METHOD FOR PRODUCING A BALLOON FOR ANGIOPLASTY

The present invention describes a method for producing a balloon from a suitable blank, wherein the blank is introduced into an outer mold and is heated, and also a balloon of this type, which is suitable for use with a catheter in angioplasty.

Angioplasty, also referred to as transluminal angioplasty, is a method for widening or re-opening constricted or closed blood vessels (usually arteries, more rarely also veins) by means of balloon dilation or other methods (laser, thrombectomy catheter, etc.).

The balloon catheters are almost always placed into the stenosis (constriction) from the groin via a guide wire and guide catheter and are inflated with pressure (7-30 bar), and the constriction is usually eliminated as a result and an operation is avoided. In addition, stents (wire meshes that support the vessel from the inside and are intended to hold the vessel open) are often implanted (stent angioplasty).

The balloon catheters of this type, at their distal end region (within the scope of this application the term "distal" is used in the sense of remote from the user), have a balloon, which is acted on by a pressurized fluid and which is thus expanded (dilated). Due to the expanding balloon, the constricted bodily vessels are widened again or opened again. A support structure (stent) can also be fitted on such balloons and is then implanted by the expansion of the balloon at the formerly constricted site.

Such a balloon consists of a substantially cylindrical region in the middle and two conical end regions (often also referred to as neck regions), where the balloon is connected to the catheter, in particular the lumen for applying fluid to the balloon. The terms "radial" and "axial" are used within the scope of the application accordingly. The term "axial" denotes

US 7,771,450 describes a method for producing a balloon, wherein material is removed by laser ablation in the conical end regions.

EP1620160 describes a method where the wall thickness of the conical end regions is reduced by a means of laser ablation, mechanical abrasion or chemical etching.

However, all such methods of the prior art have the disadvantage that the material removal in the conical end regions is very difficult to control and that, in addition, local imperfections in the balloon structure are formed by the subsequent thermal or mechanical local treatments and lead to a lower pressure load-bearing capacity of the balloon on the whole.

The object of the present invention is therefore to design a method for producing a balloon and to design a balloon of the type mentioned in the introduction in such a way that the disadvantages of the prior art are avoided.

The present object is solved in terms of the method by the combination of features of Claim 1 and in terms of the device by a balloon having the features of Claim 10. Advantageous embodiments of the invention are described in the dependent claims.

The blow molding method according to the invention for producing a balloon for a balloon catheter from a suitable blank, which is introduced into an outer mold, contains four key steps:

•the blank is heated in a first step and acted on with pressure in such a way that it expands until against the inner wall of the outer mold,

•the pressure is reduced in a second step following expansion of the blank, such that the blank relaxes again,

•the three-dimensional expansion of the mold is changed in a third step, and

•the blank is acted on again with pressure in a fourth step, such that it again expands until against the inner wall of the changed volume of the outer mold.

The contact with the hot mold wall in the fourth step ensures a reduction of the frozen stresses, as in the known blow molding methods, and thus ensures a stabilization of the balloon geometry. The heating and pressure application in the first step are preferably selected in such a way that the yield stress of the blank is exceeded.

As already explained, the primary cause for undesirable higher wall thickness in the conical end regions with a balloon from a blow molding method according to the prior art is the fact that the balloon wall thickness with assumed material constancy of blank and balloon is reciprocal relative to the balloon radius. However, the inventors have identified that blank material is additionally removed from the balloon mold by the axial stretching. This makes the balloon additionally thinner in the cylindrical region, since the axial stretching in large regions increases proportionally to the radial stretching.

In accordance with the basic concept of the invention, the correlation of axial and radial stretching in the balloon molding method according to the invention is therefore changed selectively. This occurs in accordance with the invention as a result of the fact that the severely radially stretched region (in the middle cylindrical part of the mold) is stretched axially to a lesser extent. This is possible only by the utilization according to the invention of the viscoelastic properties of the blank, which is not yet cooled and is still heated, during the second pressure application and the associated change of the correlation between axial and radial stretching

The change of the correlation between axial and radial stretching is implemented by the modification of the three-dimensional expansion of the outer mold and the renewed application of pressure to the heated blank in the three-dimensionally changed mold. The changed outer mold changes the correlation between radial and axial stretching. Within the scope of the invention, a modification of the three-dimensional expansion of the outer mold is understood to mean that the outer mold is changed in such a way that the three-dimensional space, which in principle can be taken up in the mold by the blank, which is acted on with pressure, is changed. In principle, the inner surface of the outer mold must be changed accordingly. Due to the change according to the invention of the correlation between radial and axial stretching, there is no need to thin out material in the predefined

regions of the balloon in a subsequent step. The method according to the invention, put more simply, ensures that, during the blow molding process, less material flows into certain regions than in a method according to the prior art. More material is held within the mold compared with the prior art.

The blow molding method according to the invention can also be configured as a stretch blow molding method, that is to say, during the method according to the invention, an additional tensile force can be exerted on the blank in an axial direction (for example by means of a weight).

The length of the mold is preferably reduced. The simple change of the axial expansion of the outer mold (reduction of the length of the mold) during the second pressure application leads to a more uniform distribution of the material compared with a blow molding method according to the prior art. Above all, the wall thickness in the middle cylindrical regions can thus be increased at the cost of the wall thickness in the conical end region compared to a balloon produced by a blow molding method according to the prior art. The need for a mechanical post-processing of the conical end or neck regions and the associated disadvantages are therefore eliminated.

This preferred embodiment of the method according to the invention leads to a particularly homogenous material distribution in a balloon thus produced of the type mentioned in the introduction. In a method according to the prior art, the conical end regions have a higher wall thickness than the cylindrical middle region. In the conical end regions, more material is left in a method according to the prior art than is desired. This has to be removed again subsequently in the case of a balloon produced by a method according to the prior art. The preferred embodiment of the method according to the invention follows a completely contrary principle. Due to the change of the three-dimensional expansion of the mold in the third step and the additional pressure application in the fourth step, a homogenization of the material distribution is achieved.

Following the pressure application of the blank in the first step and the subsequent pressure relief, the blank contracts axially and radially very severely in the second step. The change

of the three-dimensional extent of the mold in the third step takes this contraction into account. The blank is accordingly shaped to the changed three-dimensional mold in the fourth step. During these four steps of the method according to the invention, the blank continues to be at a temperature above the glass transition point. Accordingly, the material is very resilient here. Due to the change of the three-dimensional expansion of the mold (in particular of the mold length), the axial stretching in the cylindrical region can be considerably reduced during the second inflation of the balloon. The wall thickness in this region thus increases accordingly.

The balloon produced in accordance with the invention in this way has a much better stress distribution than conventional balloons, since the cones and necks having thicker walls due to the forming process can be re-formed so as to be thinner without weakening the cylindrical region. This leads to a balloon cone that can be better folded and therefore leads to much smaller folded balloon profiles. In addition, there is much less material in the conical end regions with constant wall thickness in the middle compared with the prior art, and therefore the overall catheter system is less rigid. The combination of the smaller diameter and the lower rigidity allows a much simpler and gentler guidance of the balloon catheter by the handler, in particular when the site of treatment and therefore the target site of the balloon is situated in a very winding bodily vessel with a small diameter. At the same time, the balloon produced in accordance with the invention folds together back into its relaxed form much more easily following expansion at the treatment site than a balloon according to a production method according to the prior art.

The inflatability of balloon tubes is subject to natural limits with predefined tube outer diameter. The inflation pressure also has to be able to be fed on the tube inner surface, which makes it possible to increase the stress in the thermally softened blank wall to such an extent that the material starts plastically to form a balloon. A further increase of the balloon wall thickness is therefore only possible with a method according to the prior art by increasing the outer diameter of the tube. The method according to the invention provides the possibility of achieving an additional increase of the balloon wall thickness of more than 10 % (preferably up to 30 %) in the middle cylindrical region of the balloon by the reduction of the axial stretching during the second forming and annealing.

Within the scope of the application, "annealing" is understood to mean the combined action of forced forming by pressing the balloon against the balloon mold and heating to a temperature or the maintenance of the temperature in the fourth step of the method according to the invention.

The annealing step is used to break down the high stresses in the balloon wall resulting from the blow molding process. Without the annealing step, the balloon would shrink excessively following storage or under the action of increased temperature and would lose its shape.

The annealing does not influence the original wall thickness distribution in the balloon, but rather its response to a mechanical load.

In accordance with a preferred embodiment of the invention, the mold consists of a cylindrical part and two cones, wherein at least one of the cones is movable in the cylindrical part in such a way that the distance between both cones can be changed. The mold particularly preferably has two movable cones in a cylindrical part, which are slid together more closely in the third step of the method.

A balloon as is used in angioplasty has to be substantially cylindrical for its function. This balloon shape is achieved by the mold used. The substantially cylindrical middle of the balloon is shaped by the cylindrical part, and the two movable cones form the conical end regions of the balloon, which serve for the connection to the catheter, in particular the balloon lumen. In the simplest form, the cylinder of the mold is expediently a tube with an inner diameter that corresponds to the target diameter of the balloon. The movable cones can consist of metal for example and each have openings in the middle, through which the tubular part of the blank is guided and through which the blank can be acted on by a pressurized fluid. The blank is fixed in the mold by the two cones. The strength with which the cones can be pushed together (the extent to which the length of the mold is reduced) is dependent on the (visco)elastic capability of the material to be able to relax again in the second step directly after the first step of the molding process.

The blank is expediently heated to a temperature above the glass transition temperature, preferably 30 °C above the glass transition temperature, particularly preferably 20 °C above the glass transition temperature. The temperature to be selected in each case is dependent on the glass transition temperature and the melting point of the material used. The selected temperature here must lie above the glass transition temperature and below the melting point of the material. Here, the blank can either be heated at least in part prior to the introduction into the mold. However, the heating of the blank in the mold by heat radiation is preferred, wherein the mold itself is preferably heated for this purpose.

Here, it is advantageous for the pressure in the first step to be maintained for a short period of time, preferably 0.1 s to 5 s, particularly preferably 0.1 s to 3 s, in particular 0.1 s to 1 s. Here, the pressure is applied until it is ensured that the blank bears completely against the inner wall of the mold in the first blow cycle (in the first step). Under this condition, the pressure is maintained for a period of time that is as short as possible, since the resilient recovery capability of the balloon material reduces with increasing duration of the maintenance of the pressure.

In the fourth step of the method according to the invention, the pressure is advantageously maintained for longer than in the first step of the method according to the invention. Here, higher temperatures than in the first step of the method according to the invention may also be advantageous. The times for the maintenance of the pressure and the temperatures in the fourth step of the method according to the invention correspond here to expedient times and temperatures of a blow molding method according to the prior art and are known to a person skilled in the art for the respective materials. Here, the temperature is basically held above the glass transition temperature and below the melting point. In addition, if the pressure is maintained, reference is made to what is known as “annealing”. The combination of increased chain movability and mechanical load allows the controlled sliding of the chains directed toward one another until the chains are arranged in a most tightly packed manner relative to one another and thus crystalize. Regions crystalized in this way are dimensionally more stable than the adjacent amorphous regions, which have frozen stresses and want to contract upon heating.

After the fourth step, the blank is cooled below the glass transition temperature and removed from the mold (that is to say the pressure is reduced) without deforming further during this process. This also corresponds to the method in accordance with a blow molding method according to the prior art with a blowing step. The corresponding parameters are known to a person skilled in the art.

All viscoelastic polymers that allow blow molding, in particular polyamide, in particular PA12, polyether block amide, polyurethane, PET or PEBAX, can be considered as material for the blank and thus for the balloon.

In an expedient embodiment of the invention, a blank made of polyamide is used. Polyamide can be acted on with pressure ("blown") from a temperature of 48 °C and can be annealed up to a temperature of 178 °C. Here, lower temperatures require longer annealing times and are less cost-effective accordingly. With use of a blank made of polyamide 12, the cones in the third step of the method according to the invention can be pushed together as far as 70 % of their original spacing in the first step of the method. Here, the mold was heated to a temperature of 140 °C. Here, in the first step of the method, the pressure is maintained for less than 1 s. It has been found in this exemplary embodiment of the invention that the blank can be shaped again without difficulty in a range between 70 % and 100 % of the original length (and thus of the original spacing of the cones in the first step of the method according to the invention) in the fourth step of the method according to the invention (that is to say, when acted on with pressure, the blank again bears completely in the fourth step against the inner wall of the mold changed in this way). Accordingly, the wall thickness in this expedient exemplary embodiment of the invention in the middle cylindrical region of the balloon produced in this way can increase in a range between 30 % (when the cones are pushed together to 70 % of their original spacing) and 0 % (when the cones are not pushed together). In the exemplary embodiment of a blank made of polyamide, temperatures of 140 °C and a maintenance of the pressure between 15 s and 120 s, preferably for 20 s, are expedient in the fourth step.

The material of the blank advantageously experiences an axial stretching of less than 250 %, preferably less than 215 %, particularly preferably between 170 % and 250 %, in the cylindrical region of the mold as the method according to the invention is carried out.

Within the scope of the invention, the axial stretching is understood to mean the elongation in the axial direction by which the blank has been stretched in the axial direction during production. The radial stretching is accordingly the elongation to which the blank has been stretched in the radial direction.

Here, the following is true:

$\varepsilon_{ax} = \frac{Q_R}{Q_B}$ axial stretching during blow molding

with

$Q_R = \frac{\pi}{4}(d_a^{\,2} - d_i^{\,2})$ cross section of the blank

$Q_B = \frac{\pi}{4}(D_a^{\,2} - D_i^{\,2}) \approx \pi D_a s_B$ cross section of the balloon

$\varepsilon_{rad,i} = \frac{D_{B,i}}{d_{R,i}}$ radial stretching on the inner side during blow molding

The cross section corresponds to the total wall area of the blank or of the balloon when the blank or the balloon is cut once in a plane perpendicular to the longitudinal axis. The cross section thus forms the cross-sectional area of the blank or balloon consisting of material.

Here, in the formulas:

- d stands for the diameter of the blank (outer or inner)
- D stands for the diameter of the balloon (outer or inner)
- s stands for the wall thickness of the balloon
- ε_{rad} stand for the radial stretching, and
- ε_{ax} stands for the axial stretching,
- the index B stands for balloon, the index R for blank, the index a for outer and the index i for inner.

The diameter d of the blank and the diameter D of the balloon are measured here at the respective point with a pressure application of 3 bar. When determining the diameter, the pressure has to be selected to be so high that the balloon completely unfolds, but is not stretched. The diameters of the conical end regions are accordingly substantially independent of the applied pressure.

In the case of a method according to the prior art, a blank experiences an axial stretching in the conical end regions of approximately 220 %, and in the middle cylindrical region an axial stretching between 250 % and 350 %.

In the method according to the invention, a blank advantageously experiences an axial stretching in the conical end regions similar to that experienced in a method according to the prior art, but a much smaller axial stretching in the middle, cylindrical region.

Due to this advantageous embodiment of the invention, the ratio of the wall thickness in the middle cylindrical region to the wall thickness in the conical end region changes in the case of a balloon produced in this way. With constant wall thickness in the cylindrical region, as is the case with a balloon produced by a blow molding method of the prior art, a wall thickness that is reduced by up to 25 % can be achieved in the conical end regions in the case of a balloon produced in accordance with this embodiment of the method.

This embodiment of the invention is suitable in particular for the production of balloons for balloon catheters, of which the use requires a high application of pressure by means of fluid, that is to say for the production of balloons that are particularly resistant to high pressure. The fatigue strength of balloons can be increased by an increase of the cross section, in particular an increase of the wall thickness. In order to increase the wall thickness, either the inner diameter can be reduced or the outer diameter can be increased. Both measures are subject to limits in the case of a blow molding method according to the prior art. With a strong reduction of the inner diameter, there is a risk of exceeding the yield strength of the inner balloon layer. Accordingly, the reject rate in the balloon production increases. In a blow molding method according to the prior art, the outer layer of the blank is always stretched to a lesser extent than the inner side. This stretch

difference increases with increasing wall thickness. This lower stretch of the outer side increases the risk that a lower orientation along the peripheral direction, that is to say a lower radial orientation, is produced in the polymer material. This limits the stress that such an outer side can bear to the yield stress. Accordingly, the maximum pressure of the balloon produced in this way is limited.

In this embodiment of the invention, the method according to the invention increases the radial stretching of the outer side compared with the prior art. The higher radial stretching on the outer side compared with the prior art increases the radial orientation of the material also on the outer side and thus increases the pressure load bearing capacity of the balloon produced in this way. This is made possible by the method according to the invention, which comprises two successive applications of pressure to the blank in a mold, of which the three-dimensional expansion is changed between pressure applications.

In particular, the blank in this embodiment of the invention experiences an outer radial stretching of more than 300 %, in particular of more than 315 %.

In a further advantageous embodiment of the invention, the blank on the inner side in the middle, cylindrical part experiences a radial stretching of less than 600 %, preferably less than 550 %, in particular less than 517 %.

This embodiment of the invention is suitable in particular for producing balloons with high axial extensibility, that have an extensibility increased by 10 %, in particular by 20 %, compared with a balloon produced by means of a blow molding method according to the prior art. This embodiment of the invention is particularly suitable for the angioplasty of very strongly curved bodily vessels. Both during the expansion of the vessel and during the implantation of a support structure into a strongly curved bodily vessel of this type, there is an undesirable straightening of the bodily vessel caused by the expansion of a balloon according to the prior art. The unphysiological cylinder shape of the balloon is usually forced on the bodily vessel. A balloon according to the above-presented embodiment of the invention avoids this straightening effect of the bodily vessel by the expansion of the balloon. Due to the higher axial extensibility of the balloon of this embodiment of the

invention, the balloon can also follow more easily the physiological course of the curved vessel, even in the expanded state.

In terms of the device, the stated object is achieved by a balloon suitable for use in a catheter for carrying out a method for angioplasty, consisting of a middle cylindrical region and two end regions delimiting the middle cylindrical region, said balloon having a ratio of the cross section in the middle region to the cross section in the end region of at least 2, in particular of greater than 3, in the event of a pressure application of 6 bar.

The balloon according to the invention differs considerably from the prior art. No other balloon according to the prior art has such a ratio of the cross section in the middle, cylindrical region to the cross section of the end region and consists here of a material piece that has not been subjected to any material-removing process.

A balloon having such a cross section can be produced in particular by the method according to the invention. Here, in particular a high proportion of the material is slid by steps 3 and 4 into the middle substantially cylindrical region. A balloon of this type is characterized by a very high bursting pressure. A balloon with such a wall thickness cannot be produced by any known method of the prior art without simultaneously also generating very thick conical end regions or without fusing together a number of balloons to form a single balloon.

The balloon particularly preferably consists of one piece and has a balloon wall thickness of 0.025 mm and an outer diameter of 3 mm.

The balloon expediently consists of polyamide, in particular PA12, polyether block amide, polyurethane, PET and/or PEBAX.

The balloon produced by the method according to the invention or an embodiment thereof is preferred.

The invention will be explained in greater detail hereinafter on the basis of some exemplary embodiments compared with the prior art.

In the drawings:

Fig. 1 schematically shows the method according to the invention in principle,

Fig. 2 shows a comparison of the cross sections in the middle cylindrical region and in the conical end region of a balloon produced by a method of the prior art and by an exemplary embodiment of the method according to the invention,

Fig. 3 shows a comparison of the radial and axial stresses over the elongation of a balloon according to the prior art compared with a balloon according to an exemplary embodiment of the method according to the invention, and

Fig. 4 shows a comparison of the radial and axial stresses over the elongation of a balloon according to the prior art compared with a balloon according to another exemplary embodiment of the method according to the invention.

Figure 1 schematically illustrates the method according to the invention in principle. The tubular blank 1 is first introduced into the mold, which consists of a cylinder 3 and two cones 2 movable therein. The blank 1 is heated in the mold to a temperature above the glass transition temperature of the blank material. In this exemplary embodiment of the invention, the blank 1 is heated in the mold, wherein the heating is performed via the mold. A heating of the blank prior to the introduction into the mold is also possible here. Any method known to a person skilled in the art can be applied for the heating in or outside the mold.

In the first step A, the heated blank 1 is acted on with pressure in such a way that it nests completely against the inner wall of the mold. The inner wall of the mold is formed by the inner wall of the cylinder 3 and the inner wall of the two cones 2. In the next step B, the

blank 1 is relaxed again, that is to say the blank is no longer acted on with pressure. The blank 1 thus returns in part into its original expansion and loses the contact with the inner walls of the mold. In the third step C, the three-dimensional expansion of the mold is changed. The inner surface, against which the blank could nest during pressure application, is changed in step C. In this embodiment of the invention, the right-hand cone 2 is slid closer to the left-hand cone 2a. The inner surface and the volume that can be taken up by the blank 1 are thus reduced with renewed pressure application in step D.

In the illustrated steps A to D, the blank 1 is held permanently at a temperature above the glass transition temperature of the material. The pressure application of the blank 1 in step A is performed over a period of time that is as short as possible. It is maintained until the complete contact of the blank 1 with the inner face of the mold is ensured. However, the pressure in step A is only maintained for such a period that the resilient recovery capability of the material is impaired to a minimal extent or, optimally, is not impaired at all. In step D, the pressure is maintained for much longer. Here, the pressure is maintained until an orientation in a material of the blank is produced and crystallizes. Here, a higher temperature than in step A can be selected as necessary. The balloon now produced is then removed from the mold (pressure reduction), and the balloon is cooled below the glass transition temperature.

Step D corresponds substantially to a pressure application in a blow molding method according to the prior art. The blow molding method presented here can also be configured as a stretch blow molding method, that is to say an additional tensile force can be exerted on the blank in the axial direction (for example by a weight) during steps A-D.

Figure 2 shows a comparison of the cross sections of a balloon according to the prior art (Ex 1) and of a balloon (Ex 2) as has been produced by an exemplary embodiment of the method according to the invention.

Example 1 is a balloon in accordance with a blow molding method according to the prior art. Here, a tubular blank made of PA12 is heated to a temperature of 140 °C in a mold similar to the mold from Figure 1. The heated blank is acted on with pressure for 25 s and

is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part is 3 mm, such that a balloon with 3 mm diameter is produced as product.

Example 2 is a balloon in accordance with a blow molding method according to the invention. Here too, a tubular blank made of PA12 is heated in a mold similar to the mold in Figure 1. In contrast to Example 1, the blank according to Example 2 is acted on with pressure in step A for less than 1 s at 140 °C. Following pressure reduction and relaxation of the blank in step B, the cones are slid together in step C to approximately 75 % of their original spacing. The blank is then acted on again with pressure in step D at 140 °C for 20 s. The blank is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part was also 3 mm in Example 2, such that a balloon with 3 mm diameter is also produced here.

Figure 2 shows a comparison of the cross sections of the balloons in the middle cylindrical region (Figure 2, upper diagram) and a comparison of the cross sections in the conical end region (Figure 2, lower diagram) for Examples 1 (Ex 1) and 2 (Ex 2). Here, in Example 2 the cross section and therefore also the wall thickness in the middle balloon portion increase significantly compared with Example 1 according to the prior art. With similar wall thicknesses in the conical end region of the balloon, an increase of the wall thickness in the middle region of 27 % can be achieved with the balloon according to the exemplary embodiment of the invention (Example 2). The balloon according to Example 2 achieves a ratio of the cross section in the middle region to the cross section in the conical neck region of 3:1 with pressure application with 6 bar.

Figure 3 shows a comparison of the stress/elongation behavior between a balloon according to the prior art (Ex 3) and a balloon (Ex 4) as has been produced by an exemplary embodiment of the method according to the invention.

Example 3 is a balloon in accordance with a blow molding method according to the prior art. Here, a tubular blank with the dimensions 0.57x1.07 made of PA12 is heated to a temperature of 140 °C in a mold similar to the mold from Figure 1. The heated blank is

acted on with pressure for 25 s and is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part is 3.5 mm, such that a balloon with 3.5 mm diameter is produced as product.

Example 4 is a balloon in accordance with a blow molding method according to the invention. Here too, a tubular blank with dimensions 0.57x1.07 made of PA12 is heated in a mold similar to the mold in Figure 1. In contrast to Example 3, the blank according to Example 2 is acted on with pressure in step A for less than 1s at 140 °C. After pressure reduction and relaxation of the blank in step B, the cones are pushed together in step C to approximately 75 % of their original spacing. The blank is then acted on again with pressure at 140 °C for 20 s in step D. The blank is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part in Example 2 was also 3.5 mm, such that a balloon with 3.5 mm diameter is also produced here.

Figure 3 shows a comparison of the stress/elongation behavior in the axial direction (Figure 3, left-hand diagram) and in the radial direction (Figure 3, right-hand diagram) for Examples 3 (Ex 3) and 2 (Ex 4). Here, the axial elongation of the balloon in Example 4 decreases compared with Example 3 according to the prior art. With the same starting tube, a reduction of the axial balloon compliance from 15 % (ex 3) to 11 % (ex 4) can be achieved with the balloon according to the exemplary embodiment of the invention (Example 4). The reduced axial elongation ensures lower stresses axially and radially at constant pressure, without having changed here the radial compliance behavior of the balloon.

Figure 4 shows a comparison of the stress/elongation behavior between a balloon according to a prior art (Ex 5) and a balloon (Ex 6) as has been produced by an exemplary embodiment of the method according to the invention.

Example 5 is a balloon in accordance with a blow molding method according to the prior art. Here, a tubular blank with the dimensions 0.58x0.92 made of PA12 is heated to a temperature of 140 °C in a mold similar to the mold from Figure 1. The heated blank is

acted on with pressure for 25 s and is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part is 3.0 mm, such that a balloon with 3.0 mm diameter is produced as product.

Example 6 is a balloon in accordance with a blow molding method according to the invention. Here too, a tubular blank with the dimensions 0.58x0.92 made of PA12 is heated in a mold similar to the mold in Figure 1. In contrast to Example 3, the blank according to Example 2 is acted on with pressure for less than 1 s at 140 °C in step A. Following pressure reduction and relaxation of the blank in step B, the cones are pushed together in step C to approximately 75 % of their original spacing. The blank is then acted on again with pressure in step D at 140 °C for 20 s. The blank is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part was also 3.0 mm in Example 2, such that a balloon with 3.0 mm diameter is also produced here.

Figure 4 shows a comparison of the stress/elongation behavior in the axial direction (Figure 4, left-hand diagram) and in the radial direction (Figure 4, right-hand diagram) for Examples 5 (Ex 5) and 6 (Ex 6). Here, the axial extensibility of the balloon increases in Example 6 compared with the example according to the prior art (ex 5). With identical starting tube, an increase of the axial balloon compliance from 7 % (ex 5) to 23 % (ex 6) can be achieved with the balloon according to the exemplary embodiment of the invention (Example 6). In spite of increased axial elongation, the balloons (ex 6) do not reach the same stress state as the standard balloons (ex. 5) until 24 bar, since only at this pressure has the balloon used its axial elongation reserve established by the method according to the invention.

METHOD FOR PRODUCING A BALLOON FOR ANGIOPLASTY

The present invention relates to a method for producing a balloon from a suitable blank, wherein the blank is introduced into an outer mold and is heated, and also a balloon of this type, which is suitable for use with a catheter in angioplasty.

Angioplasty, also referred to as transluminal angioplasty, is a method for widening or re-opening constricted or closed blood vessels (usually arteries, more rarely also veins) by means of balloon dilation or other methods (laser, thrombectomy catheter, etc.).

The balloon catheters are almost always placed into the stenosis (constriction) from the groin via a guide wire and guide catheter and are inflated with pressure (7-30 bar), and the constriction is usually eliminated as a result and an operation is avoided. In addition, stents (wire meshes that support the vessel from the inside and are intended to hold the vessel open) are often implanted (stent angioplasty).

The balloon catheters of this type, at their distal end region (within the scope of this application the term "distal" is used in the sense of remote from the user), have a balloon, which is acted on by a pressurized fluid and which is thus expanded (dilated). Due to the expanding balloon, the constricted bodily vessels are widened again or opened again. A support structure (stent) can also be fitted on such balloons and is then implanted by the expansion of the balloon at the formerly constricted site.

Such a balloon consists of a substantially cylindrical region in the middle and two conical end regions (often also referred to as neck regions), where the balloon is connected to the catheter, in particular the lumen for applying fluid to the balloon. The terms "radial" and "axial" are used within the scope of the application accordingly. The term "axial" denotes

US 7,771,450 describes a method for producing a balloon, wherein material is removed by laser ablation in the conical end regions.

EP1620160 describes a method where the wall thickness of the conical end regions is reduced by a means of laser ablation, mechanical abrasion or chemical etching.

However, all such methods of the prior art have the disadvantage that the material removal in the conical end regions is very difficult to control and that, in addition, local imperfections in the balloon structure are formed by the subsequent thermal or mechanical local treatments and lead to a lower pressure load-bearing capacity of the balloon on the whole.

Therefore, the techniques disclosed herein may allow for design of a method for producing a balloon and design of a balloon of the type mentioned in the introduction in such a way that the disadvantages of the prior art may be avoided.

The invention is defined in the independent claims. Advantageous embodiments are described in the dependent claims.

The blow molding method for producing a balloon for a balloon catheter from a suitable blank, which is introduced into an outer mold, contains four key steps:

- the blank is heated in a first step and acted on with pressure in such a way that it expands until against the inner wall of the outer mold,
- the pressure is reduced in a second step following expansion of the blank, such that the blank relaxes again,
- the three-dimensional expansion of the mold is changed in a third step, and
- the blank is acted on again with pressure in a fourth step, such that it again expands until against the inner wall of the changed volume of the outer mold.

The contact with the hot mold wall in the fourth step may ensure a reduction of the frozen stresses, as in the known blow molding methods, and thus may ensure a stabilization of the

balloon geometry. The heating and pressure application in the first step are preferably selected in such a way that the yield stress of the blank is exceeded.

As already explained, the primary cause for undesirable higher wall thickness in the conical end regions with a balloon from a blow molding method according to the prior art is the fact that the balloon wall thickness with assumed material constancy of blank and balloon is reciprocal relative to the balloon radius. However, the inventors have identified that blank material may be additionally removed from the balloon mold by the axial stretching. This may make the balloon additionally thinner in the cylindrical region, since the axial stretching in large regions increases proportionally to the radial stretching.

The correlation of axial and radial stretching in the balloon molding method may therefore change selectively. This may occurs as a result of the fact that the severely radially stretched region (in the middle cylindrical part of the mold) is stretched axially to a lesser extent. This may be possible by the utilization of the viscoelastic properties of the blank, which is not yet cooled and is still heated, during the second pressure application and the associated change of the correlation between axial and radial stretching.

The change of the correlation between axial and radial stretching may be implemented by the modification of the three-dimensional expansion of the outer mold and the renewed application of pressure to the heated blank in the three-dimensionally changed mold. The changed outer mold changes the correlation between radial and axial stretching. A modification of the three-dimensional expansion of the outer mold is understood to mean that the outer mold is changed in such a way that the three-dimensional space, which in principle can be taken up in the mold by the blank, which is acted on with pressure, is changed. In principle, the inner surface of the outer mold must be changed accordingly. Due to the change of the correlation between radial and axial stretching, there is no need to thin out material in the predefined regions of the balloon in a subsequent step. The method, put more simply, may ensure that, during the blow molding process, less material flows into certain regions than in a method according to the prior art. More material may be held within the mold compared with the prior art.

The blow molding method can also be configured as a stretch blow molding method, that is to say, during the method, an additional tensile force can be exerted on the blank in an axial direction (for example by means of a weight).

The length of the mold is preferably reduced. The simple change of the axial expansion of the outer mold (reduction of the length of the mold) during the second pressure application may lead to a more uniform distribution of the material compared with a blow molding method according to the prior art. Above all, the wall thickness in the middle cylindrical regions can thus be increased at the cost of the wall thickness in the conical end region compared to a balloon produced by a blow molding method according to the prior art. The need for a mechanical post-processing of the conical end or neck regions and the associated disadvantages may therefore be eliminated.

This preferred embodiment of the method leads to a particularly homogenous material distribution in a balloon thus produced of the type mentioned in the introduction. In a method according to the prior art, the conical end regions have a higher wall thickness than the cylindrical middle region. In the conical end regions, more material is left in a method according to the prior art than is desired. This has to be removed again subsequently in the case of a balloon produced by a method according to the prior art. The preferred embodiment of the method described herein follows a completely contrary principle. Due to the change of the three-dimensional expansion of the mold in the third step and the additional pressure application in the fourth step, a homogenization of the material distribution may be achieved.

Following the pressure application of the blank in the first step and the subsequent pressure relief, the blank may contract axially and radially very severely in the second step. The change of the three-dimensional extent of the mold in the third step may take this contraction into account. The blank may be accordingly shaped to the changed three-dimensional mold in the fourth step. During these four steps of the method, the blank may continue to be at a temperature above the glass transition point. Accordingly, the material may be very resilient here. Due to the change of the three-dimensional expansion of the mold (in particular of the mold length), the axial stretching in the cylindrical region can be

considerably reduced during the second inflation of the balloon. The wall thickness in this region may thus increases accordingly.

The balloon produced in this way may have a much better stress distribution than conventional balloons, since the cones and necks having thicker walls due to the forming process can be re-formed so as to be thinner without weakening the cylindrical region. This may lead to a balloon cone that can be better folded and may therefore lead to much smaller folded balloon profiles. In addition, there may be much less material in the conical end regions with constant wall thickness in the middle compared with the prior art, and therefore the overall catheter system may be less rigid. The combination of the smaller diameter and the lower rigidity may allow a much simpler and gentler guidance of the balloon catheter by the handler, in particular when the site of treatment and therefore the target site of the balloon may be situated in a very winding bodily vessel with a small diameter. At the same time, the balloon produced may fold together back into its relaxed form much more easily following expansion at the treatment site than a balloon according to a production method according to the prior art.

The inflatability of balloon tubes is subject to natural limits with predefined tube outer diameter. The inflation pressure may also have to be able to be fed on the tube inner surface, which may make it possible to increase the stress in the thermally softened blank wall to such an extent that the material may start plastically to form a balloon. A further increase of the balloon wall thickness may therefore be possible with a method according to the prior art by increasing the outer diameter of the tube. The method described herein may provide the possibility of achieving an additional increase of the balloon wall thickness of more than 10 % (preferably up to 30 %) in the middle cylindrical region of the balloon by the reduction of the axial stretching during the second forming and annealing.

Within the scope of the application, "annealing" is understood to mean the combined action of forced forming by pressing the balloon against the balloon mold and heating to a temperature or the maintenance of the temperature in the fourth step of the method.

The annealing step may be used to break down the high stresses in the balloon wall resulting from the blow molding process. Without the annealing step, the balloon may shrink excessively following storage or under the action of increased temperature and may lose its shape.

The annealing does not influence the original wall thickness distribution in the balloon, but rather its response to a mechanical load.

In accordance with a preferred embodiment, the mold consists of a cylindrical part and two cones, wherein at least one of the cones is movable in the cylindrical part in such a way that the distance between both cones can be changed. The mold particularly preferably has two movable cones in a cylindrical part, which are slid together more closely in the third step of the method.

A balloon as is used in angioplasty has to be substantially cylindrical for its function. This balloon shape is achieved by the mold used. The substantially cylindrical middle of the balloon is shaped by the cylindrical part, and the two movable cones form the conical end regions of the balloon, which serve for the connection to the catheter, in particular the balloon lumen. In the simplest form, the cylinder of the mold is expediently a tube with an inner diameter that corresponds to the target diameter of the balloon. The movable cones can consist of metal for example and each have openings in the middle, through which the tubular part of the blank is guided and through which the blank can be acted on by a pressurized fluid. The blank is fixed in the mold by the two cones. The strength with which the cones can be pushed together (the extent to which the length of the mold is reduced) is dependent on the (visco)elastic capability of the material to be able to relax again in the second step directly after the first step of the molding process.

The blank is expediently heated to a temperature above the glass transition temperature, preferably 30 °C above the glass transition temperature, particularly preferably 20 °C above the glass transition temperature. The temperature to be selected in each case is dependent on the glass transition temperature and the melting point of the material used. The selected temperature here must lie above the glass transition temperature and below

the melting point of the material. Here, the blank can either be heated at least in part prior to the introduction into the mold. However, the heating of the blank in the mold by heat radiation is preferred, wherein the mold itself is preferably heated for this purpose.

Here, it is advantageous for the pressure in the first step to be maintained for a short period of time, preferably 0.1 s to 5 s, particularly preferably 0.1 s to 3 s, in particular 0.1 s to 1 s. Here, the pressure may be applied until it is ensured that the blank bears completely against the inner wall of the mold in the first blow cycle (in the first step). Under this condition, the pressure is maintained for a period of time that is as short as possible, since the resilient recovery capability of the balloon material may reduce with increasing duration of the maintenance of the pressure.

In the fourth step of the method, the pressure is advantageously maintained for longer than in the first step of the method. Here, higher temperatures than in the first step of the method may also be advantageous. The times for the maintenance of the pressure and the temperatures in the fourth step of the method correspond here to expedient times and temperatures of a blow molding method according to the prior art and are known to a person skilled in the art for the respective materials. Here, the temperature is basically held above the glass transition temperature and below the melting point. In addition, if the pressure is maintained, reference is made to what is known as "annealing". The combination of increased chain movability and mechanical load allows the controlled sliding of the chains directed toward one another until the chains are arranged in a most tightly packed manner relative to one another and thus crystalize. Regions crystalized in this way are dimensionally more stable than the adjacent amorphous regions, which have frozen stresses and want to contract upon heating.

After the fourth step, the blank may be cooled below the glass transition temperature and removed from the mold (that is to say the pressure is reduced) without deforming further during this process. This may also correspond to the method in accordance with a blow molding method according to the prior art with a blowing step. The corresponding parameters are known to a person skilled in the art.

All viscoelastic polymers that allow blow molding, in particular polyamide, in particular PA12, polyether block amide, polyurethane, PET or PEBAX, can be considered as material for the blank and thus for the balloon.

In an expedient embodiment, a blank made of polyamide is used. Polyamide can be acted on with pressure ("blown") from a temperature of 48 °C and can be annealed up to a temperature of 178 °C. Here, lower temperatures require longer annealing times and are less cost-effective accordingly. With use of a blank made of polyamide 12, the cones in the third step of the method can be pushed together as far as 70 % of their original spacing in the first step of the method. Here, the mold was heated to a temperature of 140 °C. Here, in the first step of the method, the pressure is maintained for less than 1 s. It has been found in this exemplary embodiment that the blank can be shaped again without difficulty in a range between 70 % and 100 % of the original length (and thus of the original spacing of the cones in the first step of the method) in the fourth step of the method (that is to say, when acted on with pressure, the blank again bears completely in the fourth step against the inner wall of the mold changed in this way). Accordingly, the wall thickness in this expedient exemplary embodiment in the middle cylindrical region of the balloon produced in this way can increase in a range between 30 % (when the cones are pushed together to 70 % of their original spacing) and 0 % (when the cones are not pushed together). In the exemplary embodiment of a blank made of polyamide, temperatures of 140 °C and a maintenance of the pressure between 15 s and 120 s, preferably for 20 s, are expedient in the fourth step.

The material of the blank may advantageously experience an axial stretching of less than 250 %, preferably less than 215 %, particularly preferably between 170 % and 250 %, in the cylindrical region of the mold as the method is carried out.

The axial stretching is understood to mean the elongation in the axial direction by which the blank has been stretched in the axial direction during production. The radial stretching is accordingly the elongation to which the blank has been stretched in the radial direction.

Here, the following is true:

$$\varepsilon_{ax} = \frac{Q_R}{Q_B}$$ axial stretching during blow molding

with

$$Q_R = \frac{\pi}{4}(d_a^{\,2} - d_i^{\,2})$$ cross section of the blank

$$Q_B = \frac{\pi}{4}(D_a^{\,2} - D_i^{\,2}) \approx \pi D_a s_B$$ cross section of the balloon

$$\varepsilon_{rad,i} = \frac{D_{B,i}}{d_{R,i}}$$ radial stretching on the inner side during blow molding

The cross section corresponds to the total wall area of the blank or of the balloon when the blank or the balloon is cut once in a plane perpendicular to the longitudinal axis. The cross section thus forms the cross-sectional area of the blank or balloon consisting of material. Here, in the formulas:

- d stands for the diameter of the blank (outer or inner)
- D stands for the diameter of the balloon (outer or inner)
- s stands for the wall thickness of the balloon
- ε_{rad} stand for the radial stretching, and
- ε_{ax} stands for the axial stretching,
- the index B stands for balloon, the index R for blank, the index a for outer and the index i for inner.

The diameter d of the blank and the diameter D of the balloon are measured here at the respective point with a pressure application of 3 bar. When determining the diameter, the pressure has to be selected to be so high that the balloon completely unfolds, but is not stretched. The diameters of the conical end regions are accordingly substantially independent of the applied pressure.

In the case of a method according to the prior art, a blank experiences an axial stretching in the conical end regions of approximately 220 %, and in the middle cylindrical region an axial stretching between 250 % and 350 %.

In the method, a blank may advantageously experience an axial stretching in the conical end regions similar to that experienced in a method according to the prior art, but a much smaller axial stretching in the middle, cylindrical region.

Due to this advantageous embodiment, the ratio of the wall thickness in the middle cylindrical region to the wall thickness in the conical end region may change in the case of a balloon produced in this way. With constant wall thickness in the cylindrical region, as is the case with a balloon produced by a blow molding method of the prior art, a wall thickness that is reduced by up to 25 % can be achieved in the conical end regions in the case of a balloon produced in accordance with this embodiment of the method.

This embodiment is suitable in particular for the production of balloons for balloon catheters, of which the use requires a high application of pressure by means of fluid, that is to say for the production of balloons that are particularly resistant to high pressure. The fatigue strength of balloons can be increased by an increase of the cross section, in particular an increase of the wall thickness. In order to increase the wall thickness, either the inner diameter can be reduced or the outer diameter can be increased. Both measures are subject to limits in the case of a blow molding method according to the prior art. With a strong reduction of the inner diameter, there is a risk of exceeding the yield strength of the inner balloon layer. Accordingly, the reject rate in the balloon production increases. In a blow molding method according to the prior art, the outer layer of the blank is always stretched to a lesser extent than the inner side. This stretch difference increases with increasing wall thickness. This lower stretch of the outer side increases the risk that a lower orientation along the peripheral direction, that is to say a lower radial orientation, is produced in the polymer material. This limits the stress that such an outer side can bear to the yield stress. Accordingly, the maximum pressure of the balloon produced in this way is limited.

In this embodiment, the method may increase the radial stretching of the outer side compared with the prior art. The higher radial stretching on the outer side compared with the prior art may increase the radial orientation of the material also on the outer side and may thus increase the pressure load-bearing capacity of the balloon produced in this way.

This may be made possible by the method, which comprises two successive applications of pressure to the blank in a mold, of which the three-dimensional expansion is changed between pressure applications.

In particular, the blank in this embodiment may experience an outer radial stretching of more than 300 %, in particular of more than 315 %.

In a further advantageous embodiment, the blank on the inner side in the middle, cylindrical part may experience a radial stretching of less than 600 %, preferably less than 550 %, in particular less than 517 %.

This embodiment is suitable in particular for producing balloons with high axial extensibility, that have an extensibility increased by 10 %, in particular by 20 %, compared with a balloon produced by means of a blow molding method according to the prior art. This embodiment is particularly suitable for the angioplasty of very strongly curved bodily vessels. Both during the expansion of the vessel and during the implantation of a support structure into a strongly curved bodily vessel of this type, there may be an undesirable straightening of the bodily vessel caused by the expansion of a balloon according to the prior art. The unphysiological cylinder shape of the balloon is usually forced on the bodily vessel. A balloon according to the above-presented embodiment may avoid this straightening effect of the bodily vessel by the expansion of the balloon. Due to the higher axial extensibility of the balloon of this embodiment o, the balloon can also follow more easily the physiological course of the curved vessel, even in the expanded state.

In terms of the device, this may be advantageously achieved by a balloon suitable for use in a catheter for carrying out a method for angioplasty, consisting of a middle cylindrical region and two end regions delimiting the middle cylindrical region, said balloon having a ratio of the cross section in the middle region to the cross section in the end region of at least 2, in particular of greater than 3, in the event of a pressure application of 6 bar.

The balloon may differ considerably from the prior art. No other balloon according to the prior art has such a ratio of the cross section in the middle, cylindrical region to the cross

section of the end region and consists here of a material piece that has not been subjected to any material-removing process.

A balloon having such a cross section can be produced in particular by the method. Here, in particular a high proportion of the material is slid by steps 3 and 4 into the middle substantially cylindrical region. A balloon of this type is characterized by a very high bursting pressure. A balloon with such a wall thickness cannot be produced by any known method of the prior art without simultaneously also generating very thick conical end regions or without fusing together a number of balloons to form a single balloon.

The balloon particularly preferably consists of one piece and has a balloon wall thickness of 0.025 mm and an outer diameter of 3 mm.

The balloon expediently consists of polyamide, in particular PA12, polyether block amide, polyurethane, PET and/or PEBAX.

The balloon produced by the method or an embodiment thereof is preferred.

The techniques disclosed herein will be explained in greater detail hereinafter on the basis of some exemplary embodiments compared with the prior art.

In the drawings:

Fig. 1 schematically shows the method in principle,

Fig. 2 shows a comparison of the cross sections in the middle cylindrical region and in the conical end region of a balloon produced by a method of the prior art and by an exemplary embodiment of the method,

Fig. 3 shows a comparison of the radial and axial stresses over the elongation of a balloon according to the prior art compared with a balloon according to an exemplary embodiment of the method, and

Fig. 4 shows a comparison of the radial and axial stresses over the elongation of a balloon according to the prior art compared with a balloon according to another exemplary embodiment of the method.

Figure 1 schematically illustrates the method in principle. The tubular blank 1 is first introduced into the mold, which consists of a cylinder 3 and two cones 2 movable therein. The blank 1 is heated in the mold to a temperature above the glass transition temperature of the blank material. In this exemplary embodiment, the blank 1 is heated in the mold, wherein the heating is performed via the mold. A heating of the blank prior to the introduction into the mold is also possible here. Any method known to a person skilled in the art can be applied for the heating in or outside the mold.

In the first step A, the heated blank 1 is acted on with pressure in such a way that it nests completely against the inner wall of the mold. The inner wall of the mold is formed by the inner wall of the cylinder 3 and the inner wall of the two cones 2. In the next step B, the blank 1 is relaxed again, that is to say the blank is no longer acted on with pressure. The blank 1 thus returns in part into its original expansion and loses the contact with the inner walls of the mold. In the third step C, the three-dimensional expansion of the mold is changed. The inner surface, against which the blank could nest during pressure application, is changed in step C. In this embodiment, the right-hand cone 2 is slid closer to the left-hand cone 2a. The inner surface and the volume that can be taken up by the blank 1 are thus reduced with renewed pressure application in step D.

In the illustrated steps A to D, the blank 1 is held permanently at a temperature above the glass transition temperature of the material. The pressure application of the blank 1 in step A is performed over a period of time that is as short as possible. It is maintained until the complete contact of the blank 1 with the inner face of the mold is ensured. However, the pressure in step A is only maintained for such a period that the resilient recovery capability of the material is impaired to a minimal extent or, optimally, is not impaired at all. In step D, the pressure is maintained for much longer. Here, the pressure is maintained until an orientation in a material of the blank is produced and crystallizes. Here, a higher

temperature than in step A can be selected as necessary. The balloon now produced is then removed from the mold (pressure reduction), and the balloon is cooled below the glass transition temperature.

Step D corresponds substantially to a pressure application in a blow molding method according to the prior art. The blow molding method presented here can also be configured as a stretch blow molding method, that is to say an additional tensile force can be exerted on the blank in the axial direction (for example by a weight) during steps A-D.

Figure 2 shows a comparison of the cross sections of a balloon according to the prior art (Ex 1) and of a balloon (Ex 2) as has been produced by an exemplary embodiment of the method.

Example 1 is a balloon in accordance with a blow molding method according to the prior art. Here, a tubular blank made of PA12 is heated to a temperature of 140 °C in a mold similar to the mold from Figure 1. The heated blank is acted on with pressure for 25 s and is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part is 3 mm, such that a balloon with 3 mm diameter is produced as product.

Example 2 is a balloon in accordance with a blow molding method as herein described . Here too, a tubular blank made of PA12 is heated in a mold similar to the mold in Figure 1. In contrast to Example 1, the blank according to Example 2 is acted on with pressure in step A for less than 1 s at 140 °C. Following pressure reduction and relaxation of the blank in step B, the cones are slid together in step C to approximately 75 % of their original spacing. The blank is then acted on again with pressure in step D at 140 °C for 20 s. The blank is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part was also 3 mm in Example 2, such that a balloon with 3 mm diameter is also produced here.

Figure 2 shows a comparison of the cross sections of the balloons in the middle cylindrical region (Figure 2, upper diagram) and a comparison of the cross sections in the conical end

region (Figure 2, lower diagram) for Examples 1 (Ex 1) and 2 (Ex 2). Here, in Example 2 the cross section and therefore also the wall thickness in the middle balloon portion increase significantly compared with Example 1 according to the prior art. With similar wall thicknesses in the conical end region of the balloon, an increase of the wall thickness in the middle region of 27 % can be achieved with the balloon according to the exemplary embodiment (Example 2). The balloon according to Example 2 achieves a ratio of the cross section in the middle region to the cross section in the conical neck region of 3:1 with pressure application with 6 bar.

Figure 3 shows a comparison of the stress/elongation behavior between a balloon according to the prior art (Ex 3) and a balloon (Ex 4) as has been produced by an exemplary embodiment of the method.

Example 3 is a balloon in accordance with a blow molding method according to the prior art. Here, a tubular blank with the dimensions 0.57x1.07 made of PA12 is heated to a temperature of 140 °C in a mold similar to the mold from Figure 1. The heated blank is acted on with pressure for 25 s and is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part is 3.5 mm, such that a balloon with 3.5 mm diameter is produced as product.

Example 4 is a balloon in accordance with a blow molding method as herein described. Here too, a tubular blank with dimensions 0.57x1.07 made of PA12 is heated in a mold similar to the mold in Figure 1. In contrast to Example 3, the blank according to Example 2 is acted on with pressure in step A for less than 1s at 140 °C. After pressure reduction and relaxation of the blank in step B, the cones are pushed together in step C to approximately 75 % of their original spacing. The blank is then acted on again with pressure at 140 °C for 20 s in step D. The blank is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part in Example 2 was also 3.5 mm, such that a balloon with 3.5 mm diameter is also produced here.

Figure 3 shows a comparison of the stress/elongation behavior in the axial direction (Figure 3, left-hand diagram) and in the radial direction (Figure 3, right-hand diagram) for

Examples 3 (Ex 3) and 2 (Ex 4). Here, the axial elongation of the balloon in Example 4 decreases compared with Example 3 according to the prior art. With the same starting tube, a reduction of the axial balloon compliance from 15 % (ex 3) to 11 % (ex 4) can be achieved with the balloon according to the exemplary embodiment (Example 4). The reduced axial elongation ensures lower stresses axially and radially at constant pressure, without having changed here the radial compliance behavior of the balloon.

Figure 4 shows a comparison of the stress/elongation behavior between a balloon according to a prior art (Ex 5) and a balloon (Ex 6) as has been produced by an exemplary embodiment of the method.

Example 5 is a balloon in accordance with a blow molding method according to the prior art. Here, a tubular blank with the dimensions 0.58x0.92 made of PA12 is heated to a temperature of 140 °C in a mold similar to the mold from Figure 1. The heated blank is acted on with pressure for 25 s and is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part is 3.0 mm, such that a balloon with 3.0 mm diameter is produced as product.

Example 6 is a balloon in accordance with a blow molding method as herein described. Here too, a tubular blank with the dimensions 0.58x0.92 made of PA12 is heated in a mold similar to the mold in Figure 1. In contrast to Example 3, the blank according to Example 2 is acted on with pressure for less than 1 s at 140 °C in step A. Following pressure reduction and relaxation of the blank in step B, the cones are pushed together in step C to approximately 75 % of their original spacing. The blank is then acted on again with pressure in step D at 140 °C for 20 s. The blank is then removed from the mold and cooled below the glass transition temperature. The diameter of the mold in the cylindrical part was also 3.0 mm in Example 2, such that a balloon with 3.0 mm diameter is also produced here.

Figure 4 shows a comparison of the stress/elongation behavior in the axial direction (Figure 4, left-hand diagram) and in the radial direction (Figure 4, right-hand diagram) for Examples 5 (Ex 5) and 6 (Ex 6). Here, the axial extensibility of the balloon increases in Example 6 compared with the example according to the prior art (ex 5). With identical

starting tube, an increase of the axial balloon compliance from 7 % (ex 5) to 23 % (ex 6) can be achieved with the balloon according to the exemplary embodiment (Example 6). In spite of increased axial elongation, the balloons (ex 6) do not reach the same stress state as the standard balloons (ex. 5) until 24 bar, since only at this pressure has the balloon used its axial elongation reserve established by the method.