weight to volume) and most preferred between 2 to 8% (weight to volume). The polyvinylpyrrolidone in the solvent is applied by dipping, spraying or the like for a short period of time, e.g. during 5 to 50 sec.

Curing of the coating is preferably performed at a temperature of 50 to 130° C, in for example an oven, for a duration of between 5 to 300 min.

According to the invention there is further provided a medical device which presents a hydrophilic surface coated elongate shaft for insertion into a body passageway manufactured by the method according to the invention.

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According to the invention there is yet further provided a medical device which presents an elongate shaft for insertion into a body passageway, the elongate shaft being made from a polyether block amide or a styrene block copolymer and provided with a hydrophilic outer surface coating formed from an interpenetrating network of polyvinylpyrrolidone and polyurea.

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According to the invention there is additionally provided a medical device which presents an elongate shaft for insertion into a body passageway, the elongate shaft being made from a



polyether block amide or a styrene block copolymer and provided with a polyvinylpyrrolidone hydrophilic outer surface coating having enhanced osmolality.

5 In an embodiment of the invention the hydrophilic coating contains an osmolality-increasing compound, for instance an inorganic salt selected from sodium and potassium chlorides, iodides, citrates and benzoates. The osmolality-increasing compound may be applied in the manner detailed in prior European patent application publication No. 0217771.

10 In an embodiment of the invention the medical device is a catheter, for example those designated for urological, angioplasty and valvuloplasty uses or the like. In this case, the polyether block amide or styrene block copolymer selected for the elongate shaft respectively has a hardness in the range 25 Sh D to 70 Sh D and 40 shore A to 70 shore D. Where the medical device is a urinary catheter a hardness in the range 25 Sh D to 45 Sh D for polyether block amide and 40 shore A to 45 shore D for styrene block copolymer is  
15 ideal with greater hardnesses being preferred for intravascular catheters.

According to the invention there is also provided the use of a styrene block copolymer in the manufacture of a medical device which presents an elongate shaft for insertion into a body passageway.

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The invention will now be illustrated but not limited by the following examples.

### **Example 1**

25 A diisocyanate (named Desmodur IL) is dissolved in methylene chloride to a concentration of 2% (weight/volume). A urinary catheter formed exclusively or essentially exclusively from Pebax<sup>®</sup> (hereinafter a "urinary Pebax<sup>®</sup> catheter") with a hardness of 70 shore D is dipped in this solution for 15 seconds and is then dried at ambient temperature for 60 seconds. The catheter is then dipped for 1 second in a solution containing 6%  
30 (weight/volume) of polyvinylpyrrolidone (K90; mean molecular weight ~360 000) dissolved

in methylene chloride. The catheter is then allowed to dry at ambient temperature for 60 seconds and is finally cured for 50 minutes at 100 °C. The catheter is finally allowed to cool to room temperature and is then rinsed in water. The catheter has a slippery and adherent surface when wet.

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The experiment was repeated with variations in the dipping time in the isocyanate bath ranging from 5 seconds to 1 minute, but no advantage was obtained by increasing the dipping time.

## 10 **Example 2**

A diisocyanate (named Desmodur IL) is dissolved in ethyl acetate to a concentration of 2% (weight/volume). A urinary Pebax<sup>®</sup> catheter with a hardness of 35 shore D is dipped in this solution for 15 seconds and is then dried at ambient temperature for 60 seconds. The catheter is then dipped for 1 second in a solution containing 6% (weight/volume) of polyvinylpyrrolidone (K90; mean molecular weight ~360 000) dissolved in ethyl lactate (50%) and ethyl acetate (50%). The catheter is then allowed to dry at ambient temperature for 60 seconds and is finally cured for 50 minutes at 80 °C. The catheter is finally allowed to cool to room temperature and is then rinsed in water. The catheter has a slippery and adherent surface when wet.

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## **Example 3**

25 A diisocyanate (named Desmodur IL) is dissolved in methylene chloride (75%) and tri chloro ethylene (25%) to a concentration of 2% (weight/volume). A urinary Pebax<sup>®</sup> catheter with a hardness of 63 shore D is dipped in this solution for 15 seconds and is then dried at ambient temperature for 60 seconds. The catheter is then dipped for 1 second in a solution containing 6% (weight/volume) of polyvinylpyrrolidone (K90; mean molecular weight ~360 000) dissolved in methylene chloride (75%) and tri chloro ethylene (25%). The

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catheter is then allowed to dry at ambient temperature for 60 seconds and is finally cured for 50 minutes at 100 °C. The catheter is finally allowed to cool to room temperature and is then rinsed in water. The catheter has a slippery and adherent surface when wet.

5     **Example 4**

A diisocyanate (named Desmodur IL) is dissolved in ethyl acetate to a concentration of 2% (weight/volume). A urinary catheter manufactured from Evoprene<sup>®</sup> G with a hardness of 65 shore A is dipped in this solution for 15 seconds and is then dried at ambient temperature  
10     for 60 seconds. The catheter is then dipped for 1 second in a solution containing 6% (weight/volume) of polyvinylpyrrolidone (K90; mean molecular weight ~360 000) dissolved in methylene chloride. The catheter is then allowed to dry at ambient temperature for 60 seconds and is finally cured for 50 minutes at 100 °C. The catheter is finally allowed to cool to room temperature and is then rinsed in water. The catheter has a slippery and adherent  
15     surface when wet.

The urinary catheters prepared according to the examples show low friction, good kink resistance, good dimension stability and possibility to be sterilised. Moreover, the longitudinal shrinkage of the catheters as a result of the coating process was less than 1% of  
20     the original length.

While the examples refer to the manufacture of urinary catheters it is to be understood that the invention is not restricted to this sole application but is equally applicable to other forms of catheters and moreover other constructions falling within the broad class of medical  
25     devices having an elongate shaft adapted for insertion into a body passageway as whole, for instance transurethral devices for treating erectile dysfunction and wound drains for insertion into body passageways in the form of wound cavities.

**CLAIMS:**

1. A method for the manufacture of a medical device which presents a hydrophilic surface coated elongate shaft for insertion into a body passageway comprising the steps of  
5 having the elongate shaft formed from a thermoplastic elastomer material selected from the group consisting of a polyether block amide and a styrene block copolymer and forming the hydrophilic coating on the elongate shaft by applying sequentially to the surface of the elongate shaft a solution comprising between 0.05 to 40% (weight to volume) of an isocyanate compound and a solution containing between 0.5 and 50% (weight to volume) of  
10 polyvinylpyrrolidone and curing at an elevated temperature.
2. A method according to claim 1, characterised in that the isocyanate compound comprises at least two unreacted isocyanate groups per molecule.
- 15 3. A method according to claim 1 or 2, characterised in that the solvent of the isocyanate solution is an organic solvent which does not react with isocyanate.
4. A method according to claim 1, 2 or 3, characterised in that the method further comprises the steps of evaporating the solvent of the isocyanate solution prior to application  
20 of the polyvinylpyrrolidone solution and evaporating the solvent of the polyvinylpyrrolidone solution prior to curing.
5. A method according to any one of the preceding claims, characterised in that the curing is carried out in the presence of a water-containing gas.  
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6. A method according to any one of the preceding claims, characterised in that the curing is carried out at a temperature of between about 50 and 130° C.
7. A method according to any one of the preceding claims, characterised in that the  
30 styrene block copolymer is a styrene-ethylene/butylene-styrene block copolymer.

8. A method according to any one of claims 1 to 6, characterised in that the polyether block amide selected for the elongate shaft has a hardness in the range of 25 Sh D to 70 Sh D.
- 5 9. A method according to claim 7, characterised in that the styrene-ethylene/butylene-styrene block copolymer selected for the elongate shaft has a hardness in the range of 40 Sh A to 70 Sh D.
- 10 10. A method according to any one of the preceding claims, characterised in that the isocyanate is selected from 2,4-toluene diisocyanate and 4,4'-diphenylmethane diisocyanate, or a pentamer of hexamethylene diisocyanate and toluene diisocyanate of cyanurate type, or trimerized hexamethylene diisocyanate biuret or mixtures thereof.
- 15 11. A method according to any one of the preceding claims, characterised in that the method comprises the steps of applying to the hydrophilic coating a solution containing an osmolality-increasing compound and evaporating the solution containing the osmolality-increasing compound.
- 20 12. A method according to claim 11, characterised in that the osmolality-increasing compound is an inorganic salt selected from sodium and potassium chlorides, iodides, citrates and benzoates.
- 25 13. A medical device which presents a hydrophilic surface coated elongate shaft for insertion into a body passageway manufactured by the method according to any one of claims 1 to 12.
- 30 14. A medical device which presents an elongate shaft for insertion into a body passageway characterised in that the elongate shaft is made from a polyether block amide or a styrene block copolymer and provided with a hydrophilic outer surface coating formed from an interpenetrating network of polyvinylpyrrolidone and polyurea.

15. A medical device which presents an elongate shaft for insertion into a body passageway characterised in that the elongate shaft is made from a polyether block amide or a styrene block copolymer and provided with a polyvinylpyrrolidone hydrophilic outer surface coating having enhanced osmolality.
- 5 16. A medical device according to claim 14 or 15, characterised in that the styrene block copolymer is a styrene-ethylene/butylene-styrene block copolymer.
17. A medical device according to claim 14 or 15, characterised in that the elongate  
10 shaft is formed from a polyether block amide having a hardness in the range 25 Sh D to 70 Sh D.
18. A medical device according to claim 16, characterised in that the elongate shaft is formed from a styrene-ethylene/butylene styrene block copolymer having a hardness in the  
15 range 40 Sh A to 70 Sh D.
19. A medical device according to any one of claims 14 to 18, characterised in that the hydrophilic coating contains an osmolality-increasing compound.
20. A medical device according to claim 19, characterised in that the osmolality-increasing compound is an inorganic salt selected from sodium and potassium chlorides, iodides, citrates and benzoates.
21. A medical device according to any one of claims 13 to 20, characterised in that the  
25 device is a catheter.
22. A medical device according to claim 21, characterised in that the device is a urinary catheter.
23. Use of a styrene block copolymer in the manufacture of a medical device which presents an elongate shaft for insertion into a body passageway.
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24. Use according to claim 23 characterised in that the styrene block copolymer is a styrene-ethylene/butylene-styrene block copolymer.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/01121

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61L 29/00, C08J 7/04

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)

IPC6: A61L, C08J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, US PAT.FULL., REGISTRY FILE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0483941 A2 (C.R.BARD,INC.), 6 May 1992 (06.05.92), column 7, line 7 - line 58; column 8, line 34 - line 56, abstract, claims --	1-24
Y	EP 0093093 A1 (ASTRA MEDITEC AB), 2 November 1983 (02.11.83), page 2, line 16 - page 4, line 11, abstract, claims --	1-24
A	EP 0592870 A1 (C.R.BARD,INC.), 20 April 1994 (20.04.94), column 5, line 11 - line 30; column 6, line 1 - line 13; column 7, line 42 - line 52, column 9, line 29 - line 36; claim 3 --	1-24



Further documents are listed in the continuation of Box C.



See patent family annex.

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## INTERNATIONAL SEARCH REPORT

International application No.

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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.
A	WO 9523619 A1 (SCIMED LIFE SYSTEMS, INC.), 8 Sept 1995 (08.09.95), page 5, line 14 - line 18, abstract, claims  -----	1,8

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

01/09/97

International application No.  
PCT/SE 97/01121

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0483941 A2	06/05/92	AU 7382291 A DE 69119696 D,T ES 2087243 T JP 5156203 A US 5160790 A US 5290585 A	07/05/92 02/10/96 16/07/96 22/06/93 03/11/92 01/03/94
EP 0093093 A1	02/11/83	SE 0093093 T3 AU 556351 B AU 1326783 A CA 1215597 A DK 170983 D GB 2122510 A,B HK 92186 A JP 1670911 C JP 3035990 B JP 58193767 A SE 430695 B,C SE 8202523 A US 4585666 A US 4666437 A	30/10/86 27/10/83 23/12/86 00/00/00 18/01/84 12/12/86 12/06/92 30/05/91 11/11/83 05/12/83 23/10/83 29/04/86 19/05/87
EP 0592870 A1	20/04/94	CA 2107271 A JP 6197978 A	31/03/94 19/07/94
WO 9523619 A1	08/09/95	CA 2184383 A EP 0748232 A US 5556383 A	08/09/95 18/12/96 17/09/96