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(54) Title: CATHETER BALLOONS

(57) Abstract: The invention relates to a balloon for medical devices, in particular for catheters used in angioplasty, comprising a polyamide copolymer material characterized in that said polyamide copolymer material is represented by the general formula (I), HO- (PF-OOC-PA-COO-PF-COO-PA)$_n$-COOH, in which PA is a polyamide segment and PF is a diol segment comprising dimer diols and/or corresponding OH- terminating diol polyesters and n is a number between 5 and 20.

DESCRIPTION

"CATHETER BALLOONS"

The present invention relates to a balloon for medical devices, in particular for a balloon positioned at the distal end of a catheter for use in angioplasty.

The use of catheters in angioplasty is widely known. A catheter equipped at its distal end with a balloon is moved forward, following a guide wire, until the opening of the narrowed artery is reached. Once the balloon is positioned at the narrowing of the artery, it is repeatedly inflated and deflated. Inflating the balloon and subsequently deflating it inside the artery reduces the amount of narrowing of the arterial duct and restores an adequate blood flow in the cardiac area affected by the stenosis.

The chemical/physical and mechanical characteristics of the plastics material of which the balloon is constituted determine its compliance, that is the adaptability of the balloon to the artery system, and its resistance to stretching, fundamental characteristics for optimum operation of the balloon. The requirements of compliance and strength and the dimensions of the balloon may vary depending on the type of use and the size of the vessel into which the catheter is inserted. The advantages offered by the

various polymers are matched to the specific mechanical applications of the balloons.

The problem addressed by the invention is that of making available a catheter balloon having improved compliance characteristics compared with state of the art balloons.

The subject of the invention is therefore the use of a constituent material for catheter balloons for use in angioplasty, and a balloon manufactured with it, as outlined in the appended claims.

Other characteristics and advantages of the balloon which is the subject of the invention will become clearer from the following detailed description of the invention and from figure 1 which follows it and which shows the graph indicating the tensile strength of balloons prepared from polymer material according to the invention.

Balloons for use in medical devices according to the invention are formed from block copolymers with polyester-amide blocks. Said polyester-amide polymers are commonly identified by the acronym PEA.

In particular, the polymer material suitable for obtaining a balloon as in the present invention is constituted by monomers forming blocks of polyamide which has been modified with dimer diols and/or with

corresponding OH-terminating polyesters containing dimer diols.

Principally, the most common conventional lactams, the amino-carboxylic acids and diamines, may be used to form the polyamide segment. However, the polyamide segment is preferably selected from PA 6, PA 6/6, PA 6/9, PA 6/10, PA 6/12, PA 6/36, PA 11, PA 12, PA 12/12. Moreover, it is preferable to use copolyamides or multipolyamides obtained from C_2-C_{36} dicarboxylic acids and C_2-C_{12} diamines and also from lactam 6, lactam 12, isophthalic, terephthalic and naphthalene dicarboxylic acid.

More preferably, the polyamide segments are obtained from monomers of C_6-C_{12} lactams or from monomers of C_6-C_{12} amino-carboxylic acids. The polyamide component may also be obtained from polycondensation of the corresponding salts of the diamines and of the carboxylic acids described above.

The dimer diols used to obtain the polyester-amide polymer are aliphatic dimer diols having a molecular weight of between 400 and 2000, preferably between 400 and 1000. These dimer diols are obtained by conventional industrial methods, including for example the reduction of both the carboxylic groups of a hydrated dimer fatty acid into alcohol groups or by means of the dimerization

of unsaturated alcohols. The diols obtained with these technologies always have a certain variable quantity of trimer triols and monofunctional alcohols as by-products. The diol components preferably used in the present invention are C_{36} and/or C_{44} dimer diols with a diol dimer content of at least 90%, a monodiol content of less than 1% and a triol content of less than 5%, and have a hydroxide number of between 195 and 225 mg KOH/g. Still more preferable are dimer diols with a dimer diol content of more than 94% and a monofunctional alcohol and trimer triol content of less than 0.5%.

The OH-terminating diol polyesters constituting the polyamide polymer are obtained from condensation of the above dimer diols with aliphatic and/or aromatic C_4-C_{44} dicarboxylic acids. Preferably the hydrated C_{36} dimer fatty acid is used. The preferred diol polyesters have a hydroxide number of between 28 and 90 mg KOH/g, preferably between 50 and 80 mg KOH/g.

The polyamide-polyester polymer used to form the balloons according to the present invention may be prepared using a method with one step or a method with two steps. In the first case, the monomers forming the polyamide blocks are placed in the same reaction reactor with the diol components described above and are condensed, firstly at normal pressure and then at

reduced pressure, to give the resulting high molecular weight polyester-amide polymer. The method of synthesizing the polyester-amide polymer comprises two steps: in a first step, the polyamide segment is formed from the polyamide monomers described above and in a second step the polyamide segment thus obtained is combined with the diol components in esterification reaction conditions normally known by a person skilled in the art.

The general chemical formula of the polyester-amide polymers thus obtained may be represented as follows (formula (I)):

HO- $(PF\text{-}OOC\text{-}PA\text{-}COO\text{-}PF\text{-}COO\text{-}PA)_n$-COOH (I)

in which PA represents the polyamide block while PF represents the diol block containing dimer diols and/or OH-terminating diol polyesters and n is a number between 5 and 20.

The diol component content within the polyester-amide copolymer is 5-50% by weight. Preferably, the diol component concentration is kept within the interval 10 to 30% by weight, still more preferably between 10 and 20% by weight of the total formulation.

The polymers just described above used in the invention to obtain balloons for medical devices are sold, for example, under the brand name Grilamid® by the

company Ems-Chemie AG, Switzerland. Particularly suitable examples of commercially available polymers are Grilamid® FE7303 and Grilamid® FE7372. In particular, the polymer Grilamid® FE7303 is formed from polyamide segments deriving from the lauryl lactam with a molecular weight equal to 197 gr/mol and from polyester segments deriving from dimer diol components commercially available under the brand name Pripol® 2033 and Priplast® 3197 respectively with molecular weights equal to 550 gr/mol and 1980 gr/mol, sold by the company Unichema North America, Chicago, Ill., USA. The lauryl lactam component is present in a ratio by weight of 80.2% of the total weight of the final formulation of the copolymer, while the ratios by weight of the diol segments in the final formulation of the copolymer are respectively 12.0% of Pripol® 2033 and 3.7% of Priplast® 3197. In particular, Pripol® 2033 is a diol dimer deriving from a dimer C_{36} fatty alcohol with a molecular weight of 550, a diol component of more than 94.5% and a hydroxide value equal to 200-215 mg KOH/g.

Priplast® 3197 is a diol aliphatic polyester constituted by a C_{36} dimer acid component obtained from dimerization of an unsaturated C_{18} fatty acid and a diol component obtained from hydrogenization of a C_{36} dimeric acid. This specific diol polyester has a

molecular weight of 200 and a hydroxide value of between 52 and 60 mg KOH/g.

The polyamide polymer of the general formula (I) is characterized by high flexibility and viscosity, high tensile strength and good resistance to hydrolysis. In particular, the PF blocks deriving from the diol components are responsible for the flexibility and softness of the copolymer, while the PA polyamide blocks give the copolymer hardness, rigidity and crystallinity.

In particular, considering the properties of the copolymer material described above, the insight underlying the present invention is that of utilising these characteristics since they are highly advantageous in the particular application of said polyester-amide copolymers in the use of medical devices, and still more in the particular use of balloons used in angioplasty.

Table 1 below shows the data obtained from a flexibility test carried out on extruded tubes, from which the balloons are subsequently obtained, of polyester-amide material according to the invention. This test confirms the characteristic of high flexibility of the material described above. In particular, the bounce flexibility of tubes for balloons of Grilamid® FE7303 was measured. The test was carried out according to the particulars given by the

International Standards Organisation and described in standard ISO 14630: 1997. A tube for a balloon with an outside diameter of 0.9 mm is placed in position by securing it to a support fixture, so as to have a useful length of 0.15 mm. The point of a probe, connected to a force gauge, is placed just touching the surface of said tube-balloon. The probe is moved downwards in contact with the tube and the force necessary to obtain a certain downward movement of the probe is measured. The rate of downward movement of the probe is 20 mm/min. Table 1 below gives the load values (in Newtons) obtained at predefined values for downward movement of the probe (from 1 to 8 mm).

Table 1

	Cross-piece movement							
Load (N)	Sample	1 mm	2 mm	3 mm	4 mm	5 mm	6 mm	7 mm	8 mm
	1	0.08	0.15	0.24	0.25	0.25	0.23	0.21	0.15
	2	0.09	0.19	0.25	0.25	0.26	0.23	0.21	0.16
	3	0.09	0.19	0.26	0.26	0.26	0.24	0.2	0.15
	4	0.08	0.2	0.26	0.28	0.27	0.24	0.22	0.17
	5	0.07	0.17	0.25	0.26	0.25	0.24	0.23	0.17
	Mean	0.08	0.18	0.25	0.26	0.26	0.24	0.21	0.16

The table shows a maximum applied load point equal

to 0.26 N corresponding to a probe travel equal to 4-5 mm. This value indicates the point of maximum flexibility of the material. This result is particularly significant as it clearly shows the excellent properties of flexibility of the material of the invention, expressed in terms of the elastic elongation of the material.

Moreover, a tube of polyester-amide material of the general formula (I) has a hardness on the Shore D scale of more than 60, a tensile modulus of between 400 and 800 MPa, a tensile load at failure of between 35 and 55 MPa and elongation at failure of approximately 300%. In particular, the preferably used Grilamid® FE7303 has a hardness of 66 on the Shore D scale, a tensile modulus of elasticity of 500 MPa, a tensile load at failure of 40 MPa and elongation at failure of 300%.

The distinctive characteristic of excellent flexibility of the polyester-amide material mentioned above is therefore of particular interest for the application of the material described in balloons for angioplasty. In fact, together with the other characteristics described above of hardness and tensile behaviour, the balloons obtained are characterized by a combination of properties of strength, compliance and softness which characterizes the balloons of the present

invention.

The balloons obtained with the polymer material described in the invention certainly have an excellent characteristic of high flexibility and elasticity. Indeed, since the flexibility of a material means the ability of the material to resume its original shape after a deformation has temporarily altered the initial shape, it is immediately apparent that a balloon constituted from highly flexible material will easily withstand the mechanical stresses caused by the repeated action of inflation and deflation required in an angioplasty intervention.

It has moreover been found unexpectedly that the balloon of polyester-amide material which is the subject of the invention has an excellent characteristic of compliance, understood as the percentage increase in the diameter of the balloon as pressure is increased, in addition to an excellent characteristic of adaptability to the arteries and of resistance to stretching.

This combination of the characteristics of good flexibility on the one hand and excellent compliance and strength on the other characterizes the balloons of the present invention and is moreover a combination of properties fundamental to a balloon inserted into the arterial system of a patient during angioplasty

treatment.

For the compliance and flexibility tests, 31 samples of balloon with an outside diameter of 3 mm were tested at a nominal pressure of 7 bar, with a double wall thickness equal to 0.04 mm and obtained from the polymer Grilamid® FE7303.

The flexibility test was carried out on a balloon resting at the ends on supports. The probe was positioned in the middle just touching the surface of the balloon. The probe was then moved downwards and the load required to obtain a certain downward movement of the probe was measured. The value for the bending load, measured for a probe travel equal to 4 mm, is 0.25 N. This value confirms the excellent flexibility of the balloons examined, obtained with the new material according to the present invention.

The compliance test is carried out by measuring the increase in diameter (in mm) of the balloons under examination relative to the increase in pressure (in bar) until the burst pressure is reached. Table 2 gives the most significant data obtained from this test. The table shows the data relating to the mean burst pressure recorded, the standard deviation of the measurements carried out and the calculated RBP (*Rated Burst Pressure*). The value of the *Rated Burst Pressure* was

derived from a probabilistic calculation, in which three times the value of the standard deviation is subtracted from the value of the mean burst pressure measured in the tests on the balloon.

Table 2

Balloon diameter (mm)	3.00
Mean wall thickness (mm)	0.041
Mean burst pressure (bar)	22.36
Standard deviation	0.89
Calculated RBP (bar)	19.67

To a person skilled in the art it is immediately evident how the values given in the table are significant for defining the property of the good compliance of the balloons according to the invention. In particular, the burst pressure data obtained above are significant in conjunction with the characteristic of the good flexibility of the balloons. In fact it can be seen that the balloons which are the subject of the invention have a compliance characteristic usually found in far less flexible materials. Moreover, the new balloons described here have a significant advantage of a higher burst pressure and therefore of a higher RBP, in addition to a smaller percentage increase in diameter

between the nominal pressure and said RBP, compared with state of the art balloons which have comparable flexibility characteristics.

Moreover, the low standard deviation value calculated on the balloon samples examined demonstrates the high uniformity of behaviour and of the characteristics of the balloons obtained with the new material according to the invention. Furthermore this item of data indicates a high level of reproducibility of the distinctive advantageous characteristics of the balloons which are the subject of the present invention.

Because of its good flexibility, the balloon according to the invention also exhibits better manoeuvrability. In fact the balloon of polyester-amide material exhibits a good ability to follow the track and good adaptation to the path of the vessel. This characteristic therefore also improves the ability to move forward the catheter at the distal end of which the balloon is positioned, along the vascular system until the stenotic lesion is reached. Once the narrowing of the artery is reached, moreover, the good flexibility of the balloon also ensures a better capability for positioning the uninflated balloon at the stenotic obstruction. The better adaptability of the material facilitates the passage of the balloon, uninflated,

through the narrowed arterial zone. Finally, this easier passage of the balloon along the path of the vein and through the stenotic lesion means that there is a reduced risk of causing further damage to the vein system concerned and to the stenotic lesion itself.

The good compliance characteristics of the balloon obtained with the polyester-amide material described in the invention mean that said balloons are suitable for an application in therapy of the coronary arteries since the risk of rupture of the vessel as a result of excessive expansion of the balloon is limited.

The good characteristics of flexibility and elasticity of the balloon of the present invention also make it possible to obtain balloons which are advantageously characterized by improved behaviour in returning to the original diameter dimensions after each successive inflation. This enables the same balloon to be inflated a greater number of times and for a longer period. Also deriving from this, moreover, are the good wear characteristics of the balloon. In fact, in normal use of balloons in angioplasty, the burst pressure of the balloon decreases during repeated successive inflations. Contrary to this, the good flexibility of the balloon of polyester-amide material of the present invention improves the ability to maintain the burst

pressure determined for the new balloon. This characteristic also allows use of the balloon according to the present invention for a larger number of inflations and for longer periods.

A further advantage of the balloons obtained with the polyester-amide material of the present invention is that they behave well in the tensile test.

In fact, a test was carried out on the balloons of the present invention with the purpose of evaluating the force necessary to cause the balloon to fail under a tensile load. This test too was carried out according to the particulars given by the International Standards Organisation and described in standard ISO 14630: 1997. Thus, for the purpose of testing the failure load of balloons as in the present invention, balloons prepared from Grilamid® FE7303 with an outside diameter of 3 mm, a length of 20 mm and a thickness of 0.04 mm were used. To carry out the test, the balloons are attached at one end to a fixed clamp, and at the opposite end to a movable cross-piece which moves at a rate of 50 mm/min, stretching the balloon until failure occurs. The elongation of the balloon is then calculated, as is the respective yield load until a load peak is reached which represents the point of failure of the balloon and therefore the corresponding failure load. The results

obtained from said tensile test on the balloon according to the present invention are shown in figure 1, which gives the force-movement graph.

From this test it is found that the balloons of the present invention of polyester-amide material have a failure load value of 32.5 N, which corresponds to a percentage elongation equal to approximately 123%. Comparing these data with those obtained from balloons commonly used in angioplasty, the greater strength and greater elongation capability of the balloons according to the present invention are noted.

Another advantage of using the material described applied to balloons for angioplasty is given by the property of the high viscosity of this material and the ability to maintain a high degree of viscosity even over a period of time. This advantage is reflected particularly in the good slideability characteristics of the material in the process of extrusion to form the tube from which the balloon is then obtained. The copolymer material described in the invention does not therefore require the addition to the polyamide formulation of plasticizing agents to assist in the process.

A further advantage of the polyester-amide material described here is the low absorption of water in aqueous

solutions. In fact it is known that polymer substances absorb water and therefore tend to swell. However, the polyester-amide polymers of the present invention, because of low water absorption, do not have a tendency to swell and therefore have a very small increase in weight and volume in aqueous solutions, maintaining their proper shape, volume and dimensions unchanged.

This characteristic is also very advantageous above all in the step of extrusion of the tube from which the balloon is then obtained. In fact, prior to extrusion, all the materials must be placed in an oven to remove the residual moisture present in the granules. A polymer material which has lower water absorption therefore first of all requires a shorter preliminary drying time. Moreover, during the step of extrusion, the tube which emerges from the die is passed through gauging and cooling tanks containing water. The greater the quantity of water which the polymer tube tends to absorb, the greater the risk of formation of microcavities inside the wall of the tube and consequently of microcavities inside the wall of the balloon. These microcavities represent sudden variations in the thickness of the balloon wall and therefore represent potential weak points of failure of the balloon.

It should moreover be noted that the polyester-

amide material described in the invention has a high chemical resistance to hydrolysis in an aqueous environment. This chemical stability with respect to hydrolytic degradation contributes to an increased storage life of the balloon obtained from this material, since it ensures that the distinctive mechanical properties of the balloon are maintained over a period of time.

The balloons according to the present invention are manufactured using known techniques for the production of catheter balloons, such as for example the techniques of extrusion of the polymer material, familiar to a person skilled in the art.

The invention is further described by means of the following examples, given by way of illustration and non-limiting, from which the characteristics and advantages of the present invention will become still more evident.

Examples

Conditions of extrusion of tubes for balloons of the material according to the invention

Examples 1 and 2 describe tubes for balloons produced by extrusion of the polymer material GRILAMID FE7303. Before extrusion, the pellets of this polymer were dried until the moisture content was less than

0.10%. The tube was extruded at a controlled melting temperature of between 210°C and 240°C, by means of hot extrusion through five extrusion zones with respectively controlled temperatures. The parameters for the extrusion process were based on the conditions for processing the polymer recommended by the producer of the polymer. After the polymer material was extruded from the die in tube form, it was passed through a small aeration zone in which it was cooled in a bath of deionized water kept at a temperature of approximately 20°C. A manual winch was then used to transport the tube through the water bath. The tube was then cut into 260 mm sections.

Tubes of various sizes were prepared using this method.

Example 1

In this example, balloons 3.00 mm in size, obtained from Grilamid® FE7303, were produced. This polymer has a hardness of 66 on the Shore D scale, a tensile modulus of elasticity of 500 MPa, a tensile load at failure of 40 MPa and elongation at failure of 300%. The sections of tube have an OD value of 0.85 mm and 0.55 mm. To obtain a balloon 3.00 mm in size with a body 20 mm in length, a suitably sized mould was used to allow both the body of the tube and the inside diameter of the

central part of the tube to be expanded and inflated to the desired final dimensions. These balloons 3.00 mm in size were obtained with a process temperature of 90°C and an internal inflation pressure of 28 atm.

The balloons thus obtained underwent a standard bursting test. In particular, the double thickness of the wall of the uninflated balloon was measured. Moreover, the balloon was inflated with successively increasing pressures, so as to measure the outside diameter at each pressure increase until the balloon burst. The results obtained from this test are summarised below in table 3.

Example 2

In this example, balloons 3.50 mm in size, obtained from Grilamid® FE7303, were produced. This polymer has a hardness of 66 on the Shore D scale, a tensile modulus of elasticity of 500 MPa, a tensile load at failure of 40 MPa and elongation at failure of 300%. The sections of tube have an OD value of 0.85 mm and 0.55 mm. The balloons 3.50 mm in size were obtained using the same process as described in example 1, except for the different conditions of temperature and internal inflation pressure. In particular, a process temperature of 100°C and an internal inflation pressure of 26 atm were used. The results obtained from the bursting test

with these balloons are summarised below in table 3.

Table 3

Example	Balloon size (mm)	Thickness of double wall (mm)	Mean burst pressure (atm)	RBP (atm)
1	3.00	0.032	21	18
2	3.50	0.036	20	16

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CLAIMS

1. A balloon for medical devices, in particular for catheters used in angioplasty, comprising a polyamide copolymer material characterized in that said copolymer polyamide material is represented by the general formula (I):

HO- (PF-OOC-PA-COO-PF-COO-PA)$_n$-COOH

in which PA is a polyamide segment and PF is a diol segment comprising dimer diols and/or corresponding OH-terminating diol polyesters and n is a number between 5 and 20.

2. A balloon according to claim 1 in which said diol segment has a molecular weight of between 400 and 2000.

3. A balloon according to claim 2 in which said diol segment has a molecular weight of between 400 and 1000.

4. A balloon according to claim 1, 2 or 3 in which said dimer diols are C_{36} and/or C_{44} dimer diols, with a diol dimer content of at least 90%.

5. A balloon according to any one of claims 1 to 4 in which the hydroxide value of said dimer diols is between 195 and 225 mg KOH/g.

6. A balloon according to any one of claims 1 to 3 in which said OH-terminating diol polyesters are

obtained from condensation with aliphatic and/or aromatic C_4-C_{44} dicarboxylic acids.

7. A balloon according to claim 6 in which the hydroxide value of said diol polyesters is between 28 and 90 mg KOH/g.

8. A balloon according to any one of claims 1 to 7 in which the concentration of said diol segment is between 5% and 50% by weight of the total formulation.

9. A balloon according to claim 8 in which the concentration of said diol segment is between 10% and 30% by weight of the total formulation.

10. A balloon according to claim 9 in which the concentration of said diol segment is between 10% and 20% by weight of the total formulation.

11. A balloon according to any one of claims 1 to 10 in which said polyamide segment is selected from PA 6, PA 6/6, PA 6/9, PA 6/10, PA 6/12, PA 6/36, PA 11, PA 12, PA 12/12.

12. A balloon according to any one of claims 1 to 10 in which said polyamide segment is obtained from linear or cyclic, aliphatic or aromatic C_2-C_{36} dicarboxylic acids and from aliphatic or aromatic C_2-C_{12} diamines.

13. A balloon according to any one of claims 1 to 10 in which said polyamide segment is a C_6-C_{12} lactam.

14. A balloon according to any one of claims 1 to 10 in which said polyamide segment is a C_6-C_{12} amino-carboxylic acid.

15. A balloon according to any one of the preceding claims in which said polyamide segment is the lauryl lactam.

16. A balloon according to any one of the preceding claims in which said diol segment is the dimer diol Pripol® 2033 and/or the diol polyester Priplast® 3197.

17. A balloon according to any one of the preceding claims in which the polyamide copolymer material is Grilamid® FE7303.

18. A balloon according to claim 17 characterized in that it has a diameter of 3 mm at a nominal pressure of 7 bar and a wall thickness of 0.04 mm.

19. A balloon according to claims 17 or 18 characterized in that it has a bending load equal to 0.25 N for a probe travel equal to 4 mm.

20. A balloon according to claims 17 or 18 characterized in that it has a calculated mean burst pressure equal to 22.36 bar.

21. A balloon according to claims 17 or 18 characterized in that it has a *Rated Burst Pressure* equal to 19.67 bar.

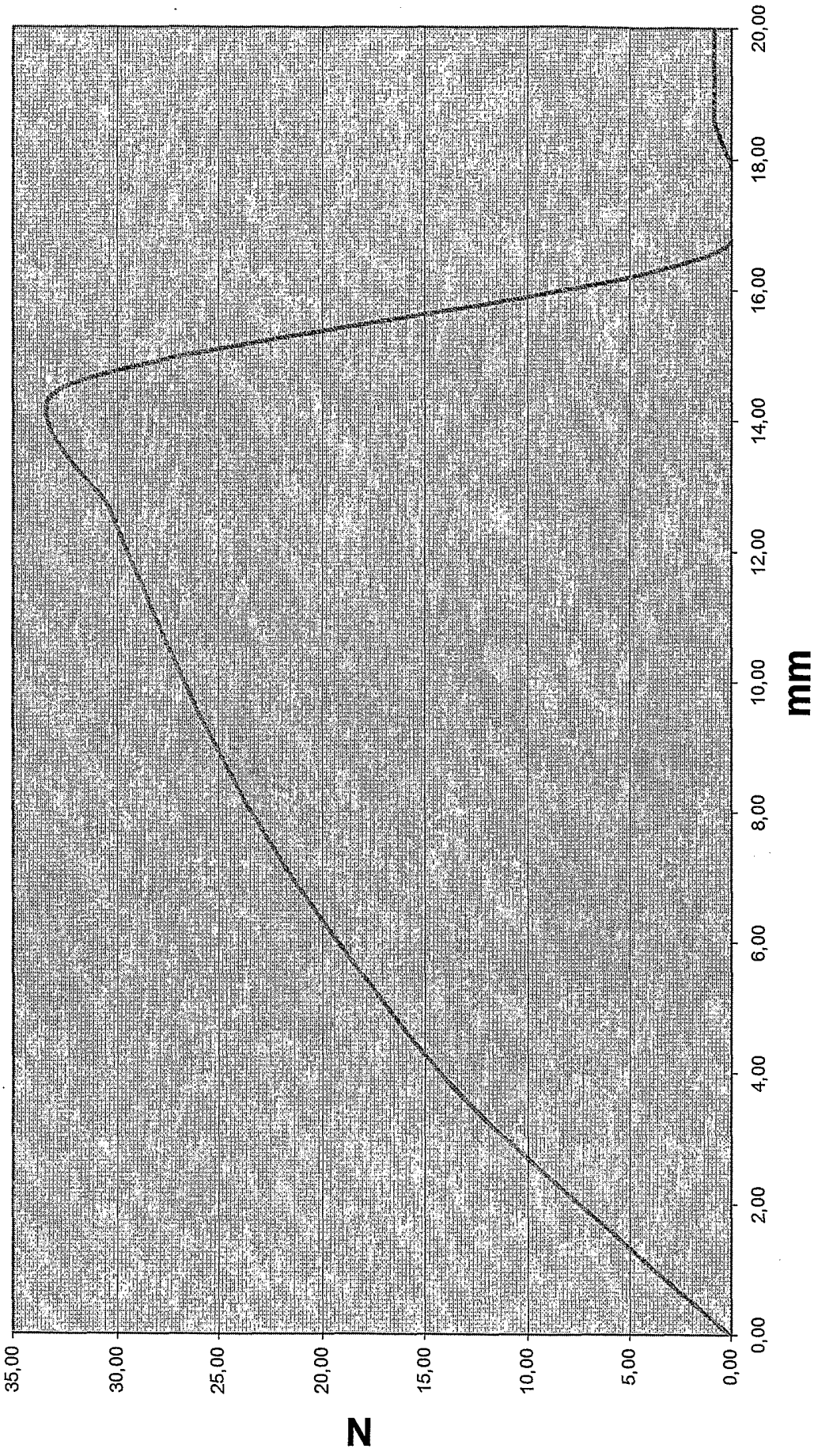
22. A balloon according to claims 17 or 18 characterized in that it has a tensile load at failure of 32.5 N and a percentage elongation at failure equal to approximately 123%.

23. A balloon according to any one of the preceding claims characterized in that the polyamide copolymer material has a hardness of 66 on the Shore D scale, a tensile modulus of elasticity of 500 MPa, a tensile load at failure of 40 MPa and elongation at failure of 300%.

24. Use of the polyamide copolymer material as outlined in any one of claims 1 to 17, for the manufacture of balloons for medical devices, in particular for catheters used in angioplasty.

25. Use of the polyamide copolymer material as in claim 24 characterized in that said material has a hardness of 66 on the Shore D scale, a tensile modulus of elasticity of 500 MPa, a tensile load at failure of 40 MPa and elongation at failure of 300%.

Fig. 1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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/04584

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L29/06 A61L31/04 A61M25/10

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 C08L

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)
EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 406 457 B1 (WANG LIXIAO ET AL) 18 June 2002 (2002-06-18) column 3, line 1 - line 27 column 3, line 50 - column 4, line 58	1-3, 9-11,24
X	EP 0 921 832 A (SCIMED LIFE SYSTEMS INC) 16 June 1999 (1999-06-16) page 5, line 21 - line 43 page 5, line 55 - line 58	1-3, 9-11,24
X	WO 96/37240 A (SCHNEIDER USA INC) 28 November 1996 (1996-11-28) page 6, line 3 - line 22 tables 1-18	1-3, 9-11,24
X	WO 01/19425 A (COOK INC) 22 March 2001 (2001-03-22) page 9, line 30 - page 10, line 6	1,24

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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 :

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Date of the actual completion of the international search	Date of mailing of the international search report
28 June 2004	05/07/2004

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	Staber, B

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