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(21) International Application Number: PCT/US98/09495 (22) International Filing Date: 8 May 1998 (08.05.98) (30) Priority Data: 60/045,953 8 May 1997 (08.05.97) US (63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 60/045,953 (CIP) Filed on 8 May 1997 (08.05.97) (71) Applicant (for all designated States except US): C.R. BARD, INC. [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): TEDESCHI, Eugene [US/US]; 216 Still River Road, P.O. Box 95, Still River, MA 01467 (US). HUDSON, John [US/US]; 27 Fairview Drive, Wells, ME 04090 (US). WOLFGANG, Laurel [US/US]; 12 Phillips Street, Lowell, MA 01854 (US). (74) Agent: CALVARUSO, Joseph, A.; Morgan & Finnegan, L.L.P., 345 Park Avenue, New York, NY 10154 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, 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, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, 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). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: IMPROVED MEDICAL DEVICE HAVING DESIRABLE COMBINATION OF PROPERTIES AND METHOD OF MAKING SAME		
(57) Abstract This invention relates to coated medical devices adapted to pass through narrow body openings such as catheters. The coatings provided by this invention impart durability to the catheter without appreciably adding to the thickness of the catheter and without decreasing the hoop tensile strength of the catheter.		

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**IMPROVED MEDICAL DEVICE HAVING DESIRABLE
COMBINATION OF PROPERTIES AND METHOD OF MAKING SAME**

5 **CROSS-REFERENCE TO RELATED APPLICATIONS**

 This application claims the benefit of U.S. Provisional Application
Serial No. 60/045,953, filed May 8, 1997.

10 **FIELD OF THE INVENTION**

 This invention relates to medical devices, particularly medical devices
adapted to pass through narrow body vessels such as catheters which have an outer
surface polymeric substrate having coated thereon a coating of such nature and
15 sufficiently low thickness that the resulting coated medical device has high hoop
tensile strength and good puncture resistance (durability).

BACKGROUND OF THE INVENTION

20 Catheters are placed at various locations within a patient for a wide
variety of purposes and medical procedures. For example, one type of catheter is a
balloon dilatation catheter which is used in the treatment of a vascular stenosis.
Such a catheter has a balloon at its distal end which is intended to be placed, in a
25 deflated condition, within the stenosis, and then inflated while in the stenosis to
expand radially the stenosed lumen of the blood vessel. Typically, the placement of
such catheters involves the use of a guidewire which may be advanced through the
patient's vasculature to the location which is to be treated. The catheter, which has a
30 guidewire lumen adapted to receive the guidewire, then is advanced over the wire to
the stenosis, or, alternatively, the wire and catheter may be advanced in unison to
the stenosis with the wire protruding from the distal end of the catheter.

 It has long been known that hydrophilic coatings with low friction
35 (coefficient of friction of 0.3 or less) are useful for a variety of medical devices such

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- as catheters, catheter introducers and the like. When low friction coating surfaces are applied to the substrate of such medical devices, such devices when introduced into the body slide easily within arteries, veins and other body orifices and passageways. Examples of prior art catheters which have been provided with a lubricious coating in the manner referred to in the foregoing paragraph are coated catheters disclosed in U.S. Elton Patent No. 5,077,352, U.S. Elton Patent No. 5,160,790, U.S. Opolski Patent No. 5,272,012 and U.S. Rowland Patent No. 5,041,100.

While a number of prior art medical catheters possess high hoop tensile strength they are lacking in a sufficiently high enough puncture resistance. By the present invention, a medical device, e.g., a catheter having a coating of such nature on its outer surface substrate is provided whereby the medical device has a puncture resistance greater than its uncoated form without affecting hoop tensile strength which results in an improved catheter of improved durability.

DESCRIPTION OF THE INVENTION

It is an object of this invention to provide a medical device, e.g., a medical catheter made of a polymeric material which has been coated with a coating of such nature and applied in such a manner that the puncture resistance of the medical device (durability) has been increased while not decreasing any desirable physical property like hoop tensile strength nor significantly increasing the diameter of the product.

Another object of the invention is to obtain a medical catheter composed of a polymeric material having a coating wherein the resulting coated catheter is composed of materials of such characteristics, morphology and thickness that said coated catheter has a desirable combination of properties, including a high hoop tensile strength and acceptable puncture resistance.

It has been found that the objects of this invention may be realized by applying to the outer polymeric surface of a medical device, e.g., a medical catheter, and in particular, the inflatable balloon portion of the catheter, a polymeric coating of such nature and of sufficient thickness to obtain an improved puncture resistance

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- over that of the uncoated parent substrate so as to impart greater durability to the coated medical device over the parent uncoated medical device.

Suitable methods for applying the polymeric coating to the substrate surface of the catheter include dipping, painting, spraying or wiping the coating on the catheter outer surface substrate. Dipping is a preferred method as it allows for more control over the coating process. The thickness of the coatings is typically less than about 1 mil. A thickness range of about 0.02 to about 0.5 mils is more preferred. Thickness ranges of about 0.05 to about .25 mils and about 0.1 to about 0.25 mils are also preferred.

Examples of suitable coating compositions are solutions or dispersions of polyurethane, acrylic polymers and epoxy resin materials in a suitable solvent or liquid carrier. For example, it has been surprisingly found that commercial polyurethane coatings such as Helmsman Urethane Coating or Carver Tripp Clear Polyurethane, commercial acrylic polymers such as Thompson's Minwax Polyacrylic Finish or commercial epoxy resins such as Hardman EpoWeld® can be used. It is noted that these commercial products may contain additives such as coloring which are unnecessary for practicing this invention. The basic building blocks of polyurethanes are isocyanates containing two or more isocyanate groups and polyols containing two or more hydroxyl functions. Toluenediisocyanate, polymeric diphenylmethanediisocyanate, monomeric 4,4'-diphenylmethanediisocyanate, 1,6-hexamethylene diisocyanate and isophorone diisocyanate are common isocyanates that can be used either individually or as a mixture to produce polyurethanes for use in this invention. Polyurethanes are classified according to the polyol used. The polyols are generally polyethers and polyesters. Polyether-based urethanes are more resistant to hydrolysis and have higher resilience, good energy-absorption characteristics, good hysteresis characteristics, and good all-around chemical resistance. A polyester-based material will generally be stiffer and will have higher compression and tensile moduli, higher tear strength and cut resistance, higher operating temperature, lower compression set, and optimum abrasion resistance. Castor-oil-based potting compounds are also convenient to use. CasChem markets a

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family of polyurethane systems based on ricinoleate polyols derived from castor oil. Diamines are the best general purpose curing agents for polyurethanes. Non-limiting examples of suitable acrylic polymers are those made up of methyl acrylate, ethyl acrylate or methyl methacrylate acrylic-esters. Other examples include the use of copolymers of methyl methacrylate with other monomers such as methyl and ethyl acrylate, acrylonitrile and styrene. Non-limiting examples of suitable epoxy resin materials are those based on the reaction of bisphenol A and epichlorohydrin in the presence of an alkaline catalyst, novolac epoxies such as cresols, and cycloaliphatics. Epoxy resins can be cured with cross-linking agents or catalysts to develop desirable properties. Additional information on the production and use of polyurethane, acrylic polymer and epoxy resin can be found in the Modern Plastics Encyclopedia, October 1986, Volume 63, Number 10A, published by McGraw Hill, New York, NY and references therein or the Handbook of Plastics, Elastomers, and Composites, Third Ed., by Charles A. Harper, published 1996 by McGraw Hill, New York, NY and references therein. The preparation of the coatings can be a multi-step process.

Non-limiting examples of suitable solvents or carriers are water, aliphatic or aromatic hydrocarbons, heterocyclic aromatics, ethers, amines, amides, ketones, esters, halogenated aliphatic or aromatic hydrocarbons, sulfides, sulfoxides and the like. If the coating composition employs a curable material, the curable material is cured after evaporation of the liquid solvent or carrier of the coating composition after the coating solution has been applied to the substrate.

After applying the coating solution or dispersion, the solvent or liquid carrier is preferably allowed to evaporate from the coated substrate often by exposure to ambient conditions for from about 10 to about 180 minutes but can be evaporated at temperatures of from about 35° F to about 400° F for time periods of a few seconds to overnight depending upon the selection of solvent or liquid carrier and the speed with which evaporation is desired.

The organic balloon substrate that can be coated with a suitable coating for obtaining a coated catheter with high hoop tensile strength and acceptable

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◦ puncture resistance in accordance with this invention include nylon, polyether block amide, polyethylene terephthalate (PET), polyetherurethane, polyesterurethane, natural rubber, rubber latex, synthetic rubbers, polyester-polyether copolymers, ethylene methacrylic acid di- and inter polymers containing metal salts, polyethers, polyesters, and other polyurethanes, polycarbonates, polytetramethylene glycol ether urethane, and other organic materials including polyvinylchloride and other vinyl polymers, polyethylene and the like, as well as blends and alloys of the above. Some of these materials are available under the trademarks such as Pebax available from Atochem, Inc. of Glen Rock, New Jersey, Mylar available from E.I. duPont deNemours and Co. of Wilmington, Delaware, Texin 985A from Mobay Corporation of Pittsburgh, Pennsylvania, Surlyn available from E.I. duPont deNemours and Co. of Wilmington, Delaware, Pellethane available from Dow Chemical of Midland, Michigan, and Lexan available from General Electric Company of Pittsfield, Massachusetts.

The balloons are preferably made from nylon, PET or blends or alloys thereof. It is desired that the hoop tensile strength or Hoop Stress of the balloons (uncoated and after coating to enhance durability) be about 10,000 psi or greater. It is more preferred that such balloons have a hoop tensile strength of about 25,000 psi or greater. The size of the balloons typically is in the range of about 0.5 to about 25 mm in diameter. More preferably the balloons range from about 1 to about 18 mm in diameter and most preferably from about 1 to about 4 mm in diameter. The balloons are typically biaxially orientated, but the use of other forms is also useful in the practice of this invention. The uncoated double wall thickness (DWT) of the balloon is typically from about 0.25 to about 3 mils thick. An uncoated DWT of about 0.5 to about 1.2 mils is more preferred.

All publications, patents and articles referred to herein are expressly incorporated herein *in toto* by reference thereto. The following examples are presented to illustrate the present invention but are in no way to be construed as limitations on the scope of the invention. It will be recognized by those skilled in the art that numerous changes and substitutions may be made without departing from the

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- spirit and purview of the invention.

EXAMPLE 1

Coatings5 Coating A

Coating A is a solvent based polyurethane coating. The coating was prepared by dissolving Helmsman Urethane Coating in toluene. The dilution ratio of polyurethane to solvent was from about 1:2 to about 1:10 depending on the thickness of the coating desired.

Coating B

Coating B is a water soluble polyurethane coating. The coating was prepared by dissolving Carver Tripp Clear Polyurethane in water. The dilution ratio of polyurethane to water was about 1:1 to about 1:10 depending on the thickness of the coating desired.

20 Coating C

Coating C is a water soluble acrylic polymer coating. The coating was prepared by dissolving Thompson's Minwax Polyacrylic Finish in water. The dilution ratio of polyacrylic to water was about 1:1 to about 1:10 depending on the thickness of the coating desired.

Coating D

Coating D is a solvent based polyurethane coating. The coating was prepared as follows. Initially, Cellulose Acetate Butyrate (1.8 g), e.g., Eastman Cellulose Acetate Butyrate 500-5 available from Eastman Chemical Company, Kingsport, Tennessee was combined with 16.2 g N-Butyl Acetate available from Van Waters & Rogers Incorporated, San Mateo, California. The solution was mixed for

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approximately 24 hours on a paint roller or until all of the Cellulose Acetate Butyrate was dissolved. When dissolved, polyisocyanate (45.5 g), e.g., Mondur CB-60 PMA available from Miles Corporation, Pittsburgh, Pennsylvania, castor oil (35.0 g), e.g., DB Castor Oil available from CasChem, Incorporated, Bayonne, New Jersey, an additional 116.9 g N-Butyl Acetate available from Van Waters & Rogers Incorporated, San Mateo, California, 122.4 g of iso-Butyl Acetate available from Van Waters & Rogers Incorporated, San Mateo, California and 5.5 g Mineral Spirits available from Van Waters & Rogers Incorporated, San Mateo, California were added.

In addition, the components listed above can be varied to achieve different coating characteristics. Cellulose Acetate Butyrate can be used in the range of about 0.02 to about 2% with a preferred range being about 0.03 to about 0.68%. N-Butyl Acetate can be used in the range of about 0.1 to about 10% with a preferred range being about 0.2 to about 6.5%. The polyisocyanate can be used in the range of about 0.5 to about 22% with a preferred range being about 0.7 to about 18%. The castor oil can be used in the range of about 0.4 to about 14.5% with a preferred range being about 0.5 to about 14%. Additional N-Butyl Acetate can be used in the range of about 24 to about 54% with a preferred range being about 30 to about 45%. iso-Butyl Acetate can be used in the range of about 24 to about 60% with a preferred range being about 30 to about 50%. All percentages are weight/weight.

Table 1 shows variations of coating D that were made and applied to balloons.

Table 1. Various Compositions of Coating D.

Components	W	X	Y	Z
Mondur CB-60	2.85g	8.47g	13.27g	17.61g
Butyl/Iso-Butyl Acetate ¹	92.91g	81.52g	71.44g	61.89g
DB Castor Oil	2.24g	6.69g	10.24g	13.87g
CAB Soln. ²	1.65g	3.67g	5.34g	6.82g

¹Stock Butyl/Iso-Butyl Acetate solution was made by mixing Butyl Acetate (363.27 g), Iso-

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- o Butyl Acetate (381.58 g) and mineral spirits (19.32 g) in a clear bottle and rolling until homogeneous.

²Stock CAB solution was made by mixing Cellulose Ester (28.21 g) and Butyl Acetate (253.65 g) in a clear bottle and rolling for 24 hours.

5 Table 2 shows balloons dipped in the various formulations of coating D shown in Table 1. The burst pressure and hence the hoop tensile strength of the coated balloons was determined and compared to similar balloons that were not coated. The results show that the coatings of this invention do not reduce the hoop
10 tensile strength of balloons.

Table 2. Hoop tensile Strength of Catheters with Coating D

Balloon	Coating	# of Dips	Burst Pressure (bar)
A1	W	1	30.97
B1	X	1	27.84
B2	X	2	26.04
C1	Y	1	27.84
C2	Y	2	29.06
D1	Z	1	24.06
D2	Z	2	31.04
Uncoated	--	--	29.02
Uncoated	--	--	26.07

Coating E

Coating E is a solvent based epoxy resin coating. Hardman Epoxy Part A (2.5 g) and Hardman Epoxy Part B (2.4 g) both available as Hardman Epoweld® 8173 from Elementis Performance Polymers, Belleville NJ were dissolved
30 in toluene (4.9 g) to produce a 50% solution of solids. Serial dilutions were performed to produce coating solutions of 33%, 25% and 20% solids. Balloons were single dipped immediately after mixing.

Balloons were coated with coating E as outlined in Table 3 below.

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- The burst pressure and hence the hoop tensile strength of the balloons coated with coating E was determined. The hoop tensile strength of the coated balloons was then compared to similar, uncoated balloons. The results show that the coatings of this invention do not reduce the hoop tensile strength of balloons.

5 **Table 3.** Hoop Tensile Strength of Balloons with Coating E

Balloon	Balloon Coated With	# of Dips	Burst Pressure (bar)
A	50% solids	1	21.80
B	33% solids	1	20.99
C	25% solids	1	20.51
D	20% solids	1	20.65
E	Uncoated	--	20.78
F	Uncoated	--	19.98

15 Polyurethane Coatings

A polyol (170 g), e.g., Desmophen A 405A, available from Bayer Corp. Pittsburgh, PA, a polyisocyanate (44 g), e.g., Modur CB-60 PMA, available from Bayer Corp., and acetone (2014 g) can be mixed to produce a polyurethane coating. The polyol can be used in the range of about 2 to about 15%, with the preferred range being about 5 to about 10%. The polyisocyanate can be used in the range of about 0.5 to about 10%, with the preferred range being about 1 to about 5%. Acetone can be used in the range of about 80 to about 99%, with the preferred range being about 85 to about 95%.

25 Acrylic Polymer Coatings

An acrylic polymer (4 g), e.g., PMMA HI 835S, available from LG Chemical, is dissolved in tetrahydrofuran (96 g) available from Aldrich. Acrylic polymers like PMMA HI 835S can be used in the range of about 0.1 to about 25% with the preferred range being about 0.5 to about 10%.

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◦ Epoxy Resin Coatings

An epoxy resin (60 g), e.g., Epon 828 Bis A Epoxy Resin, available from Shell Chemical, an acrylate modifier (25 g), e.g., M-Cure 200 Acrylate Modifier, available from Sartomer, and an acrylate modifier (15 g), e.g., M-Cure 202 Acrylate Modifier, available from Sartomer, is mixed to produce part A of the epoxy resin. An amine (6 g), e.g., EpiCure 3005 Amidoamine, available from Shell Chemical, and a second amine (16 g), e.g., Ancamine 1638 Aliphatic Amine is mixed together to produce part B of the epoxy resin. Epoxy resins, e.g., Epon 828 Bis A Epoxy Resin can be used in the range of about 45 to about 75% with the preferred range being about 48 to about 72%. Modifiers, e.g., M-Cure 200 Acrylate Modifier can be used in the range of about 18 to about 32% with the preferred range being about 22.5 to about 27%. Modifiers, e.g., M-Cure 202 Acrylate Modifier can be used in the range of about 11 to about 19% with the preferred range being about 13 to about 17%. Amines, e.g., EpiCure 3005 Amidoamine can be used in the range of about 4 to about 8% with the preferred range being about 5 to about 7%. Amines, e.g., Ancamine 1638 Aliphatic Amine can be used in the range of about 12 to about 20% with the preferred range being about 14 to about 18%. Equal parts of part A and part B can dissolved in two parts toluene. The mixture can then be serially diluted to produce coating mixtures.

A high durometer coating can be made as follows. Two epoxy resins, e.g., AboCast 8-8 (100 g), available from Abatron, Kenosha, WI, AboCure 8-8 (100 g), available from Abatron, can be combined with toluene (100 g) to produce an epoxy coating. Typically the resins can be used in equal portions and toluene can be used in the range of about 10 to about 95%, with a preferred range being about 25 to about 75%.

EXAMPLE 2

Dipping Procedure

Dipping is the preferred method of coating because the thickness of

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the coat is more uniform and easier to control compared to other methods. For example, when coating a PET balloon, the balloon was first cleaned with acetone, isopropyl alcohol or the like. The balloon was then inflated to from about 2 to about 4 bars pressure and dipped into the coating mixture. Factors that affect the coating thickness and adhesion properties were the speed at which the article was introduced into and withdrawn from the mixture, the dwell time in the mixture and the number of times dipped into the coating mixture. The dwell time was found to influence the extent to which the coating was imbibed into the article surface. The down speed (inches/minute) can be over the range of about 1 to about 200 with a preferred range being about 40 to about 140. The dwell (seconds) time has no limit but typically is about 2 to about 40. The withdrawal rate (inches/minute) can be over the range of about 1 to about 200 with a preferred range being about 40 to about 140.

Typically, the double wall thickness of each balloon is first measured. The balloon is then cleaned with isopropyl alcohol, acetone or similar solvent and heat sealed at each end with about 2 to about 4 bars pressure inside the balloon. The balloon is dipped, distal end first, into the coating solution. After removal from the coating solution, the balloon is air-dried. For multiple dipping, the balloon was allowed to air-dry for 20 minutes between dips. The balloons were then placed in a drying oven to cure. After curing, the balloons were removed and the double wall thickness measured.

EXAMPLE 3

Durability Testing

Balloons were examined for durability using the following procedures. The device used for testing was specifically designed for balloon catheters and to represent the environment the balloon catheters are typically used in. The device consists of a series of stainless steel sleeves with internal diameters that match the balloon's nominal outer diameter (OD). A balloon's nominal OD is defined as the outer diameter of the balloon after it has been pressurized from the collapsed

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- position to the inflated position that is free of wrinkles (normally pressures are from about 50 to about 125 psi). Each sleeve has one screw ground to a 60° included taper down to a 0.0065 inch diameter flat. The screw can be extended 0.011 inches toward the center of the cylinder. The sleeve was placed in a submersible fixture and the deflated balloon loaded into the sleeve. The screw was adjusted to a length of 0.011 inches and the apparatus submerged into a body temperature water bath. The balloon catheter was attached to an inflation device i.e., burst machine and inflated to either 12 or 16 bars. If the balloon did not burst, it was deflated and reinflated repeatedly until the balloon burst. The table below compares coating thickness, DWT, inflation pressure and durability between similar, coated and uncoated balloons.

Table 4. Durability of Coatings A, B, C, D and E.

Coating	DWT ¹	Coating Thickness (mil)	Inflation Pressure	Durability Cycles (Avg) ²
None	0.5	-	12	< 1 ³
None	0.9	-	16	< 1 ³
Coating A	1.4	0.45	12	4
Coating A	1.1	0.10	12	8
Coating B	1.2	0.15	12	59
Coating B	0.8	0.15	12	> 73
Coating B	0.6	0.05	16	3
Coating C	1.2	0.35	12	32
Coating C	1.2	0.35	16	74
Coating C	1.5	0.30	12	76
Coating C	0.9	0.20	16	10
Coating C	0.8	0.15	16	20
Coating C	0.7	0.10	16	5
Coating C	0.6	0.05	16	1
Coating D	0.9	0.02	16	1
Coating D	1.1	0.03	16	27
Coating D	1.0	0.05	16	8
Coating D	1.2	0.09	16	32
Coating D	1.1	0.10	16	12
Coating D	1.1	0.11	16	7
Coating D	1.3	0.21	16	6
Coating E	1.4	0.35	16	12
Coating E	0.9	0.13	16	19
Coating E	0.8	0.09	16	2
Coating E	0.8	0.06	16	8

¹Double wall thickness (DWT) is a measure of the thickness of the coating plus the wall thickness of the balloon catheter when the balloon is laid flat and both walls and the coating is measured.

²Durability is measured by cyclically inflating the balloon catheter to a certain pressure in a 3.0 mm sleeve against a 0.011" pin.

³The uncoated balloons burst during the first inflation.

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Durability is defined as a coated balloon attaining at least one more cycle in the above-described test than a similar, uncoated balloon. A more preferred durability is greater than about 5 cycles more than an uncoated balloon and a most preferred durability is greater than about 10 cycles. A preferred range of durability is about 5 to about 50 cycles and a more preferred range is about 10 to about 20 cycles. Typically the testing is done from about 12 bar to about 16 bar which is the working pressure of the balloon. The testing can be done at pressures ranging from about the nominal pressure of the balloon to about the busting pressure of the balloon.

EXAMPLE 4

A length of PET balloon tubing was dipped into polyurethane solution D. It was then allowed to air dry approximately 20 minutes, followed by baking at 120° F for 480 minutes. The coated tube was then formed into a balloon. The resulting product was a balloon catheter with durability (as measured by cyclic penetrations with a pointed probe to measure puncture resistance) greater than a catheter without above coating.

EXAMPLE 5

Hoop Tensile Strength Testing

Hoop tensile strength also known as Hoop Stress was determined as follows. A balloon at body temperature was attached to a burst machine and inflated to the point at which the balloon ruptures. The Hoop Stress was then calculated by the following equation:

$$HS = \frac{(\text{Force @ Break (psi)}) (\text{Balloon Diameter})}{2(\text{Wall Thickness})}$$

For example, the Hoop Stress of a balloon of 3 mm diameter with a wall thickness of

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- 0.0005 inches that ruptures at 20 bar is calculated as follows:

$$HS = \frac{(20 \text{ bar}) (14.7 \text{ psi/bar}) (3.0 \text{ mm}/25.4 \text{ mm/in})}{2(0.0005 \text{ in})}$$

- 5 which calculates as a Hoop Stress of 34,720 psi.

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We claim:

1. A coated medical device having a hoop tensile strength of about 10,000 psi or greater, wherein the coating has a thickness of between about 0.02 and about 0.5 mils and wherein the coated medical device has a greater durability than a similar uncoated medical device.

2. The coated medical device according to claim 1, wherein the coating comprises polyurethane.

3. The coated medical device according to claim 1, wherein the coating comprises acrylic polymer.

4. The coated medical device according to claim 1, wherein the coating comprises epoxy resin.

5. A coating for a polymeric medical device having a hoop tensile strength of about 10,000 psi or greater that imparts durability to the medical device, wherein the coating does not reduce the hoop tensile strength and has a thickness of between about 0.02 and about 0.5 mils.

6. The coating of claim 6, wherein the coating comprises polyurethane.

7. The coating of claim 6, wherein the coating comprises acrylic polymer.

8. The coating of claim 6, wherein the coating comprises an epoxy resin.

9. A method of increasing durability of a polymeric medical device, wherein a coating of between about 0.02 and about 0.5 mils is applied to the medical device.

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o 10. The method according to claim 11, wherein the coating comprises polyurethane.

11. The method according to claim 11, wherein the coating comprises polyacrylic.

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12. The method according to claim 11, wherein the coating comprises epoxy resin.

10 13. A coated medical device having a substrate, wherein the coating has a thickness of about 0.02 to about 0.45 mils, and wherein the substrate has a double wall thickness of about 0.5 to about 0.9 mils and wherein the coating provides the coated medical device with a durability of at least 1 cycle at at least 12 bars pressure.

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14. The coating of claim 13, wherein the durability is at least 1 to about 76 cycles.

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INTERNATIONAL SEARCH REPORT

Internatir	Application No
PCT/US	98/09495

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L29/00

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 A61L

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 592 870 A (BARD INC C R) 20 April 1994 see claims; examples ---	1-14
A	EP 0 274 411 A (BARD INC C R) 13 July 1988 ---	
A	US 5 041 100 A (ROWLAND STEPHEN M ET AL) 20 August 1991 cited in the application -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search

17 September 1998

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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

ESPINOSA, M

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/09495

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