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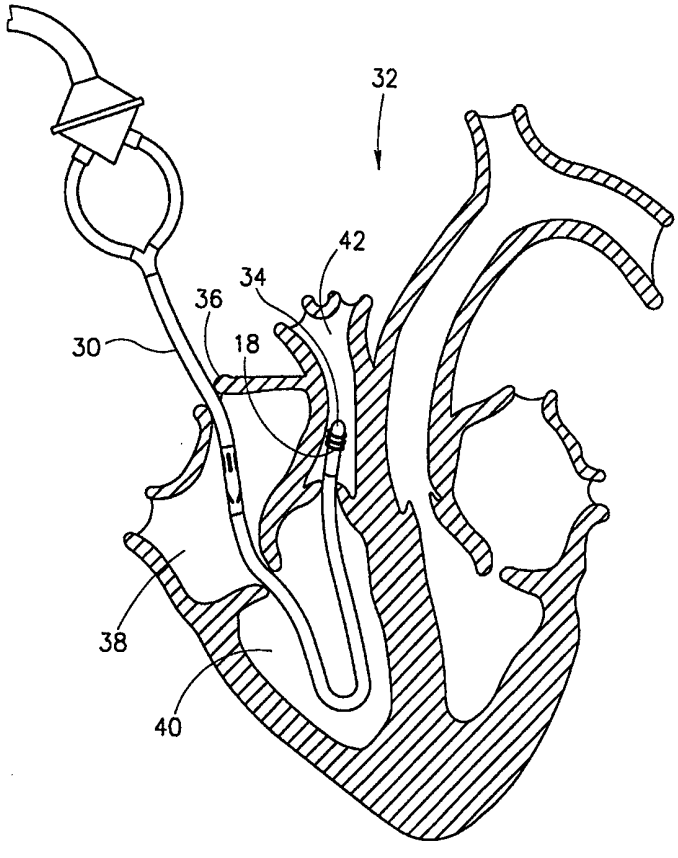
(54) Title: FINNED–TIP FLOW GUIDED CATHETERS

(57) Abstract

Apparatus for percutaneous insertion into the cardiovascular system comprising: a catheter or catheter guide having a distal end; and at least one flexible permanently extended generally radial protrusion, for example a thin flexible fin or plurality of radially spaced fins, situated adjacent the distal tip of the catheter.



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FINNED-TIP FLOW GUIDED CATHETERS

FIELD OF INVENTION

The present invention relates generally to catheters for percutaneous insertion into the cardiovascular system, and specifically to catheters that rely on a flow impediment to generate a drag force that is used for their positioning.

BACKGROUND OF THE INVENTION

Cannulae that rely on the blood stream drag force for their positioning, with the help of balloons at the cannula distal tips are known.

PCT/IL98/000142, "Heart Assist System with Cannula Pump," whose disclosure is incorporated herein by reference, describes a cannula with an attached extensible protrusion, such as a balloon, wherein the balloon provides sufficient impediment to blood flow, so that the tip of the cannula is guided or carried in the direction of the flow. In preferred embodiments, a balloon is attached at or near the distal end of the cannula. The balloon is inflated during placement of the cannula. In its inflated configuration, the balloon presents a resistance to the blood flow and is thus carried along by the flowing blood. This helps guide the end of the cannula through curves in the right atrium and ventricle and into the pulmonary artery. Such an extensible balloon may be used whether the cannula enters the body via the jugular vein, the femora vein, or the vena cava and therefrom to the right ventricle. Similarly, the balloon may be used to aid in the placement of the cannula tip in the aorta when the cannula is inserted from the left ventricle into the aorta.

US 4,985,014, "Ventricular Venting Loop," whose disclosure is incorporated herein by reference describes a percutaneous insertion of a catheter in a ventricular venting loop wherein in right ventricular venting, the catheter tip, with an inflated arterial balloon, is allowed to flow with the blood stream and to pass the right ventricle into the pulmonary artery.

Cannulae and catheters with extensible balloons have certain advantages. The balloon is deflated during insertion into small-diameter blood vessels, such as the femoral or the jugular vessel, so it does not interfere with the insertion. Furthermore, the balloon is light.

At the same time, cannulae and catheters with extensible balloons have certain disadvantages. In order to inflate the balloon, the cannula must have an additional lumen of air or liquid. As a result, the cannula diameter must be large enough to accommodate two lumens. Furthermore, the system is unsuitable for long-term inflation, because of the possibility of rupture of the thin-wall balloon.

WO 97/24983, "Mapping Catheter," whose disclosure is incorporated herein by

reference, describes a catheter whose distal end comprises at least three non-collinear electrodes, preferably attached to a substantially rigid ring of resilient, super elastic material, at the distal end of the catheter. In preferred embodiments, for insertion, or removal from the body, the ring is compressed inside a narrow sleeve adjacent to the distal end of the catheter. After insertion of the catheter, the ring is ejected from the sleeve and assumes its predetermined shape and position. Thus, the above system does not use the extended protrusion to generate a drag force.

SUMMARY OF THE INVENTION

One aspect of some preferred embodiments of the present invention provides a catheter with an attached extended protrusion in the form of flexible fins, wherein the fins generate drag force that carries the catheter with the blood flow to its proper position.

Another aspect of some preferred embodiments of the present invention provides fins that are radial or ring-shaped.

Another aspect of some preferred embodiments of the present invention provides a plurality of fins close to the tip of the catheter.

Another aspect of some preferred embodiments of the present invention provides fins that are axially displaced from the tip of the catheter.

Another aspect of some preferred embodiments of the present invention provides fins of substantially the same material as that of the catheter. Preferably, the material is silicon rubber.

In preferred embodiments of the present invention, a catheter with extended fins is guided or carried in the direction of the flow. In preferred embodiments, the extended fins are attached near the distal end of the catheter. The fins present a resistance to the blood flow and are thus carried along by the flowing blood. This helps guide the end of the catheter through curves in the right atrium and ventricle and into the pulmonary artery. The fins may be used whether the catheter enters the body via the jugular vein, the femora vein, or the vena cava and therefrom to the right ventricle. Similarly, the fins may be used to aid in the placement of the catheter tip in the aorta when the catheter is inserted from the left ventricle into the aorta. Similarly, the fins may be used for non-cardiac catheters.

Preferably, the extended fins are very flexible, so they fold backwards when passing through a constriction such as a sclerosis or a valve. When folded backwards, they do not enlarge the catheter diameter, or else they enlarge the catheter's diameter only slightly. Preferably, the fins generate a high drag force. The drag force that is generated is a function of

the fins' geometry, the number of fins and the space between them.

It should be noted that the extended fins have a distinct advantage over the balloon system. When extended, the fins provide a constant space between the catheter and the blood vessel walls. Therefore, when the catheter is a pump cannula, blood expelled from an outlet of the cannula does not impinge directly on the blood-vessel walls. In this way, possible damage to the blood vessels is averted.

An added advantage of the extended fins is that they pass more easily through valves and constrictions than balloons and do not require any action by the operator (such as deflation of the balloon) to do so. Also, no additional lumen is required so that the lumen may be completely used for blood flow or for passing object therethrough.

There is thus provided, in accordance with a preferred embodiment of the invention, apparatus for percutaneous insertion into the cardiovascular system comprising:

a catheter or catheter guide having a distal end; and

at least one flexible permanently extended generally radial protrusion, adjacent the distal tip of the catheter.

Preferably, the at least one protrusion comprises a plurality of axially displaced protrusions. Alternatively, the at least one protrusion is situated at a substantially single axial dimension.

Preferably, the at least one flexible extended protrusion is situated proximal to the distal end. Alternatively, at least one protrusion is situated at the distal end.

In a preferred embodiment of the invention, the at least one extended protrusion comprises at least one fin.

Preferably, the at least one fin continuously surrounds the catheter or guide. Alternatively, the at least one fin comprises at least one row of petal-leaf fins. Preferably, the at least one row of petal-leaf fins comprises a plurality of rows of axially and circumferentially displaced rows of petal-leaf fins.

In a preferred embodiment of the invention, the fin has a curved face and wherein the face is convex when viewed from the distal end. Alternatively or additionally, the fins are swept back with respect to the axis of the catheter or catheter guide.

Alternatively, the at least one extended protrusion comprises at least one row of finger fins. Preferably, the finger fins comprise a plurality of fins arranged in axially displaced rows. Preferably, the axially displaced rows are also circumferentially displaced with respect to each other.

In a preferred embodiment of the invention, the at least one extended protrusion is a made of the same material as the catheter. Preferably, the at least one protrusion is not reinforced. Preferably, the at least one protrusion is integrally formed with the catheters.

In a preferred embodiment of the invention, the at least one protrusion is so constructed that is provides substantial resistance to flowing fluid but substantially no resistance when contacted with a solid object.

In a preferred embodiment of the invention, the catheter has an outlet hole or holes situated slightly proximal to at least one extended protrusion. Alternatively or additionally the catheter has an outlet hole at the center of the distal end.

In a preferred embodiment of the invention, the protrusions protrude between 0.8 and 5 mm from the catheter or guide, more preferably, between 1.2 and 4 mm from the catheter or guide and most preferably, between 1.5 and 2.5 mm from the catheter or guide.

In a preferred embodiment of the invention, each of the at least one protrusions has a thickness of between 0.2-0.8 mm thick, in the axial direction, more preferably between 0.3-0.5 mm thick, more preferably about 0.4 mm.
in the axial direction.

In a preferred embodiment of the invention, the protrusions are formed of a silicone rubber material.

Preferably, the catheter of guide is formed with a tapered tip.

In a preferred embodiment of the invention, the catheter or guide is a catheter. Alternatively, it is a guide.

In a preferred embodiment of the invention, in which the catheter is a cannula pump the apparatus includes:

an intake associated with the cannula; and

an outlet associated with the cannula.

The intake and the outlet may be one-way valves.

In a preferred embodiment of the invention, the catheter serves for injection or for withdrawal of fluids. Alternatively or additionally, the catheter serves for the insertion of a specific instrument to the cardiovascular system.

The present invention will be more clearly understood with reference to the following detailed descriptions of non-limiting preferred embodiments of the invention, taken together with the following drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic, sectional representation of a finned-tip catheter in accordance with a preferred embodiment of the present invention, illustrating a catheter with three rows of radial fins and showing the dimensions and tolerances of the catheter;

Fig. 2 is a schematic, sectional representation of a finned-tip catheter in accordance with a preferred embodiment of the present invention, illustrating a catheter with a system of petal-leaf fins;

Fig. 3 is a schematic, sectional representation of a finned-tip catheter in accordance with a preferred embodiment of the present invention, illustrating a catheter with a system of finger fins; and

Fig. 4 is a schematic representation of a heart-assistance pump, in accordance with a preferred embodiment of the present invention, illustrating the percutaneous insertion of a cannula pump using a finned-tip cannula.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1, which is a schematic sectional representation of a finned-tip catheter 10, in accordance with a preferred embodiment of the present invention. Catheter 10 comprises a tube 12 having a distal end 14. Preferably, the distal end has a tapered solid tip 16 to aid in passing the tip into constrictions. Preferably, at least one ring fin 18 is attached to the catheter at distal end 14, preferably, somewhat proximal to the end. Preferably, the ring fin completely surrounds the circumference of tube 12. Alternatively, at least one fin 18 is attached at the distal-most tip of catheter 10. Preferably, at least one fin 18 comprises a single fin or row of fins. Alternatively, at least one fin 18 comprises a plurality of axially displaced fins. Preferably, at least one fin 18 is made of the same material as tube 12. Preferably, tube 12 is made of silicon rubber, although other flexible, biocompatible materials may be used. While three fins are shown in Fig. 1, one, two, three or more fins may be used.

Fig. 1 also shows dimensions and tolerances for catheter 10. Note that the overall diameter of the catheter and extended fins is preferably about 10 mm, while the outside diameter of the catheter alone is, for example, 6.5 mm. Therefore, each fin extends radially for 1.75 mm from the outside of tube 12. Since the distance between fins shown is 2.0 mm, there is no overlap when the fins are folded back. It should be understood that these dimensions are only representative and that other dimensions for tube 12 and fins 18 may be used. In especially preferred embodiments of the invention, the fins are thin enough so that they pose substantially no resistance to solid objects such as valves or obstructions, while being rigid

enough to pose substantial resistance to blood flow. Optionally, the outer diameter of tube 12 is reduced, proximal to the fins, such that when the fin is folded back, the total diameter of the tube and fins is essentially the same as that of the (unreduced diameter) tube.

Preferably, tube 12 comprises a through hole 20 slightly more proximal than at least one fin 18. Alternatively, a hole 20 or more preferably a number of holes, may be located at the very tip of tube 12. The hole may serve as a fluid outlet or as a port for special instruments.

In some preferred embodiments of the invention, catheter 10 serves as a cannula pump. In these preferred embodiments, hole 20 serves as a blood outlet. Preferably, where catheter 10 is a cannula pump, an inlet-outlet valve unit is used. Preferably, the inlet-outlet valve unit is such as that described in one or more of the following patent applications: PCT/IL96/00044, PCT/IL97/00201, WO 97/02850, PCT/IL97/00386 and PCT/IL98/00142, the disclosures of which are incorporated by reference. However, the invention is not limited to cannula pumps using these valves and other valves, as known in the art, may be advantageously utilized. Furthermore, the invention is not limited to cannula pumps and may be used with all types of catheters to be guided by blood or other fluid flow in the heart or in other parts of the body.

It should be noted that where catheter 10 serves as a cannula pump, the fin structure provides an additional advantage, in that the fins provide constant space between the cannula and the blood-vessel walls. As such, they keep the blood-vessel walls at a distance from the expelled blood, and prevent possible damage to the blood vessels.

In some preferred embodiments, catheter 10 serves for injection or for withdrawal of fluids. Hole 20 may serve as a port for the injection or for the withdrawal. Again the fin structure protects blood-vessel walls from impingement of injected fluid.

In some preferred embodiments, catheter 10 serves for the insertion of special instruments such as a pressure gauge or an electrode. Preferably, the special instrument is inside catheter 10 or passed through the lumen to the catheter. Alternatively, the special instrument is attached to catheter 10 so that it is inserted with it wherein catheter 10 serves as a guide. Generally, catheter 10 would be provided with one or more ports for deployment of the instruments.

Reference is now made to Fig. 2 which is a schematic sectional representations of another fin structure in accordance with another preferred embodiment of the present invention. Fig. 2 illustrates a fin structure in the form of petal leaves 22. Preferably petal leaves 22 comprise at least one row of petal-leaf fins. Preferably, there are at least three, and possibly more than three petal leaves in a row. Preferably, there are a plurality of rows of petal

leaves, each slightly more proximal than the other. In some preferred embodiments of the invention, there is a radial offset between one row of petal leaves and the other.

Figs. 1 and 2 show purely radially disposed fins. In other preferred embodiments of the invention, while the fins are radial, they may be of a cupped shape and/or may be swept back. Such fins provide even lower resistance to instructions and more (and more consistent) resistance to the blood flow.

Reference is now made to Fig. 3 which is a schematic sectional representations of still another fin structure in accordance with still another preferred embodiment of the present invention. Fig. 3 illustrates a fin structure in the form of a plurality of fingers 24, arranged in at least one row, and preferably in several rows.

In preferred embodiments of the invention, the fins (of all three figures) are integrally formed with the tube, preferably made of the same material as the tube and preferably integrally molded with the tube.

Reference is now made to Fig. 4 which is a schematic representation of a heart-assistance pump, in accordance with a preferred embodiment of the present invention, illustrating the percutaneous insertion of a cannula pump 30 to a heart 32 using a finned tip cannula. Cannula 30 is inserted through a vena cava 36, via a right atrium 38, to a right ventricle 40, and to a pulmonary artery 42. The finned-tip structure (preferably including a plurality of axially displaced fins 34) acts as a flow impediment to generate a drag force that is used for positioning the cannula. The system is very similar to that of PCT/IL98/00142 whose disclosure is incorporated herein by reference, where a fin structure replaces the balloon of PCT/IL98/00142.

The present invention has been described in terms of preferred, non-limiting embodiments thereof. It should be understood that features described with respect to one embodiment may be used with other embodiments and that not all embodiments of the invention have all of the features shown in a particular figure. In particular, the scope of the invention is not defined by the preferred embodiments but by the following claims. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

CLAIMS

1. Apparatus for percutaneous insertion into the cardiovascular system comprising:

a catheter or catheter guide having a distal end; and

at least one flexible permanently extended generally radial protrusion, adjacent the distal tip of the catheter.

2. Apparatus according to claim 1 wherein the at least one protrusion comprises a plurality of axially displaced protrusions.

3. Apparatus according to claim 1 wherein the at least one protrusion is situated at substantially a single axial dimension.

4. Apparatus according to any of the preceding claims wherein the at least one flexible extended protrusion is situated proximal to the distal end.

5. Apparatus according to any of claims 1-3 wherein at least one protrusion is situated at the distal end.

6. Apparatus according to any of the preceding claims, wherein the at least one extended protrusion comprises at least one fin.

7. Apparatus according to claim 6, wherein the at least one fin is a ring fin that continuously surrounds the catheter or guide.

8. Apparatus according to claim 6 herein the at least one fin comprises at least one row of petal-leaf fins.

9. Apparatus according to claim 8 wherein the at least one row of petal-leaf fins comprises a plurality of rows of axially and circumferentially displaced rows of petal-leaf fins.

10. Apparatus according to any of claims 6-9 wherein the fin has a curved face and wherein the face is convex when viewed from the distal end.

11. Apparatus according to any of claims 6-10 wherein catheter has an axis and wherein the fins are swept back with respect to the axis of the catheter or catheter guide.

12. Apparatus according to any of claims 1-6, wherein the at least one extended protrusion comprises at least one row of finger fins.

13. Apparatus according to claim 12, wherein the finger fins comprise a plurality of fins arranged in axially displaced rows.

14. Apparatus according to claim 13 wherein the axially displaced rows are also circumferentially displaced with respect to each other.

15. Apparatus according to any of the preceding claims, wherein the at least one extended protrusion is a made of the same material as the catheter.

16. Apparatus according to claim 15 wherein the at least one protrusion is not reinforced.

17. Apparatus according to claim 15 or claim 16 wherein the at least one protrusion is integrally formed with the catheters.

18. Apparatus according to any of the preceding claims wherein the at least one protrusion is so constructed that is provides substantial resistance to flowing fluid but substantially no resistance when contacted with a solid object.

19. Apparatus according to any of the preceding claims, wherein the catheter has an outlet hole situated slightly proximal to at least one extended protrusion.

20. Apparatus according to any of the preceding claims, wherein the catheter has an outlet hole at the center of the distal end.

21. Apparatus according to any of the preceding claims wherein the protrusions protrude between 0.8 and 5 mm from the catheter or guide.

22. Apparatus according to any of the preceding claims wherein the protrusions protrude between 1.2 and 4 mm from the catheter or guide.

23. Apparatus according to any of the preceding claims wherein the protrusions protrude between 1.5 and 2.5 mm from the catheter or guide.

24. Apparatus according to any of the preceding claims wherein each of the at least one protrusions has a thickness of between 0.2-0.8 mm thick, in the axial direction.

25. Apparatus according to any of the preceding claims wherein each of the at least one protrusions has a thickness of between 0.3-0.5 mm thick, in the axial direction.

26. Apparatus according to claim 25 wherein the thickness is about 0.4 mm.

27. Apparatus according to any of the preceding claims wherein the protrusions are formed of a silicone rubber material.

28. Apparatus according to any of the preceding claims wherein the catheter of guide is formed with a tapered tip.

29. Apparatus according to any of the preceding claims wherein the catheter or guide is a catheter.

30. Apparatus according to any of the preceding claims wherein the catheter or guide is a guide.

31. Apparatus according to any of the preceding claims, wherein the catheter is a cannula pump and including:

an intake associated with the cannula; and

an outlet associated with the cannula.

32. Apparatus according to claim 31, wherein the intake and the outlet are one-way valves.

33. Apparatus according to any of claims 1-30, wherein the catheter serves for injection or for withdrawal of fluids.

34. Apparatus according to any of claims 1-30 or 33, wherein the catheter serves for the insertion of a specific instrument to the cardiovascular system.

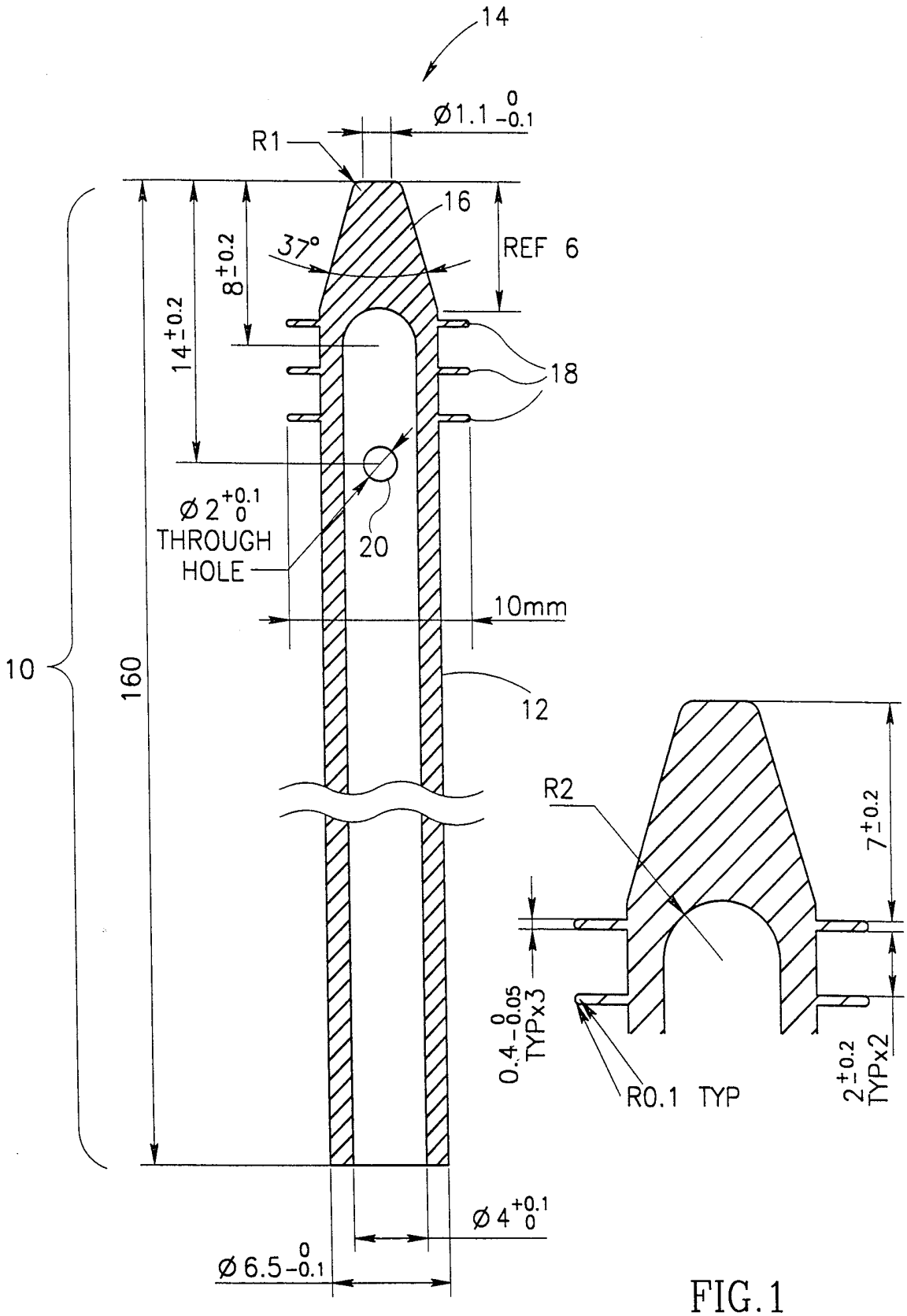
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FIG.1

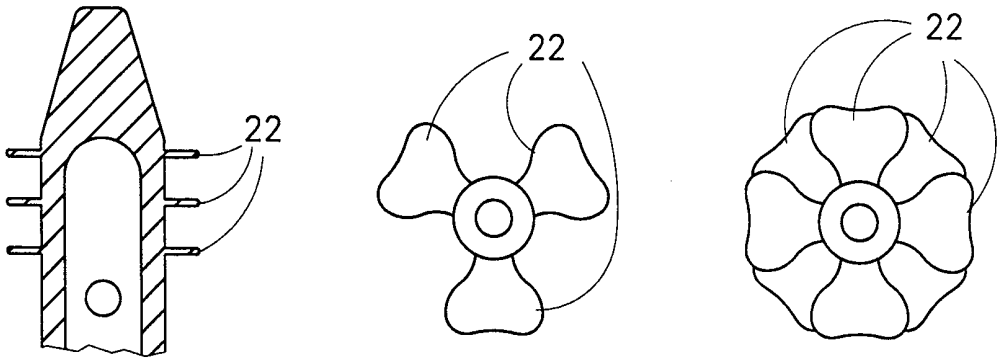

FIG.2

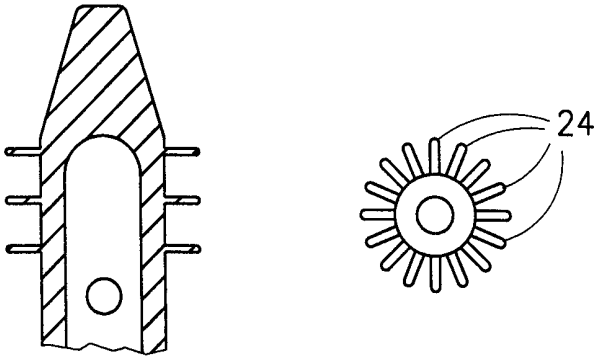

FIG.3

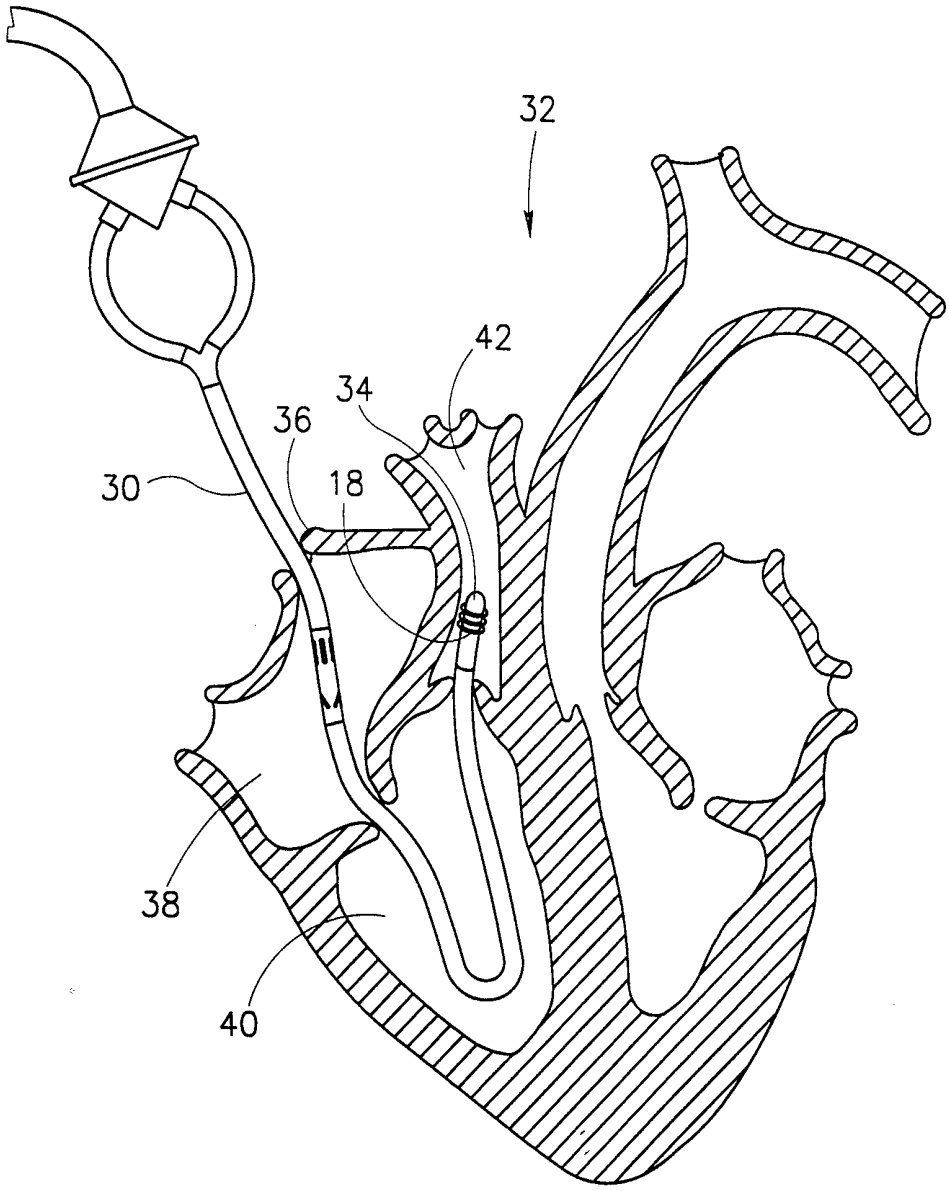

FIG.4

INTERNATIONAL SEARCH REPORT

national Application No
PCT/IL 98/00431

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/01

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 6 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 48435 A (MEDTRONIC, INC.) 24 December 1997 see page 9, line 31 - line 38 see page 11, line 6 - line 11 see page 13, line 8 - line 26 see figures 3,5-8	1-7,10, 12-18, 20, 27-29, 33,34
Y	---	31,32
Y	US 3 592 184 A (WATKINS) 13 July 1971 see column 2, line 14 - line 63 see figures 1,2	31,32

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
26 April 1999	06/05/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schönleben, J

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

	national Application No
	PCT/IL 98/00431

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 38194 A (SCIMED LIFE SYSTEMS, INC.) 5 December 1996 see page 15, line 14 - page 16, line 14 see figures 8,8A,8B ---	1-4, 15-18, 29,30
X	US 4 403 985 A (BORETOS) 13 September 1983 see column 2, line 48 - line 56 see figure 1 -----	1,3,4,6, 7,11, 15-20, 28,29

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 98/00431

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