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(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US];
One Scimed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventors: HEATH, Kevin, R.; 26 Bittersweet Lane, Weston, MA 02493 (US). BERRY, Michelle, M.; 47 Cottage Street, Franklin, MA 02038 (US).

(74) Agents: LEWIS, Christopher, R.; RatnerPrestia, 301 One Westlakes (Berwyn), P.O. Box 980, Valley Forge, PA 19482-0980 et al. (US).

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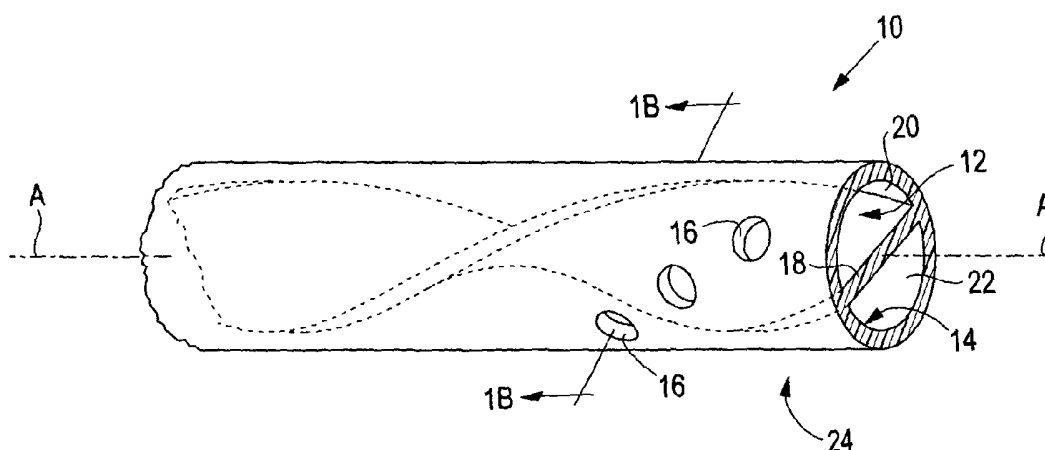
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(54) Title: OCCLUSION-RESISTANT CATHETER



(57) Abstract: A catheter comprises an elongated tube having an interior defined by a sidewall having openings. At least a portion of the catheter is spirally formed into a corkscrew pattern or has an inwardly spiraling portion with at least one opening coincident therewith. Additionally or alternatively, the catheter comprises a septum that divides the interior into at least first and second lumens. The first and second lumens may form a double helix in a portion of the catheter coincident with the plurality of openings or along the entire length of the catheter. Methods of manufacturing the catheters involve extruding the portion of the catheter having the openings. Making this portion separately then attaching it to another catheter, or heating and deforming a portion of a catheter to form a tip portion. The catheter can be used for hemodialysis by drawing blood through one lumen and returning it through another.



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OCCLUSION-RESISTANT CATHETER

TECHNICAL FIELD

This invention relates generally to perfusion catheters and, more specifically, to a catheter that is resistant to occlusion of its sidewall openings.

BACKGROUND OF THE INVENTION

5 Perfusion catheters used for introducing or removing fluids from a body lumen are well known in the art. Such catheters may be used in drug therapy, such as chemotherapy, where the fluid to be introduced is a pharmaceutical agent. Perfusion catheters have also been used to allow for bypassing occlusions in blood vessels. For example, during angioplasty, plaque may become partially or completely dislodged and may form a restriction that at least partially occludes an arterial
10 passage. A perfusion catheter may be positioned in the occluded blood vessel across the restriction, such as is described in U.S. Patent No. 4,661,094, incorporated herein by reference, to allow blood to flow into the catheter through a first opening upstream of the restriction and flow out through a second opening downstream of the restriction. As described in the '094 patent, the openings may be distributed in a helical pattern in the sidewalls of the catheter.

15 During the intake of fluids, however, the sidewall hole orientation may have certain disadvantages. For example, the holes may contact and seal against the walls of the duct or vessel in which the catheter resides, thereby blocking the holes and minimizing flow. One typical use for perfusion catheters for fluid intake is in extracorporeal blood purification procedures, such as hemodialysis. Modern procedures favor the use of dual-lumen catheters such as those described in
20 U.S. Patent No. 4,134,402, incorporated herein by reference, or other multi-lumen catheters, such as those described in U.S. Patent No. 4,995,865, incorporated herein by reference. In a standard dialysis procedure using a dual- or multi-lumen catheter, blood is withdrawn from a blood vessel in a patient through one or more lumens of the multi-lumen catheter and supplied to a hemodialysis unit that purifies the blood. The purified blood is then returned to the patient through another lumen of
25 the catheter.

 The '865 patent describes multi-lumen catheters having side openings located on "spiral pathways." The ranges of these spiral pathways, however, are limited to the portions of spirals contained within two pie-shaped intake lumens that each comprise only a 90° quadrant of the circular lumen. Thus, if there is a tendency for one circumferential portion of the catheter to be
30 blocked and that portion happens to fall within one or both of the quadrants comprising the two intake

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lumens, the spiral configuration is insufficient to keep the flow into the openings from becoming occluded. Occlusion of intake holes may reduce the intake flow significantly enough to lengthen the amount of time a patient may have to undergo the hemodialysis procedure, causing unnecessary discomfort for the patient, and causing inefficient use of resources for the dialysis provider.

5 Therefore, there is still a need in the art for a catheter structure that resists occlusion of openings in the sidewall.

SUMMARY OF THE INVENTION

It is to be understood that both the foregoing general description and the following detailed description are exemplary, but not restrictive, of the invention.

10 One aspect of the invention is a catheter comprising an elongated tube having an interior defined by a sidewall having a plurality of openings in the sidewall. At least a portion of the catheter is spirally formed into a corkscrew pattern to define a corkscrew-patterned portion. One or more of the openings is coincident with the corkscrew-patterned portion. The corkscrew pattern comprises an outer diameter and an inner diameter, and the plurality of openings faces the inner diameter in one embodiment. In another embodiment, the catheter may comprise a septum that divides the interior into at least a first lumen and a second lumen. The first lumen and the second lumen may form a double helix in a portion of the catheter coincident with the plurality of openings or along the entire length of the catheter. The septum may divide the interior into more than two lumens that form a multiple helix, and the multiple lumens may form a multiple helix along the portion of the catheter coincident with the plurality of openings or along the entire length of the catheter.

20 According to another aspect of the invention, a catheter comprises an elongated tube having an interior defined by a sidewall having a plurality of openings, and a septum that divides the interior into at least a first lumen and a second lumen, wherein the first lumen and the second lumen form a double helix at least in a portion of the catheter coincident with the plurality of openings. In one embodiment, the double helix may run along the entire length of the catheter. In another embodiment, the septum may divide the interior into more than two lumens that form a multiple helix in a portion of the catheter adjacent the plurality of openings or along the entire length of the catheter.

25 Other aspects of the invention comprise methods for making catheters. One method comprises forming the multi-lumen catheter body; molding the catheter tip into the multi-helix, the corkscrew pattern, or both; and attaching the catheter body to the catheter tip. Another method

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comprises forming the multi-lumen catheter; heating at least the catheter tip of the multi-lumen catheter to a sufficient temperature at which the catheter tip can be deformed; deforming the catheter tip into the multi-helix, the corkscrew pattern, or both; and cooling the catheter tip. For a catheter of this invention with the twisting septum dividing an interior of the catheter into multiple lumens in a multi-helix, one method comprises extruding the catheter using an extrusion tooling insert that rotates to form the twisting septum. Another method comprises extruding the catheter and septum without a twist in the septum and then twisting the catheter as it exits the extruder.

Yet another aspect of the invention is a method for providing hemodialysis comprising the steps of introducing a multi-lumen catheter of this invention into a body lumen, taking in blood through the plurality of openings into a first catheter lumen; cleansing the blood by hemodialysis; and returning the blood through the second catheter lumen into the body lumen. The twisting septum, corkscrew pattern, or combination thereof in the multi-lumen catheter minimizes occlusion of the openings by the body lumen wall. Specifically, the method may comprise deploying the catheter with its distal end in or adjacent to the right atrium of the patient's heart. Where the catheter embodiment comprises a catheter tip with a corkscrew pattern and the second lumen extending distally further than a distal end of the first lumen and pointed in a direction toward the right atrium, the method may comprise returning the blood to the body lumen in a stream directed toward the right atrium.

Still another aspect of the invention comprises a catheter for deployment in a lumen having a wall, the catheter comprising an elongated tube comprising a catheter tip, one or more openings in the catheter tip, and a deformation in the catheter tip for preventing the one or more openings from contacting the lumen wall. In one embodiment, the deformation may be a corkscrew pattern, while in another embodiment the deformation may be an inwardly spiraling portion. The inwardly spiraling portion typically comprises an inner periphery that defines an open area, with sidewall openings facing into the open area and/or a distal end opening positioned within the open area.

BRIEF DESCRIPTION OF THE DRAWING

The invention is best understood from the following detailed description when read in connection with the accompanying drawing, in which:

Fig. 1A shows a perspective view of an exemplary double-lumen catheter of the present invention in partial cross-section;

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Fig. 1B shows a cross-sectional illustration of the catheter of Fig. 1A taken across line 1B-1B;

Fig. 2A shows a perspective view of an exemplary double lumen catheter having a corkscrew pattern with a relatively wide pitch;

5 Fig. 2B shows a perspective view of an exemplary double lumen catheter having a corkscrew pattern with a relatively narrow pitch;

Fig. 3A shows an end view of the corkscrew pattern of Fig. 2A;

Fig. 3B shows an end view of an exemplary single lumen composite catheter comprising a corkscrew pattern;

10 Fig. 4A shows a perspective view of an exemplary multi-lumen catheter of the present invention in partial cross-section;

Fig. 4B shows a cross-sectional illustration of the catheter of Fig. 4A taken across line 4B-4B; and

15 Fig. 5 shows an exemplary catheter embodiment having sidewall openings with an angled orientation;

Fig. 6A shows an exemplary catheter embodiment having an inwardly spiraling portion at its distal end; and

Fig. 6B shows an end view of the catheter embodiment of 6A along with two other exemplary catheter embodiments.

20 DETAILED DESCRIPTION OF THE INVENTION

The invention will next be illustrated with reference to the figures wherein the same numbers indicate similar elements in all figures. Such figures are intended to be illustrative rather than limiting and are included herewith to facilitate the explanation of the apparatus of the present invention.

25 Referring now to Figs. 1A-5, there are shown several embodiments of the invention. As shown in Figs. 1A and 1B, catheter 10 comprises an elongated tube having an interior 12 defined by a sidewall 14 having a plurality of openings 16 formed in the sidewall, and a septum 18. Septum 18 divides interior 12 into a first lumen 20 and a second lumen 22. As shown by the dashed lines in Fig. 1A, the first lumen and second lumen form a double helix about one another as septum 18 twists
30 about the common axis *A* of the catheter, as further illustrated by the cross section of Fig. 1B. Fig. 1B, a cross-section of catheter 10 taken a predetermined distance from the end 24 of the catheter

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shown in Fig. 1A, shows how septum 18, first lumen 20, and second lumen 22 are twisted 90° from their relationship as shown in Fig. 1A. Openings 16, which follow the path of the corresponding lumen 20 or 22, are therefore also in a helical pattern about axis *A*.

For a double-lumen catheter as shown in Fig. 1A, openings 16 may be aligned (using
5 the central axis of the opening) at an angle to the plane formed by septum 18, as shown in Fig. 1B. Openings may be distributed in a line so that angle is 90° for all the openings as shown in Fig. 1B. In an alternative embodiment, the openings may be placed in two lines following the path of the lumen, one line at 60° and another line at 120°, including a pattern where the openings alternate
10 between the two lines along the length of the catheter tip. One advantage of the multi-helical configuration, however, is that the simple 90° hole orientation may be used because the multi-helix prevents occlusion of multiple holes, so there is no need to offset the holes from one another relative to the septum. The catheters of this invention, however, are not limited to any particular hole pattern or distribution.

The degree of twist of per unit length of catheter 10 may have any value necessary to
15 produce a desired effect. For example, for catheters having a diameter of 6-14 french (approximately 0.203-.474 centimeters), a 360° twist may occur every 3-20 centimeters. Catheters of this invention, however, are not limited to any particular degree of twist.

The twisted septum 18 and resulting double helix pattern of first lumen 20 and second
20 lumen 22 may extend along the entire length of the catheter for ease of manufacture, or may extend only in a portion of the catheter in which the openings are present. Stated another way, the first lumen 20 and the second lumen 22 form the double helix at least in a portion of the catheter 10 coincident with (i.e., occupying the same space as) the plurality of openings. The twisting relationship of the septum provides each lumen 20 and 22 of catheter 10 with an ever-changing relationship with the sidewall of a body lumen in which the catheter is positioned. This minimizes the
25 number of openings 16 actually obstructed, even if some openings are obstructed in one circumferential portion of the catheter, because the twisting relationship of the lumens provides openings in other circumferential portions of the catheter that are not obstructed.

To further minimize potential obstruction of the openings, at least a distal portion 26
of catheter 10 (or a distal portion 126 of catheter 110) may be spirally formed into a corkscrew
30 pattern defining a corkscrew-patterned portion, as shown in Figs. 2A and 2B, respectively. Corkscrew patterned portion 26 shown in Fig. 2A has a relatively wide pitch, whereas the corkscrew-

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patterned portion 126 of catheter 110 has a relatively narrower pitch. The “pitch” as referred to herein refers to the unit length over which the corkscrew makes a full turn, a full turn being visible in an end view as completing a full circle. Although shown in Figs. 2A and 2B having made approximately a single turn, catheters of the present invention may comprise a corkscrew pattern that makes less than or more than a full turn.

The end of the catheter of the present invention may comprise a design as shown in Figs. 2A and 2B, where lumen 22 extends axially beyond open end 32 of lumen 20 in an extended end portion 30. Such an extended end portion may typically extend beyond lumen 20 by about 1-2 cm, and generally no more than about 3 cm. Any amount of extension may be present, however. Such a design is typically used in hemodialysis where lumen 20 is an intake lumen and lumen 22 is a discharge lumen, so that the discharge of cleansed blood may be directed downstream of openings 16 through extended end portion 30. This axial extension of the discharge lumen prevents recirculation of the discharged blood back through the intake openings 16. The extended end portion 30 may further be configured to direct the discharge in a particular location. For example, hemodialysis catheters are typically positioned above in or adjacent to the right atrium of the heart so that the discharged, cleansed blood may be discharged into the right atrium.

The catheter of the present invention is not limited to any particular end design, however, and accordingly, the end of the catheter may comprise an end perpendicular to axis *A* of the catheter where there is no axial offset between the end of lumens 20 and 22. The end may also be cut on a bias relative to axis *A*. Furthermore, the extended end portion 30 shown in Figs. 2A and 2B is not limited to catheters with corkscrew-patterned portions, but also may be provided at the end of catheters having multi-helical twisted configurations of this invention, without a corkscrew-patterned end. Furthermore, catheters with a corkscrew patterned end portion may terminate with the extended end portion 30 of the catheter pointed axially as shown in Fig. 2A, pointed circumferentially (not shown), or pointed tangentially as shown in Fig. 2B. Furthermore, the axially, circumferentially, or tangentially pointed end portion 30 may be pointed in any direction desired to direct the discharged fluid toward a desired location, such as toward the right atrium, as discussed above.

An end view of corkscrew-patterned portion 26, shown in Fig. 3A, illustrates that a corkscrew pattern inherently comprises an outer diameter d_o and an inner diameter d_i . In one embodiment, the plurality of openings 16 may all face away from the corkscrew pattern outer diameter so that none of the openings are obstructed by contact with the body lumen. By “face away

from the outer diameter” it is meant that none of the openings are located on the portion of the catheter that defines the corkscrew pattern outer diameter d_o . The plurality of openings may be formed in any pattern, however, including a helical pattern.

Although discussed primarily herein with respect to multi-lumen catheters, the various embodiments of this invention are also applicable to single lumen catheters. Referring now to Fig. 3B, there is shown a single lumen catheter 300 having a corkscrew pattern, wherein open end 302 is positioned centrally inside the space 304 defined by the corkscrew pattern outer diameter d_o . By “positioned centrally” it means that tube diameter d_i of open end 302 lies completely inside space 304 without touching outer diameter d_o . Although shown with the central axis I of catheter 300 coaxial with diameter d_o , the open end may still be considered “positioned centrally” as defined herein, even if central axis I is not coaxial with diameter d_o . Thus, outer diameter d_o of the corkscrew pattern serves as a spacer to keep the lumen wall away from the open end.

Other structural deformations in the catheter tip may similarly be used for keeping the lumen wall away from the open end. For example, as shown in Fig. 6A, catheter 600 may have an inwardly spiraling portion 602 having an inner periphery 604 with a diameter d_b that defines open area 606. Open end 608 of catheter 600 may be positioned within the open area 606 so that the periphery 604 of inwardly spiraling portion 602 serves as the spacer to keep the lumen wall away from the open end. Catheter 600 may be a single lumen catheter, as shown, or a multi-lumen catheter, such as a dual lumen catheter. Catheter 600 may also have openings 610 in the sidewall. Where such openings are present, the openings may be positioned so that they face into open area 606 so as not to be obstructed by the lumen wall.

Although shown in Fig. 6A with the bottom 612 of the inwardly spiraling portion curl spaced a distance d_c above axis I which runs through straight section 614 of catheter 600, the bottom of the curl may be parallel to the straight section ($d_c=0$) or may be spaced below the straight section. As used herein, the relative terms “bottom,” “above,” and “below” relate to the orientation on the page of the illustration provided as Fig. 6A. In other words, as shown from an end view in Fig. 6B, an inwardly spiraling portion may generally be considered a curl that lies at least partially within plane $P2$ perpendicular to plane $P1$ tangential to the lower surface of straight section 614 and parallel with axis I , the inwardly spiraling portion curling away from plane $P1$. In one embodiment 602, shown in Fig. 6A and as the leftmost embodiment in Fig. 6B, the curl of the inwardly spiraling portion may terminate without crossing or touching the plane $P1$. In another embodiment 620, the

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curl of the inwardly spiraling portion may come full circle with some portion coming to rest on plane *PI* parallel to the straight portion 614. In yet another embodiment 630, the curl may cross plane *PI*. Although shown with a curl of somewhat greater than 360 degrees (wherein a 360 degree curl defines approximately a full circle), the inwardly spiraling portion may also curl less than 360 degrees or
5 more than 360 degrees.

As noted above, although not limited to any particular catheter diameter, the tube diameter d_t is typically 6-20 french (approximately 0.2-0.7 centimeters, more precisely 0.203-0.677 centimeters). Although not limited to any particular diameter, the corkscrew pattern outer diameter d_o may be in the range of about 1-5 centimeters, with acceptable values being dependent upon the
10 geometry of the body lumen into which the catheter is to be positioned.

Although described above with respect to an embodiment having both the corkscrew pattern and the first lumen and second lumen forming a double helix, each of these features may be provided alone. For example, a single lumen catheter without a multi-helical relationship between or among the lumens may have an end shaped in a corkscrew pattern. Furthermore, the multi-helical
15 twisting relationship between multiple lumens is not limited only to a double lumen design, but may be provided in a design with more than two lumens, as shown in Figs. 4A and 4B. As shown in Figs. 4A and 4B, catheter 400 has a first D-shaped lumen 420 and two pie-shaped lumens 422 and 423 that are formed by septum 418. Openings 16 in sidewall 14 are provided for both lumens 422 and 423. Such a design may or may not have a corkscrew-shaped end.

The plurality of openings 16 may be radially formed in the sidewalls as shown in Fig. 1A (i.e., having an angle of 90° of the central axis of the opening relative to the plane formed by the septum 18), or may comprise openings 516 that are angled (i.e., other than 90°) relative to axis *A*, as shown in Fig. 5. Catheter may be a perfusion catheter, such as a dialysis catheter, or any type
20 of catheter known in the art. The catheter may be formed of any material known in the art for formation of catheters, such as flexible polymers including but not limited to polyvinylchloride (PVC), polyethylene, polypropylene, polyurethane, nylon, and thermoplastic elastomers such as PEBAX[®] polyether block amide, manufactured by Atofina, metal, such as nitinol or stainless steel, or a combination or composite thereof. The catheter may comprise a braided architecture, such as
25 formed by braiding a plurality of fibers or filaments together. The filaments may comprise, for example, metal wire such as but not limited to stainless steel or nitinol, glass fibers, or carbon fibers. By "composite" it is meant that the catheter may comprise layers of different materials, or
30

longitudinal sections of different materials. For example, one catheter embodiment may comprise a first layer of braided nitinol wire covered by a layer of polyethylene. Another catheter embodiment may comprise a relatively stiffer first longitudinal section comprising metal abutting with one or more relatively more flexible second longitudinal sections comprising a thermoplastic elastomer.

5 The catheters of the present invention may be manufactured by any number of methods. One method may be to injection mold the end portion of the catheter having the double-helix and/or corkscrew shape, and attach the injection-molded tip to the end of a catheter, such as a standard double-lumen catheter.

10 Another manufacturing method may be to first form the standard catheter, such as a double- or multi-lumen catheter, and then remold the end portion to have the desired shape. The remolding step may comprise heating the end portion to a sufficient temperature above the plastic transition temperature to allow deformation of the catheter end into the desired configuration, after which the remolded portion of the catheter cools in the desired configuration. A mandrel may be used for remolding the catheter. For example, for a double-lumen catheter, a mandrel that fits into
15 one of the two lumens and having the desired helical relationship may be threaded into one of the catheter lumens. A second mandrel may then be fitted into the other of the two lumens, if desired, although a single mandrel may be sufficient. While one or more mandrels are preferred for producing the multi-helix configuration, a corkscrew configuration may be created by placing the catheter inside an appropriately shaped tube.

20 Multi-lumen catheters comprising the multi-helical design may also be fabricated during the catheter extrusion step. For example, a rotating insert in the extrusion tooling may create a catheter having the multi-helix along its entire length. Another method comprises extruding the catheter and septum with no twist and then twisting the catheter as it exits the extruder to create the multi-helix design. Although several exemplary manufacturing methods have been provided herein,
25 the invention is not limited to any particular method.

 The catheters of the present invention may be introduced into the body by any method known in the art, including by percutaneous methods over a guidewire or with an introducer, and may include introduction through a surgically implanted access port. In a method for providing hemodialysis, a multi-lumen catheter of the present invention is first introduced into a body lumen.
30 Then, blood from the body lumen is drawn through the openings and into the first catheter. After the

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blood is cleansed in a known way by hemodialysis, it is returned through the second catheter lumen and into the body lumen.

Although illustrated and described herein with reference to certain specific embodiments, the present invention is nevertheless not intended to be limited to the details shown.

5 Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the spirit of the invention.

What is Claimed:

- 1 1. A catheter comprising an elongated tube having an interior defined by a
2 sidewall and having one or more openings, and at least a portion of the catheter spirally formed into a
3 corkscrew pattern to define a corkscrew-patterned portion, wherein at least one of said openings is
4 coincident with the corkscrew-patterned portion.
- 1 2. The catheter of claim 1, wherein the one or more openings comprise a
2 plurality of openings in the sidewall.
- 1 3. The catheter of claim 2, wherein the corkscrew pattern comprises an outer
2 diameter (d_o) and the at least one of said sidewall openings is positioned facing away from the outer
3 diameter.
- 1 4. The catheter of claim 1, wherein the tube has a tube diameter (d_i) in a range
2 of approximately 0.2-0.7 centimeters, and the corkscrew pattern has an outer diameter (d_o) in a range
3 of approximately 1-5 centimeters.
- 1 5. The catheter of claim 2, wherein the plurality of sidewall openings are
2 distributed in a helical pattern along the sidewall.
- 1 6. The catheter of claim 1 further comprising a septum that divides the interior
2 into at least a first lumen and a second lumen.
- 1 7. The catheter of claim 6, wherein the first lumen and the second lumen form a
2 double helix in a portion of the catheter coincident with the one or more openings.
- 1 8. The catheter of claim 7, wherein the openings are distributed on the sidewall
2 at an angle of 90° relative to the septum.
- 1 9. The catheter of claim 6, wherein the first lumen and the second lumen form a
2 double helix along an entire length of the catheter.
- 1 10. The catheter of claim 6, wherein the septum divides the interior into more
2 than two lumens that form a multiple helix.
- 1 11. The catheter of claim 10, wherein the more than two lumens form a multiple
2 helix along an entire length of the catheter.
- 1 12. The catheter of claim 10, wherein the first lumen extends distally further than
2 a distal end of the second lumen.
- 1 13. The catheter of claim 1, wherein the corkscrew pattern terminates with the
2 catheter pointed in an axial direction.

- 1 14. The catheter of claim 1, wherein the corkscrew pattern terminates with the
2 catheter pointed circumferentially.
- 1 15. The catheter of claim 1, wherein the corkscrew pattern terminates with the
2 catheter pointed tangentially.
- 1 16. The catheter of claim 1, wherein at least a plurality of the one or more
2 openings are radially formed in the sidewall.
- 1 17. The catheter of claim 1, wherein the catheter has a central axis, and at least a
2 plurality of the one or more openings are formed in the sidewalls at a non-perpendicular angle
3 relative to the central axis.
- 1 18. The catheter of claim 1, wherein the catheter is a perfusion catheter.
- 1 19. The catheter of claim 18, wherein the catheter is a hemodialysis catheter.
- 1 20. The catheter of claim 1, wherein the catheter comprises a flexible polymer.
- 1 21. The catheter of claim 1, wherein the catheter comprises a thermoplastic
2 elastomer.
- 1 22. The catheter of claim 1, wherein the catheter comprises a material of
2 construction selected from the group consisting of: polyvinylchloride, polyethylene, polypropylene,
3 polyurethane, nylon, a polyether block amide, metal, carbon fibers, glass fibers, a combination
4 thereof, and a composite thereof.
- 1 23. The catheter of claim 1, wherein the catheter comprises at least one layer that
2 comprises a braided architecture.
- 1 24. The catheter of claim 1, wherein the catheter is a single lumen catheter
2 having an open end and a tube diameter(d_i), the corkscrew pattern defines a space comprising an
3 outer diameter (d_o) greater than the tube diameter, and the open end is positioned centrally within the
4 space.
- 1 25. The catheter of claim 1, wherein the catheter comprises a tunneling catheter.
- 1 26. A catheter comprising an elongated tube having an interior defined by a
2 sidewall and a septum dividing the interior into at least a first lumen and a second lumen, wherein the
3 first lumen and the second lumen form a double helix at least in a portion of the catheter coincident
4 with one or more openings in the catheter.
- 1 27. The catheter of claim 26, wherein the first lumen and the second lumen form
2 a double helix along an entire length of the catheter.

- 1 28. The catheter of claim 26, wherein the septum divides the interior into more
2 than two lumens that form a multiple helix.
- 1 29. The catheter of claim 28, wherein the more than two lumens form a multiple
2 helix along an entire length of the catheter.
- 1 30. The catheter of claim 26, wherein the catheter is a perfusion catheter.
- 1 31. The catheter of claim 26, wherein the catheter is a hemodialysis catheter.
- 1 32. The catheter of claim 26, wherein the first lumen extends distally further than
2 a distal end of the second lumen.
- 1 33. The catheter of claim 26, wherein the one or more openings comprises a
2 plurality of openings in the sidewall.
- 1 34. The catheter of claim 26, wherein the catheter comprises a flexible polymer.
- 1 35. The catheter of claim 26, wherein the catheter comprises a thermoplastic
2 elastomer.
- 1 36. The catheter of claim 26, wherein the catheter comprises a material of
2 construction selected from the group consisting of: polyvinylchloride, polyethylene, polypropylene,
3 polyurethane, nylon, a polyether block amide, metal, carbon fibers, glass fibers, a combination
4 thereof, and a composite thereof.
- 1 37. A multi-lumen catheter having a sidewall and one or more openings, the
2 catheter adapted for minimized obstruction of the one or more openings by a lumen wall in which the
3 catheter is positioned, wherein, in at least in a portion of the catheter coincident with the one or more
4 openings, the catheter:
- 5 (a) further comprises a twisting septum dividing an interior of the catheter into
6 multiple lumens, the multiple lumens forming a multi-helix;
- 7 (b) is spirally formed into a corkscrew pattern;
- 8 (c) is formed into an inwardly spiraling portion having a periphery that defines
9 an open area, the one or more openings positioned facing or within the open area; or
- 10 (d) a combination of (a) and (b) or (a) and (c).
- 1 38. A multi-lumen catheter tip having a sidewall and one or more openings, the
2 catheter tip adapted for minimized obstruction of the one or more openings by a lumen wall in which
3 the catheter tip is positioned, wherein the catheter tip:

4 (a) further comprises a twisting septum dividing an interior of the catheter tip
5 into multiple lumens, the multiple lumens forming a multi-helix;

6 (b) is spirally formed into a corkscrew pattern;

7 (c) is formed into an inwardly spiraling portion having a periphery that defines
8 an open area, the one or more openings positioned facing or within the open area; or

9 (d) a combination of (a) and (b) or (a) and (c).

1 39. A method of making a multi-lumen catheter having a body and a catheter tip,
2 the catheter tip comprising a sidewall and one of: a twisting septum dividing an interior of the
3 catheter tip into multiple lumens in a multi-helix, being spirally formed into a corkscrew pattern, or a
4 combination thereof, the method comprising the steps of:

5 (a) forming the multi-lumen catheter body;

6 (b) molding the catheter tip into the multi-helix, the corkscrew pattern, or both;

7 and

8 (c) attaching the catheter body to the catheter tip.

1 40. A method of making a multi-lumen catheter having a body and a catheter tip,
2 the catheter tip comprising a sidewall and one of: a twisting septum dividing an interior of the
3 catheter tip into multiple lumens in a multi-helix, being spirally formed into a corkscrew pattern or an
4 inwardly spiraling portion, or a combination thereof, the method comprising the steps of:

5 (a) forming the multi-lumen catheter;

6 (b) heating at least the catheter tip to a sufficient temperature at which the
7 catheter tip can be deformed;

8 (c) deforming the catheter tip into the multi-helix, the corkscrew pattern, the
9 inwardly spiraling portion, or a combination thereof; and

10 (d) cooling the catheter tip.

1 41. A method of making a multi-lumen catheter having a sidewall and a twisting
2 septum dividing an interior of the catheter into multiple lumens in a multi-helix, the method
3 comprising extruding the catheter using an extrusion tooling insert that rotates to form the twisting
4 septum.

1 42. A method of making a multi-lumen catheter having a sidewall and a twisting
2 septum dividing an interior of the catheter into multiple lumens in a multi-helix, the method

3 comprising extruding the catheter and septum with no twist in the septum and then twisting the
4 catheter as it exits the extruder.

1 43. A method of providing hemodialysis, the method comprising the steps of:

2 (a) introducing a multi-lumen catheter into a body lumen having a wall, the
3 catheter comprising a body and a catheter tip and defining at least a first lumen and a second lumen,
4 wherein the catheter tip comprises a sidewall and either: further comprises a twisting septum dividing
5 an interior of the catheter tip into at least the first lumen and the second lumen in a multiple-helix; is
6 spirally formed into a corkscrew pattern or an inwardly spiraling pattern; or a combination thereof;

7 (b) drawing blood from the body lumen through one or more openings into the
8 first catheter lumen, wherein the multiple-helix, corkscrew pattern, inwardly spiraling pattern, or
9 combination thereof minimizes occlusion of the one or more openings by the body lumen wall;

10 (c) cleansing the blood by hemodialysis; and

11 (d) returning the blood through the second catheter lumen into the body lumen.

1 44. The method of claim 43, wherein step (a) comprises deploying the catheter in
2 the body lumen of a patient having a heart with a right atrium such that the a distal end of the catheter
3 is located in or adjacent to the right atrium of the patient's heart.

1 45. The method of claim 44, wherein the catheter tip comprises a corkscrew
2 pattern and the second lumen extends distally further than a distal end of the first lumen and is
3 pointed in a direction toward the right atrium, wherein step (d) comprises returning the blood in a
4 stream directed toward the right atrium.

1 46. A catheter comprising an elongated tube having one or more openings, at
2 least a portion of the catheter coincident with the one or more openings formed into an inwardly
3 spiraling portion having a periphery that defines an open area, the one or more openings positioned
4 within the open area or facing the open area.

1 47. The catheter of claim 46, wherein the catheter comprises an open end,
2 wherein the open end is positioned within the open area.

1 48. The catheter of claim 47, wherein the catheter comprises a single lumen
2 catheter.

1 49. The catheter of claim 46, wherein the catheter comprises a sidewall and a
2 plurality of openings in the sidewall wherein the plurality of sidewall openings are positioned facing
3 the open area.

1 50. A catheter for deployment in a lumen having a wall, the catheter comprising
2 an elongated tube comprising a catheter tip, one or more openings in the catheter tip, and a
3 deformation in the catheter tip for preventing the one or more openings from contacting the lumen
4 wall.

1 51. The catheter of claim 50, wherein the deformation comprises a corkscrew
2 pattern.

1 52. The catheter of claim 50, wherein the deformation comprises an inwardly
2 spiraling portion.

1 53. The catheter of claim 52, wherein the catheter comprises an uncurled portion
2 proximal of the inwardly spiraling portion having a lower surface that lies within a first plane
3 tangential to the lower surface, the inwardly spiraling portion curling away from the first plane and
4 lying at least partially within a second plane perpendicular to the first plane.

1 54. The catheter of claim 53, wherein the inwardly spiraling portion comprises a
2 curl of greater than 360 degrees.

1 55. The catheter of claim 53, wherein the inwardly spiraling portion comprises a
2 curl of approximately 360 degrees.

1 56. The catheter of claim 53, wherein the inwardly spiraling portion comprises a
2 curl of less than 360 degrees.

1 57. The catheter of claim 53, wherein the inwardly spiraling portion does not
2 cross the first plane.

1 58. The catheter of claim 53, wherein the inwardly spiraling portion comprises a
2 portion that is parallel to the uncurled section and lies on the first plane.

1 59. The catheter of claim 53, wherein the inwardly spiraling portion crosses the
2 first plane.

1 60. The catheter of claim 52, wherein the one or more openings comprise a
2 plurality of openings in a sidewall of the catheter.

1 61. The catheter of claim 60, wherein the inwardly spiraling portion comprises an
2 inner periphery that defines an area of open space inside the inner periphery and the openings face
3 into the open space.

1 62. The catheter of claim 61, wherein the one or more openings comprises at
2 least one opening at a distal end of the catheter positioned inside the open space.

- 17 -

1 63. The catheter of claim 52, wherein the inwardly spiraling portion comprises an
2 inner periphery that defines an area of open space inside the inner periphery and the one or more
3 openings comprises at least one opening at a distal end of the catheter positioned inside the open
4 space.

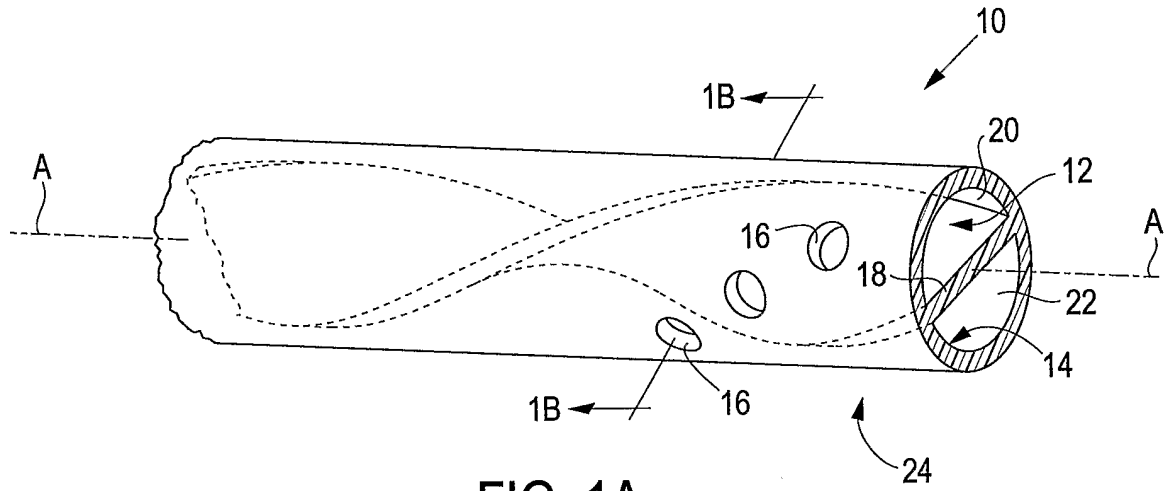


FIG. 1A

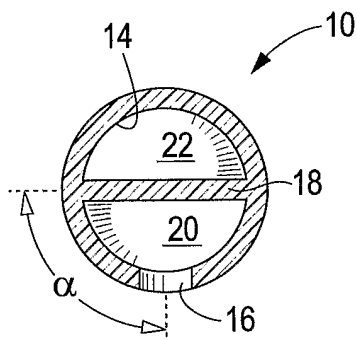


FIG. 1B

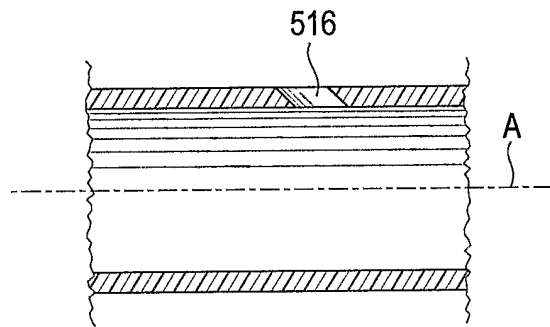


FIG. 5

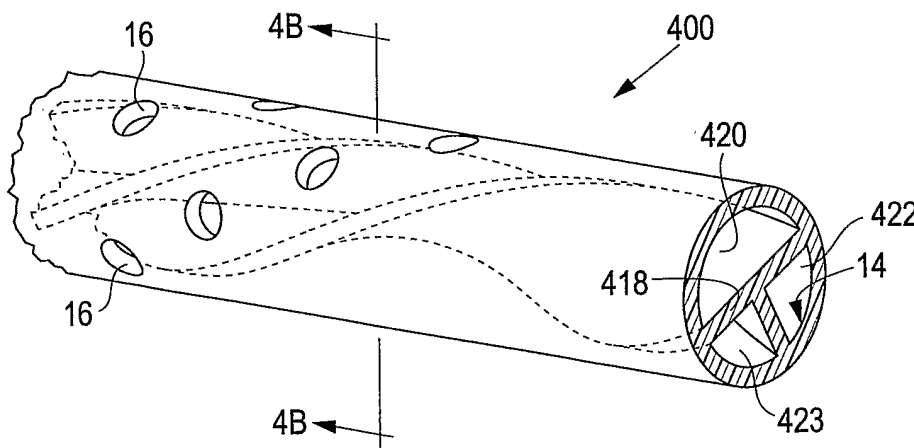


FIG. 4A

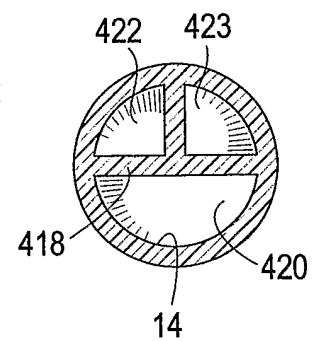


FIG. 4B

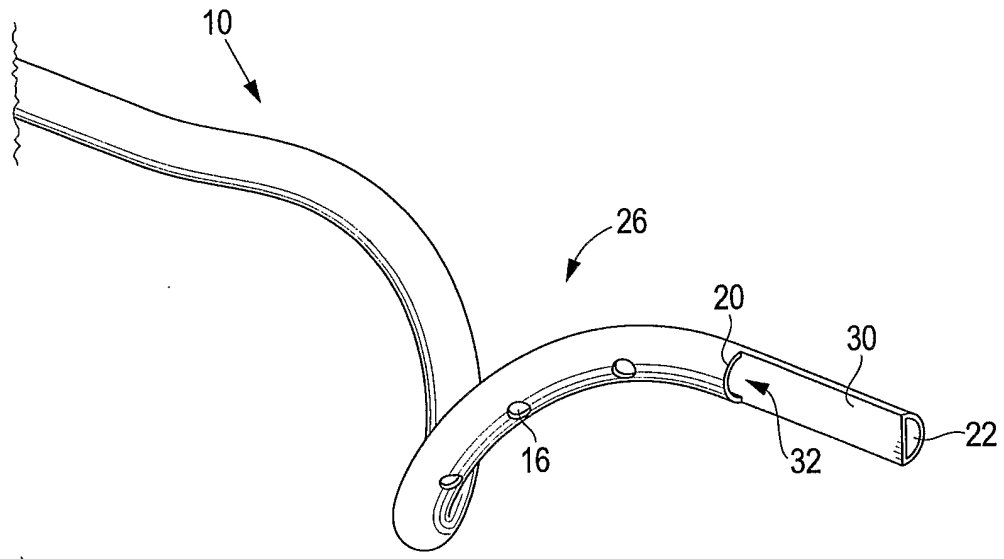


FIG. 2A

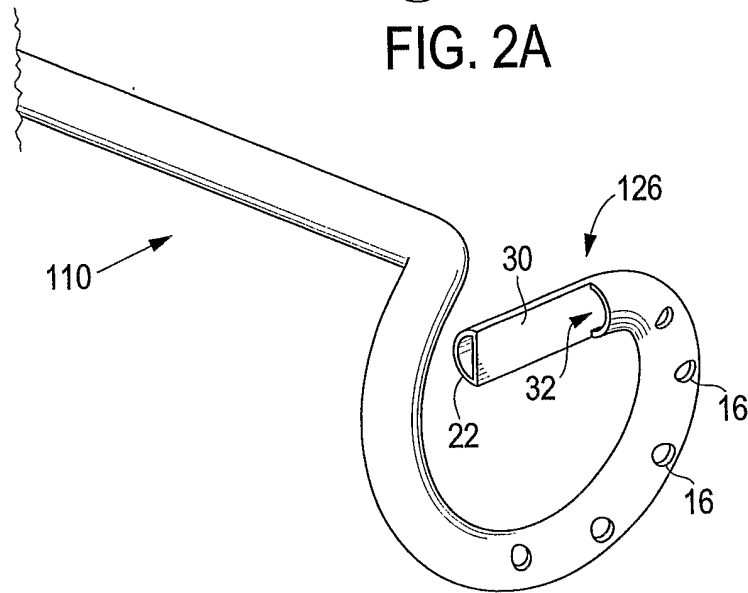


FIG. 2B

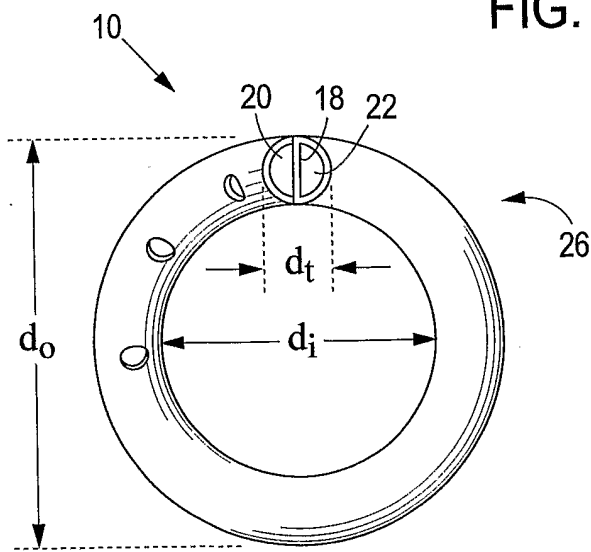


FIG. 3A

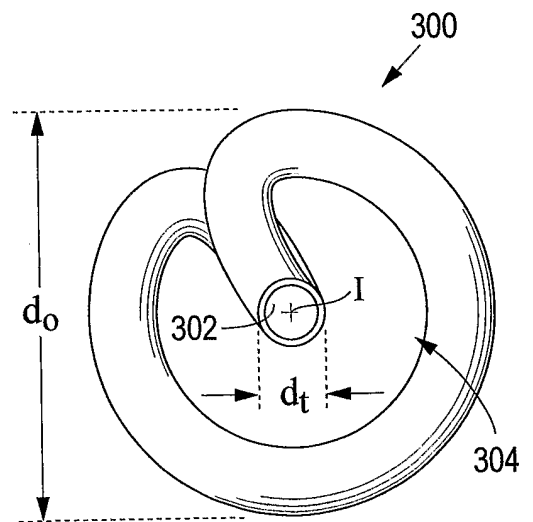


FIG. 3B

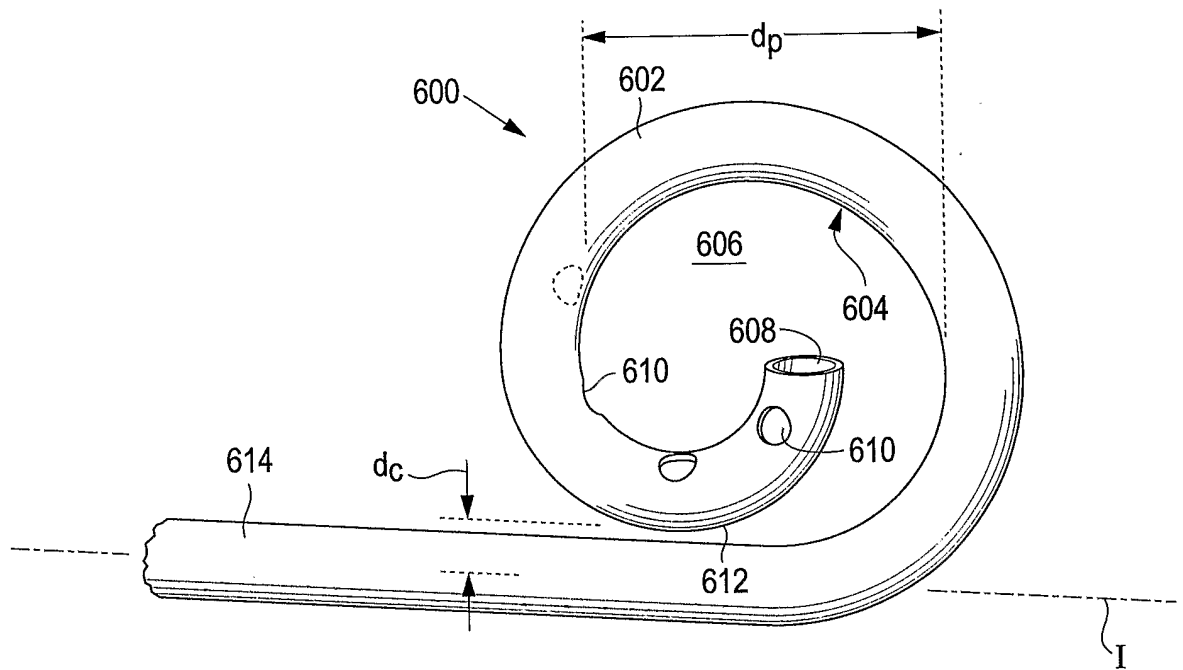


FIG. 6A

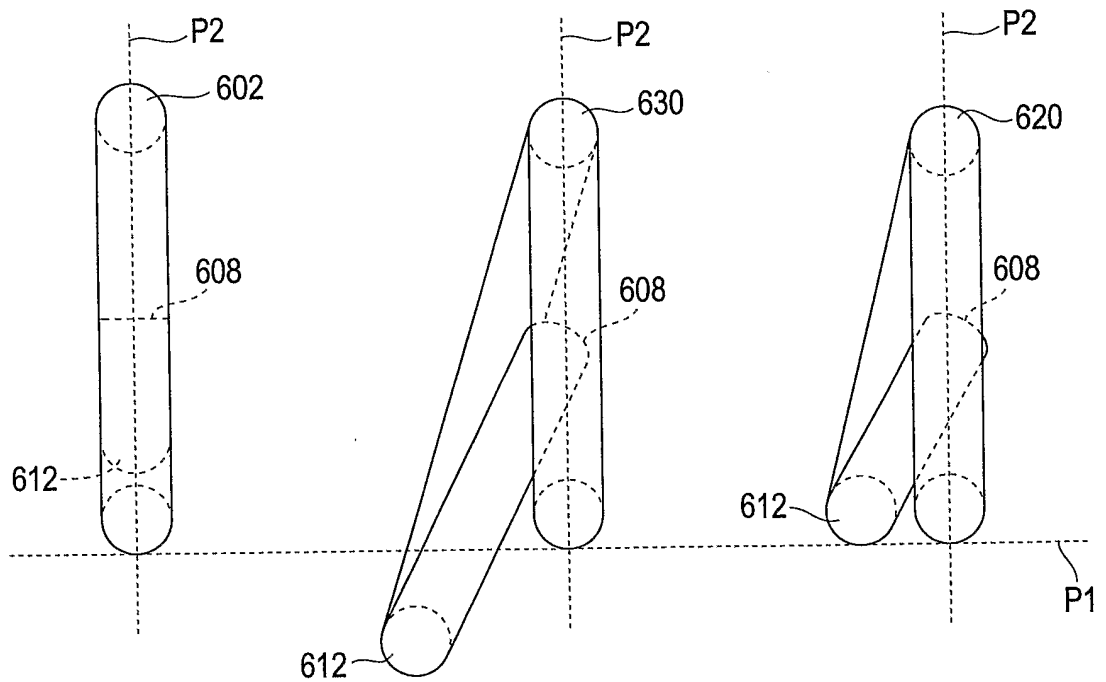


FIG. 6B

INTERNATIONAL SEARCH REPORT

Internati Application No
PCT/us 03/02603A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 386 408 A (BRAUN MELSUNGEN AG) 12 September 1990 (1990-09-12) the whole document ---	1-9, 13, 16-22
X	US 5 873 865 A (HORZEWSKI MICHAEL ET AL) 23 February 1999 (1999-02-23) column 6, line 63 -column 8, line 21; figures ---	1-4, 13, 16-24
X	US 4 681 570 A (DALTON MICHAEL J) 21 July 1987 (1987-07-21) claims; figures ---	1-5, 13, 16-22
X	US 4 694 838 A (WIJAYARTHNA BANDULA ET AL) 22 September 1987 (1987-09-22) column 7, line 50 -column 8, line 16; figure 9 --- -/--	1-4, 14

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document 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

23 June 2003

Date of mailing of the international search report

27/06/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Kousouretas, I

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/02603**Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 43-45
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: 26-42, 46-63
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:
see FURTHER INFORMATION sheet PCT/ISA/210
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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

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 fee, this Authority did not invite payment of any additional fee.
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.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 26-42,46-63

The present application contains 63 claims, 11 of which are presented as independent claims differing from one another by their technical content and/or in the wording used to define such technical content, and including within their scope an extremely large number of possible devices and methods.

In view of the large number and also the wording of the claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search is impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear (and concise), namely claims 1-25.

No formal objection concerning lack of unity has been raised at this point because of the above-mentioned clarity and conciseness objection. However, it could be that several of the independent and dependent claims define inventions which are not linked so as to form a single inventive concept (Rule 13 - PCT) and the applicant's attention is thus drawn to this point.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Internat Application No
PCT/US 03/02603

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 554 114 A (EVANS SCOTT M ET AL) 10 September 1996 (1996-09-10) column 10, line 12 - line 54; figures -----	1-5, 13, 16-22
A	US 4 795 439 A (GUEST ROBERT L) 3 January 1989 (1989-01-03) the whole document -----	1, 2, 5-11, 16

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/02603

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0386408	A	12-09-1990	DE 3907618 A1 EP 0386408 A1	20-09-1990 12-09-1990
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US 4681570	A	21-07-1987	NONE	
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US 5554114	A	10-09-1996	CA 2160847 A1 EP 0787018 A1 JP 10509350 T WO 9613295 A1	21-04-1996 06-08-1997 14-09-1998 09-05-1996
US 4795439	A	03-01-1989	NONE	