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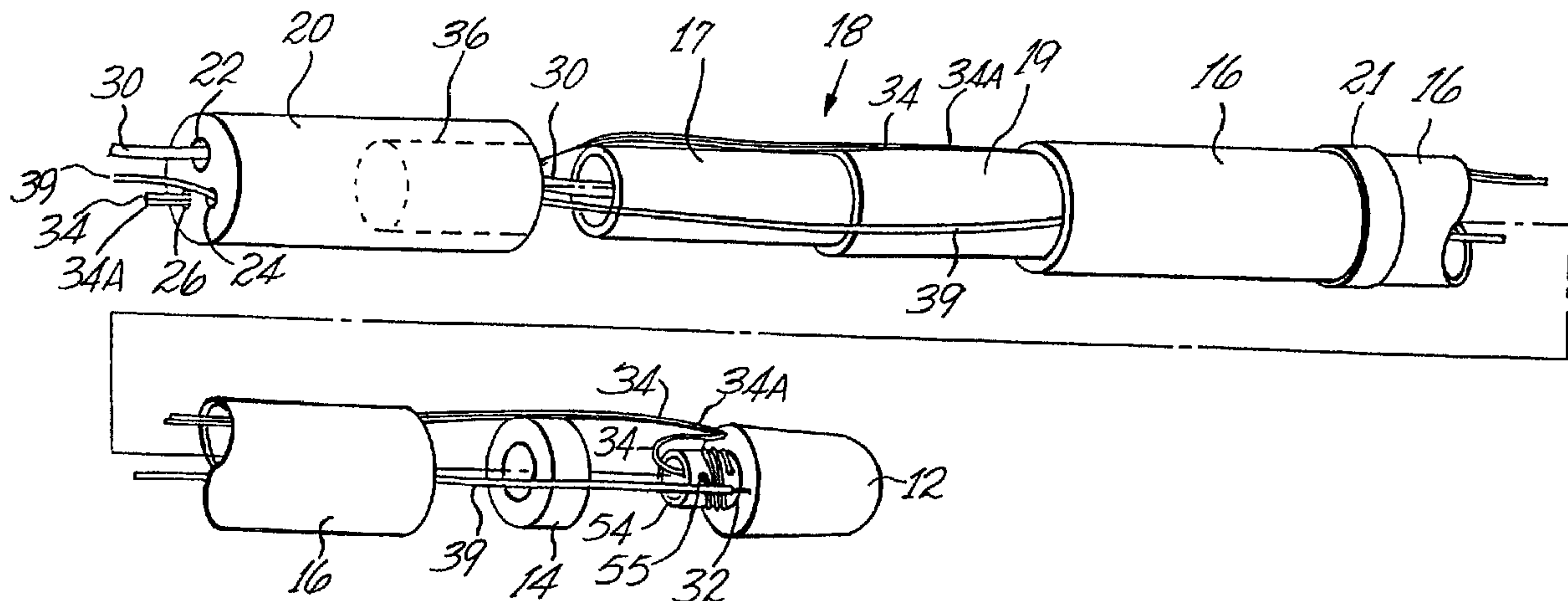
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(54) Titre : CATHETER POURVU D'UN CAPTEUR DE GUIDAGE ELECTROMAGNETIQUE

(54) Title: CATHETER WITH AN ELECTROMAGNETIC GUIDANCE SENSOR



(57) Abrégé/Abstract:

The present invention relates to an electrophysiology catheter (102) (an electrode catheter) having an electromagnetic sensor (18) designed internally into the top portion (20). The catheter is a size 7 French or 8 French of metal braided construction with preferably three lumens (22, 24, 26). The catheter (102) has a deflectable tip (20) utilizing an offset lumen with a puller wire, a non-compressible coil in the body section, and a compressible TEFLON sheath (39) in the tip section. The electromagnetic sensor (18) is mounted internally in the catheter tip (20) by a combination of a hole drilled (36) in the three lumen tip, and a hollow bridging that covers the electromagnetic sensor (18) and connects the tip electrode (12) to the catheter shaft (102). The tip electrode (12) is secured to the end of the bridging tube (90) by an etched TEFLON ring which mates the electrode stem to the inside of the ring.



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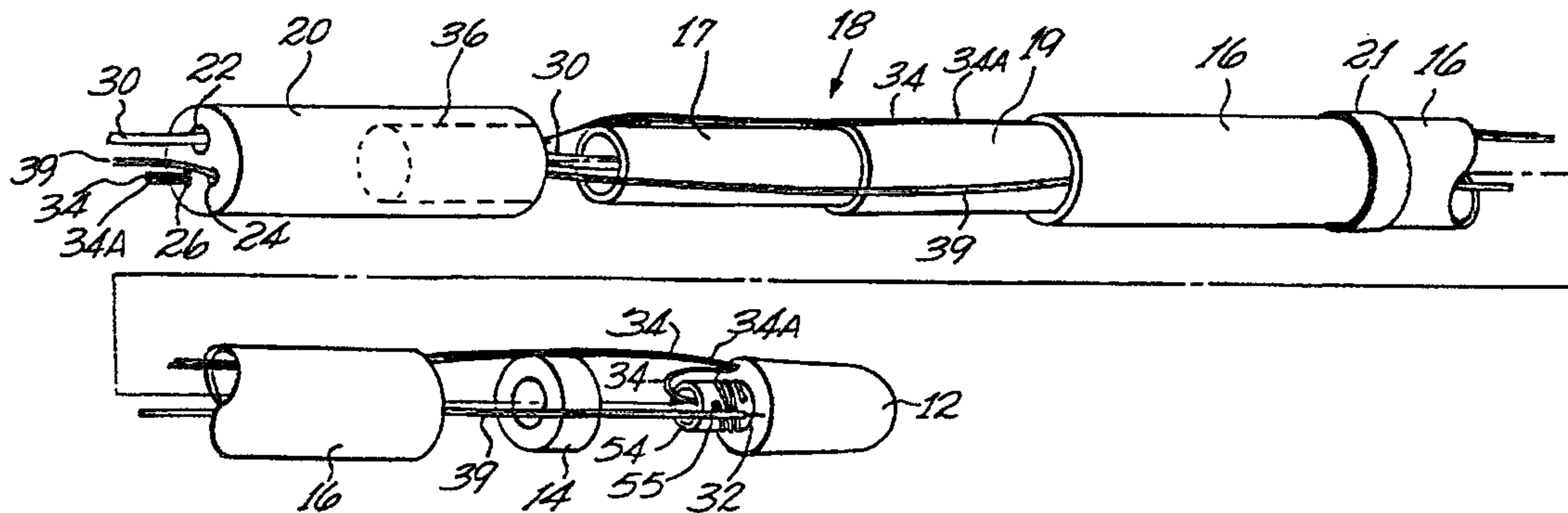
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(54) Title: CATHETER WITH AN ELECTROMAGNETIC GUIDANCE SENSOR



(57) Abstract

The present invention relates to an electrophysiology catheter (102) (an electrode catheter) having an electromagnetic sensor (18) designed internally into the top portion (20). The catheter is a size 7 French or 8 French of metal braided construction with preferably three lumens (22, 24, 26). The catheter (102) has a deflectable tip (20) utilizing an offset lumen with a puller wire, a non-compressible coil in the body section, and a compressible TEFLON sheath (39) in the tip section. The electromagnetic sensor (18) is mounted internally in the catheter tip (20) by a combination of a hole drilled (36) in the three lumen tip, and a hollow bridging that covers the electromagnetic sensor (18) and connects the tip electrode (12) to the catheter shaft (102). The tip electrode (12) is secured to the end of the bridging tube (90) by an etched TEFLON ring which mates the electrode stem to the inside of the ring.

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CATHETER WITH AN ELECTROMAGNETIC GUIDANCE SENSOR**Field of the Invention**

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This invention relates to steerable catheters for use in a vessel, and more specifically to an electrode catheter having a steerable tip and an electromagnetic sensor at the distal tip.

Background of the Invention

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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.

20

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 Nos. 4,960,134 and Re. 34,502 to Webster disclose a particularly useful steerable tip catheter.

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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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Another example of a steerable catheter can be found in U.S. Patent No. 5,431,168 to Webster.

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In this patent, a triple lumen catheter is disclosed. 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. Three lumens extend through the catheter body and tip portion. The first lumen has a diameter of at least about one third and preferably at least about one half

1 the outer diameter of the catheter body. 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
5 lumens are off-axis. The second lumen comprises an elongated, flexible, but
noncompressible 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
10 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
movement of the puller wire relative to the catheter body and coil spring results
15 in deflection of the catheter tip with minimal and preferably no deflection of the
catheter body. The third lumen also 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
20 to an electrical stimulator and/or recorder, an RF energy source or the like.

20 U.S. Patent No. 5,391,199 to Ben-Haim, discloses an electrode catheter
with an imaging system for the treatment of cardiac arrhythmias.

The system comprises an
electrode catheter with an electromagnetic sensor at the distal tip of the
catheter. The patent, however, does not teach how to manufacture a steerable
25 catheter with the electromagnetic sensor. The electromagnetic sensor has a
relatively large outside diameter of about 6 to 7 French (1 French = 0.012 inch).
This large diameter creates numerous difficulties in designing a catheter that is
steerable. Additionally, the sensor has to be completely insulated from the
electrodes and electrode lead wires to perform properly.

30 Therefore, it is desirable to have a steerable catheter which incorporates
an electromagnetic sensor like the one described in U.S. Patent No. 5,391,199
that allows the operator to steer the catheter into position while monitoring the
three dimensional images of the heart generated by the use of the
electromagnetic sensor.

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Summary of the Invention

The present invention is a steerable electrophysiology catheter (an electrode
 5 catheter) having an electromagnetic sensor designed internally into the tip portion.
 The catheter is a size 7 French or 8 French metal braided construction with preferably
 three lumens. The catheter has a deflectable tip utilizing an offset lumen with a puller
 wire, a noncompressible coil in the body section and a compressible Teflon sheath in
 the tip section. The coil is glued to the body section at both ends of the coil. The puller
 10 wire is slidably disposed within the coil and extends to the flexible tip section such
 that proximal movement of a puller wire deflects the tip section but the coil keeps the
 body from compressing and deflecting. The puller wire is soldered to a tip electrode
 and runs axially to a control handle. The electromagnetic sensor is mounted internally
 in the catheter tip by a combination of a hole drilled in the three lumen tip and a
 15 hollow bridging tube that connects the three lumen tip with the tip electrode. On the
 bridging tube is optionally mounted one or more ring electrodes adjacent to the tip
 electrode. The tip electrode has a stem and is secured to the end of the bridging tube
 by an etched Teflon ring which mates the electrode stem to the inside of the bridging
 tube. The bridging tube can be made from polyamide tubing, polyimide tubing, plastic
 20 filament impregnated composite, or other suitable thin walled non metallic material.

The lead wires from the electromagnetic sensor are disposed in a plastic
 covered shielded cable which is placed within a second lumen in the catheter. The
 electrode lead wires pass around the sensor within the bridging tube and are disposed
 within the third lumen in the catheter.

25 Accordingly, the present invention provides a steerable electromagnetic sensor
 catheter comprising:

a control handle;

a catheter shaft comprising proximal and distal ends and a plurality of
 lumens wherein the distal end is deflect-able and the proximal end of the catheter
 30 shaft is connected to the control handle;

an electromagnetic sensor cable connected to the electromagnetic sensor wherein the sensor cable is disposed within one of the catheter shaft lumens and is connected to the control handle;

5 a tip electrode adjacent to the distal end of the sensor having a corresponding electrode lead wire attached which runs through one of the shaft lumens and is connected to the control handle;

a puller wire having proximal and distal ends wherein the proximal puller wire end is connected to the control handle and the distal puller wire end is
10 connected to the tip electrode, and wherein the puller wire extends through one of the shaft lumens;

a noncompressible coil extending through the lumen through which the puller wire extends, the noncompressible coil provided in surrounding relation to the puller wire and extending from about the proximal end of the catheter shaft to a location
15 spaced apart from the distal end of the catheter shaft, said compression coil being fixedly attached at its proximal and distal ends to the catheter shaft; and

a bridging tube glued to the distal end of the catheter shaft and to the tip electrode, wherein the electrode lead wire and the electromagnetic sensor are glued within the bridging tube and the puller wire is slidably retained within the
20 bridging tube.

The present invention also provides a steerable electromagnetic sensor catheter comprising:

an elongated catheter body having proximal and distal ends;

a flexible tip portion connected to the distal end of the catheter body having
25 proximal and distal ends;

at least one lumen extending lengthwise through the catheter body and the tip portion;

a tip electrode connected to the distal end of the tip portion and having an electrode lead wire attached to the tip electrode which extends through one of the at
30 least one lumen to the proximal end of the catheter body;

a bridging tube located at the distal end of the tip portion, the bridging tube

having a distal end connected to the tip electrode and a cavity communicating with one of the at least one lumen in the flexible tip portion wherein the tip electrode lead wire passes through the cavity in the bridging tube;

an electromagnetic sensor contained within the tip portion adjacent to the distal end of the tip portion, at least a portion of the electromagnetic sensor being disposed in the bridging tube;

an electromagnetic sensor cable having a distal end connected to the electromagnetic sensor and extending through one of the at least one lumen to the proximal end of the catheter body; and

a puller wire having a distal end fixedly attached to the tip portion, the puller wire extending through one of the at least one lumen to the proximal end of the catheter body, wherein longitudinal movement of the puller wire relative to the catheter body results in deflection of the tip portion.

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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 plan view of a catheter of the present invention;

 FIG. 2 is an exploded rear perspective view of the catheter of the present invention;

 FIG. 3 is a longitudinal partial cross section schematic view of the present invention;

10 FIG. 4 is a schematic view of a preferred control handle section of the present invention;

 FIG. 5 is a cross section of the present invention as illustrated in FIG. 1 at line 5-5;

15 FIG. 6 is a cross section of the present invention as illustrated in FIG. 1 at line 6-6;

 FIG. 7 is a schematic view of the catheter body of the present invention illustrating the noncompression coil and puller wire assembly;

 FIG. 8 is a plan view of a tip electrode of the present invention with accompanying tip electrode lead wire;

20 FIG. 9 is a end view of the tip electrode of FIG. 8 without the electrode lead wire attached;

 FIG. 10 is a cross section of the tip electrode with a puller wire attached along plane 10-10 of FIG. 9;

25 FIG. 11 is a cross section of the tip electrode with a thermocouple attached along plan 11-11 of FIG. 9;

 FIG. 12 is a schematic view of an alternate embodiment of the electromagnetic sensor assembly of the present invention;

 FIG. 13 is a cross section of the electromagnetic sensor assembly of FIG. 12 along line 13-13;

30 FIG. 14 is a plan view of a first bridging tube of the electromagnetic sensor assembly of FIG. 12; and

 FIG. 15 is a plan view of the distal end of an electromagnetic steerable catheter with a second bridging tube attached.

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1 **Detailed Description**

As illustrated in the drawings, the present invention is directed to a steerable cardiac electrode catheter that incorporates an electromagnetic sensor at its distal end. An electromagnetic sensor 18 suitable for use in the present invention is available from Biosense, Inc., Orangeburg, New York, and is described in U.S. Patent No. 5,391,199,

The steerable catheter is divided into three main sections which correspond to three primary subassemblies: a control handle section 101, a shaft section 102, and an electromagnetic sensor section 103.

10 The catheter is constructed by first assembling the shaft section, then assembling the electromagnetic sensor section and then assembling the control handle section.

I. **SHAFT SUBASSEMBLY**

15 A suitable catheter shaft 102 comprises a catheter body 107 (see FIG. 7) and a deflectable tip 20 and is a multiple lumen catheter of metal braided construction. A particularly suitable multilumen catheter shaft construction is disclosed in U.S. Patent No. 5,431,168.

20 Briefly, the catheter comprises an elongated catheter body 107 having proximal and distal ends. A catheter deflectable tip portion 20 extends from the distal end of the catheter body and a control handle 201 is provided at the proximal end of the catheter body. With reference to FIGS. 5, 6, and 7, the catheter shaft including the catheter body and tip portion comprises first, second and third lumens 22, 24 and 26 respectively. As detailed below, lumen 22 is relatively large (about 0.036 inch in diameter) and lumens 24 and 26 are relatively small (about 0.022 inch in diameter). Lumen 22 is used to carry an electromagnetic sensor 18 cable for the electromagnetic sensor of the present invention. The electromagnetic sensor cable comprises multiple electrode wires encased within a plastic covered shield. Lumen 24 is used to carry a puller wire, and lumen 26 is used to carry electrode lead wires and thermocouple wires.

30 The length and diameter of the catheter body are not critical and may vary according to the application, however the diameter must be large enough to accommodate the electromagnetic sensor 18 which has an outer diameter of about 6 to 7 French. For the cardiovascular catheter shown in the accompanying drawings, a length of about 40 to 48 inches and an outer diameter of about 8 French is preferred.

1 The catheter tip portion 20 preferably has a short length of about 5 to 7 inches. The diameter is preferably about the same as that of the catheter body or slightly less (e.g., 7 French) than the diameter of the catheter body.

5 The catheter body and tip portion may be made of any suitable non-toxic material. In a preferred embodiment, the catheter body and tip portion comprise a single elongated tubular extrusion made of a thermoplastic resin such as polyurethane. One or more layers of a reinforcing braided mesh 28 (see FIG. 5) of, for example, stainless steel or dacron, overlie the polyurethane extrusion in the catheter body portion. The reinforcing mesh is, in turn, coated with a layer
10 of polyurethane or other suitable plastic material.

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

 Turning to FIG. 7, a presently preferred catheter shaft is illustrated. The catheter body 107 is about an 8 French diameter body that extends for about
20 40 inches. The body tapers at taper 108 to the tip portion which is about 7 French and extends for about 6 inches. At the distal end of the tip portion, a 4 mm deep 0.063 inch diameter hole 36, is drilled and then smoothed out. Two compression coil glue holes 43 and 44 are drilled into the catheter shaft into lumen 24, one at the distal end in the catheter body about 3 inches from the
25 distal tip and one at the proximal end in the catheter tip about 3/8 inch to about 1/2 inch from the proximal end. A noncompressible coil, slightly smaller than the diameter of lumen 24 is inserted into the lumen until the distal end 42 of the coil is about 1/2 inch distal to the glue hole 44 and the proximal end 45 extends proximally out of the catheter shaft. The noncompressible coil has an outer
30 diameter of about 0.02 inch and an inner diameter of about 0.01 inch. A Teflon coated 0.007 inch stainless steel puller wire is then inserted into the noncompression coil. The puller wire is substantially longer than the noncompression coil such that the proximal and distal ends of the puller wire can be secured to the control handle and the tip electrode respectively later during
35 the manufacturing process. The noncompression coil is then secured in place by applying glue such as polyurethane in both glue holes until it wicks over about 1/2 inch to about 3/4 inch long areas. The glue is cured in a warm air oven.

1 **II. ELECTROMAGNETIC SENSOR SUBASSEMBLY**

 The next step in the manufacturing process is to assemble the
electromagnetic sensor subassembly. First, The Teflon coating over the puller
wire is stripped off at its distal end for about 2 cm. A 3.5 mm long 27 gage
5 stainless steel hollow crimping tube 50 is then crimped onto the distal end of the
puller wire (see FIG. 10).

 Three, 6 feet long #38 copper electrode insulated lead wires 34 and one
6 feet long #38 constantan thermocouple insulated lead wire 34A are placed
inside lumen 26 of the catheter shaft. All of the lead wires are insulated with the
10 insulation being stripped approximately one inch from the distal end. Using one
of the copper lead wires and the constantan lead wire a thermocouple is
constructed by twisting the distal ends together, about one turn per millimeter.
The twisted lead wires are then tinned with 25% indium Litton Kester Solder
SN96AG04 and Staykleen flux. The twisted pair is then cut to approximately
15 1 mm in length and inserted into a piece of 0.014 inch inner diameter and
0.016 inch outer diameter tube 61 (see FIG. 11) that is about 2-1/2 to 3 mm
long. The tube is preferably constructed out of polyimide, but other well known
materials could be used. The twisted wires are then secured within the tube
with epoxy.

20 The next step of the manufacturing process is to construct the first
bridging tube. In the embodiment illustrated in FIGS. 2 and 3, there is only one
bridging tube 16 which is a cylindrical 0.093 inch inner diameter and 0.098 inch
outer diameter polyimide tube about 15 mm long. The bridging tube may be
made from other materials such as polyamide tubing, plastic filament
25 impregnated composite, or other suitable non-metallic weldable material. In the
embodiment illustrated in FIGS. 12, 13 and 14, the first bridging tube 16A is
constructed out of a piece of 0.080 inch inner diameter and 0.086 inch outer
diameter polyimide tube about one inch long. The polyimide tube is then placed
over a stepped mandrel with a larger diameter of 0.077 inch and a smaller
30 diameter of 0.050 inch. A 0.0065 inch monel or manganin wire is then wrapped
around the proximal end of the polyimide tube over the smaller diameter section
of the mandrel to reduce the diameter and to create taper 70 and smaller
diameter section 75. The polyimide tube is then heated at 150°C for about
5 minutes such that it will retain its new shape. The small diameter section 75
35 of the polyimide tube is then cut to about 3 mm in length and the large diameter
section is cut to about 12 mm in length such that the overall length is about
15 mm. The bridging tube is then removed from the mandrel.

1 A lead wire hole 71 is optionally punched in the distal large diameter side
of the bridging tube about 1 to about 1-1/2 mm from the edge. One of the
electrode lead wires is then inserted through the proximal end of the bridging
tube and out through the lead wire hole. The insulation is striped of the distal
5 end of the lead wire and is then soldered onto an optional ring electrode 21A.
The ring electrode is then placed over the bridging tube about 1/2 mm from the
distal edge. The ring electrode is glued in place using a small amount of glue
such as polyurethane and then cured in a warm air oven.

10 Next, the thermocouple, puller wire, and tip electrode lead wire are
inserted all the way through the bridging tube.

 A tip electrode 12 is then made out of a solid platinum or solid platinum
iridium alloy bullet shaped member (see FIG. 8) that is about 7 French in
diameter. The proximal end of the bullet shaped electrode is machined such that
a cylindrical stem 54 about 2 mm long is created. The center of the stem is
15 drilled out such that the stem is hollow on its proximal side. An electrode lead
wire hole 55 is then drilled into the side of the stem about 1/2 mm from the
proximal end of the stem. Three holes are then drilled into the body 12 of the
tip electrode, a puller wire hole 51, a thermocouple hole 52 and a vent hole 53
(see FIGS. 9, 10 and 11). The puller wire hole 51 (see FIG. 10) is drilled parallel
20 to the axis of the tip electrode about 2 mm deep and about 1/2 mm wide. The
thermocouple hole 52 (see FIGS. 9 and 11) is about 1/2 mm wide and is drilled
about 90° away from the puller wire hole and at about 30° to the axis of the tip
electrode such that the hole traverses through the central axis of the tip
electrode. Care is taken to ensure that the hole does extend out the side of the
25 tip electrode. The vent hole is also about 1/2 mm wide and is drilled 180° away
from the thermocouple hole and is drilled at about a 45° angle to the axis of the
tip electrode such that the vent hole intersects with the thermocouple hole.

 As illustrated in FIG. 8, one of the electrode lead wires 34 is inserted
through the hollow distal stem 54 of the tip electrode 12 and through the lead
30 wire hole 55. The insulation on the lead wire is stripped off its distal end and
then wrapped about 3 to about 5 times around the stem and soldered 38 into
place.

 Next, the puller lead wire 32 with the 27 gage crimping tube 50 crimped
to the puller wire's distal end are inserted into the puller wire hole 51. Preferably
35 just prior to the insertion of the puller wire and the crimping tube into the puller
wire hole 51 a small amount of soldering material 56 is placed in the puller wire

1 hole. The puller wire and crimping tube are then soldered into the puller wire hole using additional soldering material 56.

Next, the thermocouple 61 is inserted into the bottom of the thermocouple hole 52. Epoxy 62 is then applied into the vent hole 53 until it
5 appears in the thermocouple hole. The epoxy is cured in a warm air oven for about one hour.

An etched Teflon ring 14, 2 mm long is then inserted over the stem 54 of the tip electrode. The electrode lead wire connected to the stem 54 of the tip electrode is bent back distally and is directed to the thermocouple hole and thermocouple lead wires. All of the lead wires are collected together and travel
10 around the outside of the Teflon ring as best illustrated in FIG. 2. The Teflon ring is then glued to the tip electrode using polyurethane or the like and cured in a warm air oven. The tip electrode lead wires and the thermocouple lead wires are then carefully welded together using polyurethane and cured in a warm air oven.

15 The next step is to insert an electromagnetic sensor 18 or 18A into the bridging tube while aligning the optional ring electrode lead wire with the three other lead wires. As illustrated in FIGS. 2 and 3, the electromagnetic sensor 18 of this embodiment comprises two diameters, the first diameter 17 being smaller than the second diameter 19. A sensor cable 30 extends out of the smaller first
20 diameter 17 and includes the electrode lead wires needed for the operation of the electromagnetic sensor. In an alternate embodiment illustrated in FIGS. 12-15, the electromagnetic sensor 18A is uniform in diameter and is approximately 7 French in diameter with the sensor cable 30 extending from the center of the proximal end of the sensor. As illustrated in FIG. 13, the lead wires are arranged
25 at an angle α of about 90° apart from the puller wire in an orientation which will align them with the appropriate lumen in the catheter body. An etched piece of Teflon tube 66, 2 mm long, is then installed over the sensor cable 30 and slid down inside the proximal end of the bridging tube (see FIG. 12). The electromagnetic sensor is potted in the bridging tube using polyurethane. The
30 tip electrode with the Teflon ring attached is then installed into the distal end of the bridging tube. All electrode lead wires and the puller wire are oriented as shown in FIG. 13 and the polyurethane is allowed to cure in a warm air oven.

In the embodiment illustrated in FIGS. 2 and 3, the electromagnetic sensor has a reduced diameter portion 17 that is proximal to a larger diameter
35 portion 19. The tip electrode 12, with thermocouple and puller wire is made similarly as described above. The bridging tube 18 is then inserted over the lead wires and puller wire such that the Teflon ring fits within the distal end of the

1 bridging tube. The puller wire and lead wires are oriented 90° apart and the
electromagnetic sensor 18 is placed within the bridging tube. The
electromagnetic sensor and Teflon ring are then potted with polyurethane and
allowed to cure in a warm air oven.

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III. INSTALL ELECTROMAGNETIC SENSOR SUBASSEMBLY TO SHAFT SUBASSEMBLY

The next step of the manufacturing process is to install the
electromagnetic sensor subassembly into the shaft subassembly. In the
10 embodiments of FIGS. 2 and 3, the reduced diameter 17 of the electromagnetic
sensor fits into the drilled hole 36 in the distal end of the catheter shaft. Care is
taken to make sure that all the electrode lead wires and thermocouple wires are
in lumen 26 of the catheter shaft, the puller wire is in lumen 24 of the catheter
shaft, and the electromagnetic sensor cable is in lumen 22. Preferably, a
15 compressible Teflon tube 39 is inserted over distal portion of the puller wire
within lumen 24 and to the tip electrode 12 to provide a smooth channel for the
movement of the puller wire.

Once the location of all the wires is confirmed in their proper lumen, the
proximal end of the electromagnetic sensor is placed within the drilled hole 36
20 and potted with polyurethane. If the optional compressible tube is in place, care
is taken to ensure that no polyurethane enters the tube. All wires and cables are
pulled taut and the polyurethane is allowed to cure in a warm air oven.

In the embodiment illustrated in FIG. 12, a second bridging tube 90
approximately 15 mm long with an outer diameter of about 0.098 inch and an
25 inner diameter of about 0.093 inch is slid over the distal end of the catheter
shaft. The reduced diameter section 75 of the first bridging tube 16A is inserted
in the drilled hole 36 in the distal end of the catheter shaft.

Care is again taken to ensure that the lead wires and thermocouple wires
are contained within lumen 26. The distal section of the puller wire is inserted
30 into a compressible sheath 39, preferably made out of Teflon. The compressible
sheath covers the puller wire over the distance from the tip electrode to the
noncompressible coil in lumen 24. All the wires and the electromagnetic sensor
cable are pulled taut. Polyurethane is then potted over the first bridging tube and
over the distal end of the catheter shaft. The second bridging tube 90 is then
35 pulled distally such that the junction between the catheter shaft section and the
electromagnetic section is contained within the second bridging tube and the
distal end of the second bridging tube is about 2 mm proximal to the ring

1 electrode 21A. The polyurethane is then allowed to cure in a warm air oven. All
margins around the second bridging tube, ring electrode, and tip electrode are
smoothed out with the addition of polyurethane 91 (see FIG. 15) and the
catheter is allowed to completely cure in a 100°C oven for two hours.

5 IV. CONTROL HANDLE ASSEMBLY

As discussed above, the puller wire 32 is soldered to the tip electrode 12,
runs outside the Teflon sheath 14, through the bridging tube 16 or 16A around
the electromagnetic sensor 18 or 18A, into lumen 24, and runs to a control
10 handle 201 (see FIG. 4) located at the proximal end of the catheter body. The
control handle should have means for controlling the longitudinal movement of
puller wire with respect to the axis of the catheter body. A suitable control
handle is disclosed in U.S. Patent Nos. 4,960,134 and Re. 34,502.

The puller wire is preferably
15 coated with any suitable electrically insulating and lubricating material, such as
polytetrafluoroethylene. The puller wire is installed to the piston (not shown)
within the control handle as described in U.S. Patent Nos. 4,960,134 and
Re. 34,502. The proximal end of the catheter shaft 107 is also installed within
the control handle.

20 In the preferred embodiment, the control handle 201 is modified from the
one described in U.S. Patent Nos. 4,960,134 and Re. 34,502 in that it has a
threaded end 202 with a barrel extension 203 threaded into the threaded end.
The barrel extension contains a printed circuit board 204 for processing signals
to and from the electromagnetic sensor 18 or 18A. The electromagnetic sensor
25 cable 30 is connected to the printed circuit board. The printed circuit board is
manufactured to correspond to the electromagnetic sensor and is available from
Biosense, Inc. The printed circuit board is protected from magnetic fields via a
metal magnetic shield 205. Care is taken to ensure that the thermocouple wires
are passed within the magnetic shield and the electrode lead wires pass outside
30 the magnetic shield.

At the proximal end of the barrel extension is a cable adaptor 207 where
lead wires to and from the printed circuit board are attached, the electrode head
wires are attached, and the thermocouple wires are attached. A conductor 208
is connected to the cable adaptor and is then ready to be connected to a
35 processing and controlling unit as described in U.S. Patent No. 5,391,199.

1 The importance of this above described design is that the three lumens
in the catheter shaft provide a catheter core structure which supports the
metallic braid providing high torque, and a lumen for the noncompressible coil
5 allowing for good catheter flexibility without compressive waviness when the
puller wire is pulled. Proximal movement of the puller wire with respect to the
catheter shaft results in the deflectable tip section bending in one direction.
Thus the electromagnetic sensor catheter is steerable by controlling the
movement of the puller wire with the control handle.

10 The preceding description has been presented with references to presently
preferred embodiments of the invention as shown in the drawings. Persons
skilled in the art and technology to which this invention pertains will appreciate
that alterations and changes in the described structures can be practiced without
meaningfully departing from the principle, spirit and scope of this invention.
Accordingly, the foregoing description should not be read as pertaining only to
15 the precise structures described and shown in the accompanying drawings, but
rather as consistent with and as support for the following claims which are to
have their fullest and fairest scope.

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What is claimed is:

1. A steerable electromagnetic sensor catheter comprising:
 - a control handle;
 - 5 a catheter shaft comprising proximal and distal ends and a plurality of lumens wherein the distal end is deflect-able and the proximal end of the catheter shaft is connected to the control handle;
 - an electromagnetic sensor with proximal and distal ends wherein the proximal end of the sensor is adjacent to the distal end of the catheter shaft;
 - 10 an electromagnetic sensor cable connected to the electromagnetic sensor wherein the sensor cable is disposed within one of the catheter shaft lumens and is connected to the control handle;
 - a tip electrode adjacent to the distal end of the sensor having a corresponding electrode lead wire attached which runs through one of the shaft lumens and is connected to the control handle;
 - 15 a puller wire having proximal and distal ends wherein the proximal puller wire end is connected to the control handle and the distal puller wire end is connected to the tip electrode, and wherein the puller wire extends through one of the shaft lumens;
 - 20 a noncompressible coil extending through the lumen through which the puller wire extends, the non-compressible coil provided in surrounding relation to the puller wire and extending from about the proximal end of the catheter shaft to a location spaced apart from the distal end of the catheter shaft, said compression coil being fixedly attached at its proximal and distal ends to the catheter shaft; and
 - 25 a bridging tube glued to the distal end of the catheter shaft and to the tip electrode, wherein the electrode lead wire and the electromagnetic sensor are glued within the bridging tube and the puller wire is slidably retained within the bridging tube.
- 30 2. The electromagnetic sensor catheter of claim 1 comprising a compressible tube slidably covering a distal portion of the puller wire from the distal

end of the noncompressible coil to the tip electrode, and the compressible tube is glued within the bridging tube.

3. The electromagnetic sensor catheter of claim 1 wherein the catheter
5 shaft has three lumens.

4. The electromagnetic sensor catheter of claim 3 wherein one of the three lumens is relatively larger than the other two lumens.

10 5. The electromagnetic sensor catheter of claim 4 wherein the larger lumen contains the electromagnetic sensor cable; one of the two smaller lumens contains the noncompression coil, the puller wire and part of the compressible tube; and the other smaller lumen contains the tip electrode lead wire.

15 6. The electromagnetic sensor catheter of claim 1 further comprising a thermocouple attached within the tip electrode wherein the thermocouple has two lead wires attached which run through one of the shaft lumens and are connected to the control handle.

20 7. The electromagnetic sensor catheter of claim 6 wherein the thermocouple wires are grouped with the tip electrode lead wire and run through the same shaft lumen.

8. The electromagnetic sensor catheter of claim 1 further comprising a
25 ring glued between the tip electrode and the electromagnetic sensor and glued within the bridging tube.

9. The electromagnetic sensor catheter of claim 1 further comprising at least one ring electrode attached to the outside of the bridging tube and a
30 corresponding ring electrode lead wire attached to the ring electrode and to the control handle wherein the ring electrode lead wire runs through one of the shaft lumens.

10. The electromagnetic sensor catheter of claim 1 further comprising a printed circuit board disposed within the control handle and connected to the sensor cable wherein the printed circuit board helps to control the input and output of the
5 electromagnetic sensor.

11. A steerable electromagnetic sensor catheter comprising:
an elongated catheter body having proximal and distal ends;
a flexible tip portion connected to the distal end of the catheter body
10 having proximal and distal ends;
at least one lumen extending lengthwise through the catheter body and the tip portion;
a tip electrode connected to the distal end of the tip portion and having an electrode lead wire attached to the tip electrode which extends through one of the
15 at least one lumen to the proximal end of the catheter body;
a bridging tube located at the distal end of the tip portion, the bridging tube having a distal end connected to the tip electrode and a cavity communicating with one of the at least one lumen in the flexible tip portion wherein the tip electrode lead wire passes through the cavity in the bridging tube;
20 an electromagnetic sensor contained within the tip portion adjacent to the distal end of the tip portion, at least a portion of the electromagnetic sensor being disposed in the bridging tube;
an electromagnetic sensor cable having a distal end connected to the electromagnetic sensor and extending through one of the at least one lumen to the
25 proximal end of the catheter body; and
a puller wire having a distal end fixedly attached to the tip portion, the puller wire extending through one of the at least one lumen to the proximal end of the catheter body, wherein longitudinal movement of the puller wire relative to the catheter body results in deflection of the tip portion.

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12. The steerable electromagnetic sensor catheter according to claim 11 in

which the distal end of the puller wire is connected to the tip electrode.

13. The steerable electromagnetic sensor catheter according to claim 11 in
which the puller wire extends through the cavity in the bridging tube and is connected
5 to the tip electrode.

14. The steerable electromagnetic sensor catheter according to claim 11 in
which the electromagnetic sensor is glued into the cavity in the bridging tube.

10 15. The steerable electromagnetic sensor catheter according to claim 11
further comprising a noncompressible coil having a proximal end and a distal end, the
noncompressible coil surrounding the puller wire between the proximal and distal
ends of the catheter body.

15 16. The steerable electromagnetic sensor catheter according to claim 15 in
which the at least one lumen containing the puller wire is an off-axis lumen.

17. The steerable electromagnetic sensor catheter according to claim 15
further comprising a compressible tube slidably covering the puller wire from the
20 distal end of the noncompressible coil to the distal end of the puller wire.

18. The steerable electromagnetic sensor catheter according to claim 13
further comprising a compressible tube slidably covering the puller wire from the tip
electrode to at least the proximal end of the bridging tube.

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19. The steerable electromagnetic sensor catheter according to claim 18 in
which the compressible tube is glued into the cavity in the bridging tube.

20. The steerable electromagnetic sensor catheter according to claim 11 in
30 which the at least one lumen containing the puller wire is off-axis in the tip portion.

21. The steerable electromagnetic catheter according to claim 20 in which the at least one lumen containing the puller wire is in generally co-axial relation to the catheter body

5 22. The steerable electromagnetic sensor catheter according to claim 11 further comprising a control handle attached to the proximal end of the catheter body.

23. The steerable electromagnetic sensor catheter according to claim 22 in which the control handle further comprises means attached to the proximal end of the
10 puller wire for causing longitudinal movement of the puller wire in order to deflect the tip portion.

24. The steerable electromagnetic sensor catheter according to claim 22 in which the control handle is attached to the sensor cable.

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25. The steerable electromagnetic sensor catheter according to claim 24 in which the control handle contains means attached to the sensor cable for processing signals to and from the electromagnetic sensor

20 26. The steerable electromagnetic sensor catheter according to claim 11 further comprising at least one ring electrode attached to the outside of the bridging tube and a corresponding ring electrode lead wire attached to the ring electrode and passing through one of the at least one lumen to the proximal end of the catheter body.

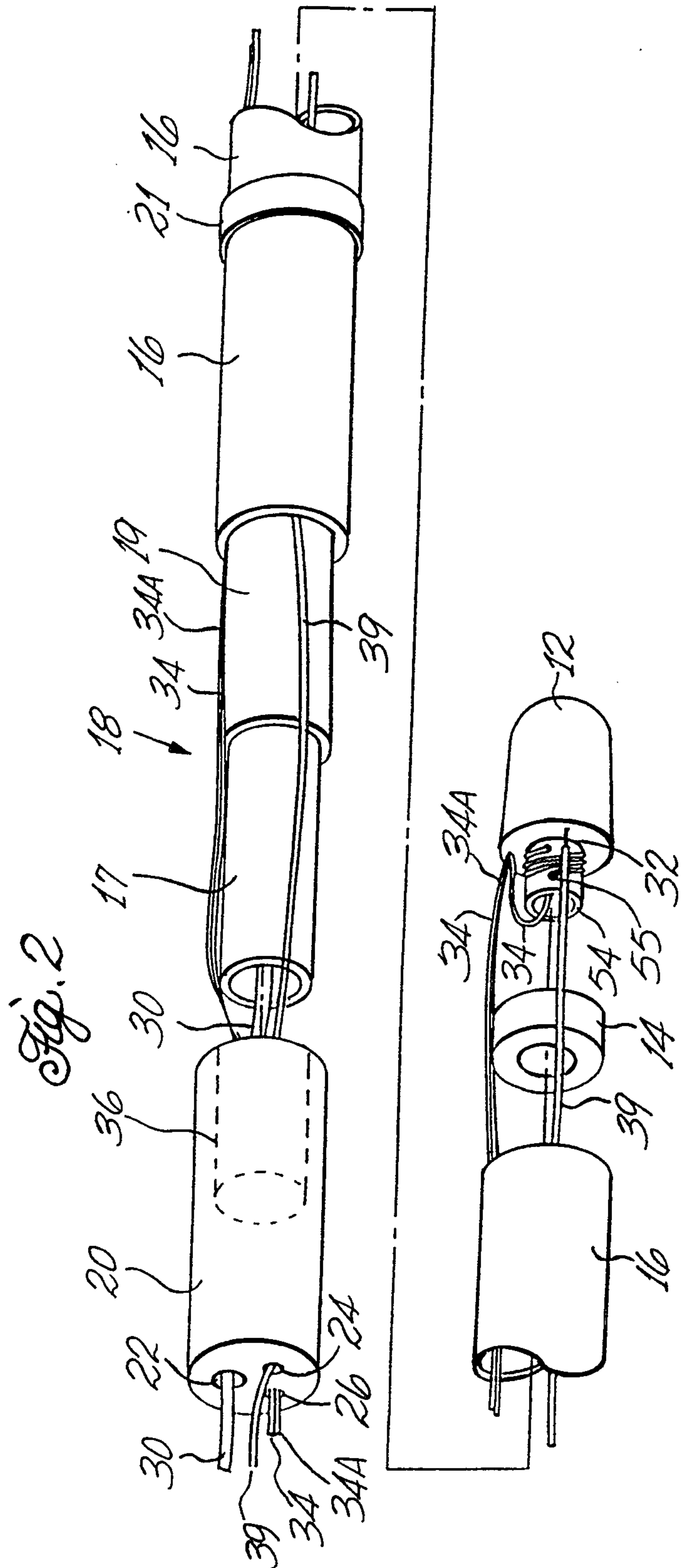
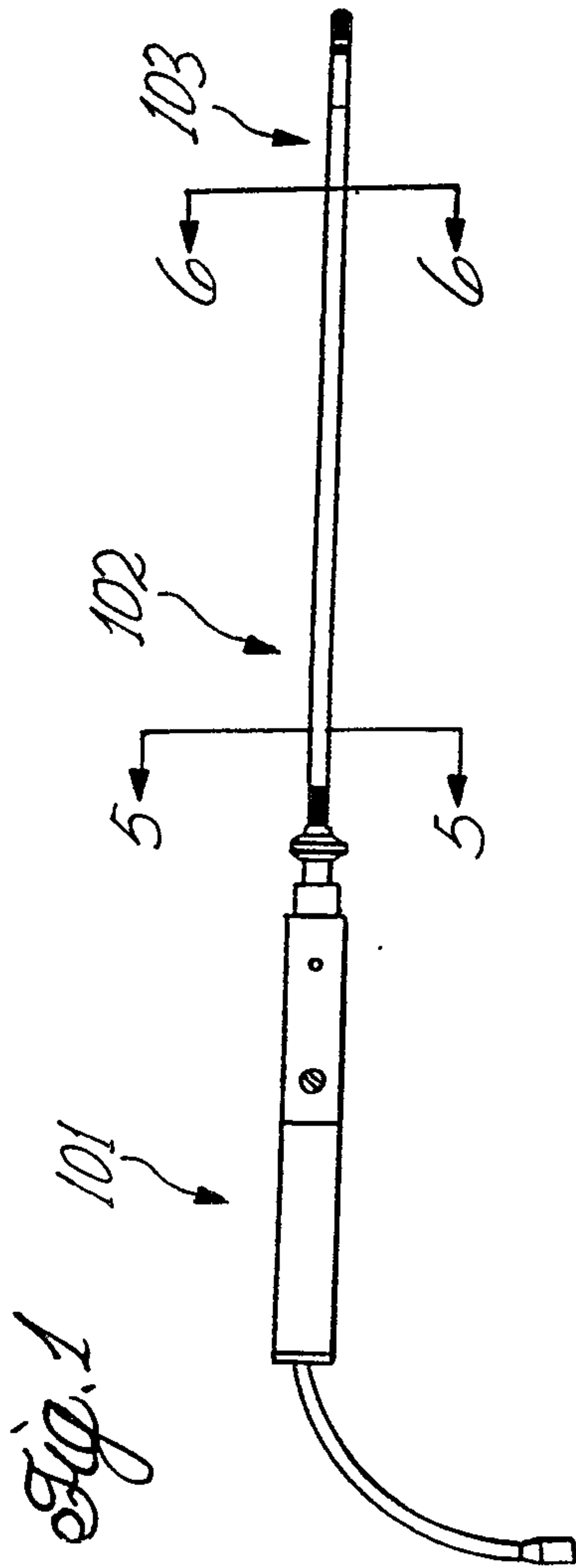


Fig. 3

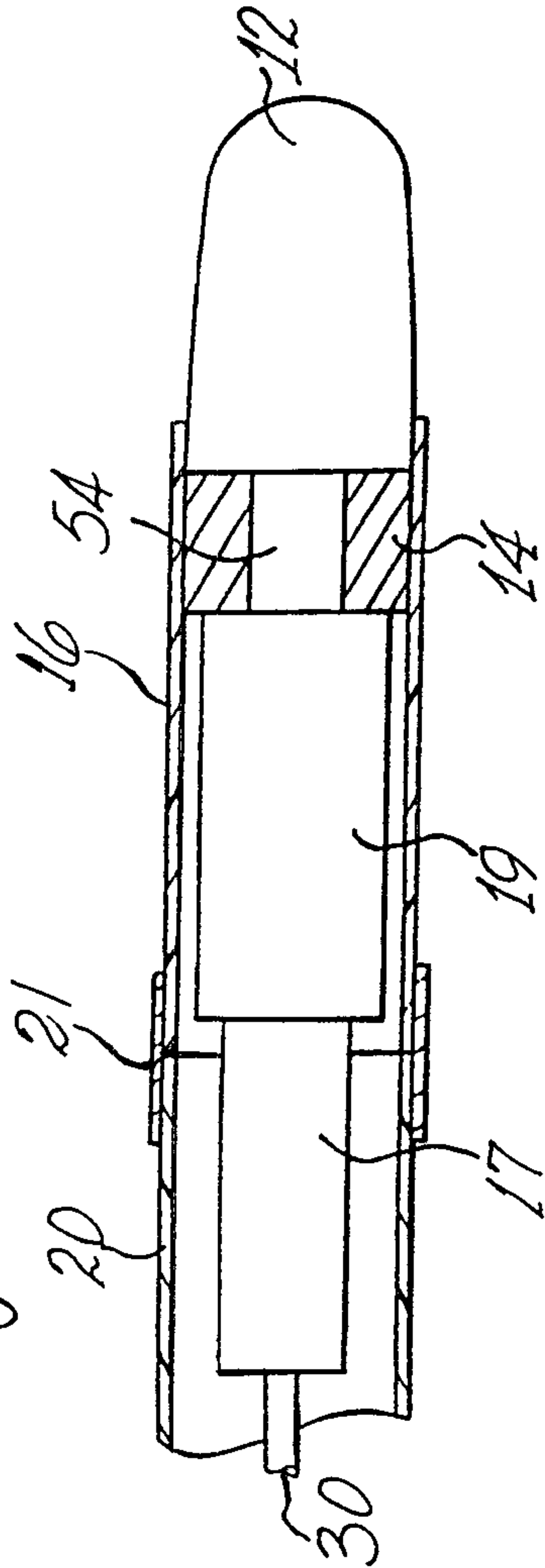


Fig. 5

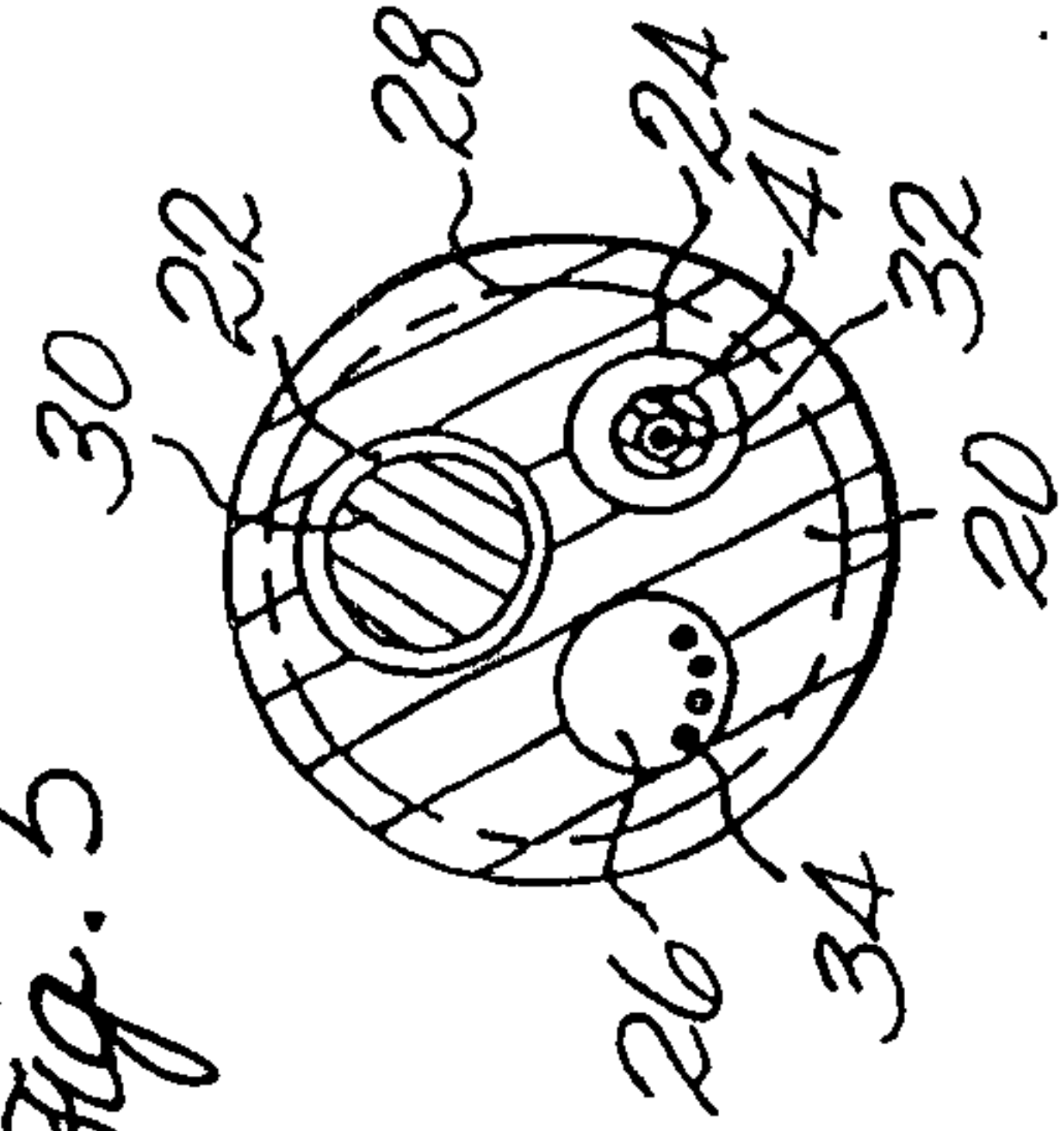


Fig. 6

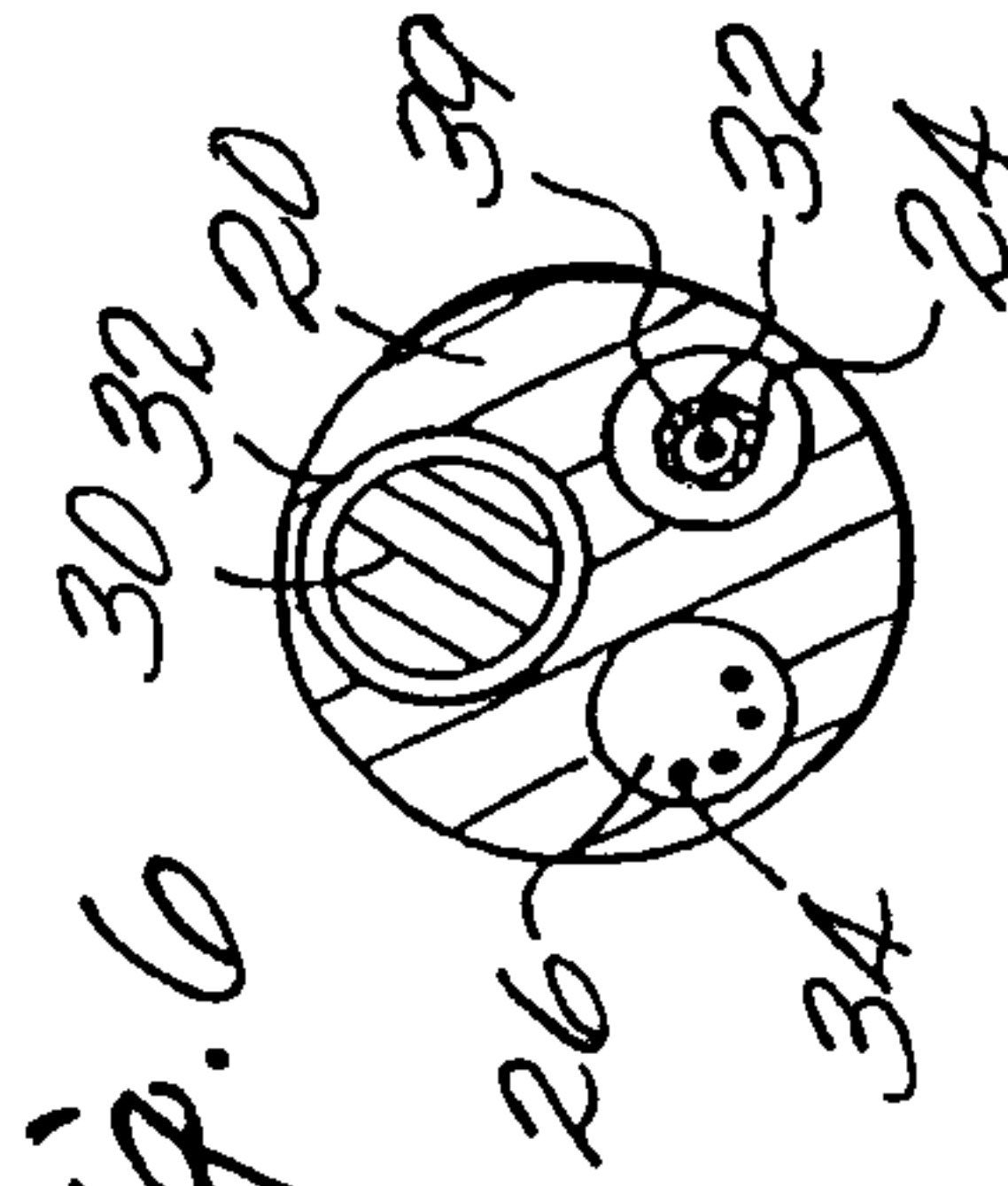
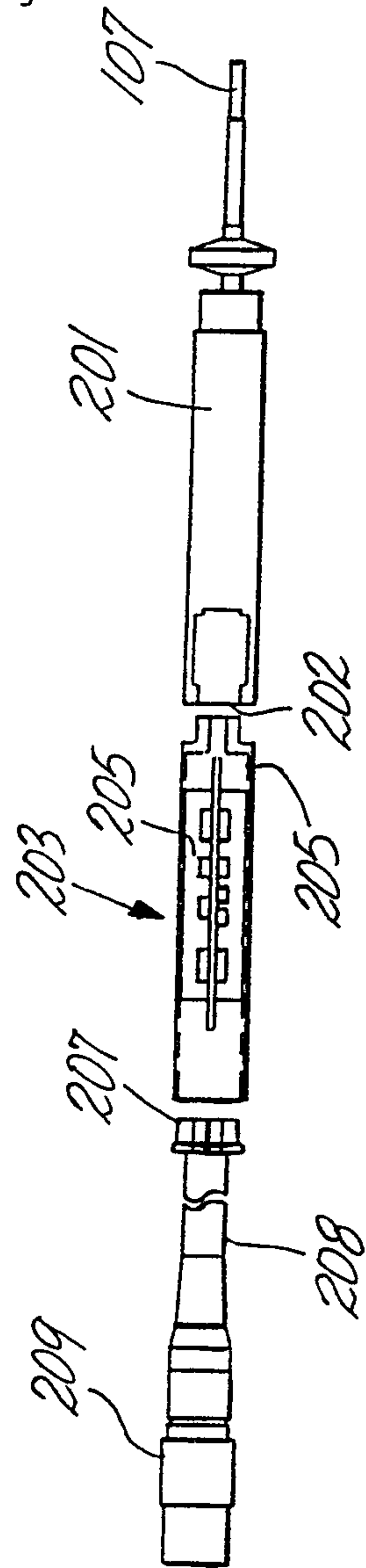
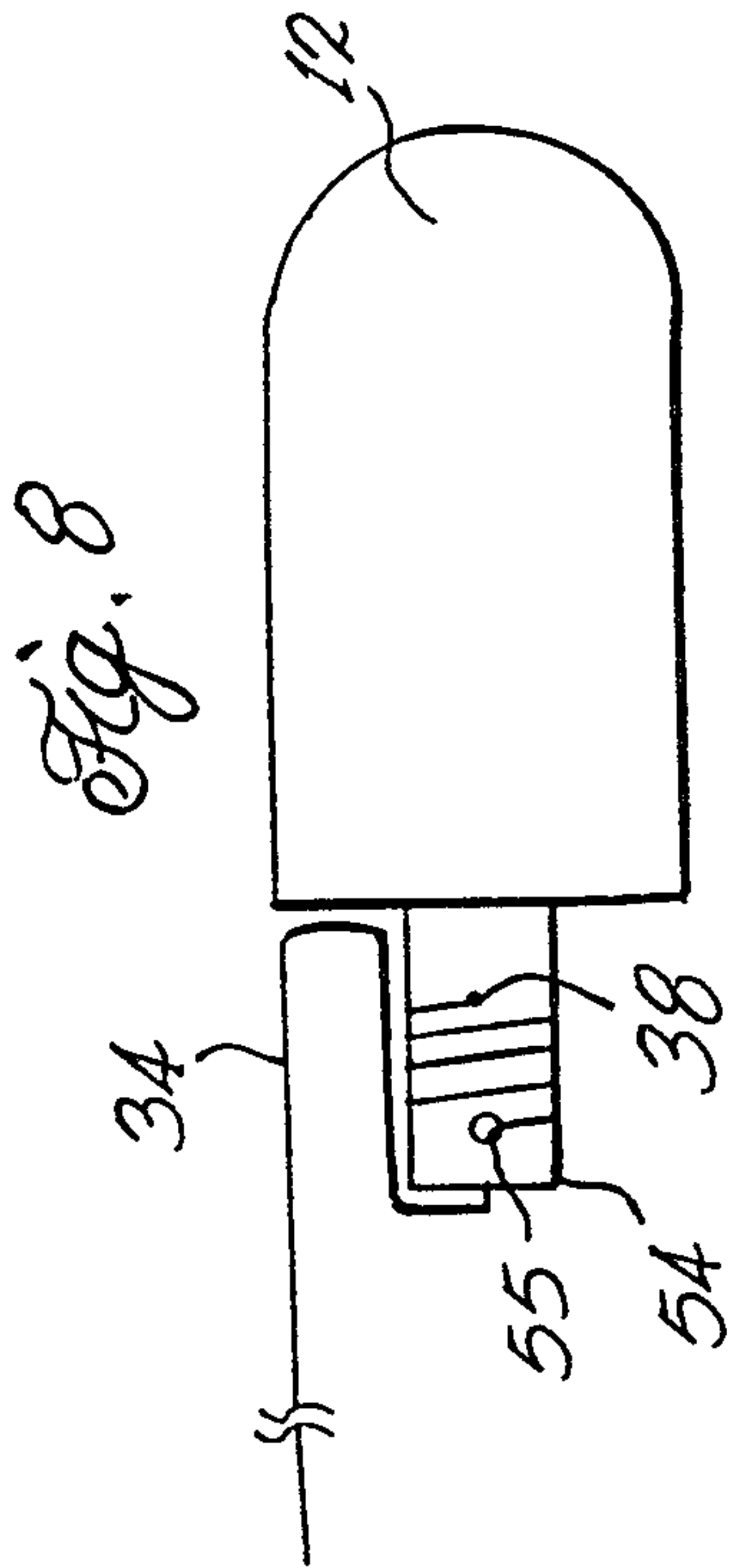
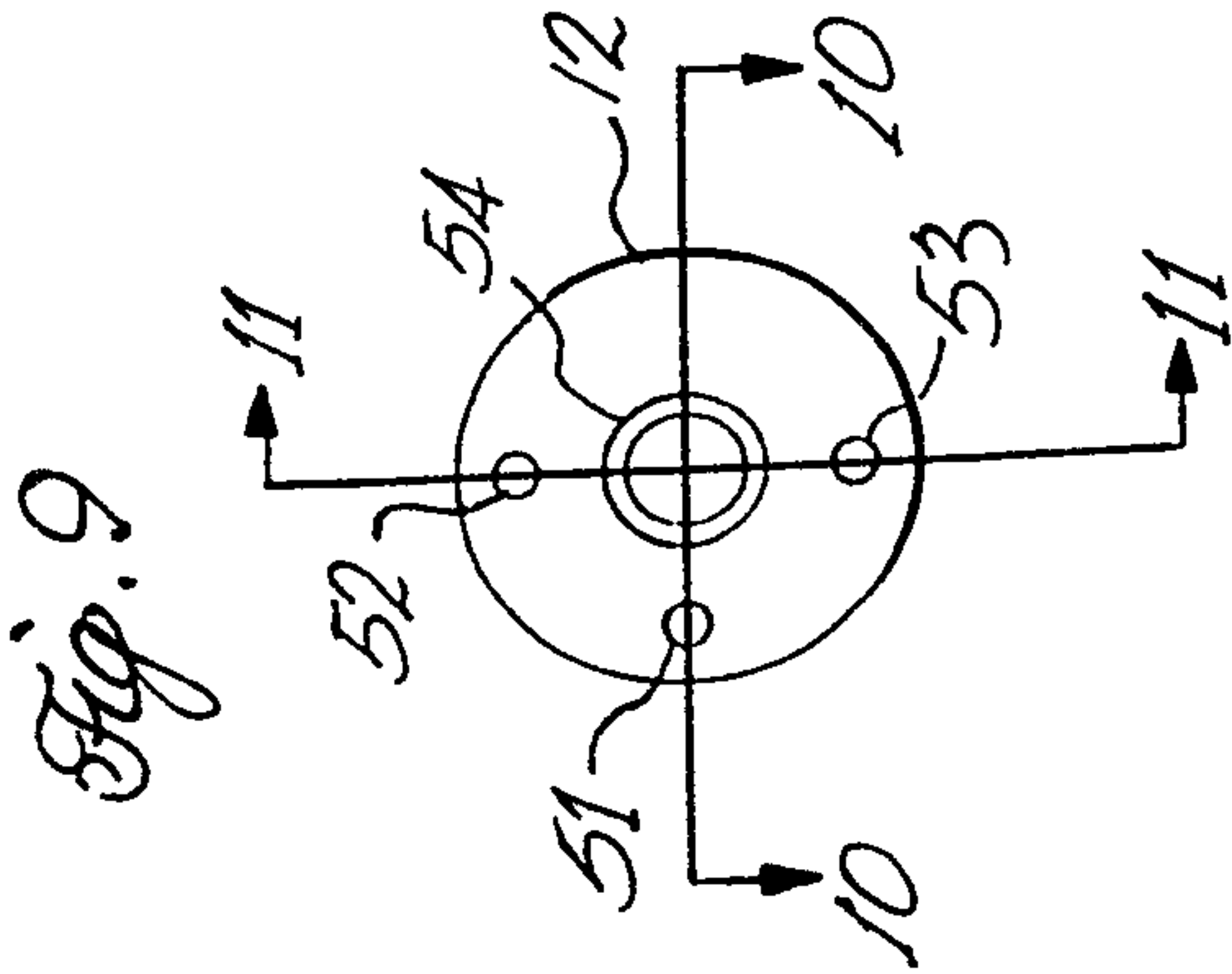
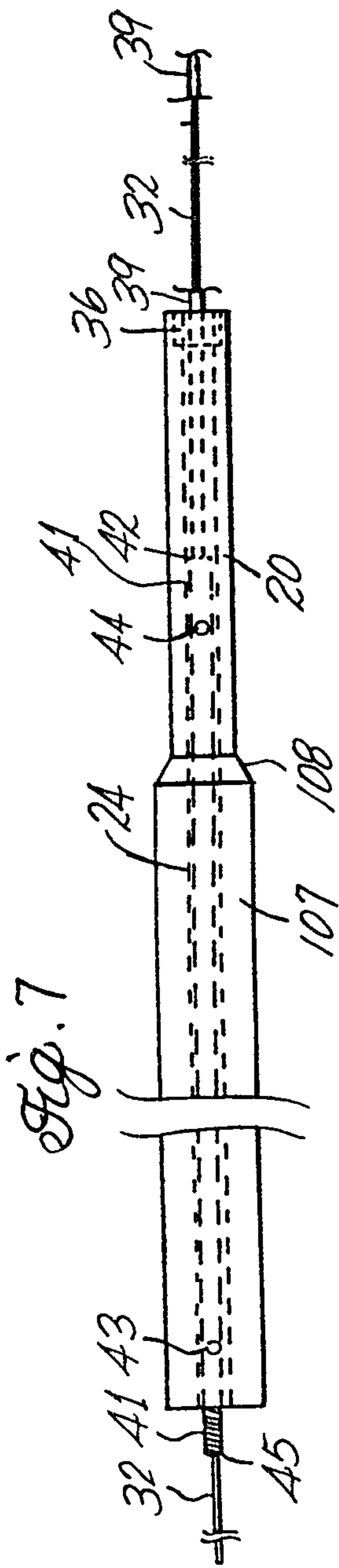


Fig. 4





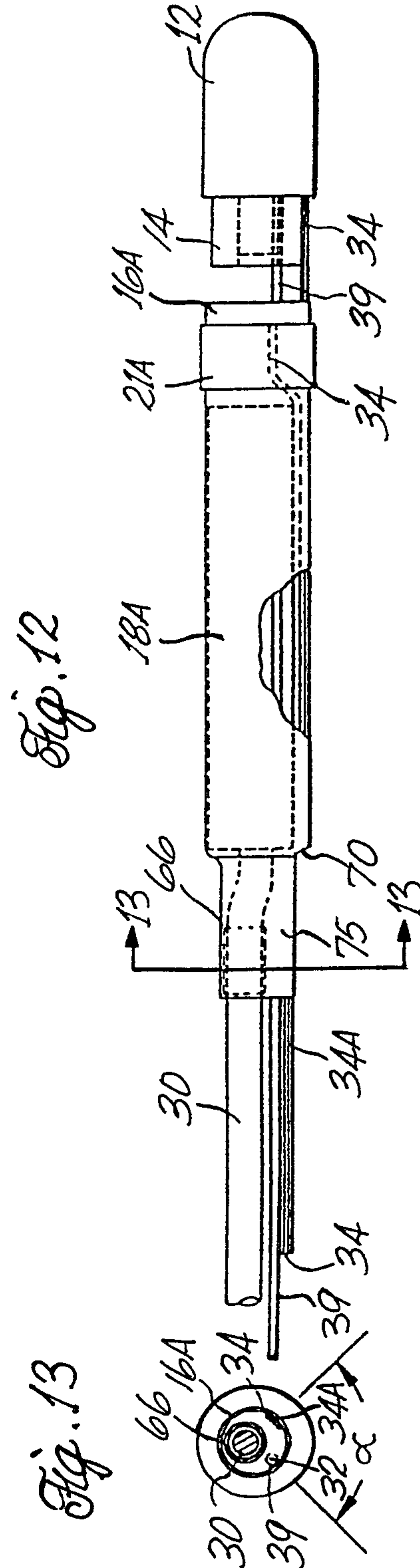
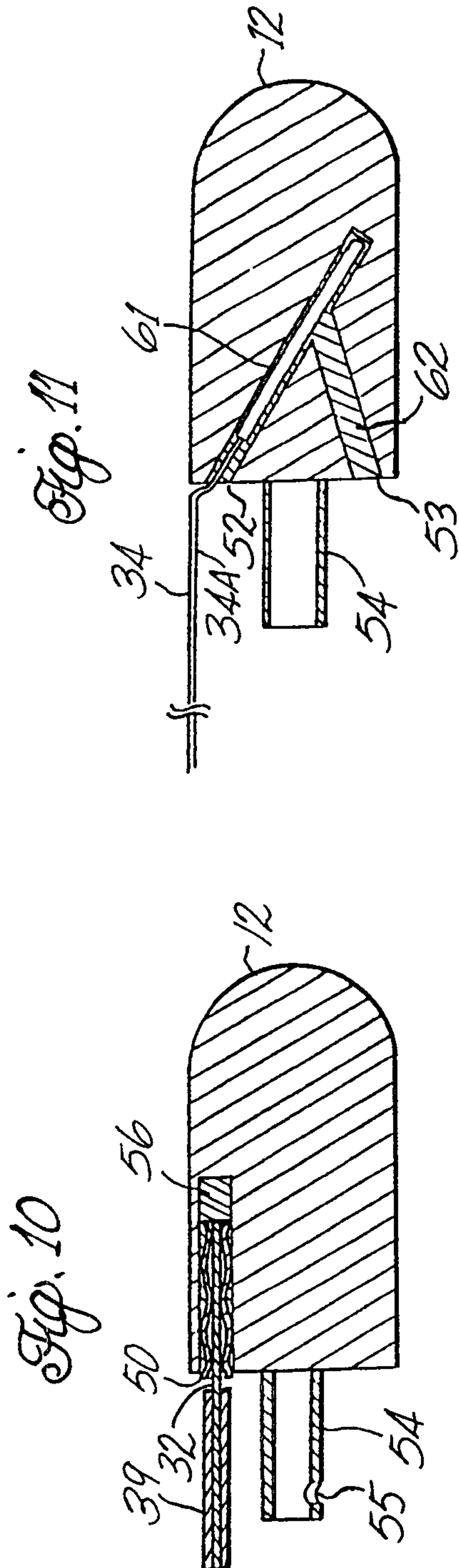


Fig. 14

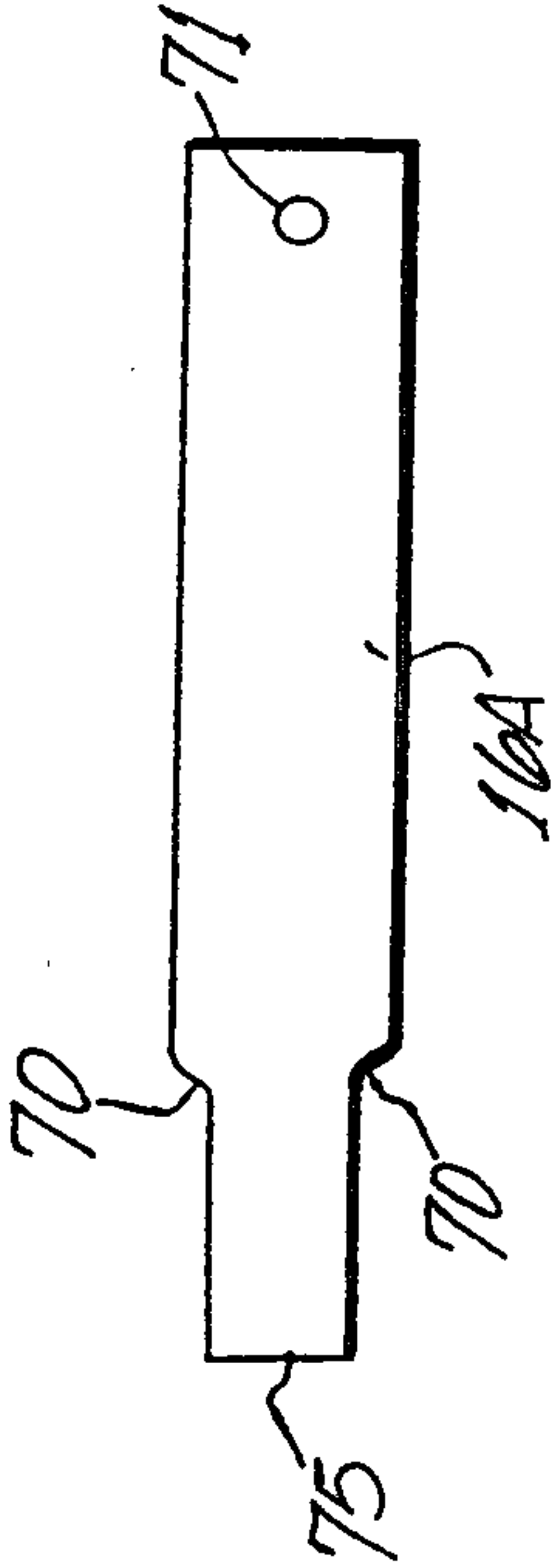


Fig. 15

