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(54) Title of the Invention: **Catheter structure with improved lumen fluid through flow and method of making a catheter structure**
Abstract Title: **CATHETER WITH INTRA-LUMEN FINS AND A METHOD OF MAKING A CATHETER**

(57) The catheter 60 has at least one lumen 64 provided with a plurality of fins 80 that extend along the length of the lumen such that an area denoted by the largest circle disposable in the lumen 100 is free of fins. The distance between the fins and the length of the fins may vary depending on the location of the fins in the lumen, for example at the narrow radius areas 70 of the lumen, around the sides of the round portion 68 and along the straight portion 66 of the lumen wall. The fins may act as anti-turbulence elements within the corners or narrow radius portions of the lumen. The fins may be disposed in a D-shaped lumen and the catheter may also comprise a lumen 62 which is circular in transverse cross-section. The fins are preferably made of flexible material and flex with the catheter, in use.

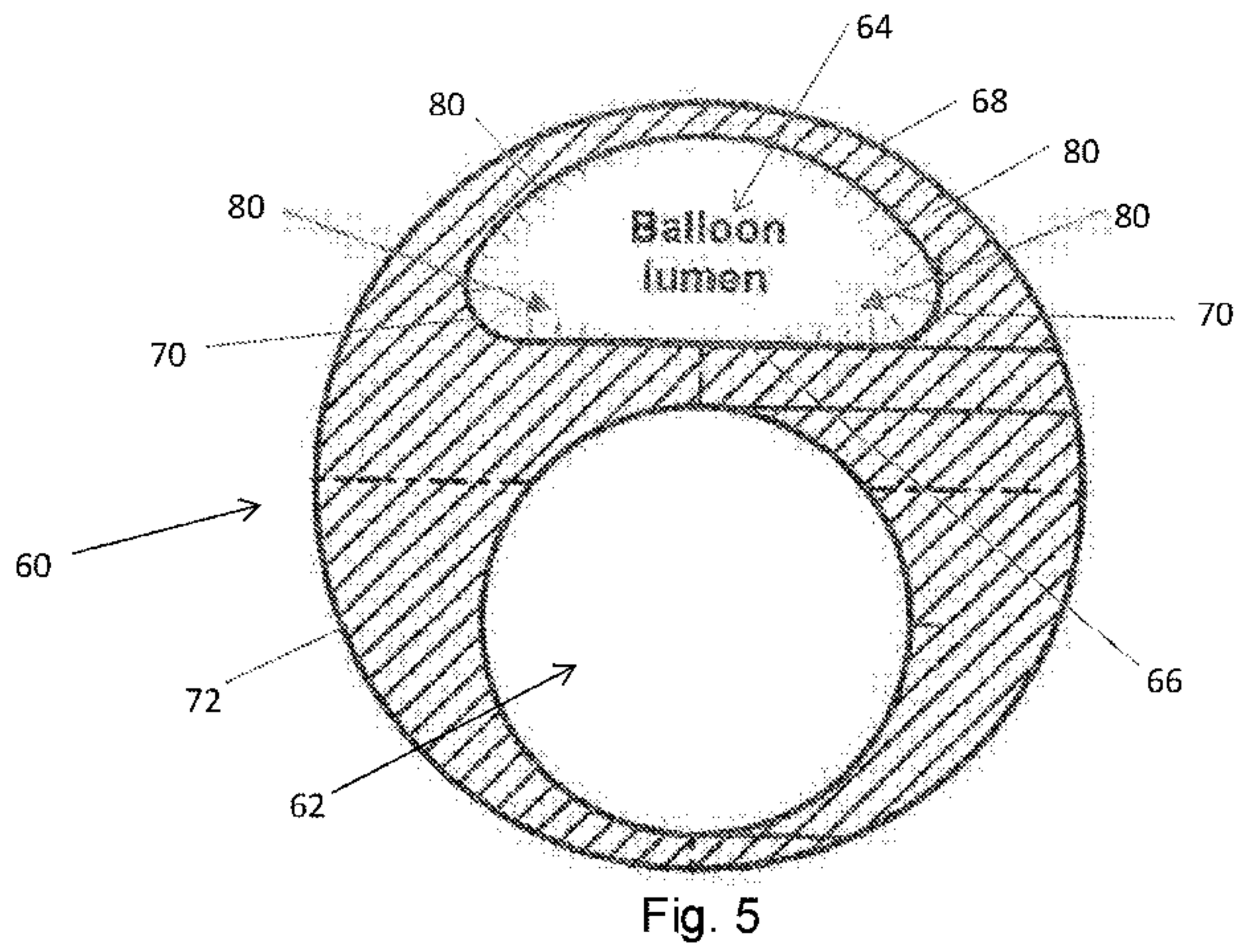

Fig. 5

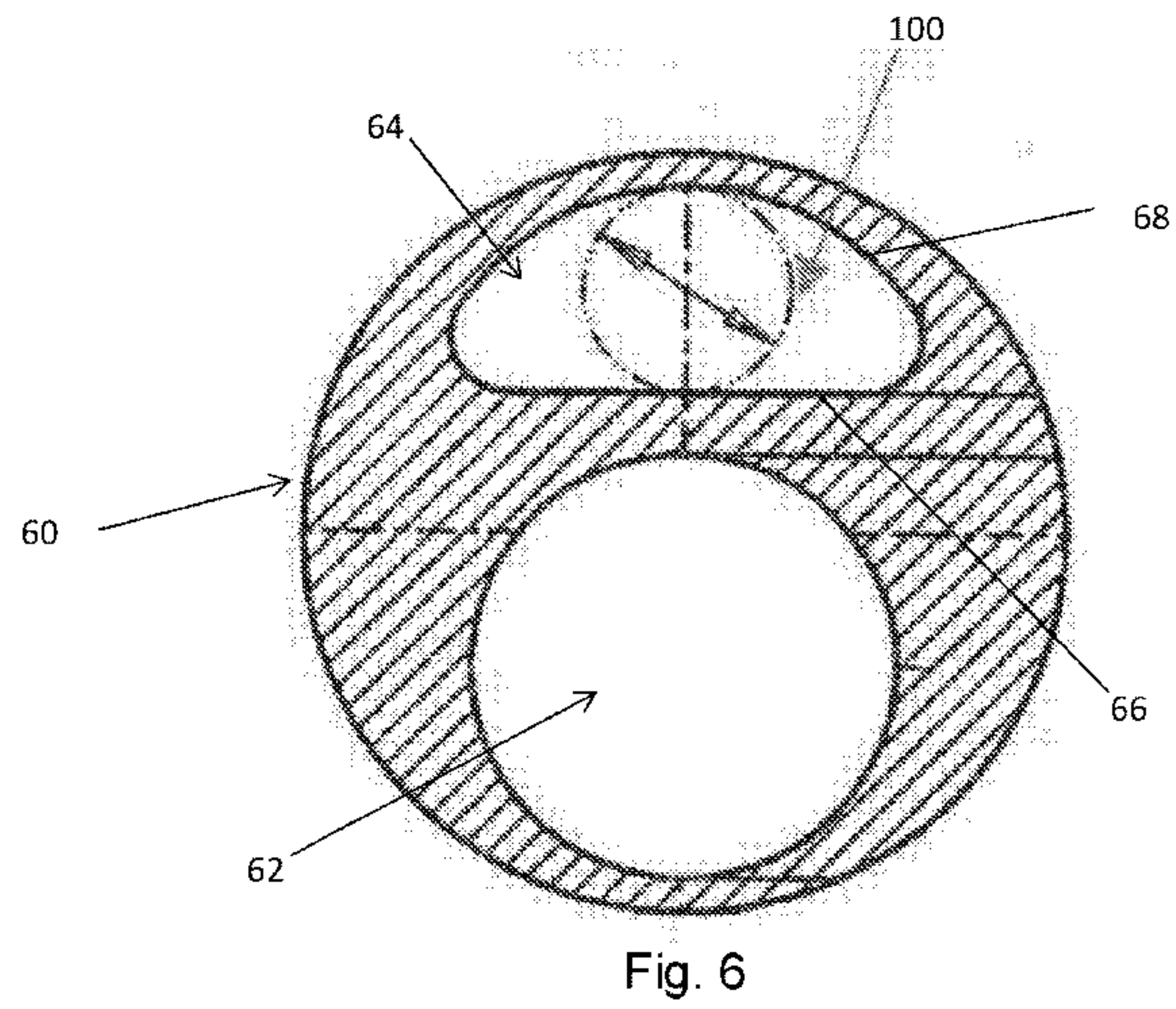

Fig. 6

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

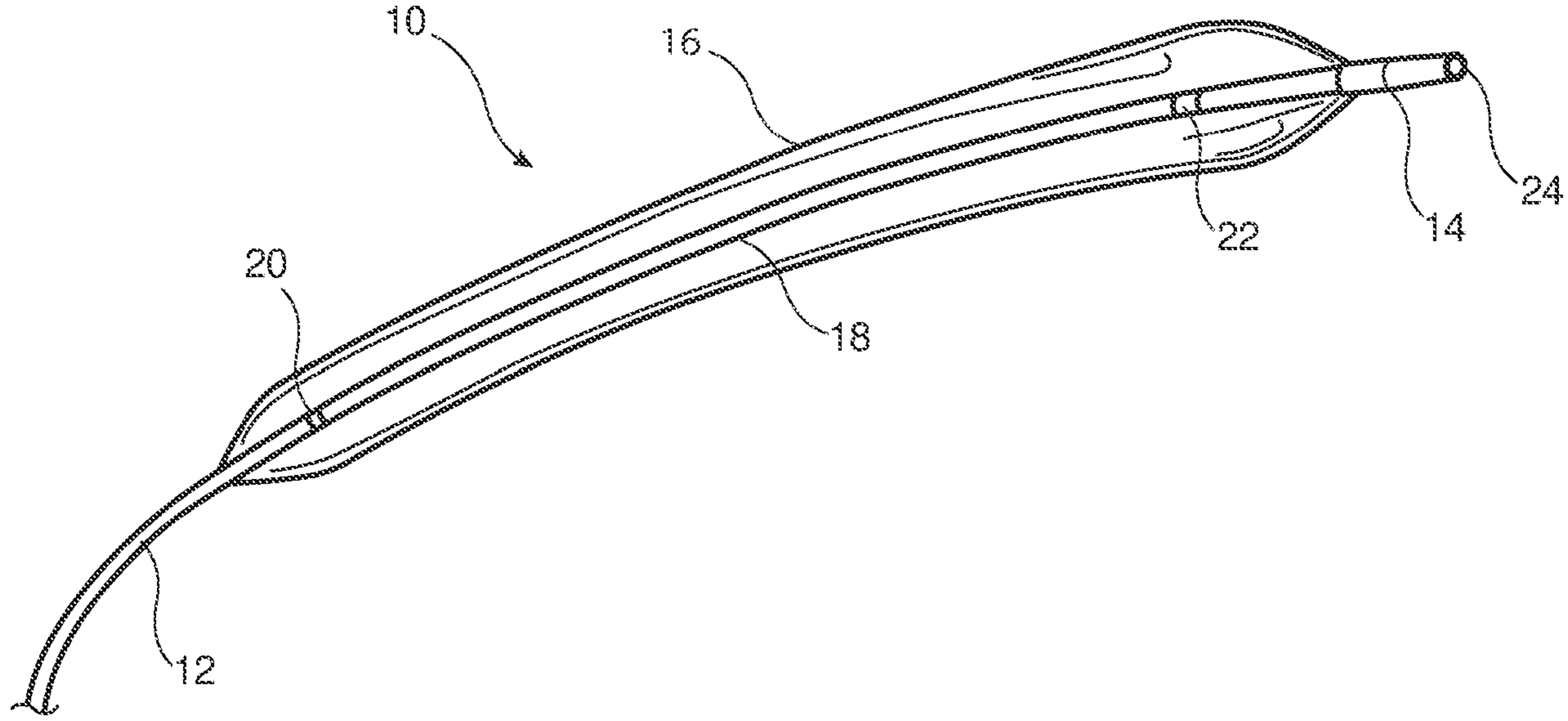

Fig. 1

18 11 19

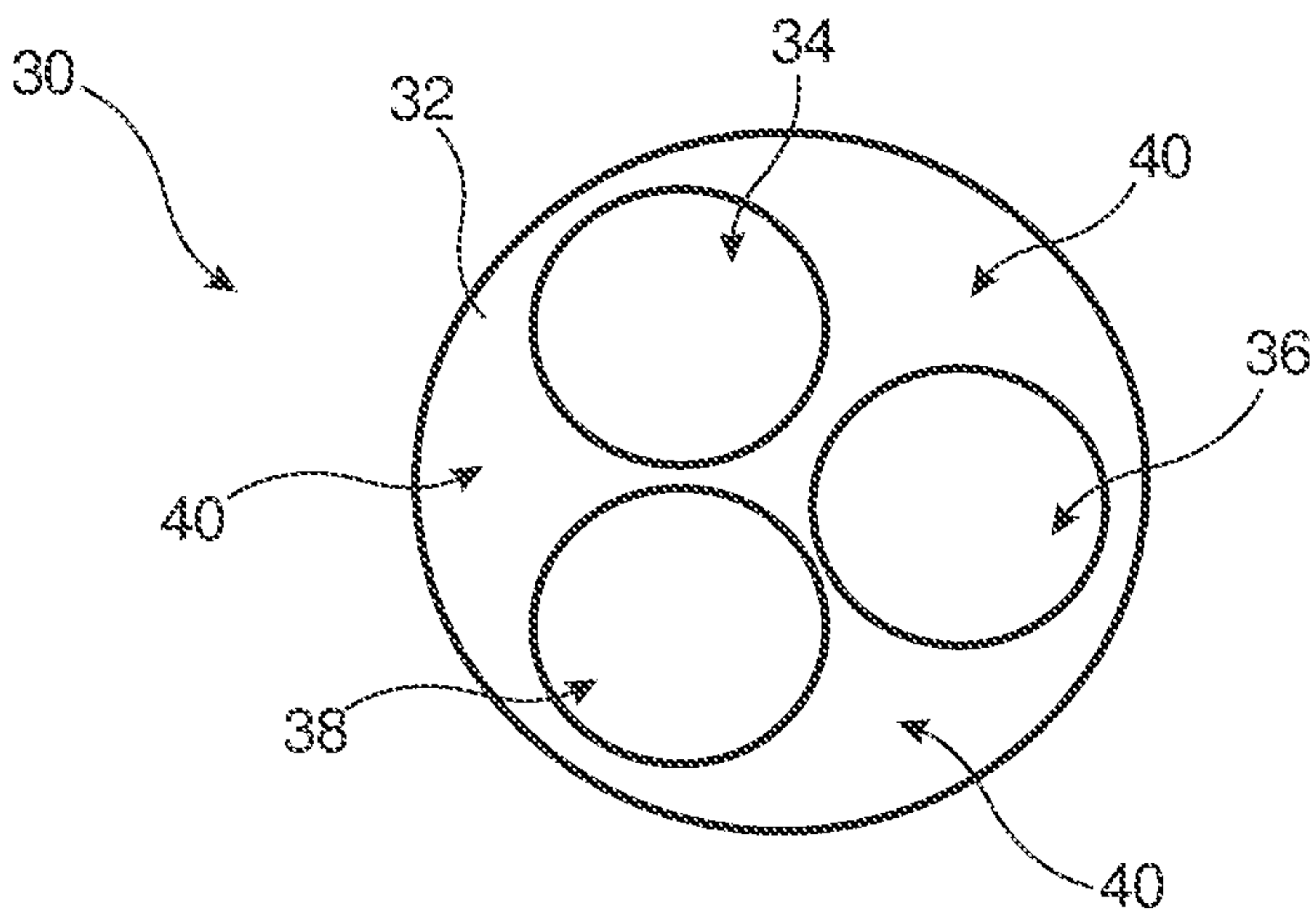

Fig. 2

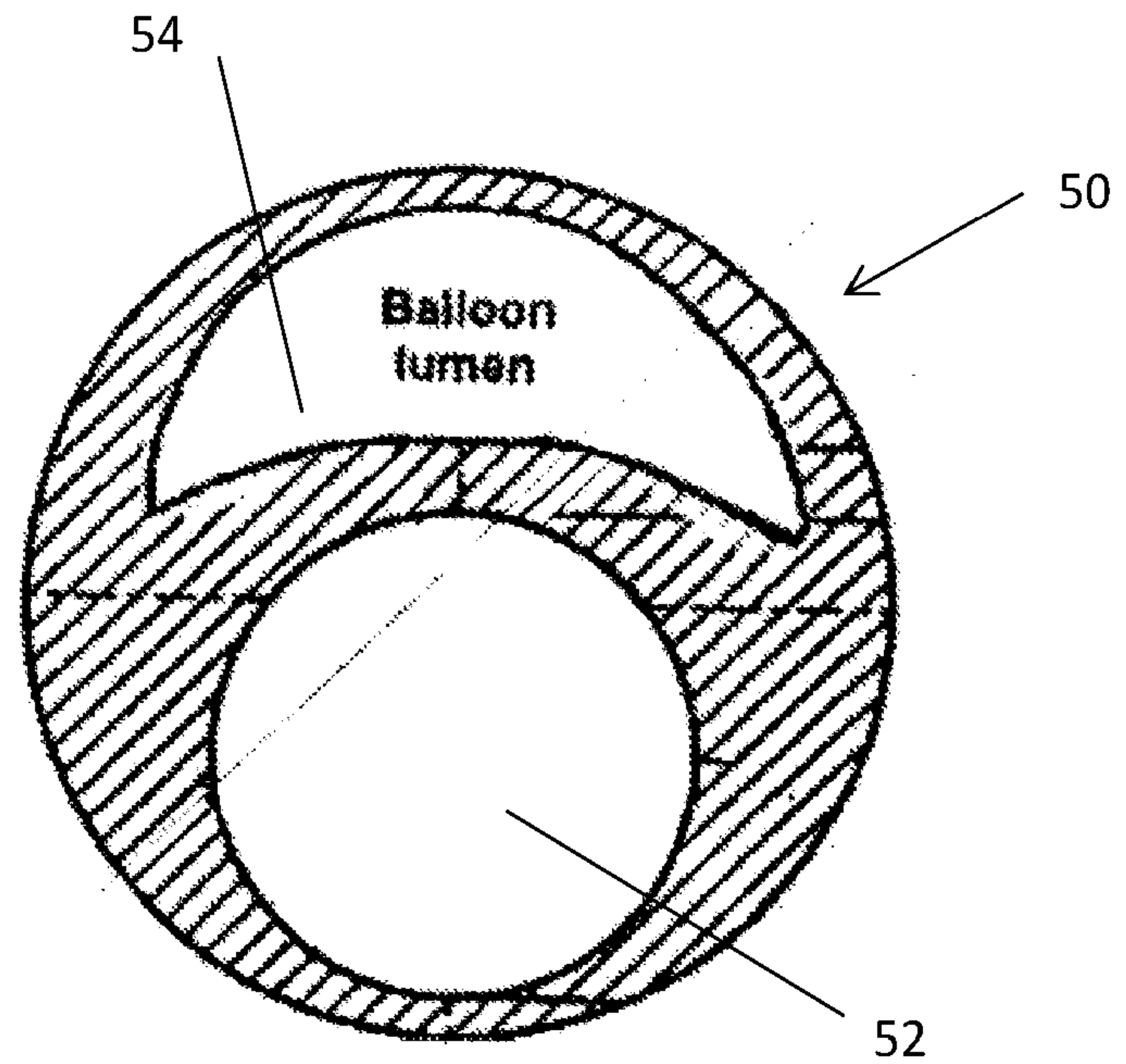

Fig. 3

18 11 19

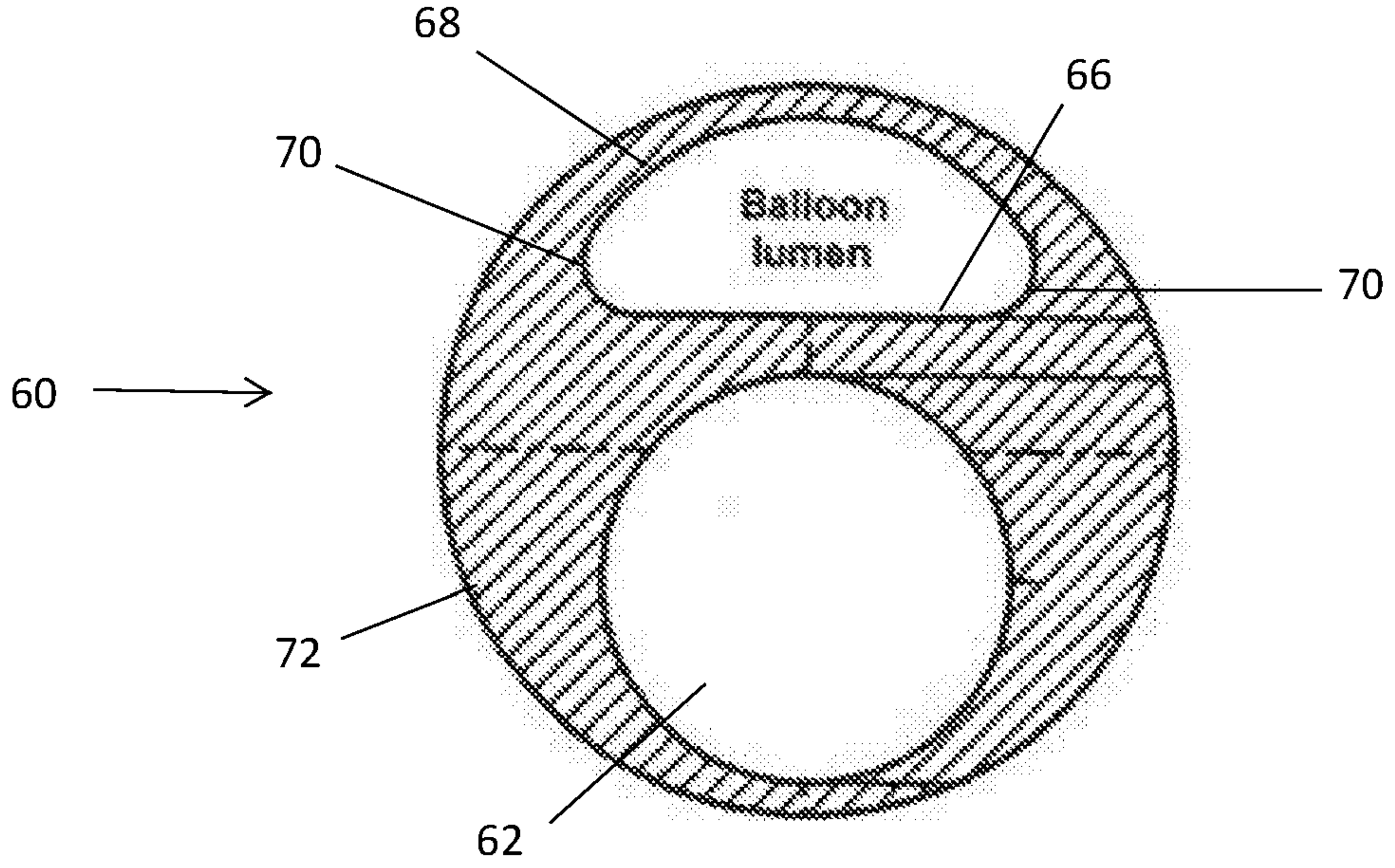

Fig. 4

18 11 19

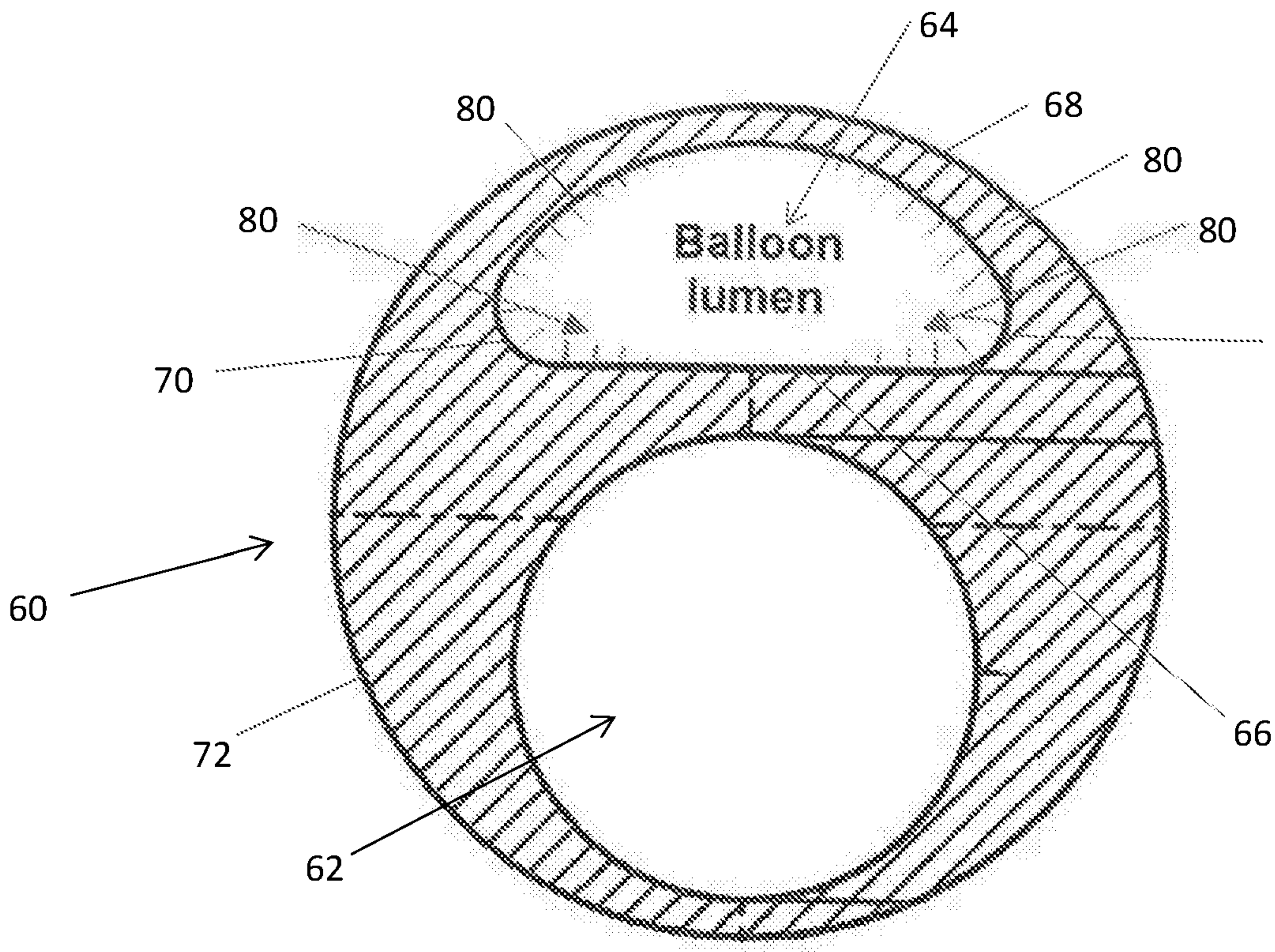

Fig. 5

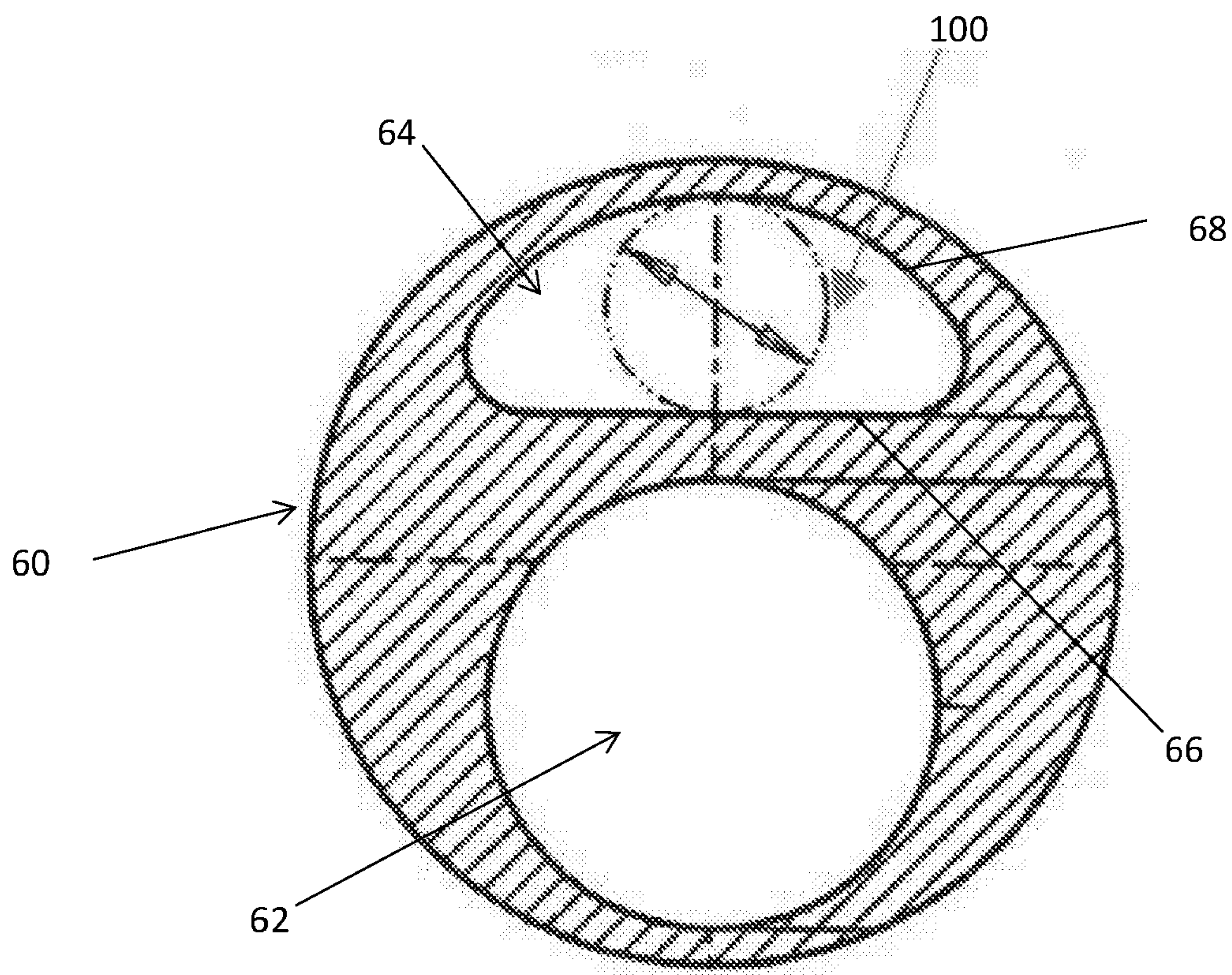

Fig. 6

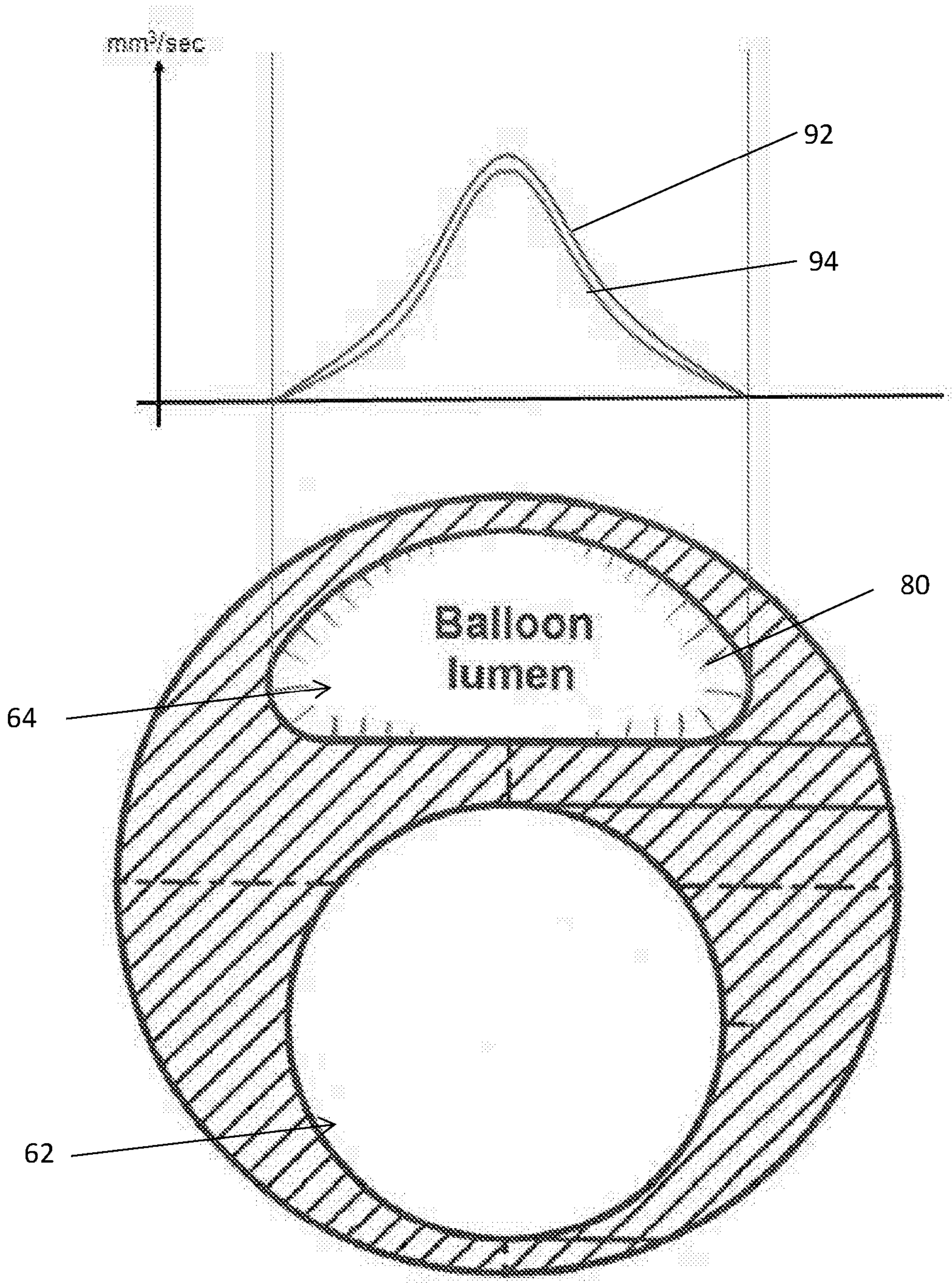

Fig. 7

18 11 19

CATHETER STRUCTURE WITH IMPROVED LUMEN FLUID THROUGH FLOW AND METHOD OF MAKING A CATHETER STRUCTURE

TECHNICAL FIELD

The present invention relates to a catheter structure with improved lumen fluid through flow and to a method of making a catheter structure. The teachings herein are directed in particular to catheters for medical applications, for instance for endoluminal procedures, and in which the catheter typically has a plurality of lumens.

BACKGROUND ART

Catheters are widely used for many medical interventions including endoluminal procedures. While in some cases catheters will have a single lumen passing through the length of the catheter, often a catheter will have a plurality of lumens for different purposes. In many cases, catheters will have a generally round transverse cross-section, which minimises the footprint of the catheter within a patient's vasculature or other organs. While some catheters may have a non-round transverse cross-section, for instance oval, they will still tend to be generally round.

Ideally, the lumen of a catheter should ideally be round in transverse cross-section. However, in cases of a catheter having a plurality of lumens this becomes impracticable if the footprint, that is the outer diameter of the catheter, is to be kept as small as possible. As a consequence, at least one of the lumens of a multi-lumen catheter is usually made with a non-round transverse cross-section. In cases where at least one of the lumens must have a round cross-section, for example a lumen for receiving a guide wire or other medical device, this will reduce the amount of space and hence the available shape of the other lumen or lumens of the catheter. For instance, in the case of a balloon catheter, the catheter may have a guide wire lumen of round cross-section and at least one balloon inflation/deflation lumen of non-round cross-section. While a non-round inflation/deflation balloon lumen is not ideal, it is often considered a necessary compromise in catheter design.

Some examples of known medical catheters and other conduits include: US-2011/0022075, US-2018/0117238, US-2012/0130314, US-2012/0065569, US-2008/0097350 and US-2007/0260199.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved medical catheter. While the preferred embodiments are directed to multi-lumen catheters, it will be appreciated that the teachings herein can be used for catheters having a single internal lumen of non-round transverse cross-section.

According to an aspect of the present invention, there is provided a catheter including a longitudinal dimension and a length, at least one lumen extending along at least a part of the longitudinal length of the catheter, the lumen being non-circular in axial cross-section, and a plurality of fins extending internally along the lumen, wherein the lumen is free of fins in a region bounded by a largest circle disposable within the lumen.

The inventor has discovered that while it is important to maximise the cross-sectional area of a lumen use particularly for fluid flow within the catheter, the shape of the lumen has a material effect on fluid flow and furthermore the manner in which fluid flow is disturbed as it travels through the lumen. Large disturbance, or turbulence, of fluid can lead to significantly reduced flow capacity and, as a consequence, a slower medical procedure. In the case of a balloon catheter, for example, this can lead to longer inflation and deflation times.

The provision of fins in the arrangement taught herein can significantly reduce turbulence and lead to smother and optimised fluid flow within a lumen of non-circular or round cross-section.

Advantageously, the fins extend along the longitudinal dimension of the catheter, and preferably parallel thereto.

In the preferred embodiment, the fins extend substantially parallel to one another.

The fins are advantageously disposed in a zone or zones of the lumen having a smaller or smallest radius or diameter.

In preferred embodiments, the lumen is D-shaped in axial cross-section and the fins are disposed in apices of the D-shape.

The fins are preferably thin membranes. The height of the fins and the spacing of the fins will be dependent of the size and shape of the D-lumen (which may be any non-circular shape), the viscosity of the fluid or/and the largest imaginary circle that can fit within the D-lumen. The dimensions and spacing of the fins can be determined for different lumen sizes and shapes by computational fluid dynamics.

Preferably, the fins are made of the same material as the catheter, but they need not be. Many catheters are made of Nylon and the fins can likewise be made of Nylon. If a dual material extrusion is used, the fins could be made of a different material.

Advantageously, the fins are flexible and able to curve with curving of the catheter.

According to another aspect of the present invention, there is provided a method of making a catheter, the catheter including a longitudinal dimension and a length, the method including the steps of:

forming at least one lumen extending along at least a part of the longitudinal length of the catheter, the lumen being non-circular in axial cross-section, and

forming a plurality of fins extending internally along the lumen, wherein the lumen is free of fins in a region bounded by a largest circle disposable within the lumen.

Other aspects, features and advantages of the teachings herein will become apparent to the skilled person having regard to the description of preferred embodiments that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic diagram of a distal end of a balloon catheter suitable for use with the present invention;

Figure 2 is a schematic transverse cross-sectional view of an example of multi-lumen catheter having circular cross-section lumens;

Figure 3 is a schematic transverse cross-sectional view of an example of multi-lumen catheter having one circular cross-section lumen and one moon shaped cross-section lumen;

Figure 4 is a schematic transverse cross-sectional view of an example of multi-lumen catheter having one circular cross-section lumen and one D-shaped cross-section lumen;

Figure 5 is a schematic transverse cross-sectional view of an embodiment of multi-lumen catheter similar to Figure 4 and having a plurality of anti-turbulence fins located therein in accordance with the teachings herein;

Figure 6 is a schematic transverse cross-sectional view of an embodiment of multi-lumen catheter similar to Figure 4 showing the depicting location of anti-turbulence fins in accordance with the teachings herein; and

Figure 7 is a diagram of an embodiment of catheter as taught herein together with a graph showing the effective flow change as a result of the provisions of the internal fins.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

It is to be understood that the drawings are schematic only and not to scale. Furthermore, the drawings depict only the principal elements of the described structure. As the skilled person will know, typical catheters used for medical procedures may include other components, such as strengthening elements, kink resistant elements and the like, which would typically be embedded within the wall of the catheter.

Furthermore, while the dimensions of the catheter and the lumens shown are not described in the present application, these are all well within the common general knowledge of the person skilled in the art and vary in dependence upon the size and intended usage of the catheter.

The embodiments disclosed below relate to a balloon catheter that may be used in a variety of medical procedures including angioplasty, valvuloplasty, drug delivery, as well as medical device delivery and deployment. While the embodiments shown have a single balloon disposed at a distal end of the catheter, it will be understood that in other embodiments there may be provided more than one balloon, for instance two or more balloons arranged in a line along the catheter and independently inflatable/deflatable. Another example is a double walled balloon for drug elution.

The teachings herein are also applicable to other forms of catheter and indeed apply to any catheter having one or more lumens intended to deliver or receive fluid, such as for inflating or deflating a balloon, delivering a bioactive agent such as a drug, a contrast agent and so on.

A typical example of a balloon catheter is shown in Figure 1. It is to be understood that this is an exemplary catheter only and not intended to be in any way limiting of the teachings herein.

The balloon catheter 10 shown in Figure 1 includes a catheter 12 of elongate form with a distal end 14, shown terminating at a dilator tip, and a proximal end not visible in Figure 1 but which would typically remain outside the patient during the medical procedure and be connected to an external manipulation unit (handle) of the introducer assembly. A balloon 16 is fitted to the catheter 12 proximate its distal end 14 and, in this example, is of generally cylindrical form having end cones that terminate in necks bonded or otherwise attached to the catheter 12 in fluid-tight manner.

There may be provided, as shown in Figure 1, one or more radiopaque markers 20, 22 around the catheter 12 and proximate the ends of the cylindrical portion of the balloon 16, useful in identifying the extremities of the balloon 16 when in situ in a patient. Typical catheters of this type are formed of materials that are not readily visible in imaging.

Located along the portion 18 of the catheter 12 that resides within the chamber of the balloon 16, there is typically provided a side port or opening (not shown in Figure 1) that couples the chamber of the balloon 16 to a lumen (not visible in Figure 1) in the catheter 12, for the passage into the chamber of the balloon 16 of an inflation fluid (typically saline solution). The side port is also used for evacuating the balloon 16 at the end of the medical procedure.

The balloon 16 is usually folded and wrapped around the catheter portion 18 for transportation and delivery purposes. It is delivered in this state through a patient’s vasculature, usually by means of a delivery sheath, and only inflated once in position. For this purpose, inflation fluid is fed through the lumen of the catheter 12 out of the side port into the chamber of the balloon 16, to cause the balloon to unwrap and unfold, and eventually expand to its operating diameter. The balloon may be non-conformable, that is have a generally set diameter over a range of operating pressures, or conformable, that is be stretchable such that its diameter will vary with inflation pressure.

It will be appreciated that the balloon 16 may have a variety of structures and characteristics known in the art. It may, for instance be a smooth walled balloon but may likewise be textured or roughened. In some cases, the balloon 16 may carry one or more cutting or scoring elements, of types known in the art. The balloon 16 may also be used for valvuloplasty procedures, for deployment of medical devices such as stents and stent grafts, and so on.

In the embodiment shown, the catheter 12 also includes a lumen 24 for receiving a guidewire (not shown in Figure 1) enabling the catheter 10 to be delivered in an over-the-wire configuration. The guidewire lumen 24 may extend for the whole length of the catheter 12, to and through its proximal end, or may pass out through a side port in the catheter 12 at a location proximal the balloon 16, so as to be deployable in a rapid exchange mode.

In the example of Figure 1, the catheter 12 will include at least two lumens, one for the guidewire and the other for inflating/deflating the balloon 16. The catheter 12 may have more than two lumens and if so one or more of these lumens may have characteristics as taught herein.

The catheter 12 may be made of any well-known catheter material, typically a polymer material such as nylon, polyurethane, polyethylene terephthalate (PET), polytetrafluorethylene (PTFE), silicone and so on.

Referring now to Figure 2, this shows a cross-sectional view of a catheter 30 similar to the catheter 12 and in this example having three lumens 34, 36 and 38 disposed side-by-side relationship. In the example of Figure 2, all of the lumens 34-38 are round or circular in transverse cross-section. Whilst a circular cross-section is optimal for a lumen, as will be apparent from Figure 2 this results in zones 40 of excess wall material 32 that in effect cause the catheter 32 to have a non-optimal, diameter. It will be appreciated, of course, that there must be a minimum thickness of catheter wall 32 between the lumens 34-38 and the outer surface of the catheter 30, as well as between the lumens 34-38 themselves, in order to maintain strength and kink resistance to the catheter. Described another way, for the catheter 30 to maintain a certain strength, the lumens 34-38 will have a restricted diameter for a given outer diameter catheter.

The shortcomings of the structure 32 can be addressed by use of non-round lumens. Even so, in most instances it is advantageous to have one lumen of round or circular cross-section, for instance for a guide wire. Other lumens that do not carry medical devices, such as lumens used for fluid, can be made to have a non-round cross-section, in order to maximise the cross-sectional area of the lumens while minimising the outer diameter of the catheter.

Figure 3 shows an example of two-lumen catheter 50 having a round lumen 52 and a moon or crescent shaped lumen 54. The lumen 52 can be used for a guidewire, while the lumen 54 may be used for passage of fluid. While this design can increase the cross-sectional areas of the lumens 52 and 54 within a certain diameter of catheter 50, the moon or crescent shape lumen 54, it has been found, can create excessive turbulence in fluid flowing therethrough and as a result can suffer from restricted fluid flow rate through the catheter.

With reference to Figure 4, the inventor has discovered that a D-shaped lumen is more efficient in terms of fluid flow rate. In the embodiment shown in Figure 4, which again is a transverse cross-sectional view from the catheter 60, there is a lumen 62 of round or circular transverse cross-section and, in this example, a balloon lumen 64 having a D-shape. The lumen 62 is offset relative to the central axis of the catheter 60, as is the balloon lumen 64, and there is retained a thickness of catheter wall 72 between the two lumens 62, 64 to ensure integrity of the structure during use of the catheter 60.

The balloon lumen 64 has a substantially flat wall portion 66, an opposite wall portion 68 which is generally circular and bound at either side by portions 70 having a smaller radius of curvature than the portion 68. The wall portions 66-70 are chosen to maximise the cross-sectional area of the lumen 64 within the space provided in the catheter wall 72 having regard to the necessary size of the circular lumen 62 and the desired maximum diameter of the catheter 60.

While the shape of the lumen 64 of Figure 4 provides a significant improvement in fluid flow compared to the crescent shaped lumen 54 of the example of Figure 3, there remains the risk of turbulent flow at the small radius ends 70 of the lumen 64.

With reference now to Figure 5 there is shown an embodiment of catheter 60 of similar design to the example of Figure 4 and also being a two-lumen catheter.

In the embodiment of Figure 5, the non-round catheter lumen 64 is provided with a plurality of fins or ribs 80 that extend along the length of the lumen 64 in the longitudinal direction of the catheter 60. The fins are preferably thin membranes. The height of the fins and the spacing of the fins will be dependent of the size and shape of the D-lumen (which may be any non-circular shape), the viscosity of the fluid or/and the largest imaginary circle that can fit within the D-lumen. The dimensions and spacing of the fins can be determined for different lumen sizes and shapes by computational fluid dynamics. Within the small radius portions 70, the fins 80 are preferably taller than around the sides of the round portion 68 and of the straight portion 66 of the lumen wall. In particular, it is preferred that the fins 80 taper in length from the narrower radius portions 70 and such that there are no fins present, in the embodiment shown, at the centre of the curved portion 68 and flat portion 60, as will be apparent from Figure 5. This is not, however, an essential characteristic of the fins and is a preference only.

The fins 80 extend along the longitudinal dimension of the catheter, preferably parallel to that longitudinal dimension, for the entire length of the lumen 64. In practice, in the embodiment shown, the fins 80 will extend from the proximal end of the catheter 10 to the side port in the catheter portion 18 that leads to the chamber of the balloon 16, in accordance with the reference numerals of the examples shown in Figure 1.

Advantageously, the fins 80 are substantially parallel to one another, that is maintain a substantially uniform spacing between one another throughout their length.

It will be appreciated that in some embodiments the fins 80 may terminate short of an extremity of the lumen 64. For example, the fins 80 may in some embodiments terminate short of the side port leading into the balloon 16 and/or terminate short of the proximal end of the catheter 60. In practice, the fins may be manufactured to extend along the entire length of the lumen and partially removed by the operator when bonding to other components takes place.

With reference now also to Figure 6, this shows schematically the preferred bounds to the fins 80 (although the fins are not shown in the schematic drawing of Figure 6). More particularly, the fins 80, while acting as anti-turbulence elements within the corners or narrow radius portions of the lumen 64, do not extend into a region of the lumen 64 that is bounded by the largest circle 100 disposable within the lumen 64. This is depicted in Figure 6 and, it will be appreciated in connection with the embodiment shown, that the area free of anti-turbulence fins 80 is a circle of diameter equivalent to the maximum distance between the flat wall portion 60 and curved wall portion 68 of the lumen 64. Referring again to Figure 5, it will be seen that in the central region of the walls 68 and 66, there are no fins 80 present, consistent with the location of the circle 100 shown in Figure 6.

The region denoted by the circle 100 in Figure 6 provides what could be described as an optimal shaped lumen zone for unimpeded fluid flow through the lumen 64. While the fins 80 may not be of a height to extend to the edges of the imaginary circle 100 shown in Figure 6, particularly those fins 80 disposed within the narrow radius regions 70, it is preferred that the fins are longer where the distance between the internal wall of the lumen 64 and the edge of the circle 100 is greater and where the lumen has a small radius or angle, as will be apparent from Figure 5. This is, however, just one example of the characteristics of the fins, which may be different primarily in dependence upon flow dynamic calculations and results of particular catheter designs. The fins reduce turbulence (any flow not in the longitudinal direction). The flow is not expected to be laminar but will be more laminar (less turbulent) than in the absence of the fins.

With reference to Figure 7, this shows the embodiment of catheter of Figure 5 together with a graph that shows the difference in the flow velocity of fluid through the catheter between one having fins 80 and one not having fins. The lower curve 94 in the graph is representative of the flow velocity through a lumen 64 without any fins. As can be expected, flow velocity is highest in the centre of the lumen 64 and less in the corners of the D-shape. The fins 80 change the flow velocity in all regions of the lumen 64, to that depicted by the upper curve 92. The fins have the effect of reducing turbulence, with the result that overall there is greater velocity of fluid through the lumen 64, which results in shorter balloon inflation and deflation times, and also reduced drug or other fluid agent delivery times in the case that the lumen 64 is used for fluid delivery into the patient. The same applies in the case of aspiration of fluid from a vessel or other organ.

The fins 80 are preferably of a length such that they do not contact one another at their free extremities, while keeping the distance between the fins 80, as measured at the internal lumen wall surface constant. The distance between the fins and the length of the fins will vary dependent upon the location of the fins in the lumen. In some embodiments, the spacing between the fins 80 in the narrowing radius portions 70 or other corner may be increased (again as measured at the base of the fins) compared to the spacing of fins 80 at wall portions 60, 68 of greater radius or that are flat.

The fins 80 are preferably of a flexible material, such that they will flex as the catheter 10 is curved, for example through a patient’s tortuous vasculature.

The fins 80 may be made of the same material as the catheter 60, for instance any of the materials mentioned above, or of any other suitable material, preferably extrudable.

A catheter having a structure as depicted in Figure 5 can be made by a number of techniques, including extrusion and casting. Extrusion is a common method known in the art and is therefore a process that can be readily applied to a catheter having a structure taught herein.

By way of example only and not by way of any limitation, for a 0.9 mm (0.035") diameter catheter having a D-shaped lumen accommodating a circle of 0.5 mm maximum diameter, the fins could have a height from 0.02mm to 0.15mm millimetres and be spaced from one another by 0.04mm to 0.3 mm. However, for a smaller catheter, the fins and their spacing will vary. For a 0.35 mm (0.014") catheter, for example, the fins may be made less high and have closer spacing.

It will be appreciated that the catheter taught herein may include one or more variety of the elements typically used in catheters, including strengthening elements such as a strengthening coil or braid embedded within the material forming the catheter wall 72. Such strengthening elements would typically bound the lumens 62, 64 in the catheter 60, that is be disposed radially outside these lumens.

While these preferred embodiments described above are directed to a catheter having two lumens, it will be appreciated that the teachings herein can be applied to a catheter having more than two lumens and equally to a catheter having a single non-round lumen. Anti-turbulence fins 80 can be provided in any non-round lumen in accordance with the teachings herein and in particular in regions of the lumen located outside a region bounded by the larger circle disposable within the lumen.

It will be appreciated that in reducing turbulence of fluid flowing through the lumen 64, the amount of fluid, that is the fluid flow rate, can be optimised, which can result in a reduction in the length of time required to inflate or deflate a balloon, or to deliver other fluids such as drugs, contrast agents and so on.

The disclosure in the abstract accompanying this application is incorporated herein by reference.

CLAIMS

1. A catheter including a longitudinal dimension and a length, at least one lumen extending along at least a part of the longitudinal length of the catheter, the lumen being non-circular in axial cross-section, and a plurality of fins extending internally along the lumen, wherein the lumen is free of fins in a region bounded by a largest circle disposable within the lumen.

2. A catheter according to claim 1, wherein the fins extend along the longitudinal dimension of the catheter.

3. A catheter according to claim 1 or 2, wherein the fins extend parallel to the longitudinal dimension of the catheter.

4. A catheter according to claim 1, 2 or 3, wherein the fins extend substantially parallel to one another.

5. A catheter according to any preceding claim, wherein the fins are disposed in a zone or zones of the lumen having a smaller or smallest radius or diameter.

6. A catheter according to any preceding claim, wherein the lumen is a D-shaped in axial cross-section and the fins are disposed in apices of the D-shape.

7. A catheter according to any preceding claim, wherein the fins are made of the same material as the catheter.

8. A catheter according to any preceding claim, wherein the fins are flexible and able to curve with curving of the catheter.

9. A method of making a catheter, the catheter including a longitudinal dimension and a length, the method including the steps of:

forming at least one lumen extending along at least a part of the longitudinal length of the catheter, the lumen being non-circular in axial cross-section, and

forming a plurality of fins extending internally along the lumen, wherein the lumen is free of fins in a region bounded by a largest circle disposable within the lumen.

10. A method according to claim 9, wherein the fins are formed to extend along the longitudinal dimension of the catheter.

11. A method according to claim 9 or 10, wherein the fins are formed to extend parallel to the longitudinal dimension of the catheter.

12. A method according to claim 9, 10 or 11, wherein the fins formed to extend substantially parallel to one another.

13. A method according to any one of claims 9 to 12, wherein the fins are formed in a zone or zones of the lumen having a smaller or smallest radius or diameter.

14. A method according to any one of claims 9 to 13, wherein the lumen is formed to be D-shaped in axial cross-section and the fins are formed in apices of the D-shape.

15. A method according to any one of claims 9 to 14, wherein the fins are made of the same material as the catheter.

16. A method according to any one of claims 9 to 15, wherein the fins are flexible and able to curve with curving of the catheter.

Application No: GB1901980.1 **Examiner:** Paul Jenkins

Claims searched: 1-16 **Date of search:** 10 July 2019

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-	WO2009/065552 A1 (IPRM) see all figures
A	-	US5823961 A (FIELDS) see figure 6 and column 7 lines 42-54

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61M

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI

International Classification:

Subclass	Subgroup	Valid From
None		