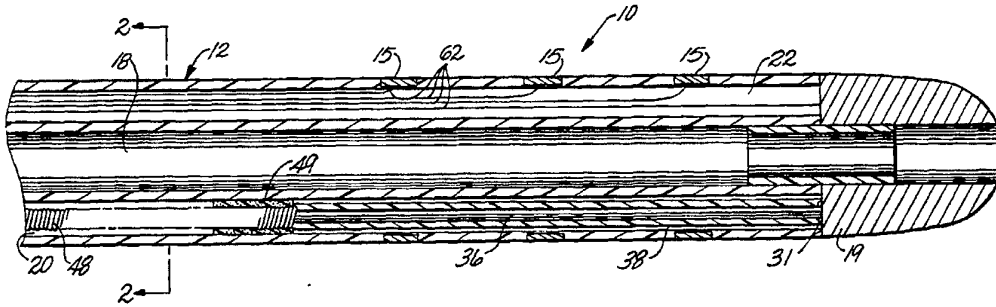




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(54) Title: STEERABLE OPEN-LUMEN CATHETER



(57) Abstract

A steerable catheter (10) comprises an elongated catheter body (12), a tip portion (14), first and second lumens (18, 20), a tightly wound coil (48), a puller wire (36), and a control handle.

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STEERABLE OPEN-LUMEN CATHETER

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Field of the Invention

This invention relates to steerable catheters for use in a body lumen, and more specifically to an electrode catheter having a steerable tip and an open lumen.

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Background of the Invention

Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity.

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In use, the electrode catheter is inserted into a major vein or artery, e.g., femoral artery, and then guided into the chamber of the heart which is of concern. Within the heart, the ability to control the exact position and orientation of the catheter tip is critical and largely determines how useful the catheter is.

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Steerable tip electrode catheters are now well known. Such a catheter generally has a control handle at its proximal end for controlling deflection of the tip in one or more directions. For example, U.S. Patent No. 4,960,134 to applicant discloses a particularly useful steerable tip catheter. This catheter comprises a puller wire which extends on-axis through an elongated reinforced catheter body and then off-axis in a deflectable tip portion. In this arrangement, longitudinal movement of the puller wire relative to the catheter body results in deflection of the catheter tip portion. The catheter body tends not to deflect for two reasons. First, it is reinforced and therefore resists compression. Second, the puller wire extends coaxially within the catheter body. The compressive forces on the catheter body are generally uniformly distributed across the catheter body and deflection is thereby minimized. This allows precise rotational control of the catheter body and tip.

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1 In certain applications, it is desirable to have the ability to inject and/or
withdraw fluid through the catheter. This is accomplished by means of an open
lumen catheter. For example, it is known that in cardiac ablation procedures
using radiofrequency (RF) energy, there is a tendency for the ablation electrode
5 to overheat. If overheating occurs, a coagulum forms on the surface of the
electrode and the catheter must be withdrawn, cleaned and reinserted for proper
use.

 It is known that the ablation electrode can be cooled by the passage of
a cooling fluid, e.g., saline solution, through a lumen in the electrode. In a small
10 diameter ablation catheter, e.g., 8 French or less, the size of a lumen sufficient
to pass a cooling fluid through the catheter to cool the ablation electrode is such
that it does not permit the presence of an on-axis puller wire. That is, the puller
wire must extend through the catheter off-axis. In such a catheter, longitudinal
15 movement of the puller wire relative to the catheter body results in not only
deflection of the tip, but of the catheter body itself. This makes rotation of the
catheter, particularly if the catheter is curved around a vascular bend,
exceedingly difficult to control. Thus, conventional designs for small diameter
catheters with deflectible tips cannot provide for an open lumen without loss of
tip control.

20 Summary of the Invention

 This invention provides a steerable open-lumen catheter with improved tip
control. The catheter comprises an elongated catheter body, a tip portion at the
distal end of the catheter body and a control handle at the proximal end of the
catheter body. At least two lumens extend through the catheter body and tip
25 portion.

 The first lumen has a diameter of at least about one-third and preferably
at least about one-half the outer diameter of the catheter body. For small
diameter catheters having an outer diameter of less than 0.1 inch, the diameter
of the first lumen is at least about 0.03 inch and preferably at least about 0.05
30 inch. The first lumen is open at the distal end of the tip portion. The first lumen
provides a pathway for the passage of fluids through the catheter, or movement
of a mechanical element, such as an optic fiber, anchoring wire or the like,
through the catheter.

 The second lumen is off-axis and comprises an elongated, flexible, but
35 non-compressible tightly wound coil spring fixedly disposed within the portion of
the second lumen extending through the catheter body. A puller wire is slidably
mounted within and extends through the coil spring into the tip portion. The

1 distal end of the puller wire is fixedly attached to the tip portion at or adjacent
to the distal end of the tip portion. The proximal end of the puller wire is
attached to the control handle for moving the puller wire longitudinally relative
to the catheter body and coil spring. By this arrangement, longitudinal
5 movement of the puller wire relative to the catheter body and coil spring results
in deflection of the catheter tip with minimal and preferably no deflection of the
catheter body.

10 Preferably, a flexible, compressible, lubricous sleeve surrounds the puller
wire in the tip portion. A sleeve made of polytetrafluoroethylene is presently
preferred.

15 In a particularly preferred embodiment of the invention, the tip portion
carries one or more electrodes, including a tip electrode. In such an embodiment,
the first lumen extends through the tip electrode and the distal end of the puller
wire may be attached directly to the tip electrode. There is preferably provided
a third lumen which extends through the catheter body and tip portion and
provides a passageway for electrode lead wires. The electrode lead wires extend
from the electrodes carried on the tip portion through the catheter body and
control handle to one or more plugs which are electrically connected to an
20 electrical stimulator and/or recorder, an RF energy source or the like.

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1 **Brief Description of the Drawings**

 These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

5 FIG. 1 is a longitudinal offset cross-sectional view of a preferred three lumen electrode catheter constructed in accordance with the present invention, showing all three lumens;

 FIG. 2 is a transverse cross-sectional view of the catheter body of FIG.1 along line 2-2; and

10 FIG. 3 is a longitudinal cross-sectional view of the proximal end of a preferred catheter showing a fitting for the injection or withdrawal of fluid through the open lumen of the catheter body.

 FIG. 4 is a longitudinal offset cross-sectional view of another preferred electrode catheter;

15 FIG. 5 is a longitudinal cross-sectional view of another ablation tip electrode;

 FIG. 6 is a longitudinal cross-sectional view of the distal end of another preferred ablation catheter including an anchor wire; and

20 FIG. 7 is a longitudinal cross-sectional view of the distal end of another preferred ablation catheter including an RF antenna.

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1 **Detailed Description**

 FIGS. 1, 2 and 3 illustrate a particularly preferred cardiovascular electrode
ablation catheter constructed in accordance with the present invention. The
catheter comprises an elongated catheter body 12 having proximal and distal
5 ends. A catheter tip portion 14 extends from the distal end of the catheter body
12 and a control handle (not shown) is provided at the proximal end of the
catheter body. With reference to FIG. 2, the catheter 10, including the catheter
body 12 and tip portion 14 comprises first, second and third lumens 18, 20 and
22 respectively.

10 The length and diameter of the catheter body 12 are not critical and may
vary according to the application. For the cardiovascular catheter shown in the
accompanying drawing, a length of about 40 to 48 inches and an outer diameter
of about 0.1 inch (7 or 8 French) is preferred.

 The catheter tip portion 14 preferably has a short length of about 2 to 3
15 inches. The diameter is preferably about the same as that of the catheter body
12 or may be slightly less (e.g., 6½-7 French) than the diameter of the catheter
body 12.

 The catheter tip portion 14 carries a plurality of electrodes, including ring
electrodes 15 and a tip ablation electrode 19. It is understood that the number,
20 size, and spacing of the electrodes may vary as desired. In the embodiment
shown, tip electrode 19 is mounted at the distal end of the tip portion 14 by
means of tubular insert 21. It is understood that any suitable attaching means
may be used.

 The catheter body 12 and tip portion 14 may be made of any suitable
25 non-toxic material. In a preferred embodiment, the catheter body 12 and tip
portion 14 comprise a single elongated tubular extrusion made of a thermoplastic
resin such as polyurethane. One or more layers of a reinforcing braided mesh
(not shown) of, for example, stainless steel or dacron, overlie the polyurethane
extrusion. The reinforcing mesh is, in turn, coated with a layer of polyurethane
30 or other suitable plastic material.

 It is understood that, if desired, the catheter body 12 and tip portion 14
may be separate sections of appropriate tubular material joined together rather
than a single extrusion. If separate sections of tubular material joined together,
the construction of the catheter body 12 need not be the same as that of the tip
35 portion 14. For example, the catheter body 12 may be reinforced with one or
more layers of stainless steel mesh, whereas the tip portion 14 may be
reinforced with dacron mesh or simply be unreinforced to increase flexibility.

1 The first lumen 18 extends the complete length of the catheter body 12
and tip portion 14 and extends through tip ablation electrode 19. First lumen 18
has a diameter of at least 0.03 inch and preferably of at least 0.05 inch.

5 With reference to FIG. 3, the proximal end of the catheter body 12
includes a splitter fitting 24 wherein the first lumen 18 branches into the interior
of side arm 26. The side arm 26 may be constructed in any suitable manner as
is well known in the art. As shown, the side arm 26 may comprise a short
segment of suitable tubing 27, e.g., polyamide tubing, one end of which is
10 inserted through an opening in the wall of the catheter body 12 and into the first
lumen 18 and cemented therein.

 The other end of tubing 27 is received by another section of tubing 29
which may, for example, terminate in a luer hub or the like to allow the injection
or withdrawal of fluids to or from the first lumen 18. Alternatively, the side arm
26 may be molded integrally with the catheter body 12.

15 Referring again to FIGS. 1 and 2, the second lumen 20 extends the length
of the catheter body 12 and tip portion 14. In the embodiment shown, the
second lumen 20 has a diameter of about 0.020 inch and is closed at its distal
end. Because of the need for a minimum diameter of at least 0.03 inch and
preferably 0.05 inch for the first lumen 18, the second lumen 20 necessarily
20 must be off-axis, i.e., cannot be coaxial with the catheter body.

 A tightly wound coil spring 48 is disposed in the portion of the second
lumen 20 which extends through the catheter body 12. The proximal and distal
ends of the coil spring 48 are fixed, e.g., by glue 49 or the like, to the wall of the
catheter body 12, forming the second lumen 20. The coil spring 48 has an outer
25 diameter slightly less than the diameter of the second lumen 20. The inner
diameter of the coil spring 48 is about 0.01 inch and extends the entire length
of the catheter body 12. The coil spring 48 is tightly wound so it can bend but
is non-compressible.

 In the embodiment shown in FIG. 1, the coil spring 48 does not extend
30 into the tip portion 14. In the portion of the second lumen 20 which extends
into the tip portion 14, there is disposed a flexible, compressible, and preferably
lubricous sleeve 38, preferably made of polytetrafluoroethylene.

 As an alternative to sleeve 38, coil spring 48 may extend completely
through the catheter body 12 and tip portion 14 as shown in FIG. 4. In such an
35 embodiment, the portion of the coil spring 48 extending through the second
lumen 20 in the catheter body 12 is tightly wound and essentially non-
compressible as in FIG. 1. In the tip portion 14, however, the coil spring 51 is

1 loosely wound and therefore flexible and compressible. This can be
accomplished, for example, by "stretching" the portion of the coil spring 51
which is to be disposed in the tip portion 14. In this embodiment, the portion of
the coil spring 48 in the catheter body 12 must still be fixedly attached, e.g., by
5 glue, to the catheter body 12 at the proximal and distal ends of the catheter
body 12.

A puller wire 36, preferably made of stainless steel, having a diameter of
about 0.006 inch is disposed within and slidably extends through the coil spring
48 and sleeve 38. Preferably, the puller wire 36 comprises a lubricous coating
10 to prevent the puller wire 36 from sticking to the coil spring 48. The coating is
preferably made of a material such as polytetrafluoroethylene which provides
excellent non-stick characteristics. Sleeve 38 prevents the puller wire 36 from
"cutting through" the wall of the tip portion 14 and also provides lubricity.

The distal end of the puller wire 36 is fixedly attached to the tip electrode
15 19, e.g., by weld 31 or the like. Alternatively, the puller wire 36 may be fixedly
attached to the outer wall of the tip portion 14. A suitable means for attaching
the puller wire 36 to the wall of the tip portion 14 of a deflectable catheter is
described in U.S. Patent No. 4,960,134, which is incorporated herein by
reference.

20 The proximal end of the puller wire 36 is connected to a control handle
as is well known in the art. A suitable control handle is disclosed in U.S. Patent
No. 4,960,134, which is incorporated herein by reference. Such a control handle
can be used to effectively manipulate the catheter tip portion.

The third lumen 22 also extends the length of the catheter body 12 and
25 into the tip portion 14 and is closed at its distal end. The third lumen 22
contains electrode lead wires 62 that are attached at their distal ends to the
electrodes carried by the tip portion 14. The lead wires extend to the proximal
end of the catheter body 12, through the control handle (not shown) and
terminate in a suitable plug as is well known in the art.

30 The coil spring is rigidly attached by polyurethane glue or the like to the
catheter body at its distal and proximal ends. Because the catheter coil spring
48 is noncompressible, tension on the puller wire 36 will not translate into
compressive tension on the catheter body 12. The noncompressible coil spring
48 thereby assures that the catheter body 12 does not bend as a result of
35 tension on the puller wire 36 and thereby assumes that rotational control of the
catheter 10 is not adversely affected when the puller wire 36 is under tension.
By incorporation of the noncompressive coil spring 48, the puller wire 36 can be

1 located off-axis without adverse effect. This, in turn, allows adequate room for
the first lumen 18 without the need to increase the overall diameter of the
catheter 10.

5 The presence of an open lumen 18 presents significant advantages. For
example, in an RF ablation procedure, the ablation electrode is often "fouled" by
the accumulation of coagulum due to overheating. The open lumen, which
extends through the ablation electrode 19 enables a cooling fluid, e.g., saline to
be passed through the ablation electrode 19, thereby cooling the electrode and
preventing overheating. This, in turn, prevents the accumulation of coagulum on
10 the surface of the electrode.

In such an application, if the first lumen 18 is to be used primarily for
cooling of an ablation tip electrode 19, it is understood that the portion of the
lumen extending through the catheter body 12 can have any desired shape. For
example, the lumen can simply extend longitudinally through the tip electrode as
15 shown in FIG. 1. Alternatively, the first lumen 18 may extend into the tip
electrode 19 and then separate into one or more radial branches 50 as shown in
FIG. 5. Obviously, if the lumen 18 forms branches 50, the number, location and
direction of the branches may vary as desired.

20 The first lumen, in addition to facilitating the injection of a fluid through
the catheter, may also be used for other purposes. Clearly it could be used for
the withdrawal of fluid from the body cavity in which the tip portion 14 of the
catheter body 12 lies. As another example, as shown in FIG. 6, an anchor wire
52 may be passed through the first lumen 18 and into the endocardium 54 to
anchor the catheter against the endocardium 54. This could be especially useful
25 in an ablation procedure wherein the anchor wire facilitates and assures contact
between the ablation electrode and the endocardium. In such an embodiment,
it is preferred that the distal end of the anchor wire 52 have a shape which
allows it to become solidly anchored in the endocardium 54. A corkscrew shape,
as shown in FIG. 6, is presently preferred as such shape allows the anchor wire
30 52 to be "screwed" into and out of the endocardium without tearing the
endocardium tissue.

As another example, as shown in FIG. 7, one or more RF antenna wires
58 may be passed through the first lumen 18 and directly into the endocardium
54 to heat the tissue from within the endocardium 54. In such an embodiment,
35 the RF antenna wires 58 are preferably insulated from the tip electrode 19, if
present, and from each other by insulation sleeves 60 and 61. If present, tip

1 electrode 19 may or may not also be used to deliver RF energy, as desired. The
RF antennas 58 may be straight or have a preformed shape, as desired.

It is apparent that, if desired, an anchor wire may also be used as an RF
antenna for delivering RF energy to the endocardium.

5 The first lumen could be used for other applications. For example, an
optic fiber may be passed through the first lumen for viewing of or delivery of
laser radiation to a selected site. A temperature probe may be passed through
the first lumen for monitoring temperature. In an ablation procedure, this would
10 enable one, for example, to place a thermistor directly against, or even into, the
portion of the endocardium being heated in an RF ablation procedure. This would
enable one to monitor the temperature of the tissue being heated and control that
temperature by controlling the intensity of the RF current being delivered to the
tissue with more precision than current designs offer.

15 It is understood that the open lumen may perform more than one function,
e.g., contain a movable anchor wire and provide a passageway for cooling fluid.
It is also understood that more than one open lumen may be provided, e.g., one
open lumen for passage of fluids and another for containing an anchor wire,
temperature probe, etc.

20 Thus, while the preceding description has been presented with reference
to presently preferred embodiments of the invention, workers skilled in the art
and technology to which this invention pertains will appreciate that alterations
and changes in the described structure may be practiced without meaningfully
departing from the principal, spirit and scope of this invention.

25 Accordingly, the foregoing description should not be read as pertaining
only to the precise structures described and illustrated in the accompanying
drawings, but rather should be read consistent with and as support to the
following claims which are to have their fullest and fair scope.

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1 **WHAT IS CLAIMED IS:**

- 1 1. A steerable open lumen catheter comprising:
 a flexible, elongated catheter body having proximal and distal ends;
5 a flexible tip portion at the distal end of the catheter body comprising
 proximal and distal ends;
 a first lumen extending lengthwise through the catheter body and tip
 portion, said first lumen being open at the distal end of the tip portion;
 a second lumen extending lengthwise through the catheter body and tip
10 portion, said second lumen being offset from the axis of the catheter body;
 a bendable, non-compressible coil spring disposed in the second lumen
 and extending the length of the catheter body, said coil spring being fixedly
 attached to the catheter body at the proximal and distal ends of the catheter
 body;
15 an elongated puller wire extending through and slidably disposed in the
 coil spring and extending into the portion of the second lumen in the tip portion,
 said puller wire having a distal end fixedly attached to the distal end of the tip
 portion and a proximal end fixedly attached to a control handle at the proximal
 end of the catheter body; and
20 a control handle mounted at the proximal end of the catheter body for
 moving the puller wire longitudinally relative to the catheter body and coil spring
 to thereby deflect the tip portion.

25 2. The steerable catheter of claim 1 wherein the catheter body
 has an outer diameter of no more than about 0.1 inch.

30 3. The steerable catheter of claim 2 wherein the first lumen
 has a diameter of at least about 0.03 inch.

35 4. The steerable catheter of claim 2 wherein the first lumen
 has a diameter of at least about 0.05 inch.

 5. The steerable catheter of claim 1 further comprising a
 flexible, compressible, lubricous sleeve in surrounding relation to the portions of
 the puller wire disposed in the tip portion of the catheter.

1 6. The steerable catheter of claim 5 wherein the sleeve
comprises polytetrafluoroethylene.

5 7. The steerable catheter of claim 1 wherein the coiled spring
extends into the tip portion of the catheter in surrounding relation to the puller
wire and wherein the portion of the coiled spring in the tip portion is both
bendable and compressible.

10 8. The steerable catheter of claim 1 further comprising:
a third lumen extending through the catheter body and tip portion;
at least one electrode carried by the tip portion; and
an electrode lead wire attached to each electrode, said electrode lead
wires extending through the third lumen to the proximal end of the catheter
body.

15 9. The steerable catheter of claim 1 further comprising a
splitter fitting adjacent the proximal end of the catheter body, said splitter fitting
comprising a tubular side arm wherein the first lumen branches into the interior
of the side arm.

20 10. The steerable catheter of claim 1 wherein the catheter body
and tip portion comprise a unitary extrusion.

25 11. A steerable open lumen electrode catheter comprising:
a flexible, elongated catheter body having proximal and distal ends;
a flexible tip portion at the distal end of the catheter body
comprising proximal and distal ends;

 a first lumen extending lengthwise through the catheter body and
tip portion, said first lumen being open at the distal end of the tip portion;

30 a second lumen extending lengthwise through the catheter body
and tip portion, said second lumen being offset from the axis of the catheter
body;

 a coil spring disposed in the second lumen and extending the
length of the catheter body, said coil spring being fixedly attached to the
35 catheter body at the proximal and distal ends of the catheter body, and wherein
the coil spring is bendable but non-compressible;

1 an elongated puller wire slidably disposed in and extending through
the coil spring and into the second lumen of the tip portion, said puller wire
having a distal end fixedly attached to the distal end of the tip portion and a
proximal end fixedly attached to a control handle at the proximal end of the
5 catheter body;

 a third lumen extending through the catheter body and tip portion;
 a control handle mounted at the proximal end of the catheter body
for moving the puller wire longitudinally relative to the catheter body and coil
spring;

10 at least one electrode carried by the tip portion; and
 an electrode lead wire attached to each electrode carried by the tip
portion, each of said electrode lead wires extending through the third lumen to
the proximal end of the catheter body.

15 12. The steerable catheter of claim 11 wherein the catheter
body has an outer diameter of no more than about 0.1 inch.

 13. The steerable catheter of claim 12 wherein the first lumen
has a diameter of at least about 0.03 inch.

20 14. The steerable catheter of claim 12 wherein the first lumen
has a diameter of at least about 0.05 inch.

25 15. The steerable catheter of claim 11 further comprising a
splitter fitting adjacent the proximal end of the catheter body, said splitter fitting
comprising a tubular side arm and wherein the first lumen branches into the
interior of the side arm.

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Fig. 1

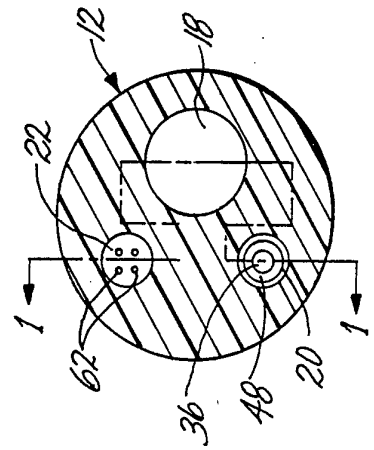
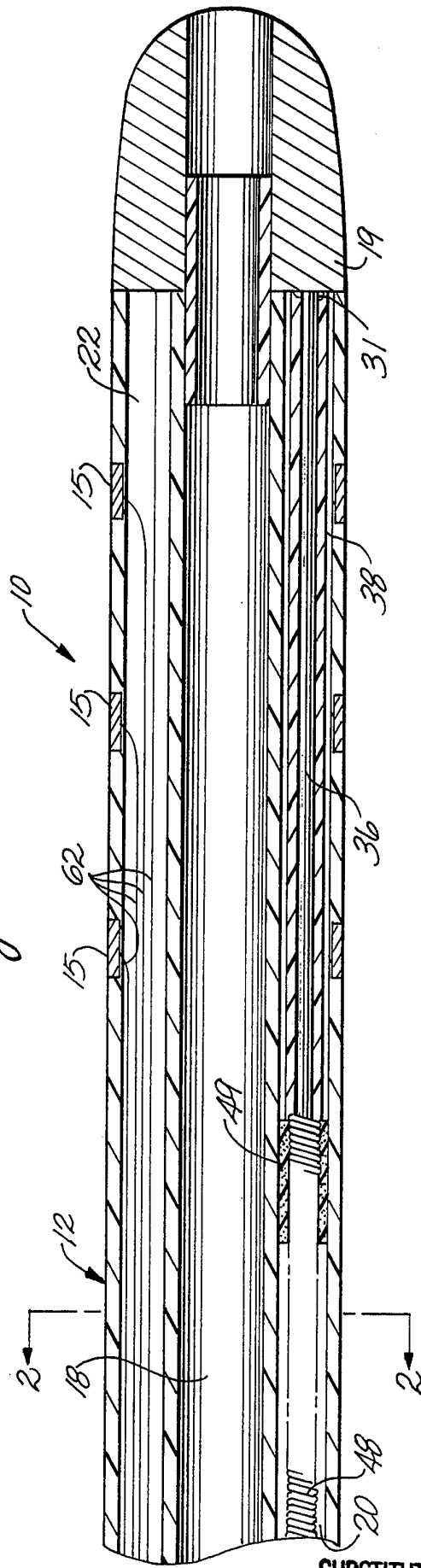
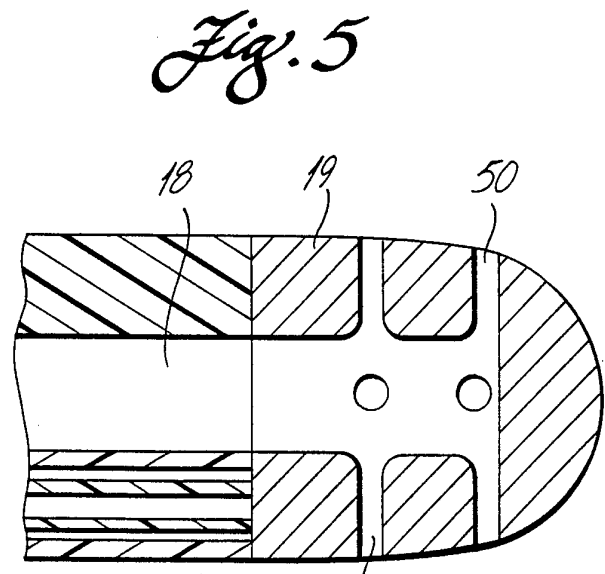
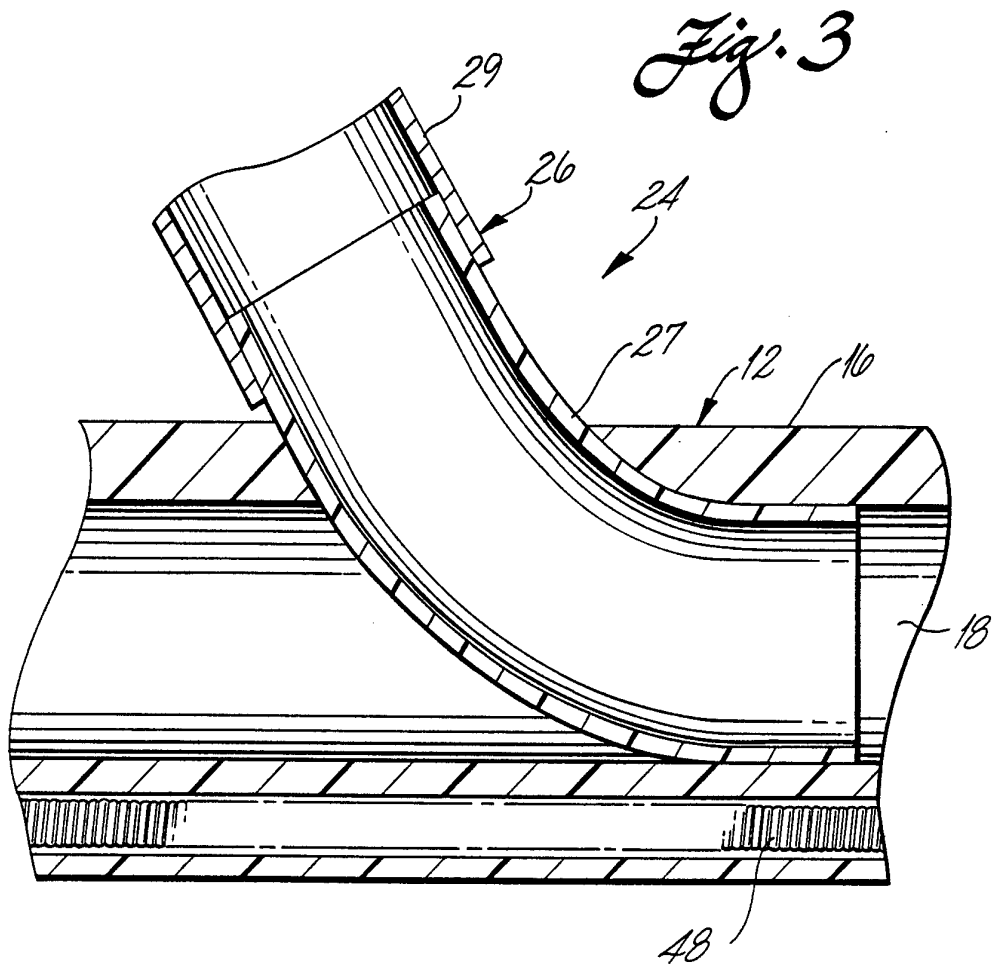
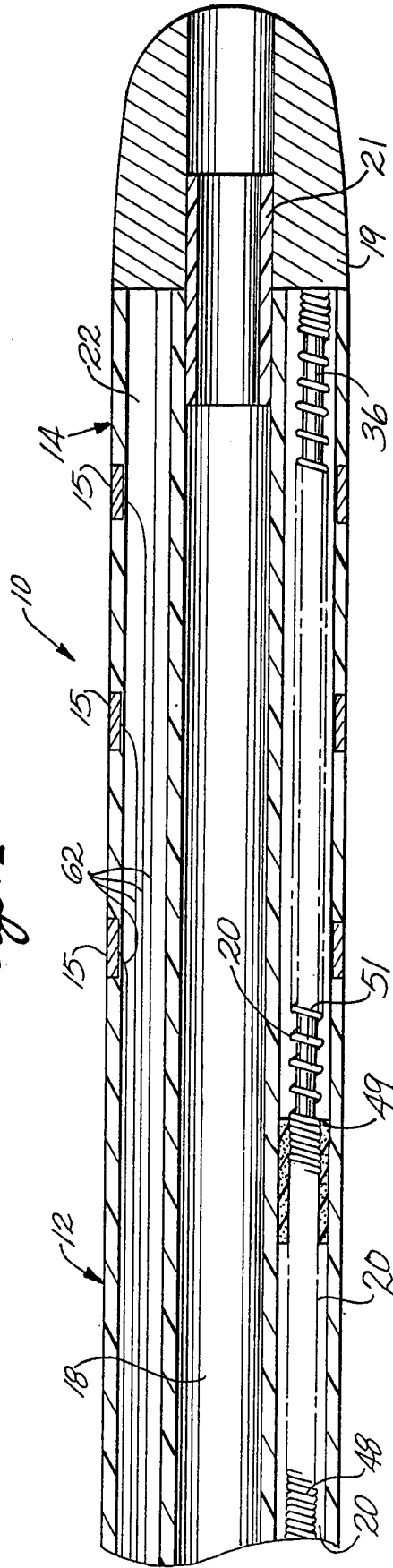


Fig. 2



SUBSTITUTE SHEET (RULE 26)

Fig. 4



SUBSTITUTE SHEET (RULE 26)

Fig. 6

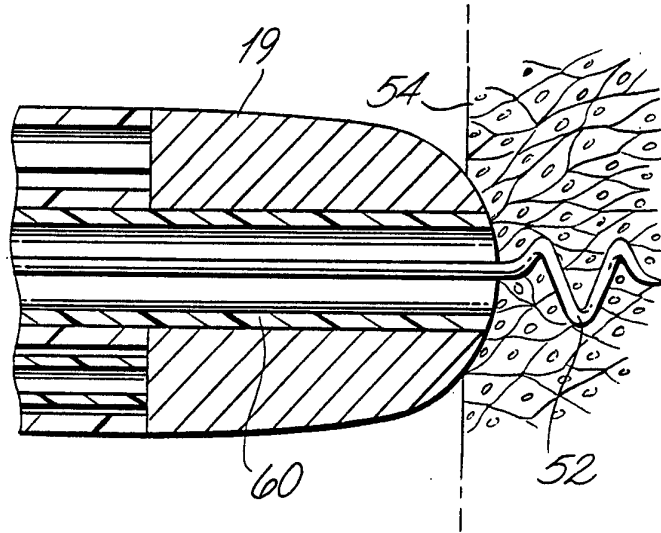
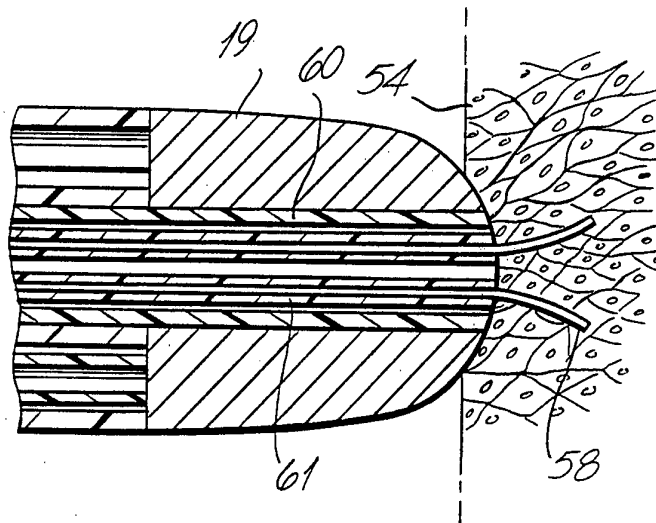


Fig. 7



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US94/09390

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/00

US CL :128/772

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)

U.S. : 128/657, 658, 772; 604/95, 164, 280-283

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

NONE

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

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,586,923, (GOULD ET AL.), 06 May 1986. See entire reference.	1-7, 9, 10
Y	US, A, 4,798,598, (BONELLO ET AL.), 17 January 1989. See entire reference.	1-7, 9, 10
Y	WO, A, 92/19151, (SEPETKA, IVAN), 12 November 1992. See sleeve (19)	5, 6

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	*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
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