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<b>(21) International Application Number:</b> PCT/US94/06024 <b>(22) International Filing Date:</b> 27 May 1994 (27.05.94)  <b>(30) Priority Data:</b> 08/070,601                      2 June 1993 (02.06.93)                      US  <b>(71) Applicant:</b> SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US).  <b>(72) Inventors:</b> SLAIKEU, Paul, C.; 425 Spring Hill Road, Vadnais Heights, MN 55127 (US). KLEE, James; 12100 69th Avenue North, Maple Grove, MN 55369 (US). DUGGAN, Roger; Apartment #14, 14 South McClaen Boulevard, Memphis, TN 38104 (US).  <b>(74) Agents:</b> ARRETT, Oliver, F. et al.; Vidas, Arrett & Steinkraus, Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402 (US).		<b>(81) Designated States:</b> JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> SELECTIVE ARRANGEMENT OF LUBRICOUS COATINGS ON BALLOON CATHETERS  <b>(57) Abstract</b>  A predetermined arrangement of differentially lubricous areas on a balloon catheter for controlling against unexpected movement when <i>in situ</i> in the body.		

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## SELECTIVE ARRANGEMENT OF LUBRICOUS COATINGS ON BALLOON CATHETERS

### Background of the Invention

5                   This invention relates to balloon catheters, sometimes referred to as dilatation catheters, for use in angioplasty. Angioplasty has become recognized as an efficient and effective method of opening stenoses in the vascular system. In the most widely used form of angioplasty, a balloon catheter is guided through the vascular system until the balloon, which is  
10   carried at the distal end of a catheter shaft, is positioned across the stenosis or lesion, i.e., vessel obstruction. The balloon is then inflated to apply pressure to the obstruction which is essentially remolded by pressing it against the inner wall of the vessel whereby the vessel is opened for improved flow.

                  Balloon catheters are of various types. One type is fed over a  
15   guide wire (i.e., "over-the-wire" catheters) and another type serves as its own guide wire (i.e., "fixed-wire" catheters). Variations of these two basic types also have been developed such as the so called "rapid exchange" type, "innerless" catheters, and others. As used herein, the term "balloon catheter" is meant to include all of the various types of angioplasty catheters which carry  
20   a balloon for performing angioplasty. Balloon catheters may also be of a wide variety of inner structure, such as different lumen design, of which there are at least three basic types: triple lumen, dual lumen and co-axial lumen. All varieties of internal structure and design variation are meant to be included by use of the term "balloon catheter" herein.

25                   When used in percutaneous transluminal coronary angioplasty (PTCA), the balloon catheter is typically advanced through a guide catheter to a preselected vessel location such as the aorta. Using fluoroscopy, the surgeon manipulates the catheter until the balloon is located across the stenosis or obstruction. As already pointed out, this may involve the use of a guide wire

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over which the catheter is moved or alternatively the catheter may act as its own guide wire, depending on the particular design. The manipulation of the balloon catheter through the guide catheter and through the vessels to the obstruction requires the balloon catheter to have a number of different features.

5                   One such feature is the use of a lubricous coating over the exterior surfaces of the catheter and balloon to facilitate movement of the catheter through the sometimes tortuous paths within the vascular system to the preselected vessel location for performing the angioplasty. A wide variety of such lubricous coatings have become commonplace for use with respect to  
10 catheters and other devices which are insertable into the body in connection with surgical procedures and the like. All such coatings are intended to be included herein with respect to the use of the term "lubricous coating".  
Examples of such coatings include silicone and most preferably hydrophilic coatings involving hydrogel polymers or the like, such as polymer networks of  
15 a vinyl polymer and an uncrosslinked hydrogel, for example. Polyethylene oxide (PEO) is a preferred hydrogel. A preferred vinyl polymer is neopentyl glycol diacrylate (NPG). Such compositions are more fully disclosed in co-  
pending U.S. Patent Application, serial number 07/809,889 which is assigned to the same assignee as is the present invention and which is incorporated  
20 herein by reference.

These coatings have even been known to include certain agents such as drugs which may be permanently entrapped in the coating or leachable therefrom into the body. For example, heparin has been used in such a fashion. Heparin is well known as an agent which is often used to inhibit clot  
25 formation in the blood. Again, the term "lubricous coating" is meant to include all such variations.

The term "watermelon seeding" refers to the commonly experienced phenomenon which occurs when one squeezes a watermelon seed between the forefinger and thumb, the result of which usually results in the

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flight of the watermelon seed. Thus, this terminology aptly describes the potential problem which might occur in a situation in which a lubricated balloon has been positioned across an obstruction and inflated. As a result of the increased pressure exerted by the expanded balloon against the obstruction, an unexpected movement of the balloon in one direction or the other in the vessel might occur as the balloon slips along the obstruction in an attempt to relieve the increased pressure. This unexpected movement might be regarded negatively by a surgeon. Thus, though high lubricity desirable for general movement, it is also desirable to provide a means of anchoring or positioning the balloon in fixed location so as to avoid unexpected movement thereof upon balloon expansion.

#### Summary of the Invention

This is accomplished by the present invention through the selective arrangement of lubricous coatings on the balloon catheter in which at least a substantial portion of the balloon body is uncoated or less slippery while a relatively more lubricous coating is placed on at least a substantial portion of the catheter shaft extending in a proximal direction from the balloon toward the proximal end of the catheter shaft.

Generally then, the invention contemplates an improvement in the arrangement of lubricous coating(s) on the catheter to avoid "watermelon seeding" and to better anchor the balloon in position for performing angioplasty. This is accomplished by what may be termed herein as "differential coating" or "selective lubricating". By this is meant that the lubricous properties of the catheter are selectively designed or constructed and arranged in a predetermined manner such that the catheter shaft i.e., substantially all of the catheter generally exhibits more lubricity than the balloon generally. In short, the catheter is more slippery than the balloon, relatively speaking. It can be seen that an important feature of the invention lies in the uncoated or less slippery balloon or portion thereof relative to the

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rest of the catheter.

Such an arrangement may be accomplished in a number of different ways. For example, in one embodiment, a lubricous coating may be provided over substantially the entire catheter i.e., as is done in the prior art, except for the balloon per se. In this embodiment, the balloon does not include any lubricous coating at all.

In a more preferred embodiment, the catheter shaft and balloon are both lubriciously coated, but the coating on the balloon is less lubricious or less slippery than the one on the catheter shaft. In such an instance, two different coatings may be used, such as a PEO composition as aforementioned on the catheter shaft and so forth while a silicone coating is placed on the balloon per se. Such an arrangement represents a preferred embodiment of the invention.

In another variation, different compositions of PEO may be used on the shaft and balloon. In the PEO compositions aforementioned, comprised of PEO and NPG in isopropyl alcohol and water, variations in the amount of PEO content affect the final lubricity of the composition; the higher the percentage PEO, the higher the lubricity. Therefore, one may utilize a relatively higher percentage PEO composition on a catheter shaft and a relatively low percentage composition on the balloon to achieve the ends of this invention also i.e., "differential" or "selective" lubricity over a catheter. Of course, other compositions may also be utilized in this way.

Another preferred embodiment comprises a coated catheter shaft, coated balloon cones and a coating on at least the distal waist of the balloon extending to the distal catheter tip, the balance of the balloon body having no coating or on of less lubricity.

Additionally and even more preferably both the proximal and distal balloon cones are so coated similarly to the catheter shaft or at least the distal cone. In accordance with the invention, the balance of the balloon body

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is uncoated or coated with a relatively less lubricous coating.

#### Brief Description of the Drawings

A detailed description of the invention is hereafter described  
5 with specific reference being made to the drawings in which:

FIG. 1 is a diagrammatic showing of a balloon catheter in which  
the balloon is positioned across an obstruction in a vessel prior to inflation.

FIG. 2 is a diagrammatic showing of the positioned balloon  
catheter of Figure 1 with the balloon inflated against the obstruction.

10 FIG. 3 is a schematic showing of a typical balloon catheter.

FIG. 4 is a schematic diagram showing the basic anatomy of a  
catheter balloon per se coated according to one preferred embodiment of the  
invention.

#### 15 Detailed Description of the Invention

Referring now to Figures 1 and 2, reference to the  
aforementioned "watermelon seeding" effect will be more readily understood.  
Figures 1 and 2 show a balloon catheter, generally indicated at 10, of the over-  
the-wire type having a guide wire 12 over which the catheter has been moved  
20 within a vessel 14 to the location of an obstruction 16. As can be seen in the  
Figures, balloon 18 is positioned across obstruction 16 while uninflated (shown  
in Figure 1). Upon inflation (shown in Figure 2), as the balloon expands and  
exerts pressure against obstruction 16 it is possible for the "watermelon  
seeding" effect to occur if care is not taken to hold the catheter in a fixed  
25 position. As shown in Figure 2, if the catheter is held in a fixed position, the  
expanding balloon presses against obstruction 16 molding it against the inner  
walls of vessel 14 to open the vessel. As already indicated with respect to the  
present invention, the surface of balloon 18 shown contacting obstruction 16 is  
best not coated or coated with a less lubricous coating than the catheter proper

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in order to provide an "anchoring" effect when it engages the obstruction.

This is more fully described hereinbelow with reference to Figures 3 and 4.

Figure 3 shows a typical balloon catheter which may incorporate any of the various aforementioned design variations for catheters. For

5 purposes of understanding the present invention it is only important to note that catheter 10 includes a balloon generally indicated at 18, a distal tip 20, a shaft 22 and a manifold portion generally indicated at 24. Shaft 22 is comprised of a proximal end portion 26 and a distal end portion 25 where it joins balloon 18.

10 As can be seen in Figure 4, balloon 18 includes a body portion 30, a proximal cone portion 36, a proximal waist portion 38 and a distal cone portion 32 along with a distal waist portion 34.

In accordance with one embodiment of the selective arrangement of the lubricous coatings on the catheter as contemplated herein, such a coating  
15 is shown at 40 extending over proximal cone 36 (optional), in a proximal direction over shaft 22 toward the proximal end portion 26 thereof to thereby cover a substantial portion of shaft 22. Coating 40 is also optionally included on the distal cone 32, distal waist portion 34 and the distal tip of the catheter 20 as can be seen best in Figures 3 and 4. The balance 30 of the balloon is  
20 either uncoated or coated with a less lubricous composition.

As is known in the art with respect to balloon catheters and lubricous coatings, the coating will be relatively thin and preferably bonded to the catheter body surfaces, although be not necessarily. Silicone is an example of an unbonded lubricant. The PEO based coating cited earlier is an example  
25 of a bonded one. In the Figures, the relative thickness of coating is greatly exaggerated for clarity. However, in accordance with standard practices in the art, such coatings may nominally be of a thickness on the order of 20-50 um or less and will be applied in a variety of ways depending on the type of coating involved and the particular selective arrangement of the coating



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desired. For example, in the case of various polymeric hydrophilic coatings it has been found convenient to utilize an elastic mask to block the body portion of the balloon from being coated with the slippery hydrophilic coating. The mask, in a preferred form, is a heat shrink polyolefin sized to provide a slight interference fit around the balloon to keep the mask in place during processing. In one preferred form, the uncoated length of the area masked has been about 5/8" of an inch centered on the body portion of the balloon and extending around its peripheral surface. Such an arrangement is indicated in Figure 4. Of course, the entire body per se of the balloon may be left uncoated as well or coated with a relatively less lubricous coating than the balance of the catheter proper.

Upon completion of the polymer coating procedure, the mask is then removed to expose the uncoated balloon body portion. In such an arrangement, the shaft and balloon cones and waists, being unmasked during the coating procedure, are coated with the same slippery hydrophilic coating as is placed on the rest of the catheter. As is already known, such coatings are typically applied to the catheter surfaces in the form of a solution which is allowed to dry and is subsequently cured usually by heat or Ultraviolet light for a short period of time.

Other means for achieving the selective placement of coating(s) on the catheter may include the use of a release agent such as an oil which may be spread over the area which it is desired will remain uncoated. After curing of the coating, this area is then exposed by simply peeling the coating off the area carrying the oil. Also, if desired, one may rinse or wipe a portion of the coating off the balloon before the coating is cured. Another alternative is to modify the coating in the area of the balloon which is to remain uncoated such as using an ultraviolet blocker.

A final selective coating arrangement according to the invention may also be made by first coating with a less slippery, compatible coating over

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the balloon and possibly more of the catheter, then masking, applying highly slippery coatings as desired and proceeding as normal or vice versa.

This invention is equally applicable to balloons of the compliant type and to those of the non-compliant type. A wide variety for the materials  
5 of the balloons is well known, some examples of which, to name a few, include ethylene vinylacetate copolymer polyethylene terephthalate, polyethylene, polyolefin copolymer and high density polyethylene.

Masking materials are most conveniently heat shrink polyethylene on mandrels to sizes appropriate to the particular balloon and are  
10 placed thereon. The coating may comprise a mix of a higher molecular weight soluble polymer such as PEO and a UV curable diacrylate in isopropyl alcohol and water containing a trace of photoinitiator. The coating solution is wiped onto selected areas of the catheter device which is then passed to a UV chamber, purged of oxygen, exposed to UV and then removed. The mask is  
15 removed, the area is cleaned ultrasonically with a water bath to remove any drips. The uncoated portion of the balloon is left as is or a less lubricous coating is applied to it such as silicone or a polymer coating with a lesser percentage of hydrogel content. Other methods of application will be known to those familiar with the art.

20 While this invention may be embodied in many different forms, there are shown in the drawings and described in detail herein specific preferred embodiments of the invention. The present disclosure is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

25 This completes the description of the preferred and alternate embodiments of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

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## WHAT IS CLAIMED IS:

1. In a balloon catheter of the type including a shaft and a balloon associated therewith, the improvement comprising lubricous means constructed and arranged to provide relatively more lubricity with respect to a major  
5 portion of the shaft than with respect to at least a portion of the balloon.
2. The catheter according to the claim 1 wherein the lubricous means is constructed and arranged to provide a lubricous coating on the shaft portion and the balloon portion is uncoated.
3. The catheter according to claim 2 wherein the uncoated portion  
10 of the balloon is a central portion of the balloon.
4. The catheter according to claim 3 wherein a similar coating to that on the shaft is included on the distal end portion of the balloon.
5. The catheter according to claim 4 wherein the proximal end portion of the balloon is also similarly coated.
- 15 6. The catheter according to claim 1 wherein the lubricous means is constructed and arranged to provide a lubricous coating on the shaft and a relatively less lubricous coating on at least a portion of the balloon.
7. The catheter according to claim 6 wherein the more lubricous coating comprises a polyethylene oxide composition.
- 20 8. The catheter according to claim 6 wherein the less lubricous coating comprises silicone.
9. The catheter according to claim 6 wherein the less lubricous coating is only on a central portion of the balloon.
10. In a balloon catheter of the type including a shaft, a balloon  
25 having a cone and a waist at each end, a distal tip portion and lubricous coatings associated with surfaces thereof, the improvement comprising a predetermined arrangement of more lubricous and less lubricous coatings on surface areas of the catheter whereby the shaft is provided with a relatively highly lubricous coating over a substantial portion of its length extending from

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the balloon toward the proximal end of the shaft, both cones of the balloon are similarly coated as is the distal tip while at least a substantial portion of the balloon body per se is coated with a relatively less lubricous coating.

11. The catheter according to claim 10 wherein the highly lubricous  
5 coating is comprised of a polyethylene oxide composition.

12. The catheter according to claim 10 wherein the less lubricous coating is comprised of silicone.

13. The catheter according to claim 10 wherein the entire balloon body is uncoated.

10 14. The catheter according to claim 10 wherein the entire balloon body is coated with the less lubricous coating.

15. The catheter according to claim 10 wherein only a central portion of the balloon body is uncoated.

16. The catheter according to claim 10 wherein only a central portion  
15 of the balloon body is coated with the less lubricous coating.

17. The catheter according to claim 10 wherein the proximal end portion of the shaft is uncoated.

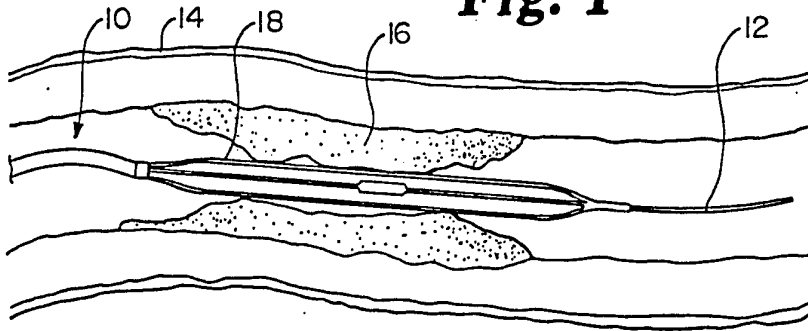
18. The catheter according to claim 10 wherein at least the distal waist of the balloon is also coated with the highly lubricous coating.

20 19. The catheter according to claim 18 including the same coating on the proximal waist of the balloon.

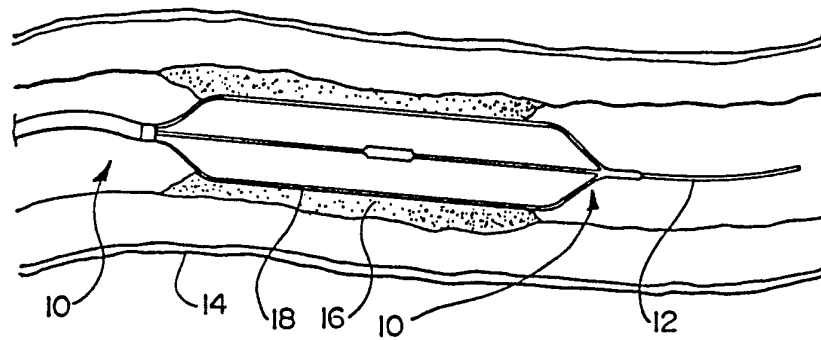
20. The catheter according to claim 10 wherein only the distal cone is coated with the highly lubricous coating, the central portion being optionally uncoated or coated with a less lubricous coating.

1/1

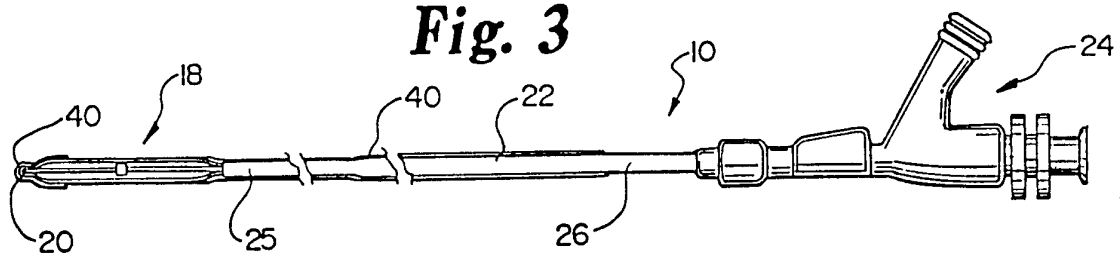
**Fig. 1**



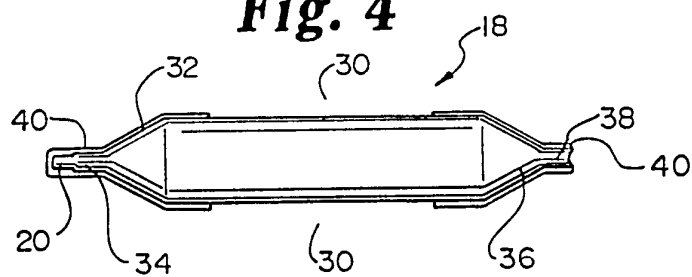
**Fig. 2**



**Fig. 3**



**Fig. 4**



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 94/06024A. CLASSIFICATION OF SUBJECT MATTER  
IPC 5 A61M25/00 A61M29/02

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## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 5 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	EP,A,0 380 102 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 1 August 1990  see page 3, line 2 - line 16 see page 4, line 30 - line 37; figure 2; example 1  ---	1-6, 8-10, 12-20
A	US,A,5 041 100 (ROWLAND ET AL.) 20 August 1991  see column 1, line 59 - column 2, line 35; claim 1; figure 1  ---	1,2,7, 10,11
A,P	WO,A,94 07561 (MEDTRONIC, INC.) 14 April 1994  see page 5, line 3 - line 7; claims 1-4; figure 1  ---  -/--	1,8,10, 12

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 94/06024

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO,A,91 08790 (BOSTON SCIENTIFIC CORP.) 27 June 1991</p> <p>-----</p>	

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.  
PCT/US 94/06024

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0380102	01-08-90	CA-A- 2007743 JP-A- 2289264	26-07-90 29-11-90
US-A-5041100	20-08-91	NONE	
WO-A-9407561	14-04-94	NONE	
WO-A-9108790	27-06-91	US-A- 5135516	04-08-92