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(54) Title: TUBULAR INSERT FOR EXTRA-CORPOREAL CIRCUIT

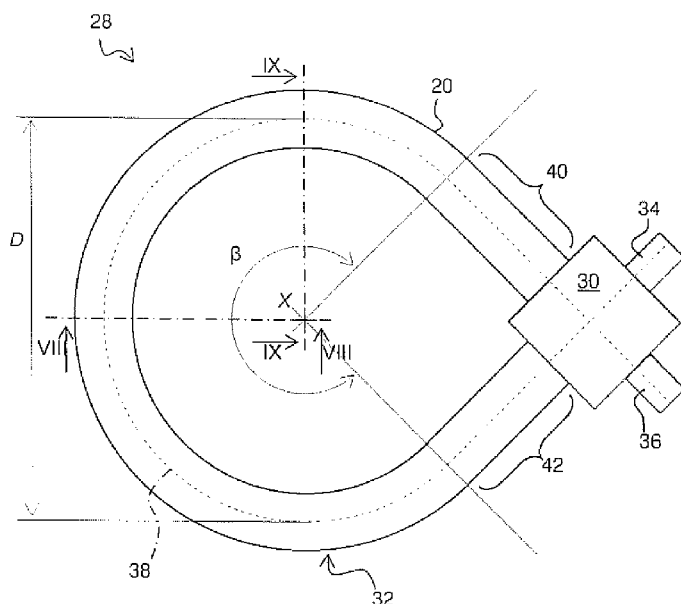


Fig. 5

(57) Abstract: The present invention relates to a novel type of tubular insert 28 for connecting an extra-corporeal circuit 26 to a peristaltic pump 22. This tubular insert 28 comprises a loop 32 formed by a tube portion 20; the loop 32 comprises a curve 38 which extends around an axis X. The tube 20 which forms the curve 38 has an oval cross-section with a major axis M and a minor axis m perpendicular to each other, where the major axis M is longer than the minor axis m. Finally, in the tubular insert 28 according to the invention, the minor axis m of each cross-section of the tube 20 along the curve 38 is parallel to the axis X. The invention further relates to a method for producing the tubular insert 28 and to a peristaltic pump 22 suitable for operating with tubular inserts according both to the invention and to the prior art.



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Tubular insert for extra-corporeal circuit

DESCRIPTION

The invention relates to a circuit for extra-corporeal circulation and in particular to the tubular insert intended to co-operate with a peristaltic pump. The invention also relates to a method for obtaining said tubular insert.

In therapeutic treatments which require the use of extra-corporeal circulation, for example during haemodialysis treatments, it is required to ensure circulation of the blood and/or of the other physiological fluids along the pipes forming the circuit.

For this purpose it is known to use peristaltic pumps comprising a stator and a rotor between which a flexible tube is inserted. The rotor of the pump comprises rollers, usually two rollers, suitable for pressing the tube against the stator. The combined action of the pressure exerted by the rollers and the rotation imparted by the rotor causes displacement of the liquid between the two rollers inside the tube. The subsequent and constant displacement of portions of liquid produces, in a known manner, pumping of the liquid along the circuit.

The extra-corporeal circulation normally lasts, in the case of an ordinary haemodialysis treatment, for about 4 hours. However, cases may arise - for example, those in which it is required to treat an acute renal insufficiency or even more complex clinical conditions affecting the functioning of several organs - where the extra-corporeal circulation must be maintained for very long periods of time, for example 24 or even 48 hours.

As the person skilled in the art can easily understand, the correct functioning of the peristaltic pump and the entire circuit, and therefore the success of the therapeutic treatment as a whole, depend to a large extent on the characteristics of the tube portion co-operating with the peristaltic pump itself.

First and foremost, the tube must be able to satisfy two requirements which are substantially of an opposing nature. On the one hand, the walls of the tube must be sufficiently soft to allow proper compression by the rotor rollers. The proper compression of the tube, resulting in the complete occlusion of its inner lumen, allows an efficient suction phase. On the other hand, the tube walls must be sufficiently rigid to allow a good elastic recovery at the end of the compression exerted by the rollers. Compression of the tube and subsequent elastic recovery thereof constitute in fact the

basis for correct operation of the peristaltic pump in terms of volumetric flow rate. It is also to be considered that operation of the circuit may in some cases start with a cold liquid which lowers the temperature of the tube itself. As it is well known, low temperature conditions negatively affect the characteristics of the polymer which forms the tubular insert.

Secondly, the tube must be able to ensure that, during the period of time for which it is used, it does not give rise to a deterioration in the performance, typically in terms of the volumetric flow rate of the peristaltic pump.

In view of the above comments, the tubes which are intended to co-operate with peristaltic pumps usually undergo tests which envisage the worst possible scenario, i.e. continuous operation for 24 to 48 hours.

Until recently, the tubes intended to co-operate with peristaltic pumps were made of PVC (polyvinyl chloride) plasticized with DOP (dioctyl phthalate, also called diisooctyl phthalate, di-2-ethyl hexyl phthalate or DEHP). This material (referred to below as PVC-DOP) ensured acceptable performance for the new, unused tube as well as a limited deterioration in performance in the case of prolonged use. Expressed in numerical terms, it is considered that the unused tubes made of PVC-DOP with an internal diameter of 8 mm ensured an average flow rate of about 320 ml/min and were subject, after 6 hours' uninterrupted operation, to a reduction in flow rate of between 8% and 10%.

Recently, following specific toxicological studies, standards have been introduced with the aim of eliminating DOP from products intended for use in a medical environment and in particular products which are exposed to systematic and prolonged contact with patients' blood.

In view of the above, recently products intended for medical use and made of materials other than PVC-DOP have been proposed. In particular, in connection with circuits used for haemodialysis, it has been proposed to replace PVC-DOP with silicone. Silicone ensures that optimum characteristics are obtained and that these are also maintained during long periods of operational use. Silicone, however, is much more costly than PVC and its widespread use would result in an increase in costs which would be unacceptable for most health systems.

In addition it has been proposed using PVC and replacing only the DOP plasticizer with

another known plasticizer such as TOTM (trioctyl trimellitate). This solution, although decidedly less expensive than silicone, results, however, in a slight increase in costs compared to the conventional solution PVC-DOP solution. The main problem with PVC-TOTM consists, however, in the fact that this material does not ensure a sufficient elasticity. In other words, a tube made of PVC-TOTM and intended for use in a peristaltic pump is hardly able to satisfy both the requirements which, as mentioned above, involve characteristics of an opposing nature. More particularly, a tube made of PVC-TOTM, having a low hardness suitable to be effectively operated in suction conditions even with cold liquids, presents an unacceptable deterioration in its performance with prolonged use and even in a relatively short amount of time comparable to a standard 4-hour haemodialysis treatment. The choice of increasing the wall thickness of the PVC-TOTM tube so as to ensure an effective elastic recovery is not feasible because of the existence of standards about connectors and other components. Moreover, if the thickness of the wall was increased by reducing the inner diameter of the tube, considerable alterations would arise for the reference flow rate.

To conclude, the use of an ordinary peristaltic pump in combination with a tube made of PVC-TOTM is hardly able to satisfy the prescribed requirements in terms of obtainable pressures and/or reduced flow rate performance. In order to compare the characteristics of PVC-TOTM with those of PVC-DOP, some tests have been carried out in which every condition was kept the same with the only exception of the tube material. Specifically, unused tubes with an internal diameter of 8 mm, which ensure an average flow rate of about 320 ml/min, have been subjected to 6 hours uninterrupted operation. As reported above, for tubes made of PVC-DOP, a reduction in flow rate was detected of between 8% and 10%. Conversely, for tubes made of PVC-TOTM, an unacceptable reduction in flow rate was detected of between 20% and 30%.

The object of the present invention is therefore to solve at least partially the problems mentioned in connection with the tubular inserts for extra-corporeal circuits of the known type.

A task of the present invention is to provide a tubular insert for extra-corporeal circuits which has a high degree of elasticity so as to ensure an optimum performance in terms of flow rate and a limited deterioration thereof during long periods of use.

Moreover, the task of the present invention is to provide a tubular insert for extra-

corporeal circuits which has a simple and low-cost design.

Furthermore, a task of the present invention is to provide a method for constructing a tubular insert for extra-corporeal circuits.

Lastly, a task of the present invention is to provide a peristaltic pump suitable for effectively operate with the tubular inserts according both to the invention and to the prior art.

The abovementioned object and tasks are achieved by a tubular insert for extra-corporeal circuits according to Claim 1, and by a method for producing said tubular insert according to Claim 11.

The characteristic features and further advantages of the invention will emerge from the description provided hereinbelow, of a number of examples of embodiment, provided by way of a non-limiting example, with reference to the accompanying drawings in which:

Figure 1 shows in schematic form an extra-corporeal circuit used in a therapeutic treatment, specifically a haemodialysis treatment;

Figure 2 schematically shows a tubular insert and peristaltic pump assembly similar to that indicated by II in Figure 1;

Figure 3 schematically shows another tubular insert and peristaltic pump assembly similar to that of Figure 2;

Figure 4 shows a cross-sectional view along the line IV-IV in Figure 3;

Figure 5 shows a front view of the tubular insert according to Figure 2;

Figure 6.a shows a first side view of the tubular insert of Figure 2;

Figure 6.b shows a second side view of the tubular insert of Figure 2;

Figure 7 shows a front view of the tubular insert according to Figure 3;

Figure 8.a shows a cross-sectional view along the line VIII-VIII in Figure 5 or 7, in the case of a tubular insert according to the prior art;

Figure 8.b shows a cross-sectional view along the line VIII-VIII in Figure 5 or 7, in the case of the tubular insert according to the invention;

Figure 9.a shows a cross-sectional view along the line IX-IX in Figure 5 or 7, in the case of a tubular insert according to the prior art;

Figure 9.b shows a cross-sectional view along the line IX-IX in Figure 5 or 7, in the case of the tubular insert according to the invention; and

Figures 10 show detailed views of some possible embodiments of the cross-section according to Figure 9.b.

An insert 28 according to the prior art is described below with reference to the accompanying Figures 1, 3 and 7. This tubular insert 28 is indicated below as the “omega insert”, due to its overall Ω -shape. Such insert is widely used for connecting the tube 20 with the peristaltic pump 22 when the machine 24 is prepared for a therapeutic treatment, for example a haemodialysis treatment.

According to this known solution, the disposable circuit, denoted overall by 26, comprises the tubular insert 28 shown in detail in Figures 3 and 7. From a theoretic point of view, the omega insert 28 can be simply a length of the tube 20 intended to be introduced in the peristaltic pump 22, rather than a separate element.

As can be seen in the accompanying figures, the tubular insert 28 has an inlet portion 34 and an outlet portion 36. For greater clarity, with specific reference to Figure 1, the inlet portion 34 is that intended to be connected to the circuit section 26 coming from the patient, while the outlet portion 36 is that intended to be connected to the circuit section 26 directed towards the dialysing filter.

The loop 32, as can be seen in the accompanying figures, comprises a broad curve 38 which extends along a circumference having a diameter D . The broad curve 38 is connected to the circuit 26 by means of two tube portions 50, 52. The circumference, along which the curve 38 of the loop 32 extends, defines an axis intended, during use, to coincide with the axis of rotation of the rotor 46 of the peristaltic pump 22. Both these axes are indicated below by a single reference letter X since, during use, they coincide along the same axis.

The curve 38 is the tube portion 20 intended to be inserted between the stator 44 and the rotor 46 of the peristaltic pump 22. In the loop 32 of the tubular insert 28, the curve 38 extends preferably along an arc β having amplitude greater than 180° , so as to be able to effectively co-operate with the rollers 48 of rotor 46, which are generally two in number and arranged at a distance of 180° from each other. For example, in the embodiment of the tubular insert 28 shown in Figure 7, the curve 38 extends along an arc β which has amplitude of 270° or more.

It should be noted that this configuration is a quite theoretical one, and it will be generally assumed by the loop 32 only when it is inserted inside peristaltic pump 22,

while, during the non-operative periods where the tubular insert 28 is separated from the peristaltic pump 22, the loop 32 will assume a generally different form determined solely by the reactions inside the tube 20.

The present invention relates to a novel type of tubular insert 28 for connecting an extra-corporeal circuit 26 to a peristaltic pump 22. The tubular insert 28 comprises a loop 32 formed by a tube portion 20. The loop 32 comprises a curve 38 which extends around an axis X . The tube 20 which forms the curve 38 has an oval cross-section with a major axis M and a minor axis m perpendicular to each other, the major axis M being longer than the minor axis m . In the tubular insert 28 according to the invention, the minor axis m of each cross-section of the tube 20 along the curve 38 is parallel to the axis X .

In other words, in the omega tubular insert 28 according to the invention, the circumference of the curve 38 lies in the plane of the major axes M of the oval cross-sections.

Hereinbelow, the expression "oval" is understood as meaning a general closed and continuous flat curve which bounds a convex region and which has a major axis M and a minor axis m perpendicular to each other. The oval is a curve preferably without cusps or angled points; this curve has preferably one axis of symmetry, even more preferably has two axes of symmetry. Figures 10 show some closed and continuous curves which represent specific embodiments of the generic oval shape according to the definition given above. In detail, Figure 10.a. shows an ellipse having major axis M and minor axis m ; Figure 10.b shows a curve composed of two circumference arcs having diameter m connected together by two straight segments having length $M-m$; Figure 10.c shows a curve composed of two circumference arcs having diameter smaller than m connected together by two circumference arcs having diameter greater than M ; finally, Figure 10.d shows a generic curve inscribed inside a rectangle having sides M and m . The axes M and m are indicated solely in Figure 10.a in relation to the mean ellipse within the thickness of the wall. Obviously, the person skilled in the art will have no difficulty in applying the indicated parameters also to other possible cases.

The above described omega insert 28 according to the invention is preferably used in connection with a specific peristaltic pump 22 which is itself part of the invention. Such peristaltic pump 22 is briefly described hereafter with specific reference to figures 3 and

4 and.

The peristaltic pump according to the invention is suitable for co-operating with a common tube 20 having a circular cross section with an external diameter d (see also figure 9.a). The peristaltic pump 22 comprises, in a manner known per se, a stator 44 and a rotor 46 defining a rotation axis X and comprising a plurality of rollers 48 suitable for pressing the tube 20 against the stator 44. In the peristaltic pump 22 according to the invention, the rotor 46 further comprises a couple of radial fingers 54 placed immediately before each roller 48 with respect to the rotation direction; the minimum axial distance a between the radial fingers 54 is less than d .

In each couple, the two radial fingers 54 are so arranged to contact the tube 20 on opposite sides. More specifically, in each couple, the two radial fingers 54 are so arranged to constrain the tube 20 along an axial direction, i.e. a direction perpendicular to the (radial) direction along which the roller 48 presses the tube 20. Such constraint forces the circular section of a common tube 20 to assume an oval shape according to the invention, i.e. with the minor axis m parallel to the axis X . Similarly, in case of a tube 20 or insert 28 with an oval cross section, the radial fingers 54 force them to maintain an oval shape according to the invention, i.e. with the minor axis m parallel to the axis X .

As stated above, the radial fingers 54 are placed before the rollers 48 with respect to the rotation direction. This expression means that, when a tube 20 is engaged with the peristaltic pump 22 and the rotor 46 is rotating, each section of the tube 20 passes first between the two radial fingers 54 and, immediately after that, is pressed by the roller 48 against the stator 44.

Each radial finger 54 preferably comprises a radial roller suitable to rotate around a radial axis Y (see figure 4). Such feature permits to minimize the friction in the contact between the radial finger 54 and the wall of the tube 20 during operation of the peristaltic pump 22.

In each radial finger 54, the outer radial end (i.e. the end far from axis X) is preferably tapered to a rounded tip (see figures 4 and 5). Such feature entails two advantages. First of all the tapering of the outer end allows, at each turn of the rotor 46, an easy engagement of the portion 50 of the tube 20 between the fingers 54. As can be clearly seen in figure 4, the profile of the two fingers 54 defines a large entrance for the tube

20. Such large entrance easily conducts the portion 50 to the narrow space between the fingers 54 even if the tube 20 is in a slightly improper position. Secondly, the rounded tip minimize the risk for the portion 50 to be pricked or even improperly pressed by the fingers 54.

According to an embodiment of the invention (not shown), the rotor 46 of the peristaltic pump 22 comprises two similar couples of radial fingers 54 for each roller 48: one placed immediately before and the other placed immediately after the roller 48, with respect to the rotation direction.

Another insert 28 according to the prior art is described below with reference to the accompanying Figures 2, 5 and 6. This tubular insert 28 is indicated below as the “alpha insert”, due to its overall α -shape. Such particular tubular insert 28 was developed by the Applicant and is widely used for facilitating assembly of the tube 20 with the peristaltic pump 22 when the machine 24 is prepared for a therapeutic treatment, for example a haemodialysis treatment.

According to this known solution, the disposable circuit, denoted overall by 26, comprises the tubular insert 28, commonly called an “alpha clip”, shown in detail in Figures 2, 5 and 6.

According to its alpha embodiment, the tubular insert 28 comprises a double connector 30 and a loop 32 formed by a tube portion 20 of suitable length. As can be seen in the accompanying figures, the tubular insert 28 has overall an alpha shape since the inlet portion 34 and the outlet portion 36 overlap each other in the region of the double connector 30. For greater clarity, with specific reference to Figure 1, the inlet portion 34 is that intended to be connected to the circuit section 26 coming from the patient, while the outlet portion 36 is that intended to be connected to the circuit section 26 directed towards the dialysing filter. As can be noted from the accompanying figures 5 and 6, the inlet portion 34 and the outlet portion 36 cross each other, in different planes, inside the double connector 30.

The loop 32, as can be seen in the accompanying figures 2, 5 and 6, comprises a broad curve 38 which extends along a cylindrical helix and is connected to the connector 30 by means of two substantially straight tube segments 40 and 42. The cylindrical helix, along which the curve 38 of the loop 32 extends, defines an axis intended, during use, to coincide with the axis of rotation of the rotor 46 of the peristaltic pump 22. Both these

axes are indicated below by a single reference letter X since, during use, they coincide along the same axis. Moreover, the cylindrical helix has a pitch p which is decidedly smaller than the diameter D such that, according to a first approximation, it may be considered that the curve 38 lies in a plane and therefore describes the arc of a circumference. It should be considered, for example, that, according to a first preferred embodiment, the diameter D of the cylindrical helix is about 50 mm, while the pitch p is only about 6 mm. In view of this approximation, most of the remarks reported above with respect to the omega insert are also valid with respect to the alpha insert.

The approximation of the cylindrical helix portion to an arc of a circumference having the same diameter D is further justified in that the peristaltic pump 22 acts on the tubular insert 28 exactly as though the latter were extending in a plane perpendicular to the axis X of the rotor 46. This slight geometric discrepancy is fully offset in reality by the deformability of the tube 20.

The curve 38 is the tube portion 20 intended to be inserted between the stator 44 and the rotor 46 of the peristaltic pump 22. In the loop 32 of the tubular insert 28, the curve 38 extends preferably along an arc β having an amplitude greater than 180° , so as to be able to effectively co-operate with the rotor 46, the rollers 48 of which are generally two in number and arranged at a distance of 180° from each other. For example, in the embodiment of the tubular insert 28 shown in Figure 5, the curve 38 extends along an arc β which has an amplitude of about 270° . It should be noted that this configuration is a quite theoretical one, and it will be generally assumed by the loop 32 only when it is inserted inside peristaltic pump 22, while, during the non-operative periods where the tubular insert 28 is separated from the peristaltic pump 22, the loop 32 will assume a generally different form determined solely by the reactions inside the tube 20.

The present invention also relates to a novel type of the alpha tubular insert 28. Such tubular insert 28 for connecting an extra-corporeal circuit 26 to a peristaltic pump 22, comprises a double connector 30 and a loop 32 formed by a tube portion 20. The loop 32 comprises a curve 38 which extends around an axis X and is connected to the double connector 30 by means of two substantially straight tube segments 40, 42. The tube 20 which forms the curve 38 has an oval cross-section with a major axis M and a minor axis m perpendicular to each other, the major axis M being longer than the minor axis m . The minor axis m of each cross-section of the tube 20 along the curve 38 is parallel

to the axis X.

If the curve described by the loop 32 is approximated to a circumference instead of to a cylindrical helix, in the tubular insert 28 according to the invention, that circumference lies in the plane of the major axes M of the oval cross-sections.

As already explained above, the expression “oval” is understood as meaning a general closed and continuous flat curve which bounds a convex region and which has a major axis M and a minor axis m perpendicular to each other.

Specific studies conducted by the Applicant have shown that the oval shape of the cross-section of the tube 20 according to the invention is able to solve most of the problems reported above with respect to the prior art.

As a person skilled in the art is well aware, the mechanical characteristics of the tube 20 depend, among other things, on the intrinsic characteristics of the material and on the geometric characteristics of the involved sections. In the specific case of the tube 20 according to the invention, the geometric characteristics are considerably more advantageous than those of the prior art tubes.

The tube 20 of the tubular insert 28 according to the prior art is generally made of PVC plasticized with a suitable additive, usually DOP. The tube 20 of the tubular insert 28 according to the invention may be made of any material suitable for the specific use. In particular, it is preferably made of PVC plasticized with a suitable additive. The plasticizer can be advantageously TOTM, in order to comply with the new standards which aim to abolish DOP.

With respect to the overall mechanical characteristics of the tube 20, it is to be noted here that the intrinsic characteristics of the PVC material are significantly penalized by the replacement of DOP with TOTM. However, the studies conducted by the Applicant have shown that the geometric characteristics of the oval cross-sections of the tube 20 according to the invention are able to overcome in an optimum manner this negative consequence.

A number of results of tests carried out by the Applicant, in order to compare the characteristics of the tube 20 with an oval cross-section according to the invention with those of the conventional tube 20 which has a circular cross-section, where both tubes are made of PVC-TOTM, are described below. A tube 20, the oval section of which has a length equal to the length of the circumference defining the section of the tube of the

known type, was considered. A new tube according to the invention ensures a flow rate of about 320 ml/min and is subject, after 6 hours continuous operation, to a slight reduction in flow rate of between 4% and 5%.

From the above it can be understood immediately how the tubular insert according to the invention ensures a better performance than similar inserts of the known type, both in the case of PVC-TOTM inserts and - this being a particularly significant result - in the case of PVC-DOP inserts.

As already reported above, both the omega and the alpha configurations previously described for the loop 32 according to the prior art, are theoretical ones. In practice the tube 20, especially when it is not engaged with the peristaltic pump 22, assumes a different overall configuration which minimizes the deformation energy.

According to its real configuration, the length of the tube 20 intended to originate an omega insert 28 is almost straight. The described omega configuration will be assumed by the loop 32 when it is inserted inside peristaltic pump 22; the act of bending the straight length of tube 20 entails a deformation of the involved cross sections which is disclosed below.

According to its real configuration, the loop 32 of an alpha insert 28 comprises a curve 38 which extends along an arc β having an amplitude smaller than the theoretical one and which has a diameter smaller than the theoretical one. Moreover, the real loop 32 comprises two tube segments 40, 42 which are slightly curved rather than straight.

According to both the real alpha and omega configurations, as schematically shown in figures 8.a, the tube 20 has, at the apex of curve 38, an oval cross-section with its major axis M parallel to the axis X , i.e. opposite to the one described above with respect to the invention. In other words, the tubular insert 28 according to the prior art, spontaneously assume an inefficient configuration, in which the geometric characteristics of the cross-sections noticeably penalize the overall mechanical characteristics of the tube 20.

As the skilled person may easily understand, the radial fingers 54 of the rotor 46 described above are intended to force the tube 20 in the right configuration according to the invention (i.e. with the minor axes m of the cross-sections of the tube 20 parallel to axis X), even if the tube 20 tends to spontaneously assume the opposite configuration which minimizes the deformation energy (i.e. with the minor axes m of the cross-sections of the tube 20 perpendicular to axis X). This function of the radial fingers 54 is

very important in the case of an omega insert 28 obtained with a length of the tube 20, i.e. an insert 28 in which the tube 20, contrary to the alpha insert, has no constraint with respect to its orientation.

As already described above, the production of the omega tubular inserts 28 according to the prior art simply involves providing a tube portion 20 of suitable length and curving it so as to form the loop 32.

The production of the alpha tubular inserts 28 according to the prior art involves providing a double connector 30 and a tube portion 20 of suitable length which is curved so as to form the loop 32. Each end of the tube 20 is then fitted onto a proper attachment provided on the double connector 30.

In order to produce a tubular insert 28 according to the invention (either an omega or alpha one) it was proposed using the conventional method described above, subject to the sole condition of using a tube 20 with an oval cross-section instead of the conventional tube 20 with a circular cross-section. Obviously, in order to obtain an insert 28 according to the invention, the tube 20 with an oval cross-section must be curved so that the axis X of the loop 32 is parallel to the minor axes m of the cross-sections. For both the omega insert and, adopting the usual approximation mentioned above, for the alpha insert, it may also be said that the tube 20 must be curved so that the loop 32 remains within the plane which contains the major axes M of the cross-sections of the tube 20 itself.

This method, however, does not produce satisfactory results. It was noted, in fact, that, owing to the geometric characteristics of the oval cross-section, the curvature of the tube 20 in the plane of the major axes M does not provide a stable equilibrium for the insert system as a whole. The result is that the tube 20 spontaneously tends to transfer the curvature into a plane containing the minor axes m , where the moment of inertia of the oval cross-section is lower. This occurs at least at a distance from the external constraints acting on the tube 20, if any, like the attachments of the double connector 30 in the alpha form. The result is that, in the alpha form with torsional constraints in the region of the attachment points on the double connector 30, the loop 32 no longer lies either along a cylindrical helix or in a plane, but describes a three-dimensional curve which lies well outside the desired plane. Conversely, in the omega form and in the alpha form without torsional constraints acting at the attachments points on the double

connector 30, also the ends of the tube 20 tend to rotate. The entire tube 20 thus assumes a position where the curvature of the loop 32 lies in the plane of the minor axes m , thus producing a result opposite to that described above for the tubular insert 28 according to the invention.

The method for producing an insert 28 according to the invention comprises the steps of:

- Providing a tube portion 20 which has a circular cross-section and a suitable length;
- Bending the tube portion 20 so as to form the loop 32;
- Subjecting the loop 32 to compression along the axis X so as to ovalize the cross-sections of the tube 20 at least in the zone of the curve 38; and
- At the same time as compression along the axis X, subjecting the loop 32 to a physical treatment suitable to allow internal reorganization of the material which stabilizes its deformed condition.

Accordingly, the loop 32 is formed from a tube portion 20 of the conventional type, typically with a circular cross-section. Only subsequently the loop 32 is subjected to a combined compressive action along the axis X and a physical treatment, e.g. a thermal cycle for heating and cooling the material. In this way it is ensured that the curvature of the loop 32 and the deformation of the cross-sections of the tube 20 caused by compression are rendered permanent by the physical treatment. The physical treatment, e.g. the heating step in the deformed state and the subsequent cooling step, in fact result in internal reorganization of the material which stabilizes its condition. In this way it is ensured that the axis X of the loop 32 is stably parallel to the minor axes m of the cross-sections or, adopting the usual approximation, that the loop 32 is stably contained within the plane which contains the major axes M of the cross-sections of the tube 20 itself.

According to some embodiments, the method further comprises the steps of providing a double connector 30 and connecting the loop 32 to the double connector 30.

According to some other embodiments of the method according to the invention, ultrasonic treatments and/or radiofrequency treatments are used, instead of the thermal cycle, in order to speed up the production of the tubular insert 28. In order to satisfy specific needs, a combination of thermal, ultrasonic and/or radiofrequency treatments can be used.

As the person skilled in the art may well understand from that described above, the tubular insert 28, the peristaltic pump 22 and the method for producing the insert 28 according to the invention are able to solve at least partly the drawbacks mentioned above in relation to the prior art.

In particular, it will be clear how the tubular insert 28 according to the invention has a high degree of elasticity so as to achieve an optimum performance in terms of flow rate and a limited deterioration thereof following long periods of operation, even in the case where the tube is made of PVC-TOTM.

Moreover, the peristaltic pump according to the invention is able to obtain, from the well-known tubular inserts, advantages similar to those obtainable with the tubular inserts 28 according to the invention. The pump according to the invention is suitable for co-operating, without distinction, with the insert 28 according to the invention (both in its alpha and omega form) or with a tubular insert commonly used in the peristaltic pumps according to the prior art.

Lastly, it will also be clear to the person skilled in the art how both the tubular inserts 28, the peristaltic pump 22 and the method for producing the insert 28 constitute a simple and low-cost solution.

With regard to the embodiments of the tubular insert, of the peristaltic pump and of the production method described above, the person skilled in the art may, in order to satisfy specific requirements, make modifications to and/or replace elements described with equivalent elements, without thereby departing from the scope of the accompanying claims.

CLAIMS

1. Tubular insert (28) for connecting an extra-corporeal circuit (26) to a peristaltic pump (22), comprising a loop (32) formed by a tube portion (20), wherein the loop (32) comprises a curve (38) which extends around an axis X , where the tube (20) which forms the curve (38) has an oval cross-section with a major axis M and a minor axis m perpendicular to each other, the major axis M being longer than the minor axis m , and wherein the minor axis m of each cross-section of the tube (20) along the curve (38) is parallel to the axis X .
2. Tubular insert (28) according to claim 1, further comprising a double connector (30), wherein the curve (38) of the loop (32) is connected to the double connector (30) by means of two substantially straight tube segments (40, 42).
3. Insert (28) according to claim 1 or 2, wherein the oval cross-section is a closed and continuous flat curve which bounds a convex region.
4. Insert (28) according to any one of the preceding claims, wherein the oval cross-section is a curve without cusps or angled points.
5. Insert (28) according to any one of the preceding claims, wherein the oval cross-section has one axis of symmetry, preferably has two axes of symmetry.
6. Insert (28) according to any one of the preceding claims, wherein the tube (20) is made of PVC comprising at least one plasticizer, preferably TOTM.
7. Peristaltic pump (22) suitable for co-operating with a tube (20) having a circular cross section with an external diameter d , the peristaltic pump (22) comprising a stator (44) and a rotor (46) defining a rotation axis X and comprising a plurality of rollers (48) suitable for pressing the tube (20) against the stator (44), wherein the rotor (46) further comprises a couple of radial fingers (54) placed immediately before each roller (48) with respect to the rotation direction, the minimum axial distance (a) between the radial fingers (54) being less than d .
8. Peristaltic pump (22) according to claim 7, wherein each radial finger (54) comprises a radial roller suitable to rotate around a radial axis Y so as to minimize the friction in the contact between the radial finger (54) and the wall of the tube (20) during operation of the peristaltic pump (22).
9. Peristaltic pump (22) according to claim 7 or 8, wherein the outer radial end of each radial finger (54) is tapered to a rounded tip.

10. Extra-corporeal circuit (26) for circulation of a physiological liquid, comprising an insert (28) according to any one of claims 1 to 6 and a peristaltic pump (22).
11. Extra-corporeal circuit (26) according to claim 10, wherein the peristaltic pump (22) is in accordance with any one of claims 7 to 9.
12. Extra-corporeal circuit (26) according to claim 11, wherein the radial fingers (54) of the peristaltic pump (22) forces the insert (28) to maintain its orientation in which the minor axis m of each cross-section of the tube (20) along the curve (38) is parallel to the axis X .
13. Extra-corporeal circuit (26) for circulation of a physiological liquid, comprising a tube (20) having a circular cross-section and a peristaltic pump (22) according to any one of claims 7 to 9, wherein the radial fingers (54) forces the tube (20) to assume an oval cross-section with a major axis M and a minor axis m perpendicular to each other, the major axis M being longer than the minor axis m , and wherein the minor axis m of each cross-section of the tube (20) along the curve (38) is parallel to the axis X .
14. Machine (24) suitable for carrying out therapeutic treatments, comprising an extra-corporeal circuit according to any claim 10 to 13.
15. Method for producing an insert (28) according to any one of claims 1 to 6, comprising the steps of:
 - providing a tube portion (20) which has a circular cross-section and suitable length;
 - bending the tube portion (20) so as to form the loop (32);
 - subjecting the loop (32) to compression along the axis X so as to ovalize the cross-sections of the tube (20) at least in the zone of the curve (38); and
 - at the same time as compression along the axis X , subjecting the loop (32) to a physical treatment suitable to allow internal reorganization of the material which stabilizes its deformed condition.
16. Method according to claim 15, further comprising the steps of:
 - providing a double connector (30); and
 - connecting the loop (32) to the double connector (30).
17. Method according to claim 15 or 16, wherein the physical treatment comprises a thermal cycle comprising a heating step and a cooling step.

18. Method according to any Claim 15 to 17, wherein the physical treatment comprises an ultrasonic treatment.
19. Method according to any Claim 15 to 18, wherein the physical treatment comprises a radiofrequency treatment.

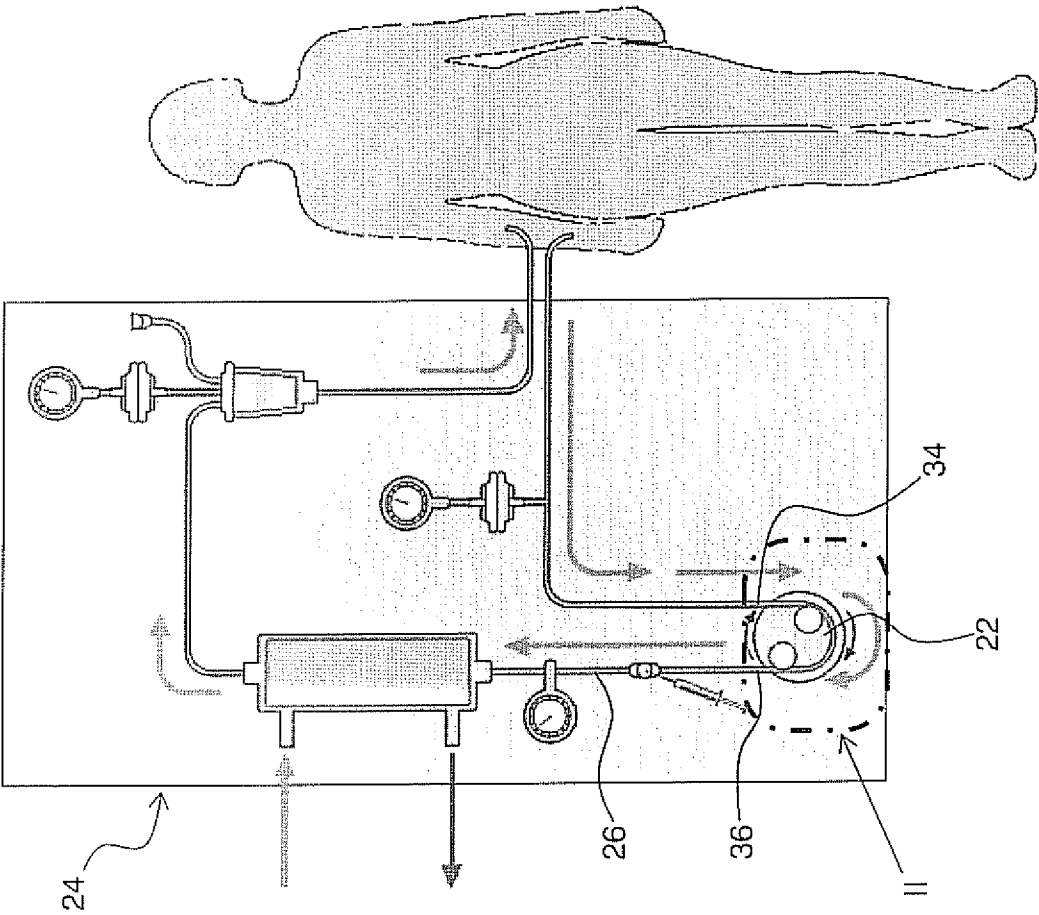


Fig. 1

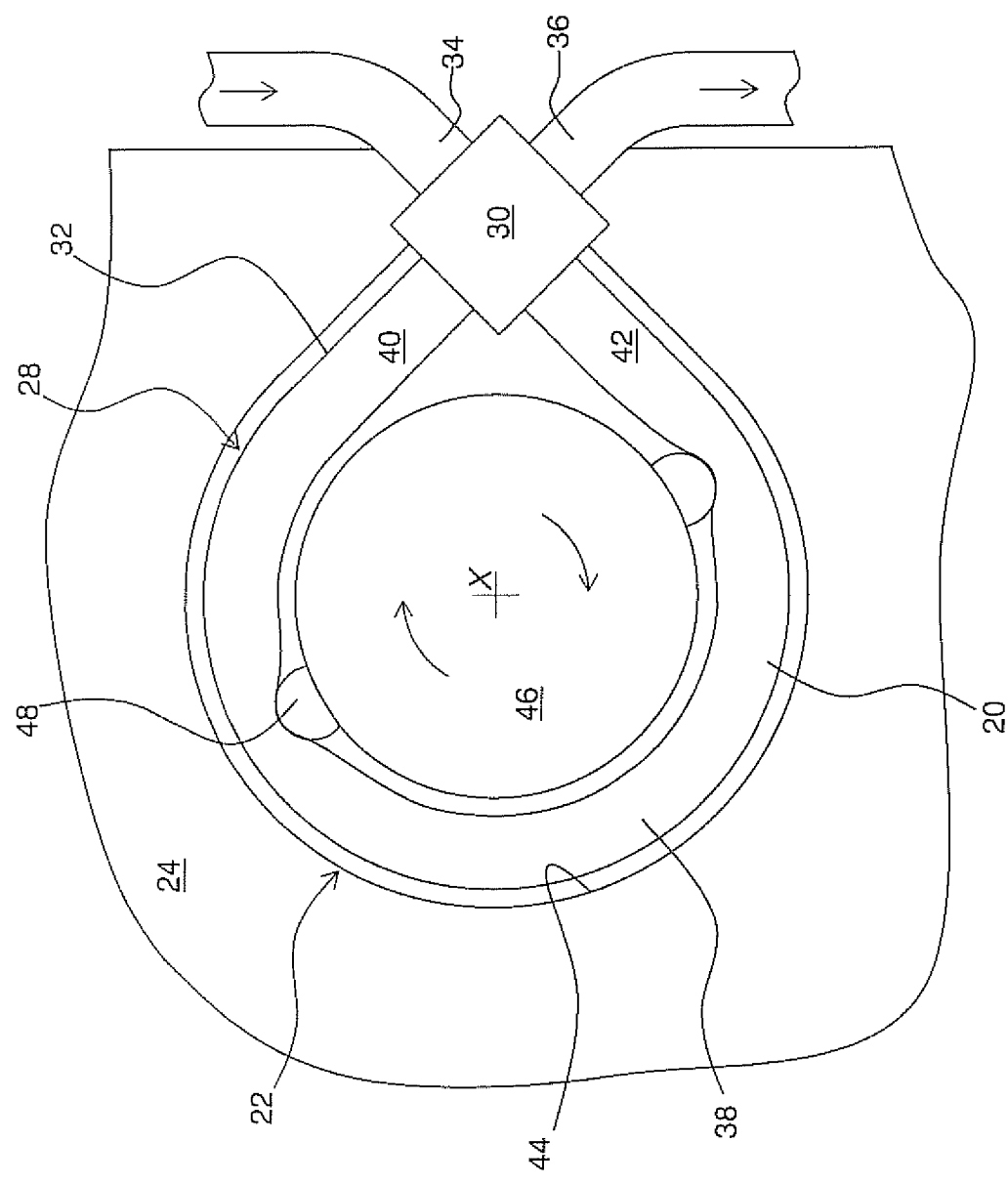


Fig. 2

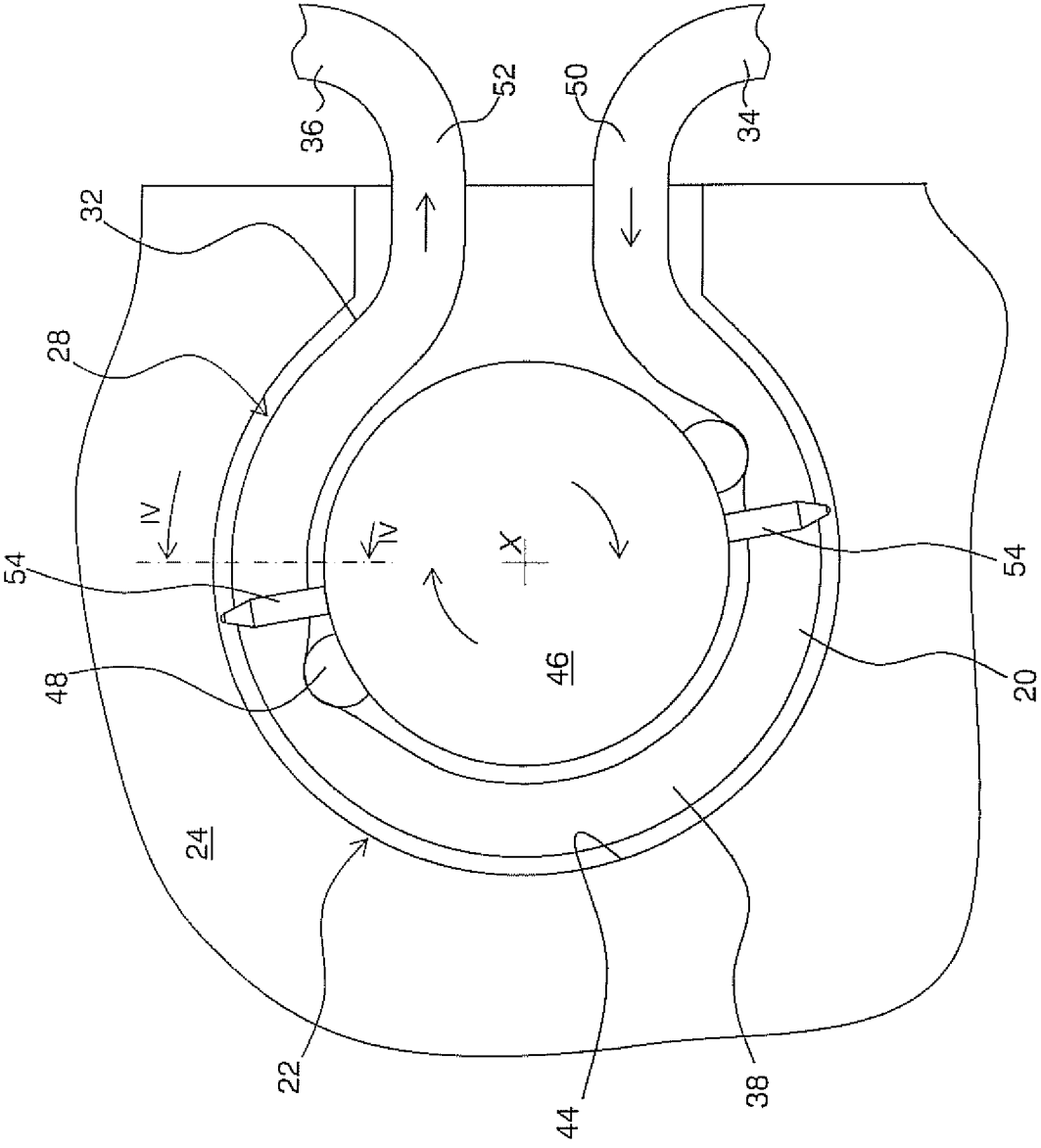


Fig. 3

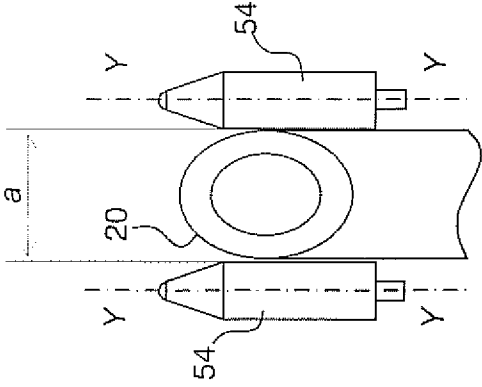


Fig. 4

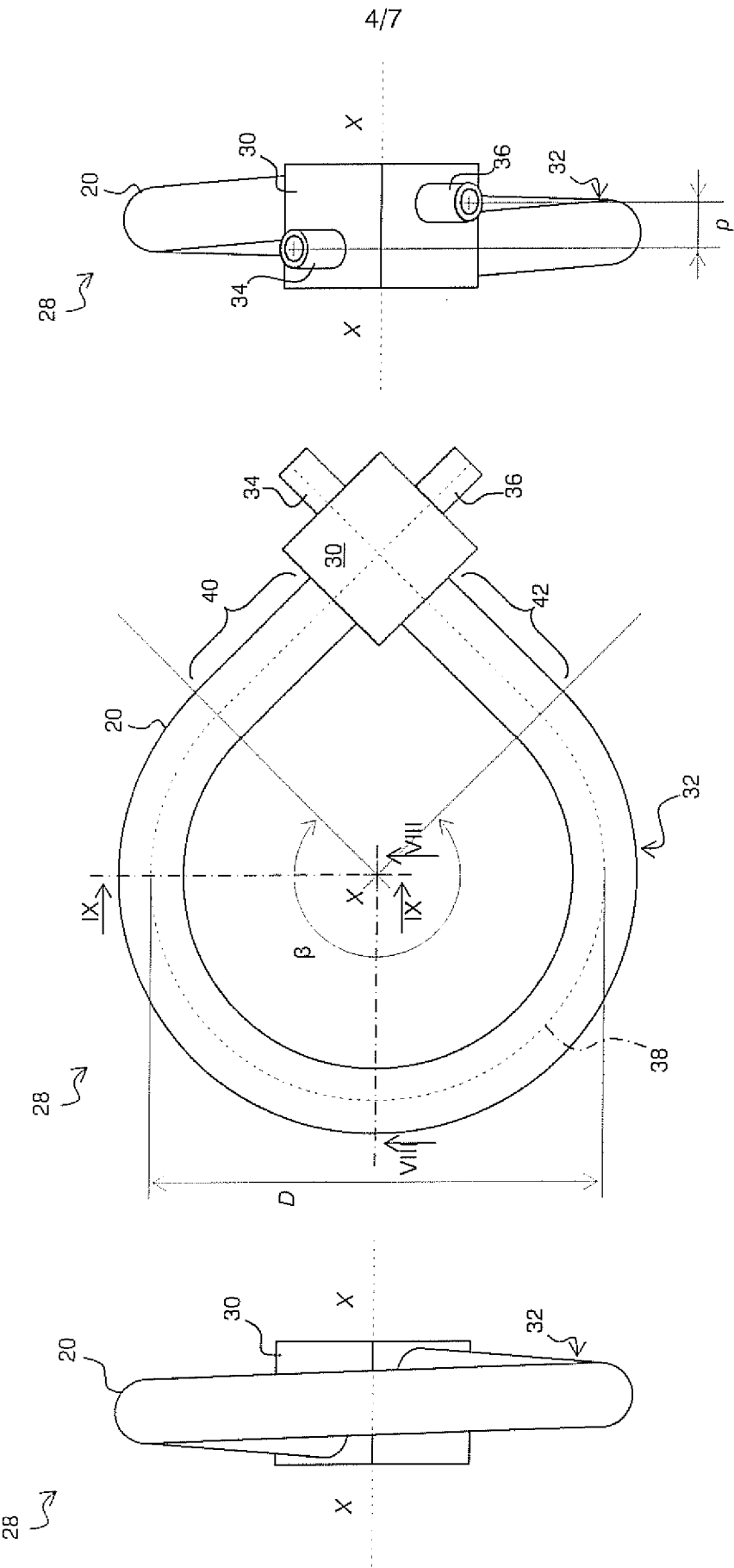


Fig. 6.a

Fig. 5

Fig. 6.b

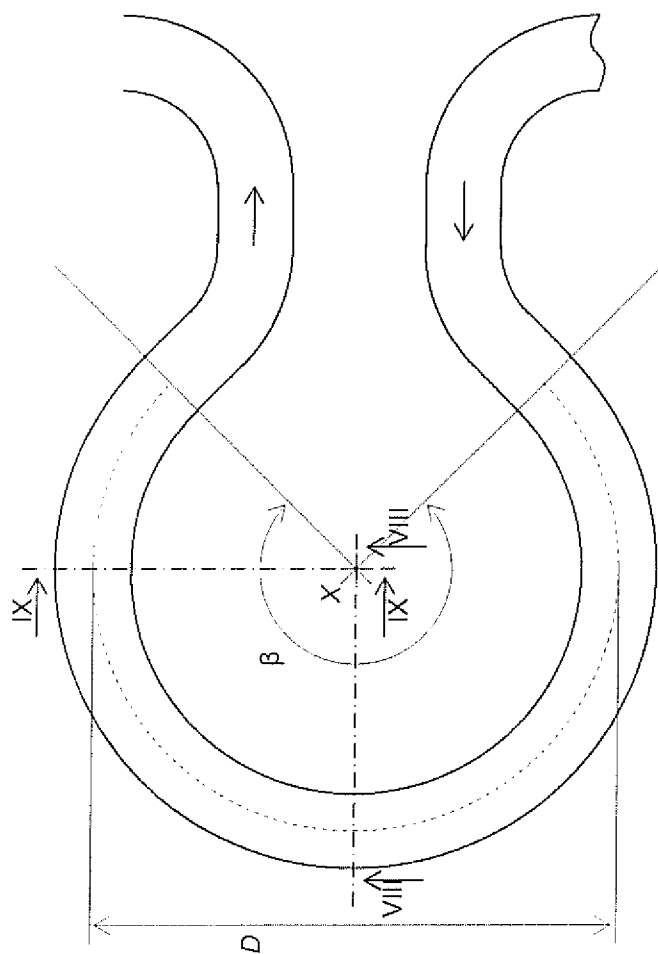


Fig. 7

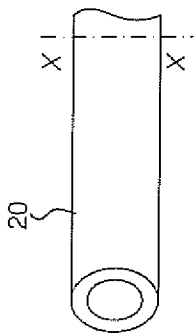


Fig. 8.a
Prior Art

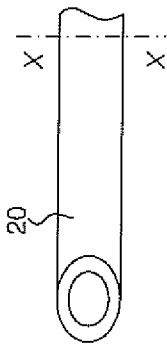


Fig. 8.b

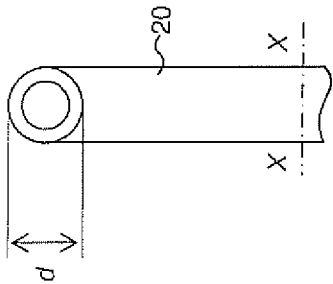


Fig. 9.a
Prior Art

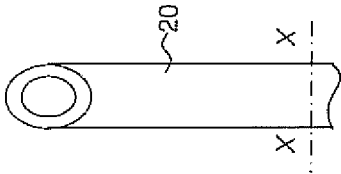


Fig. 9.b

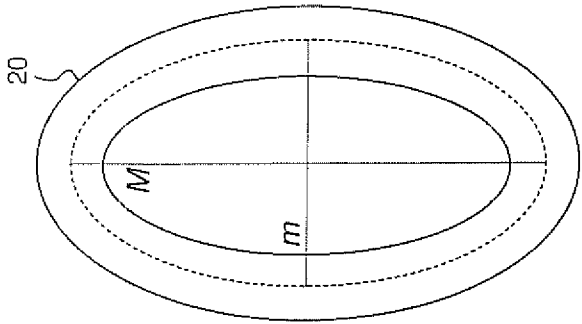


Fig. 10.a

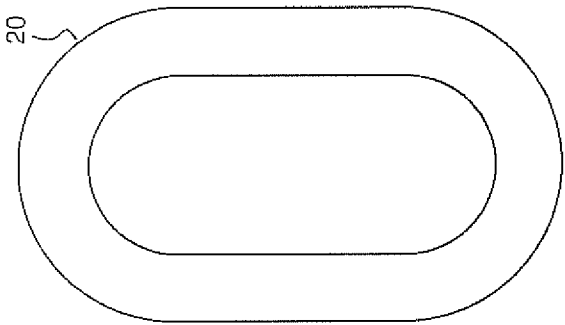


Fig. 10.b

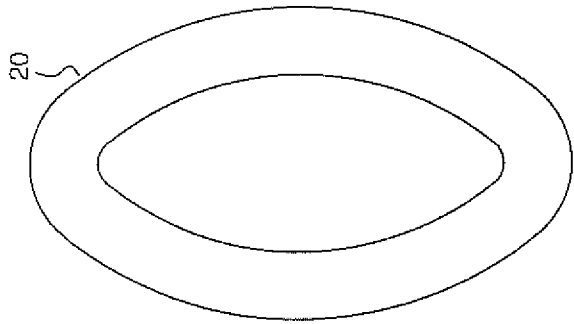


Fig. 10.c

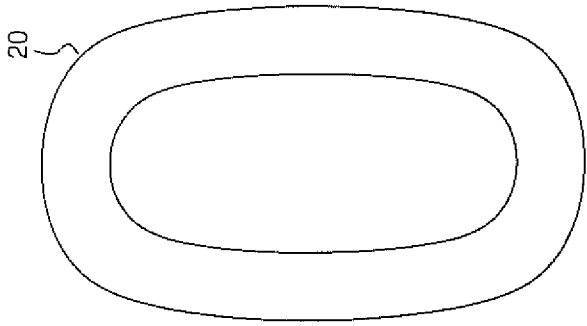


Fig. 10.d

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/057144

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M5/142 A61M1/10 F04B43/12 F04B43/00 F16L11/12 ADD.																				
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) A61M F04B F16L 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 practicable, search terms used) EPO-Internal, WPI Data																				
C. DOCUMENTS CONSIDERED TO BE RELEVANT <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>WO 00/70225 A1 (ANDERSEN G JOHN [DK]; BREKKE BARON PER [DK]) 23 November 2000 (2000-11-23) abstract</td> <td>1,3-6, 10,14, 15,17-19 2,11,12, 16</td> </tr> <tr> <td>Y</td> <td>page 5, line 24 - page 6, line 9 page 8, lines 25-32 page 9, lines 26-32 figures 1-3</td> <td></td> </tr> <tr> <td>Y</td> <td>----- US 4 558 996 A (BECKER HAROLD D [US]) 17 December 1985 (1985-12-17) column 12, lines 4-45 figures 1,12,13</td> <td>11,12</td> </tr> <tr> <td>Y</td> <td>----- US 2010/329910 A1 (BAUMANN MANFRED [DE] ET AL) 30 December 2010 (2010-12-30) paragraph [0020] figure 1</td> <td>2,16</td> </tr> <tr> <td></td> <td>----- -/-</td> <td></td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	WO 00/70225 A1 (ANDERSEN G JOHN [DK]; BREKKE BARON PER [DK]) 23 November 2000 (2000-11-23) abstract	1,3-6, 10,14, 15,17-19 2,11,12, 16	Y	page 5, line 24 - page 6, line 9 page 8, lines 25-32 page 9, lines 26-32 figures 1-3		Y	----- US 4 558 996 A (BECKER HAROLD D [US]) 17 December 1985 (1985-12-17) column 12, lines 4-45 figures 1,12,13	11,12	Y	----- US 2010/329910 A1 (BAUMANN MANFRED [DE] ET AL) 30 December 2010 (2010-12-30) paragraph [0020] figure 1	2,16		----- -/-	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																		
X	WO 00/70225 A1 (ANDERSEN G JOHN [DK]; BREKKE BARON PER [DK]) 23 November 2000 (2000-11-23) abstract	1,3-6, 10,14, 15,17-19 2,11,12, 16																		
Y	page 5, line 24 - page 6, line 9 page 8, lines 25-32 page 9, lines 26-32 figures 1-3																			
Y	----- US 4 558 996 A (BECKER HAROLD D [US]) 17 December 1985 (1985-12-17) column 12, lines 4-45 figures 1,12,13	11,12																		
Y	----- US 2010/329910 A1 (BAUMANN MANFRED [DE] ET AL) 30 December 2010 (2010-12-30) paragraph [0020] figure 1	2,16																		
	----- -/-																			
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.																				
* Special categories of cited documents : <table> <tr> <td> "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed </td> <td> "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family </td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family																
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family																			
Date of the actual completion of the international search		Date of mailing of the international search report																		
10 May 2012		20/08/2012																		
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Willig, Hendrik																		

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2012/057144

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 468 129 A (SUNDEN BENGT [SE] ET AL) 21 November 1995 (1995-11-21) abstract figures 1,2 -----	1,15
A	GB 1 380 812 A (CHAFER LTD J W) 15 January 1975 (1975-01-15) figure 1 -----	1,15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2012/057144

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-6, 10-12, 15-19(completely); 14(partially)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6, 10-12, 15-19(completely); 14(partially)

Tubular insert for a peristaltic pump.

2. claims: 7-9, 13(completely); 14(partially)

Peristaltic pump.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2012/057144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0070225	A1	23-11-2000	AT 278107 T 15-10-2004
		AU 770310 B2 19-02-2004	
		CA 2373397 A1 23-11-2000	
		CN 1350617 A 22-05-2002	
		DE 60014360 D1 04-11-2004	
		DE 60014360 T2 17-02-2005	
		DK 1180215 T3 17-01-2005	
		EP 1180215 A1 20-02-2002	
		JP 2002544439 A 24-12-2002	
		US 2002064470 A1 30-05-2002	
		WO 0070225 A1 23-11-2000	

US 4558996	A	17-12-1985	NONE

US 2010329910	A1	30-12-2010	AT 406520 T 15-09-2008
		AT 490407 T 15-12-2010	
		AU 2005243476 A1 24-11-2005	
		AU 2011202262 A1 09-06-2011	
		AU 2011202263 A1 09-06-2011	
		BR PI0511100 A 27-11-2007	
		CA 2566054 A1 24-11-2005	
		CN 1950604 A 18-04-2007	
		CN 101655082 A 24-02-2010	
		CN 101655083 A 24-02-2010	
		DK 1763636 T3 01-12-2008	
		DK 1985858 T3 21-03-2011	
		EA 200602108 A1 27-04-2007	
		EA 200900911 A1 30-12-2009	
		EA 201000191 A1 30-08-2010	
		EP 1763636 A1 21-03-2007	
		EP 1985858 A1 29-10-2008	
		EP 2275681 A1 19-01-2011	
		ES 2311988 T3 16-02-2009	
		ES 2356026 T3 04-04-2011	
		HK 1099898 A1 17-04-2009	
		JP 4870663 B2 08-02-2012	
		JP 2007537390 A 20-12-2007	
		JP 2011200668 A 13-10-2011	
		JP 2011202664 A 13-10-2011	
		KR 20070012449 A 25-01-2007	
		PT 1763636 E 26-09-2008	
		PT 1985858 E 22-12-2010	
		SI 1763636 T1 28-02-2009	
		US 2007286756 A1 13-12-2007	
		US 2010329910 A1 30-12-2010	
		US 2011150668 A1 23-06-2011	
		WO 2005111424 A1 24-11-2005	

US 5468129	A	21-11-1995	AT 179778 T 15-05-1999
		CA 2195871 A1 15-02-1996	
		DE 69509533 D1 10-06-1999	
		DE 69509533 T2 07-10-1999	
		EP 0774075 A1 21-05-1997	
		JP H10506974 A 07-07-1998	
		US 5468129 A 21-11-1995	
		US 5482447 A 09-01-1996	
		WO 9604480 A1 15-02-1996	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2012/057144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 1380812	A	15-01-1975	NONE
