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(57) Abstract

An intravascular medical catheter is provided herein. The medical catheter includes a balloon made from a specific, small group of polyurethane materials. The balloon is formed under rigid manufacturing parameters to obtain the desired compliance or stress/strain characteristics, burst strength, and flexibility. The polyurethane material preferably has a hardness prior to forming of the balloon of between approximately 50D to 65D. The polyurethane material includes (i) a hard segment derived from a diisocyanate and a short–chain diol and (ii) a soft segment derived from a polymeric glycol having an average molecular weight of between approximately 500–5000. When the polyurethane material is manufactured within the parameters outlined herein, the resulting balloon exhibits superior characteristics, including relatively high burst strength, relatively low compliance, and good flexibility.

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POLYURETHANE BALLOON CATHETER

FIELD OF THE INVENTION

The present invention relates to an intravascular medical catheter and a method of manufacturing an intravascular medical catheter. More specifically, the present invention relates to a balloon catheter having excellent burst strength, flexibility, and compliance characteristics.

BACKGROUND

Percutaneous transluminal coronary angioplasty (hereinafter "angioplasty") is a procedure used to treat a stenosis within a body vessel of a human being. A medical catheter having an inflatable balloon attached to a catheter shaft is commonly used during the angioplasty procedure. First, the catheter shaft and balloon are advanced over a guidewire which is positioned within the body vessel until the balloon is adjacent to the stenosis. Subsequently, the balloon is inflated. This causes the site of the stenosis to compress into the arterial wall and the body vessel to dilate. Depending upon the condition of the stenosis, a stent can also be placed within the body vessel.

In recent years, there has been a continuing effort to improve the performance characteristics of medical catheters. Unfortunately, the design of most existing medical catheters has always involved trading off various performance characteristics. For example, many physicians prefer the movement/tracking, and the re-wrapping of a balloon made of polyvinyl chlorides. However, a balloon made of polyvinyl chlorides, in many instances, may not have satisfactory inflation or stress-strain characteristics and may not expand in a predictable fashion. In fact, for some applications, balloons made of polyethylene terephthalate ("PET") provide superior inflation and pressure characteristics. Unfortunately, the balloons made of

PET may have poor rewrap characteristics and can be relatively difficult to maneuver in the body vessel.

Generally, balloons for medical catheters are classified according to their "compliance" or expandability relative to other balloons. Typically, a balloon is rated as being either "compliant," "semi-compliant," or "non-compliant." A comprehensive definition of these terms is provided in U.S. Patent No. 5,556,383, issued to Wang et al. and entitled "Block Copolymer Elastomer Catheter Balloons," the contents of which are incorporated herein by reference.

Typically, non-compliant balloons are often relatively inflexible, are prone to develop pin holes, and the balloons do not rewrap well after inflation in the vessel. As a result thereof, these balloons can be difficult to move and remove from the vessel. On the other extreme, compliant balloons often have a relatively low tensile strength, do not expand in a predictable fashion, and are subject to rupture during high pressure applications.

Recently, a number of semi-compliant balloons have been manufactured using materials, such as nylon and Polyether Block Amide ("PEBA"). These semi-compliant balloons exhibit many desirable characteristics including flexibility and good tensile strength. However, the present semi-compliant balloons are not completely satisfactory. For example, many semi-compliant balloons have a compliance curve which is too steep. This leads to unpredictable balloon inflation and/or over-inflation of the balloon in the vessel. Further, the balloon may not track well in the vessel and/or have a relatively large rewrap profile.

Another type of dilation balloon is disclosed in U.S. Patent No. 5,500,180, issued to Anderson et al. ("Anderson et al."). The preferred polyurethane material disclosed in Anderson et al. is manufactured by the Dow Chemical Company and marketed under the trade name PELLETHANE 2363-75D. Unfortunately, a dilation balloon made of this material and pursuant to the method of Anderson et al. is relatively inflexible, does not rewrap well after inflation and is relatively difficult to move in the vessel.

In light of the above, it is an object of the present invention to provide a medical catheter which exhibits an improved overall combination of physical properties. Another object of the present invention is to provide a balloon which is flexible and moves relatively easily in the vessel. Another object is to provide a balloon which is semi-compliant, expands in a predictable fashion, and has an acceptable burst strength. Still another object is to provide a balloon which is sufficiently soft to allow for easy removal of the balloon from the vessel after the procedure is complete. Yet another object of the present invention is to provide a simple method for manufacturing a balloon which maximizes the physical properties of the polyurethane material utilized for the balloon. Another object is to provide a balloon which rewraps to have a relatively small profile to allow easy removal after the procedure is complete.

SUMMARY

The present invention is directed to a medical catheter which satisfies these objectives. As provided in detail below, the material for the balloon is selected from a specific, relatively small group of polyurethane materials and the balloon is formed under relatively strict manufacturing procedures which maximizes the properties of the small group of polyurethane materials. The resulting balloon is semi-compliant, flexible, and has excellent burst strength. Thus, the balloon inflates in a predictable fashion, moves easily in the body vessel, commonly referred to as "improved tracking" and moves easily past a lesion in the vessel, commonly referred to as "improved lesion crossing characteristics." Additionally, the balloon rewraps to have a relatively small profile to allow easy removal from the vessel.

The physical characteristics of the balloon are primarily influenced by the polyurethane material utilized in the balloon and how the balloon is formed. As provided herein, the polyurethane material includes a hard segment derived from a diisocyanate and a short-chain diol and a soft

segment derived from a polymeric glycol. Importantly, the polyurethane material preferably has a durometer hardness of between approximately 50D-65D and more preferably between 55D and 60D prior to forming the balloon. The use of a relatively soft polyurethane material enhances the flexibility of the resulting balloon. This improves tracking in the vessel and rewrapping of the balloon after inflation to minimize the retraction force necessary to remove the balloon after completion of the procedure.

The diisocyanate is preferably selected from a group consisting of 1,4-cyclohexane diisocyanate, dicyclohexylmethane-4,4'-diisocyanate, xylene diisocyanate, hexamethylene diisocyanate, methylcyclohexyl diisocyanate, 4,4'-biphenylene diisocyanate, m- and p-phenylene diisocyanates, diphenylmethane-4,4'-diisocyanate, diphenymethane-2,4'-diisocyanate, 1,5-napthalene diisocyanate, and isophorone diisocyanate. The short-chain diol is selected from a group consisting of ethylene glycol, 1,2- and 1,3-propanediol, 1,4-butanediol, 1,4-cyclohexanediol, neopentyl glycol and 1,6-hexanediol.

The soft segment is derived from a polymeric glycol having an average molecular weight of between approximately 500-5000 and more preferably an average molecular weight of between approximately 1000-2000. In one embodiment, the polymeric glycol can be selected from a group which consists of a polyether diol and a polyester diol. Alternately, the polymeric glycol is selected from a group which consists of polyoxyethylene glycols, polyoxypropylene glycols, and poly(tetramethylene ether) glycol.

In another embodiment, the polymeric glycol can be derived from a dibasic acid and a glycol. The dibasic acid is selected from a group which includes succinic acid, maleic acid, glutaric acid, adipic acid, and sebacic acid. The glycol is selected from a group which consists of ethylene glycol, 1,3-propanediol, 1,4-butanediol, neopentyl glycol, and 1,6-hexanediol.

The balloon is formed from a tube which is heated to above its glass transition temperature and radially expanded in a mold. The tube is also subjected to an axial stretch so that the resulting balloon is highly bi-axially

oriented. Importantly, the balloon is formed with a blow up ratio of between approximately 5-9 and more preferably 6-8. The term "blow-up ratio" or "BUR" as utilized herein shall mean the ratio of the inner diameter of the balloon mold versus the inner diameter of the tube prior to forming the balloon. Because of the relatively high blow-up ratio utilized, the polyurethane material is stretched to near its limits to approach maximum alignment of the molecules in the material. Thus, a relatively soft polyurethane material can be used to achieve a high burst strength in combination with the desired flexibility and compliance characteristics.

Utilizing the small range of polyurethane materials and the method of manufacturing provided herein, the resulting balloon can achieve (i) a burst strength of at least approximately 250 psi, and more preferably between approximately 275 psi to 300 psi, and (ii) a compliance of less than approximately twenty-five percent (25%), and more preferably, a compliance between approximately ten percent to fifteen percent (10%-15%) between the nominal pressure and the rated burst pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

Figure 1 is a perspective view, in partial cutaway, of a medical catheter having features of the present invention;

Figure 2 is a perspective view of the medical catheter positioned within a patient;

Figure 3 is a cross-sectional view taken on line 3-3 of Figure 1;

Figure 4 is cross-sectional view of a tube positioned within a blow mold;

Figure 5 is a first chart which outlines the compliance curves for a number of balloons made in accordance with the present invention;

Figure 6 is a second chart which outlines the compliance curves for a number of balloons made in accordance with the present invention; and

Figure 7 is a chart which illustrate the compliance curve of a balloon made in accordance with the present invention and the compliance curves of alternate balloons;

Figure 8 is a chart which illustrates retraction force for a balloon made in accordance with the present invention and the retraction forces for alternate balloons; and

Figure 9 is a chart which illustrates the compliance curves for three balloons made in accordance with the present invention.

DESCRIPTION

Referring to Figure 1, a medical catheter 10 having features of the present invention includes a catheter shaft 12, a guidewire shaft 14, and an inflatable balloon 16. As provided in detail below, the material for the inflatable balloon 16 is selected from a specific, small group polyurethane materials and the balloon 16 is formed under relatively strict manufacturing parameters. As a result thereof, the balloon 16 has superior physical characteristics including a relatively high burst strength, a soft texture, good flexibility, and a relatively flat compliance curve. Preferred embodiments of the balloon 16 are semi-compliant, flexible, and expand in a predictable manner.

As illustrated in Figure 2, a portion of the medical catheter 10 and a guidewire 18 can be positioned in a body vessel 20 of a patient 22 during an angioplasty procedure. The location of entry into the patient 22 and the location of the balloon 16 illustrated in Figure 2 is merely exemplary. Further, the medical catheter 10 can be utilized for other procedures, such as deploying a stent (not shown) within the body vessel 20.

The catheter shaft 12 is used by the physician to position the inflatable balloon 16 within the body vessel 20 and transfer an inflation fluid (not shown) to the inflatable balloon 16. In the embodiment illustrated in Figure 1, the catheter shaft 12 includes a catheter shaft proximal end 24, a catheter shaft distal end 26, and an inflation lumen 28 in fluid communication with the balloon 16. A manifold 30 having an inflation/deflation port 32 and a guidewire port 34 is secured to the catheter shaft proximal end 24. The inflation/deflation port 32 is in fluid communication with the inflation lumen 28, while the guidewire port 34 is connected to the guidewire shaft 14.

The catheter shaft 12 encircles and is substantially coaxial with the guidewire shaft 14. The guidewire shaft 14 includes a guidewire shaft proximal end (not shown), a guidewire shaft distal end 36, and a guidewire lumen 38. The guidewire shaft proximal end is connected to the guidewire port 34, while the guidewire shaft distal end 36 is attached to the balloon 16. The guidewire lumen 38 is sized and shaped to receive the guidewire 18. A guidewire shaft 14 having a 0.017 inch inner diameter and a 0.023 inch outer diameter is suitable for a standard 0.14 inch guidewire 18. As illustrated in Figure 3, a pair of spaced apart, tubular, radiopaque markers 40 can be bonded to the guidewire shaft 14 to facilitate proper positioning of the inflatable balloon 16 in the body vessel 24.

In the embodiment illustrated in the Figure 3, the inflatable balloon 16 is secured to the catheter shaft distal end 26 and the guidewire shaft 14. Typically, the catheter shaft 12 and guidewire shaft 14 are made of a material which can be thermally bonded or adhered to the balloon 16 with a suitable adhesive. A suitable catheter shaft 12 and guidewire shaft 14 can be manufactured by extruding a polymer such as PEBA, PET, High Density Polyethylene ("HDPE"), Low Density Polyethylene ("LDPE"), Polyurethane, or Nylon.

With the teaching provided herein, those skilled in the art will recognize alternate ways to manufacture the medical catheter 10, the

catheter shaft 12, and/or the guidewire shaft 14, and that alternate materials can be utilized for these components.

Referring again to Figure 3, the balloon 16 includes a body section 42 which separates a distal cone section 44 from a proximal cone section 46. As illustrated in Figure 3, the balloon 16 has a balloon outer diameter 48, a balloon inner diameter 50, a balloon wall thickness 52, and a balloon length 54.

Importantly, physical characteristics of the balloon 16 provided herein are a result of the polyurethane material utilized in forming the balloon 16 and the relatively strict parameters used to manufacture the balloon 16. As a result thereof, the balloon 16 has superior physical characteristics, including a relatively high burst strength, a good tracking and lesion characteristics, good flexibility, and a relatively flat compliance curve. Preferred embodiments of the balloon 16 provided herein are semi-compliant, flexible, and expand in a predictable manner.

THE POLYURETHANE MATERIAL

The balloon 16 is formed from a polyurethane material which includes: (i) a hard segment derived from a diisocyanate and a short-chain diol and (ii) a soft segment derived from a polymeric glycol. The proportion by weight of the soft segment in the polyurethane material is between approximately thirty-five percent to seventy percent (35%-70%) The polyurethane material preferably has a hardness of between approximately 50D-65D and more preferably between approximately 55D-60D prior to forming the balloon. This hardness range results in a relatively flexible balloon which good tracking and lesion crossing characteristics.

Typically, the amount of hard segment controls the hardness of the polyurethane material. In order to achieve the 50D-65D range of hardness, approximately forty percent to sixty percent (40%-60%) of the balloon material would consist of the hard segment (the total of diisocyanate and

short-chain diol). A range of 55D-60D corresponds to approximately forty-five percent to fifty-five percent (45%-55%) of the hard segment. The exact amount depends on the diisocyanate, the short-chain diol, and the soft-segment diol molecular weight and selection.

1. Hard Segment

As provided above, the hard segment is derived from a diisocyanate and a short-chain diol.

1.1 Diisocyanates

Diisocyanates useful in introducing the urethane linkage into the polymer chain may be selected from a wide range of aliphatic, cycloaliphatic, and aromatic diisocyanates. Useable diisocyanates can contain non-interfering groups, e.g., aliphatic hydrocarbon radicals such as lower alkyl or other groups, having substantially non-reactive hydrogens. The diisocyanate often has at least six (6) carbon atoms and usually not more than about forty (40) carbon atoms. Diisocyanates having about eight to twenty (8-20) atoms in the hydrocarbon group are preferred.

Suitable diisocyanates include 2,4-toluene diisocyanate; 2,6-toluene diisocyanate; 1,4-cyclohexane diisocyanate; dicyclohexylmethane-4,4'-diisocyanate; xylene diisocyanate; hexamethylene diisocyanate; methylcyclohexyl diisocyanate; 4,4'-biphenylene diisocyanate; m- and p-phenylene diisocyanates; hexahydrotolylene diisocyanates; diphenylmethane-4,4' diisocyanate; diphenymethane-2,4'-diisocyanate; 1,5-napthalene diisocyanate; 1-methoxyphenyl-2, 4-diisocyanate; isophorone diisocyanate; and chlorophenylene diisocyanates. Mixtures of the above-identified diisocyanates can be utilized if desired. The most preferred diisocyanates are diphenylmethane-4,4'-diisocyanate and dicyclohexylmethane-4,4'-diisocyanate.

1.2 Short Chain Diols

Low molecular glycols which react with diisocyanate to form the hard segment, typically contain two to ten (2-10) carbon atoms. Suitable short chain diols include ethylene glycol; diethylene glycol; triethylene glycol; 1,2- and 1,3-propanediol; 1,4-butanediol; 2,3-butanediol; 1,4-cyclohexanediol; dipropylene glycol; neopentyl glycol; and 1,6-hexanediol; and mixtures thereof.

2. Soft-Segment, Polymeric Glycol

The soft segment is a long chain, polymeric glycol having a molecular weight of between approximately five hundred to five thousand (500-5000) and preferably between approximately one thousand to two thousand (1,000-2,000). The polymeric glycol is co-polymerized with the diisocyanate and short-chain diol. The ratios are normally such that after copolymerization occurs, the reacted diisocyanate-short-chain glycol blocks and the reacted diisocyanate-long-chain blocks are somewhat compatible and relatively homogeneous at temperatures above the melting point and are incompatible (on a molecular scale) at lower temperatures. This leads to "segmentation" into a "hard" phase (diisocyanate-low-molecular-weight glycol moiety) and a "soft" phase (diisocyanate-high-molecular-weight glycol moiety). These thermoplastic polyurethanes can be fabricated at elevated temperatures and have the properties of thermoset polymers at lower temperatures. The polymers can be oriented at intermediate temperatures to provide a strong and stable balloon.

Suitable polymeric glycols are divided into the following categories:

2.1 Polyether Diols

Cyclic ethers, such as ethylene oxide, proplyene oxide, butylene oxide, styrene oxide, and tetrahydrofuran react with active hydrogen initiators, such as water and glycols in the presence of catalysts, such as boron triflouride, to produce long chain polymeric ether diols. The ratio of cyclic ether to initiator determines the molecular weight. Illustrative polyethers are polyoxyethylene glycols; polyoxypropylene glycols; polytetramethylene glycol; and admixtures. In addition, the cyclic ethers can be co-reacted with an initiator as indicated above to give a copolymer polyether. The most preferred is the poly(tetramethylene ether) glycol.

2.2 Polyester Diols

Polyester diols are made from condensation of dibasic acids and glycols in various ratios to control the molecular weight and to give hydroxyl end groups. The same diols can be used that were outlined under the above section on "short chain diols."

The dicarboxylic acids are aliphatic, cycloaliphatic, aromatic, and/or heterocyclic and may be substituted, for example, by halogen atoms and/or unsaturated groups. Examples of carboxylic acids of this kind include succinic acid, adipic acid, suberic acid, azelaic acid, sebacic acid, maleic acid, maleic acid anhydride, phthalic acid anhydride, glutaric acid anhydride, fumaric acid and terephthalic acid. The aliphatic type is preferred to provide the desired soft segment. Examples of the glycol include ethylene glycol; 1-3, propanediol; 1,4-burtanediol; neopentyl glycol; and 1-6-hexanediol.

Examples of the diols are poly(ethylene adipate) glycol; poly(tetramethylene adipate) glycol; and poly(hexamethylene adipate) glycol.

2.3 Polylactone Diols

This is a second class of polyester diols. They are made by reacting a lactone, such as epsilon-caprolactone, with an active bifunctional hydrogen initiator, such as an aliphatic glycol (e.g., 1,4-butanediol). Hydroxycarboxylic acids, for example, beta-hydroxybutyric acid and omega-hydroxycaproic acid, also can be used. The preferred diol is polycaprolactone diol.

2.4 Other Long-Chain Diols

Polycarbonate diols can be made from phosgene and diols or by ester interchange with a dialkyl carbonate and a short chain diol as already described. The repeat unit is $HO-(CH_2)_4-[O-CO-O(CH_2)_4-]nOH$ using 1,4-butanediol. Hydroxy-terminated polybutadiene copolymers have been made by Arco Chemical Company.

3.0 Examples of the Polyurethane Material

Three (3) polyurethanes were prepared by mixing a poly(tetramethylene ether) glycol (Teracol 1000, sold by DuPont), and 1-4 butanediol, heating the mixture and degassing under vacuum. Teracol is a trademark of DuPont. A molten diphenylethene -4,4'-diisocyanate and 0.03 percent of dibutyltin dilaurate are added to the mixture. Subsequently, the mixture was stirred rapidly for thirty (30) seconds and then poured into an aluminum tray. After one (1) hour, the polyurethane was cured in an oven at approximately 100°C for one hour. After conditioning for seven (7) days at room temperature, the polyurethanes were tested for durometer D hardness. Each of the three (3) polyurethanes were then chipped, extruded into thin-wall tubing and subsequently formed into balloons. The approximate composition and test properties of the materials are provided below in Table 1:

TABLE 1			
	1	2	3
MDI, %	36.5	38.8	41.5
BDO, %	8.0	9.2	10.5
Teracol1000, %	55.5	52.0	48.0
durometer D	50	55	60

4.0 Commercially Available Polyurethane Materials

Commercially available polyurethane materials which are believed to be suitable, when formed in accordance with the present invention include Pellethane® Series 2102 and Pellethane® 2363 sold by Dow Chemical Company , located in Midland, Michigan. Pellethane® is a registered trademark of Dow Chemical Company. Somewhat similar products are sold by Bayer Corporation, located in Pittsburgh, Pennsylvania, B.F. Goodrich, located in Cleveland, Ohio, BASF Corporation, located in Mt. Olive, New Jersey, Thermedics located in Waburn, Massachusetts and Morton Chemical Inc., located in Chicago, Illinois.

MANUFACTURE OF THE BALLOON

The balloon 16 is manufactured utilizing a process which maximizes the physical characteristics of the specific polyurethane material disclosed herein. More specifically, the present invention utilizes a relatively high blow-up ratio during the balloon forming process to approach maximum alignment of the molecules in the polyurethane material in the hoop/transverse direction. As provided herein, the physical characteristics, such as the compliance of the balloon 16, can be specifically tailored based upon the blow-up ratio utilized.

Initially, the polyurethane material is extruded to form a tube 56 having a tube inner diameter 58, a tube outer diameter 60, and a tube wall thickness 62. Subsequently, the tube 56 is placed inside a mold 64 to form the balloon 16. Figure 4 illustrates a mold 64 utilized for radially expanding and axially stretching the piece of tube 56. A first clamp 66 and a second clamp 68 can be used to grasp the tube 56 on each side of the mold 64. For axially stretching of the tube 56, the first clamp 66 and/or the second clamp 68 can be moved apart by a stepper motor (not shown). The tube 56 can be radially expanded by releasing pressurized fluid from a container 70 into the tube 56. The pressurized fluid can be nitrogen gas, air, or some other suitable fluid which is under pressure.

The design of the mold 64 is varied according to the desired design and size of the balloon 16. As provided herein, the mold 64 has a mold inner diameter 72 which is approximately between 5-9 and more preferably between 6-8 times larger than the tube inner diameter 58 to obtain the BUR of between 5-9 and more preferably 6-8.

To facilitate radial expansion and axial stretching, the mold 64 is heated. This can be accomplished with a heating element (not shown) in the blow mold 64 or by directing a hot fluid through the mold 64. The axial stretching and the radial expansion typically occur when the material is at or above the glass transition temperature.

3.0 mm BALLOON FORMING PROCESS

The following procedure outlines the formation of what is designed as a three millimeter (3 mm) by twenty millimeter (20 mm) balloon 12 from Pellethane® Series 2102 sold by Dow Chemical Company. It should be understood that the following procedure is merely provided as an example of a manufacturing process.

Initially, a tube 56 is extruded from Pellethane® 2102-55D. The tube 56 has a tube inner diameter 58 of between approximately 0.5mm and a tube

outer diameter of between approximately 1mm and 1.5mm. The tube 56 is then placed in a mold 64 having a mold inner diameter of approximately three millimeters (3.0 mm). Next, the first and second clamps 68 are locked on the tube 56. Subsequently, the pressurized fluid is supplied to the tube 56 and the pressure is raised to approximately 250 psi, i.e., the pre-set "Pre-inflate" pressure. Further, the blow mold 64 is heated up to approximately 210°F, i.e., the "No. 1 Temperature." At the same time, the tube 56 is under a pre-set tension of 5.0 psi, which is called "Pre-stretch" to molecularly orient the material. The balloon 16 is formed as soon as the mold temperature reaches the "No. 1 Temperature." The balloon 16 is retained in the blow mold 64 at a temperature of 210°F, under 250 psi pressure and 5 psi tension for 1 second (Heat Soak Time 1). After the pre-set Heat Soak Time #1 (1 sec.) the formed balloon 16 is immediately stretched by a higher tension of 10 psi (called Final stretch) and under a higher pressure of 300 psi (called Final inflate). The mold temperature is immediately heated up to 215°F (called Temperature No. 2) for 15 seconds (called Heat Soak Time 2). After it reaches the end of the Heat Soak Time 2, the mold 64 is cooled down to 90°F (a preset cooling temperature). The cycle ends and the formed balloon 16 is removed.

Table 2 below outlines possible ranges of the process parameters.

TABLE 2 - RANGES OF PROCESS PARAMETERS

Temp 1	Temp 2	Heat Soak Time 1	Heat Soak Time 2	Pre-Stretch	Final Stretch
185°-265°F	205°-305°F	1-10 sec.	5-360 sec.	4-19 psi	8-25 psi
210°-225°F	215°-265°F	1-3	15-120	5-12	10-18 Preferred

Pre-Inflate	Final-Inflate
200-300 psi	300-450 psi
250-280 psi	350-400 psi Preferred

Again, it should be noted that the above steps are merely exemplary. The temperatures, pressures, and amount of axial stretch can be varied

according to the exact balloon material utilized and the desired physical characteristics of the dilation catheter 10.

Figure 5 illustrates the compliance curve for three alternate, three millimeter (3.0 mm) balloons made of Pellethane® 2102-55D. Each of the three millimeter (3.0 mm) balloons were formed with a different BUR. For example, the curve designated as reference number 74 illustrates the compliance curve for a balloon 16 formed with a blow-up ratio of 4.8. Somewhat similarly, curve designated as reference number 76 illustrates the compliance curve for a balloon formed with a blow-up ratio of 5.5, while curve designated as reference number 78 illustrates the compliance curve for a balloon formed with a blow-up ratio of 6.4.

Figure 6 illustrates the compliance curve for three alternate, three millimeter (3.0 mm) balloons made of Pellethane® 2102-65D. Each of the three millimeter (3.0 mm) balloons were formed with a different BUR. For example, the curve designated as reference number 80 illustrates the compliance curve for a balloon formed with a blow-up ratio of 4.8, curve designated as reference number 82 illustrates the compliance curve for a balloon formed with a blow-up ratio of 5.5, while the curve designated as reference number 84 illustrates the compliance curve for a balloon formed with a blow-up ratio of 6.4.

From Figures 5 and 6, it is evident that the compliance of a particular balloon 16 made in accordance with the present invention decreases as the blow-up ratio increases. Stated another way, as the blow-up ratio increases, the compliance of the balloon decreases. As a result thereof, with the material utilized herein, the performance of the balloon 16 can be specifically tailored by altering the blow-up ratio. Thus, by altering the blow-up ratio, a compliant, semi-compliant or non-compliant balloon can be made from the same material.

Additionally, it was determined that the unique material utilized herein could be tailored to be a compliant, semi-compliant or non-compliant simply by modifying the heat set rate used during manufacturing. Typically, a

balloon 16 is subjected to a heat set to bond the balloon 16 to the catheter shaft 14 and to provide memory for the balloon 16 at a wrapped state. Table 3 below outlines the compliance measurements for three separate balloons made of Pellethane® 2102-55D. The three balloons were formed with the same blow-up ratios. However, the balloons were subjected to three alternate heat set rates.

TABLE 3

psi	Heat Set 55c / 10 min	Heat Set 65c / 10 min.	Heat Set 75c / 5 min
50	2.08	2.36	2.32
75	2.26	2.61	2.63
100	2.48	2.90	2.94
125	2.58	3.12	3.11
150	3.10	3.17	3.23
175	3.21	3.45	3.36
200	3.35	3.48	3.44
225	3.51	3.53	3.50
250	3.67	3.59	3.57
275	3.70	3.62	3.62

Figure 7 illustrates (i) a compliance curve, designated 86, for a balloon made in accordance with the present invention of Pellethane® 2102-55D; (ii) a compliance curve, designated 88, for a balloon made by Scimed from Pebax and sold under the trademark "VIVA"; and (iii) a compliance curve, designated 90, for a balloon made by Cordis from nylon 12 and sold under the trademark "DURALYN". From Figure 7, it is evident that the balloon 16

made in accordance with the present invention, has a much smaller initial diameter. This facilitates movement of the balloon 16 through the vessel.

Further, the balloon 16 made in accordance with the present invention is bi-compliant. Stated another way, the balloon 16 has two relatively distinct sections to the compliance curve 86 and the compliance curve 86 is non-linear. More specifically, a first section 92 of compliance curve 86 extends from approximately 3.5 atms to approximately 6 atms while a second section 94 of compliance curve 86 extends from approximately 6 atms to approximately 18 atmospheres. In the first section 92, the balloon has a compliance greater than fifteen percent and preferably between approximately twenty to thirty-five percent. In contrast, in the second section 94, the balloon has a compliance of between approximately five to fifteen percent. This feature allows the balloon 16 to initially be relatively small to facilitate movement in the vessel. Subsequently, with the balloon 16 positioned in the vessel, the balloon 16 quickly expands to its nominal diameter. Subsequently, the balloon 16 is semi compliant over the desired inflation range.

Figure 8 is a bar graph which illustrates the retraction force required to pull a number of different balloons through a guiding catheter (not shown). For these tests, the guiding catheter was mounted to a peg board which was submerged in a water bath. The guiding catheter had a 1.64 millimeter diameter lumen and the distal end of the guiding catheter included a one inch radius bend to simulate a tortous vessel. Subsequently, a force gage (not shown) was used to measure the force required retract the balloon through the guiding catheter.

In Figure 8, the refraction force for (i) a balloon manufactured in accordance with the present invention (designated 96A, 96B, 96C); (ii) a balloon manufactured by Simed from Pebax and sold under the trademark "VIVA" (designated 98A, 98B, 98C); (iii) a balloon manufactured by Simed from Pebax and sold under the trademark "MAXXUM" (designated 100A, 100B, 100C); (iv) a balloon manufactured by Bard from a polyurethane

composite and sold under the trademark "CALYPSO" (designated 102A, 102B, 102C); and (v) a balloon manufactured by Advanced Cardio Systems from nylon 12 and sold under the trademark "ROCKET" (designated 104A, 104B, 104C) are illustrated. For each balloon, (i) the designation "A" represents the retraction force required without inflating the balloon; (ii) the designation "B" represents the retraction force required to retract a deflated balloon after inflation to a nominal diameter; and (iii) the designation "C" represents the retraction force required to retract a deflated balloon after inflation to the rated burst pressure.

As illustrated in Figure 8, the balloon 16 made in accordance with the present invention easily outperforms all of the other balloons in the retraction force necessary to retract the balloon 16.

Figure 9 illustrates (i) a compliance curve, designated 106, for a balloon made in accordance with the present invention of Pellethane® 2102-55D having a blow up ratio of 5.5, a double wall thickness of 2.05 mil and a rated burst pressure of 351 psi; (ii) a compliance curve, designated 108, for a balloon made in accordance with the present invention of Pellethane® 2102-55D with a blow up ratio of 6.4, a double wall thickness of 2.25 mils and a rated burst pressure of 321 psi; and (iii) a compliance curve, designated 110, for a balloon made in accordance with the present invention of Pellethane® 2102-55D, with a blow up ratio of 6.04, a double wall thickness of 3.3 mils and a rated burst pressure of 323 psi.

From Figure 9, it is evident that utilizing the same material, namely, Pellethane® 2102-55D, a compliant balloon, a semi-compliant balloon or a non-compliant balloon can be made by altering the blow up ratio and/or the double wall thickness. More specifically, the balloon having curve designated 106 is considered a compliant balloon and has a compliance of greater than approximately 16 percent between nominal diameter and rated burst pressure. The balloon having curve designated 108, is considered a semi-compliant balloon and has a compliance of between approximately ten to fifteen percent between nominal diameter and rated burst pressure. The

balloon having curve designated 110, is considered a non-compliant balloon and has a compliance of less than approximately 10 percent and preferably between eight to nine percent between nominal diameter and rated burst pressure.

Table 4 below outlines the specific measurements for the three balloons made of Pellethane® 2102-55D which are featured in Figure 9.

TABLE 4

PSI	ATMs	diameter (mm) for balloon with curve designated 106	diameter (mm) for balloon with curve designated 108	diameter (mm) for balloon with curve designated 110
50	3.401361	2.93	2.82	2.40
75	5.102041	3.08	2.95	2.79
100	6.802721	3.29	3.04	2.97
125	8.503401	3.33	3.13	3.08
150	10.20408	3.43	3.20	3.16
175	11.90476	3.52	3.25	3.21
200	13.60544	3.58	3.31	3.26
225	15.30612	3.62	3.36	3.30
250	17.0068	3.66	3.41	3.34
275	18.70748	3.69	3.48	3.37
300	20.40816	3.75	3.52	3.40

From Figures 9 and Table 4, it is evident that the compliance of a particular balloon 16 made in accordance with the present invention can be altered by altering the blow-up ratio and/or the wall thickness. As a result

thereof, with the material utilized herein, the performance of the balloon 16 can be specifically tailored by altering the blow-up ratio. Thus, by altering the blow-up ratio and/or the wall thickness, a compliant, semi-compliant or non-compliant balloon can be made from the same material.

While the particular medical catheter 10 as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages herein before stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended to the details of construction or design herein shown other than as described in the appended claims.

COMPONENT LIST

10 medical catheter
12 catheter shaft
14 guidewire shaft
16 inflatable balloon
18 guidewire
20 body vessel
22 patient
24 catheter shaft proximal end
26 catheter shaft distal end
28 inflation lumen
30 manifold
32 inflation deflation port
34 guidwire port
36 guidewire shaft distal end
38 guidewire lumen
40 markers
42 body section
44 distal cone section
46 proximal cone section
48 balloon outer diameter
50 balloon inner diameter
52 balloon wall thickness
54 balloon length
56 tube
58 tube inner diameter
60 tube outer diameter
62 tube wall thickness
64 mold
66 first clamp
68 second clamp
70 container
72 mold inner diameter
74 curve 4.8 BUR
76 curve 5.5 BUR
78 curve 6.4 BUR
80 curve 4.8 BUR
82 curve 5.5 BUR
84 curve 6.4 BUR
86 curve for our Balloon
88 curve for Pebax Balloon
90 curve for DURALYN Balloon
92 first section of curve
94 second section of curve
96A-C our Balloon
98A-C VIVA Balloon
100A-C MAXXUM Balloon
102A-C CALYPSO Balloon
104A-C ROCKET Balloon
106 our Balloon 5.5 BUR
108 our Balloon 6.4 BUR
110 our Balloon 6.4 BUR (thicker wall)

What is claimed is:

1. A medical catheter adapted for use within a body vessel, the medical catheter comprising:

an inflatable balloon formed from a polyurethane material, the polyurethane material including (i) a hard segment derived from a diisocyanate and a short-chain diol and (ii) a soft segment derived from a polymeric glycol having an average molecular weight of between approximately 500-5000, wherein the proportion by weight of the soft segment in the polyurethane material is between approximately thirty-five percent and seventy percent.

2. The medical catheter of claim 1 wherein the diisocyanate is selected from a group consisting of 1,4-cyclohexane diisocyanate, dicyclohexylmethane-4,4'-diisocyanate, xylene diisocyanate, hexamethylene diisocyanate, methylcyclohexyl diisocyanate, 4,4'-biphenylene diisocyanate, m- and p-phenylene diisocyanates, diphenylmethane-4,4'-diisocyanate, diphenymethane-2,4'-diisocyanate, 1,5-napthalene diisocyanate, and isophorone diisocyanate.

3. The medical catheter of claim 1 wherein the diisocyanate is selected from a group consisting of diphenylmethane-4,4'-diisocyanate and dicyclohexylmethane-4,4'-diisocyanate.

4. The medical catheter of claim 1 wherein the short-chain diol is selected from a group consisting of ethylene glycol, 1,2- and 1,3-propanediol, 1,4-butanediol, 1,4-cyclohexanediol, neopentyl glycol, and 1,6-hexanediol.

5. The medical catheter of claim 1 wherein the polymeric glycol is selected from a group which consists of a polyether diol and a polyester diol.

6. The medical catheter of claim 1 wherein the polymeric glycol is selected from a group which consists of polyoxyethylene glycols, polyoxypropylene glycols, and poly(tetramethylene ether) glycol.

7. The medical catheter of claim 1 wherein the polymeric glycol includes a poly(tetramethylene ether) glycol.

8. The medical catheter of claim 1 wherein the polymeric glycol is derived from a dibasic acid and a glycol, the dibasic acid being selected from a group which includes succinic acid, maleic acid, glutaric acid, adipic acid, and sebacic acid, and the glycol being selected from a group which consists of ethylene glycol, 1,3-propanediol, 1,4-butanediol, neopentyl glycol, and 1,6-hexanediol.

9. The medical catheter of claim 1 wherein the polymeric glycol includes polycaprolactone diol.

10. The medical catheter of claim 1 wherein the polymeric glycol has an average molecular weight of between approximately 1000-2000.

11. The medical catheter of claim 1 wherein the polyurethane material has a hardness of between approximately 50D-65D prior to forming the balloon.

12. The medical catheter of claim 1 wherein the polyurethane material has a hardness of between approximately 55D-60D prior to forming the balloon.

13. The medical catheter of claim 1 wherein the proportion by weight of the soft segment in the polyurethane material is between approximately forty percent to sixty percent.

14. The medical catheter of claim 1 wherein the proportion by weight of the soft segment in the polyurethane material is between approximately forty-five percent to fifty-five percent.

15. The medical catheter of claim 1 wherein the polyurethane material has a hardness of less than approximately 65D prior to forming the balloon and the balloon has a burst strength of at least approximately 250 psi, and a compliance of less than approximately fifteen percent between nominal pressure and rated burst pressure.

16. The medical catheter of claim 15 wherein the balloon has a compliance which is greater than approximately fifteen percent between three atms pressure and nominal pressure.

17. A medical catheter adapted for use within a body vessel, the medical catheter comprising:

an inflatable balloon formed from a polyurethane material, the polyurethane material having a hardness of between approximately 50D- 65D prior to forming the balloon, the polyurethane material including (i) a hard segment derived from a diisocyanate and a short-chain diol, the diisocynate being selected from a group consisting of diphenylmethane-4,4'-diisocyanate and dicyclohexylmethane-4,4'-diisocyanate, the short-chain diol being selected from a group consisting of ethylene glycol, 1,2- and 1,3-propanediol, 1,4-butanediol, 1,4-cyclohexanediol, neopentyl glycol and 1,6-hexanediol, and (ii) a soft segment derived from a polymeric glycol having an average molecular weight of between approximately 1000-2000, wherein the proportion by weight of the soft segment in the polyurethane material is between approximately forty percent and sixty percent

18. The medical catheter of claim 17 wherein the polymeric glycol is selected from a group which consists of polyoxyethylene glycols, polyoxypropylene glycols, and poly(tetramethylene ether) glycol.

19. The medical catheter of claim 17 wherein the polymeric glycol includes a poly(tetramethylene ether) glycol.

20. The medical catheter of claim 17 wherein the polymeric glycol is derived from a dibasic acid and a glycol, the dibasic acid being selected from a group which includes succinic acid, maleic acid, glutaric acid, adipic acid, and sebacic acid and the glycol being selected from a group which consists of ethylene glycol, 1,3-propanediol, 1,4-butanediol, neopentyl glycol, and 1,6-hexanediol.

21. The medical catheter of claim 17 wherein the polymeric glycol includes polycaprolactone diol.

22. The medical catheter of claim 17 wherein the polyurethane material has a hardness of between approximately 55D-60D prior to forming the balloon.

23. The medical catheter of claim 17 wherein the balloon has a burst strength of at least approximately 250 psi, and a compliance of less than approximately fifteen percent between nominal pressure and rated burst pressure.

24. The medical catheter of claim 23 wherein the balloon has a compliance which is greater than approximately fifteen percent between three atms pressure and nominal pressure.

25. A medical catheter adapted for use within a body vessel, the medical catheter comprising:

an inflatable balloon formed from a polyurethane material having a hardness of between approximately 50D-65D prior to forming the balloon, wherein the inflatable balloon having a burst pressure of at least approximately 250 psi, and a compliance of less than approximately fifteen percent between nominal pressure and rated burst pressure.

26. The medical catheter of claim 25 wherein the polyurethane material includes (i) a hard segment derived from a diisocyanate and a short-chain diol, the diisocynate being selected from a group consisting of diphenylmethane-4,4'-diisocyanate and dicyclohexylmethane-4,4'-diisocyanate, the short-chain diol being selected from a group consisting of ethylene glycol, 1,2- and 1,3-propanediol, 1,4-butanediol, 1,4-cyclohexanediol, neopentyl glycol and 1,6-hexanediol, and (ii) a soft segment derived from a polymeric glycol having an average molecular weight of between approximately 1000-2000, wherein the proportion by weight of the soft segment in the polyurethane material is between approximately forty percent and sixty percent.

27. The medical catheter of claim 25 wherein the balloon has a compliance which is greater than approximately fifteen percent between three atms pressure and nominal pressure.

28. A method of manufacturing a medical catheter, the method including the steps of:

providing a tube made of a polyurethane material, the polyurethane material including (i) a hard segment derived from a diisocyanate and a short-chain diol and (ii) a soft segment derived from a polymeric glycol having an average molecular weight of between approximately 500-5000, wherein the proportion by weight of the soft segment in the polyurethane material is between approximately thirty-five percent and seventy percent; and

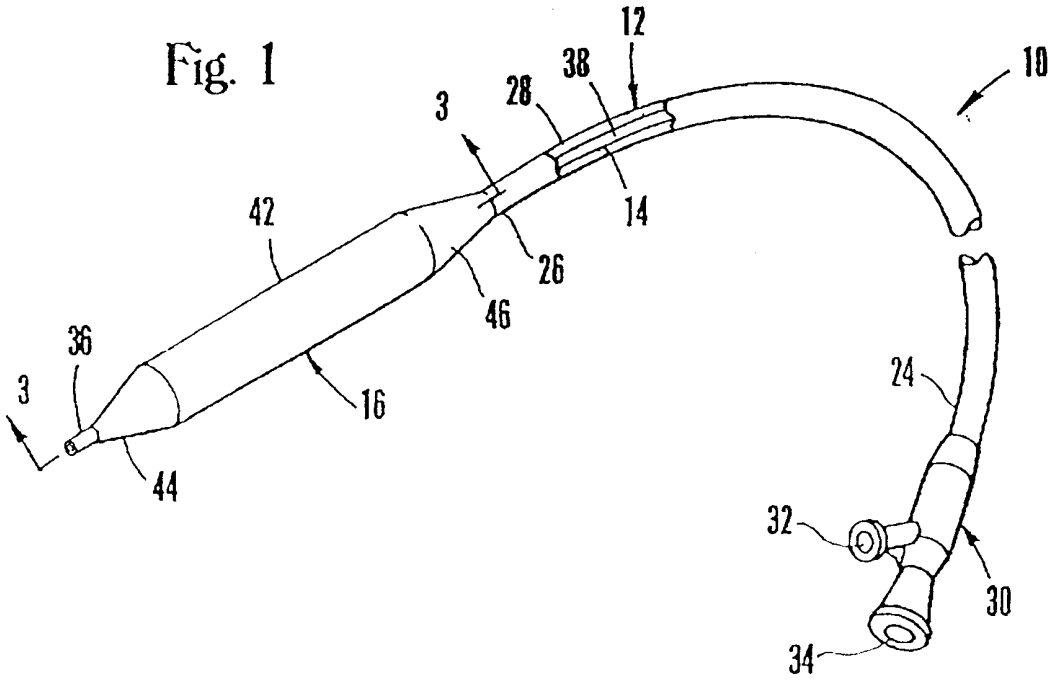
forming the tube into a balloon.

29. The method of claim 28 wherein the step of providing a tube includes the step of providing a polyurethane material having a hardness of between approximately 55D-60D.

30. The method of claim 28 wherein the step of forming the tube includes the step of blowing the tube in a mold so that the balloon has a blow-up ratio of between approximately six to eight.

31. The method of claim 28 wherein the step of forming the tube includes the step of blowing the tube in a mold; wherein a blow-up ratio of the balloon is adjusted to achieve a desired compliance for the balloon.

Fig. 1



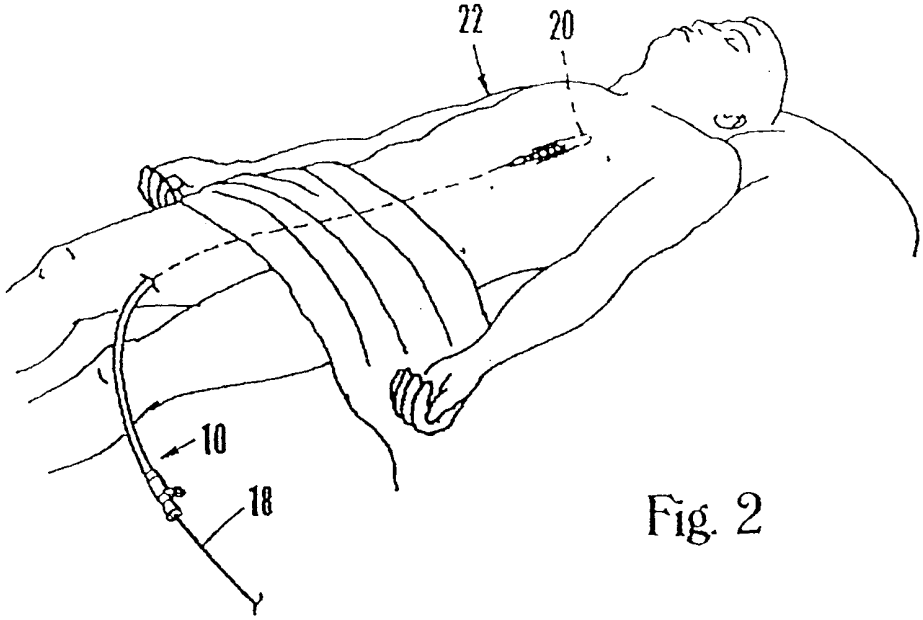


Fig. 2

Fig. 3

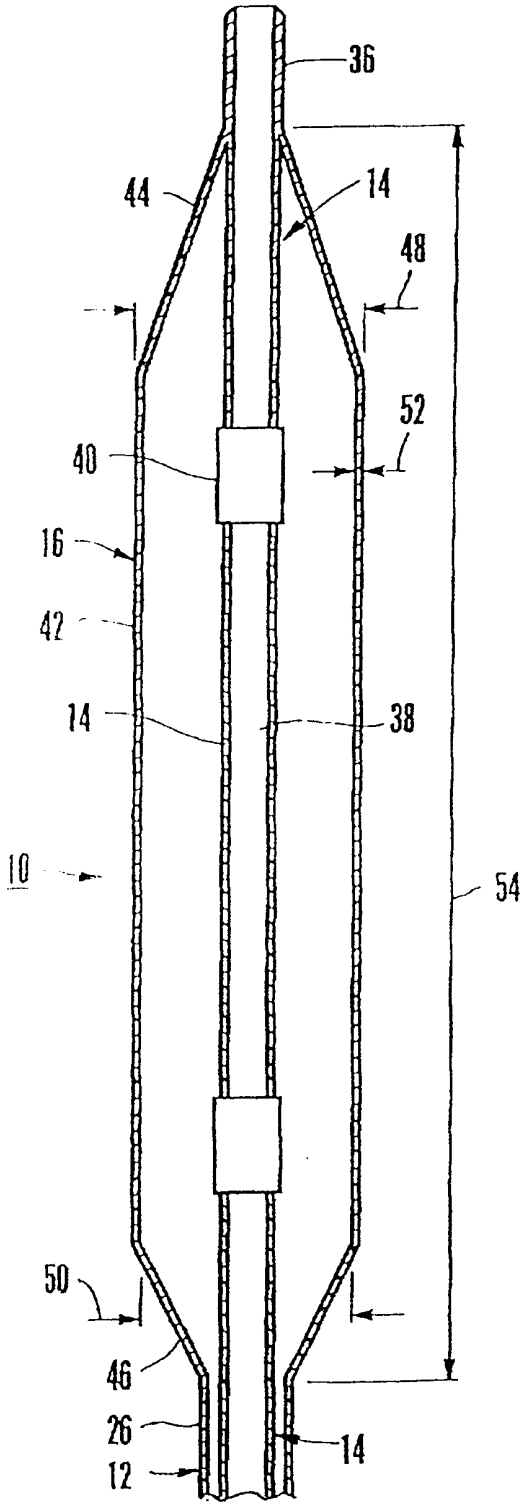

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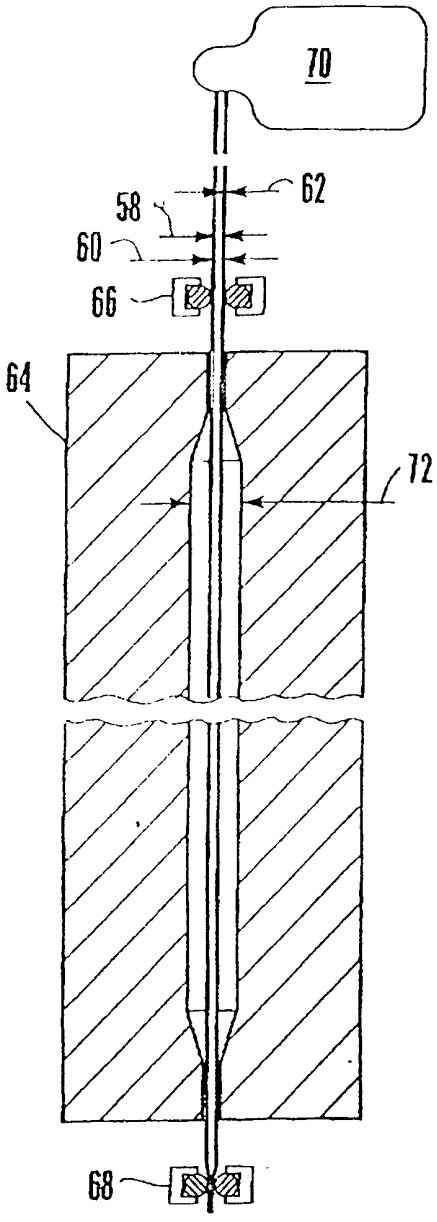
Fig. 4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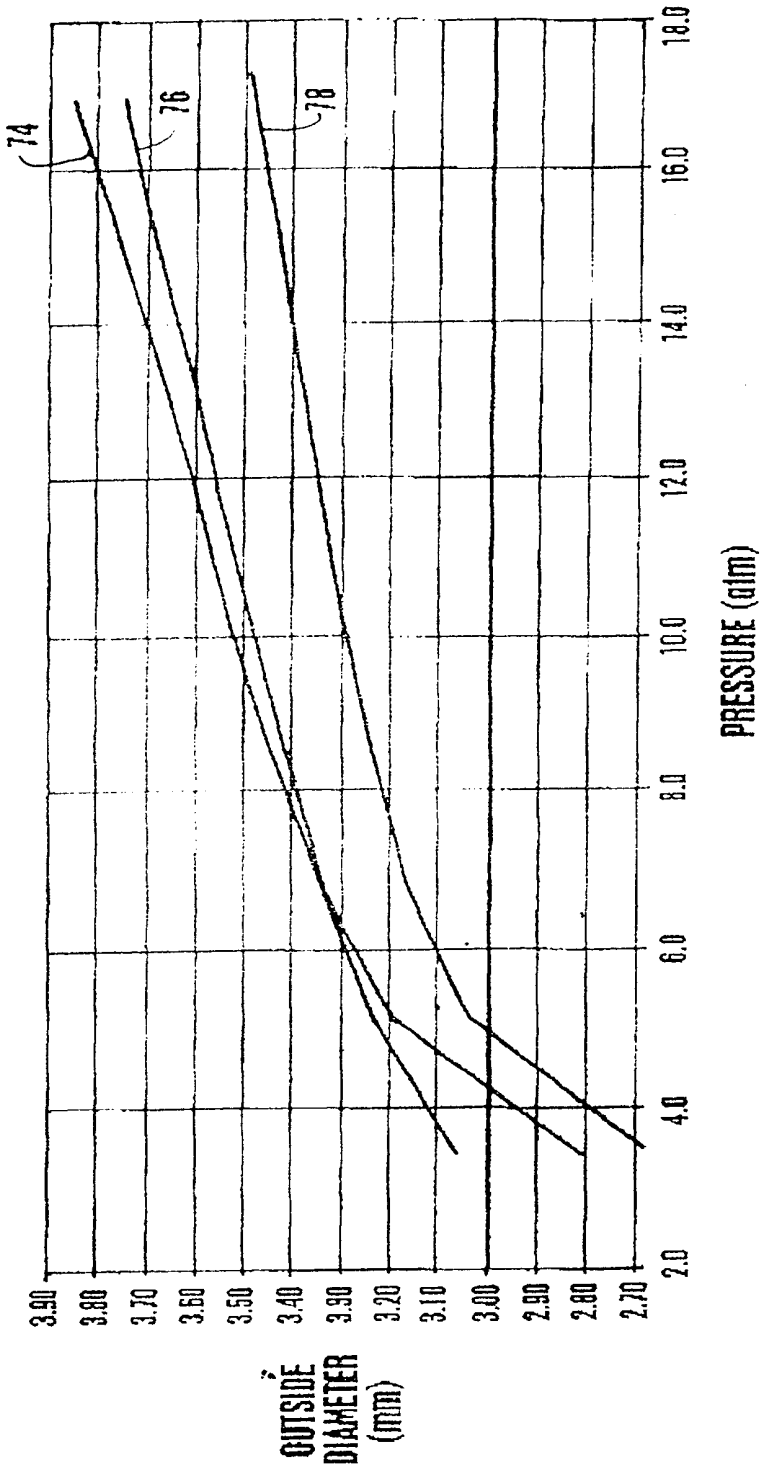
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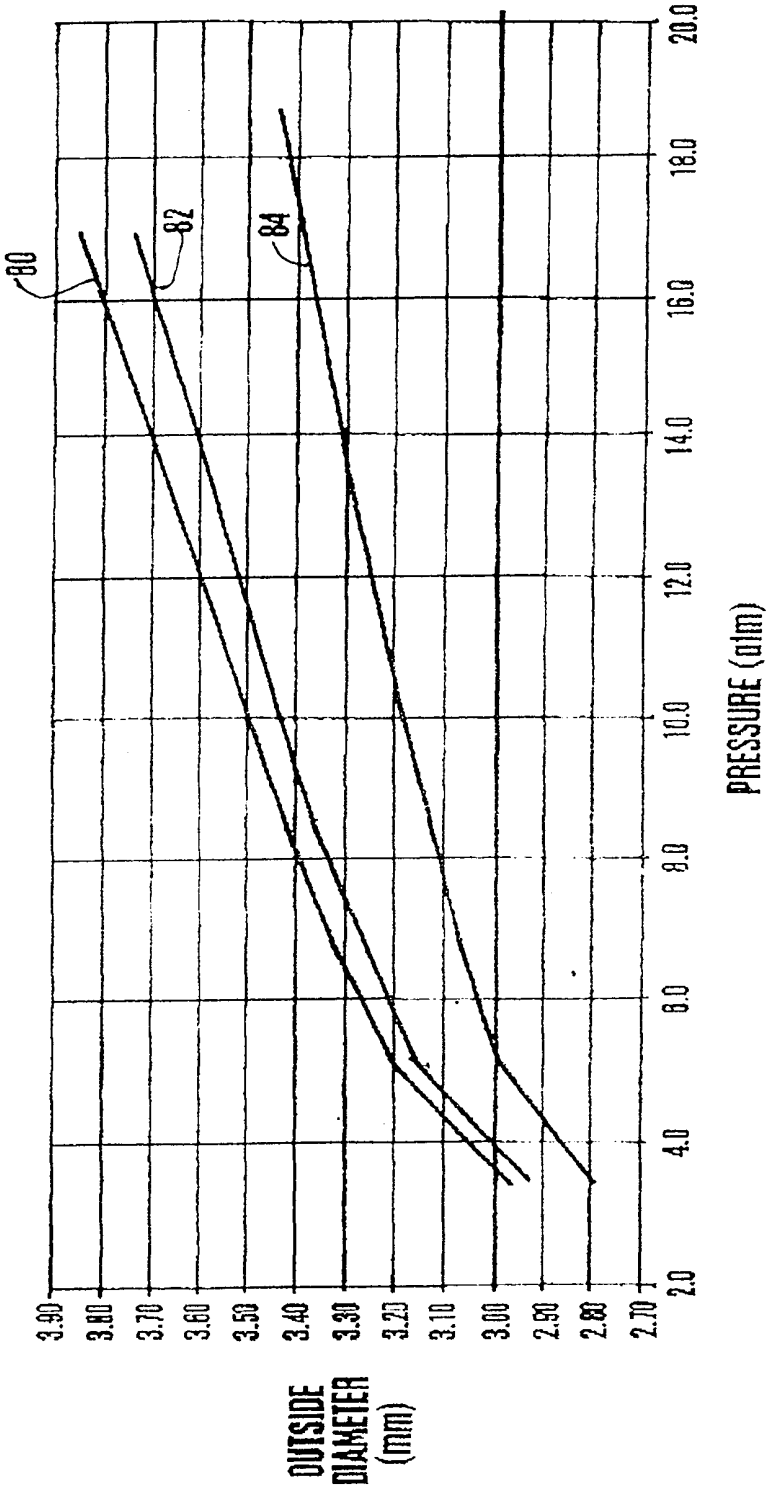
PRESSURE (atm)

Fig. 5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2.70
OUTSIDE DIAMETER (mm)
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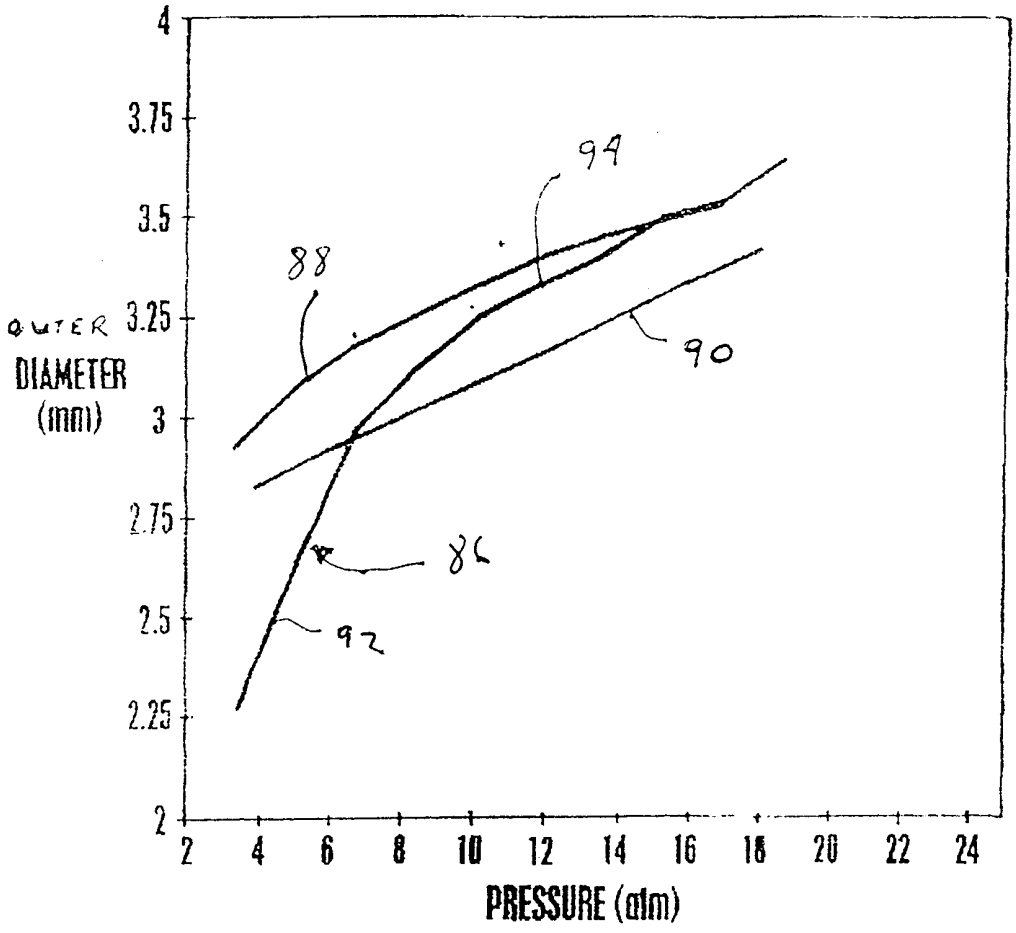
PRESSURE (atm)

Fig. 6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20
22
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PRESSURE (atm)
94
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90
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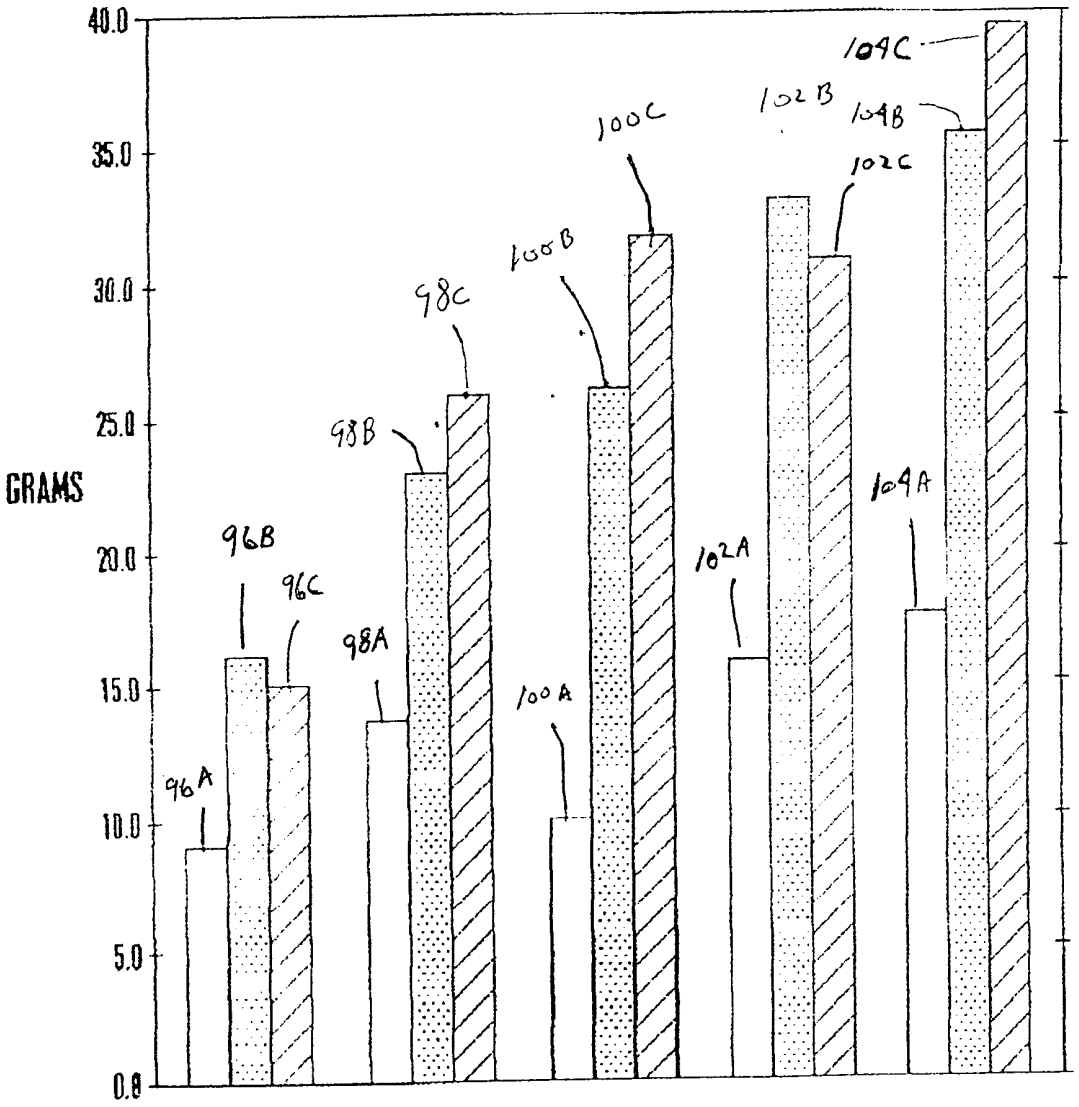
92

Fig. 7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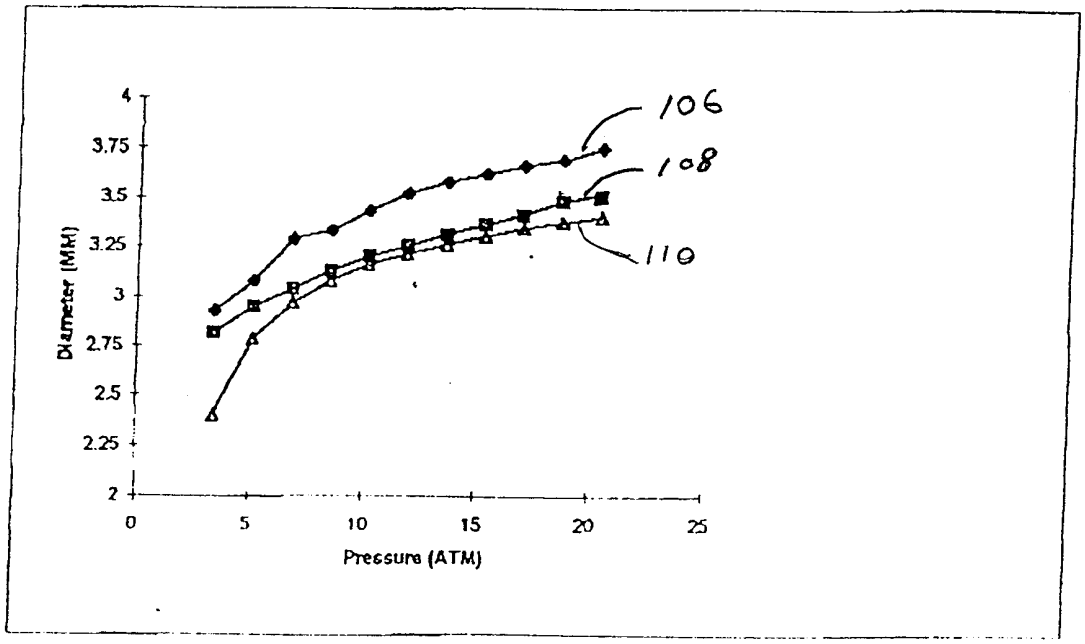
104A
104B
104C

Fig. 8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2.5
2.25
2
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5
10
15
20
25
Pressure (ATM)

Fig. 9

INTERNATIONAL SEARCH REPORT

Inte .ional Application No
PCT/US 00/05437

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L29/06

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 7 A61L 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)
WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 404 517 A (BECTON DICKINSON CO) 27 December 1990 (1990-12-27) example 1 table 1 claims 1-7,10	1-7,10, 13,14, 17-19,28
Y	US 5 439 443 A (MIYATA SHIN ICHI ET AL) 8 August 1995 (1995-08-08) column 3, line 45 - line 66 column 11, line 3 - line 8 claim 1	1-7,10, 13,14, 17-19,28

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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

"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
16 June 2000	27/06/2000

Name and mailing address of the ISA	Authorized officer
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	Thornton, S

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/05437

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 98 11860 A (DUJARDIN RALF ;BAYER AG (DE); HOBLER HARTWIN (DE); PUDLEINER HEINZ) 26 March 1998 (1998-03-26) page 3, line 3 -page 5, line 22 claims	1-14, 17-21,28

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/05437

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