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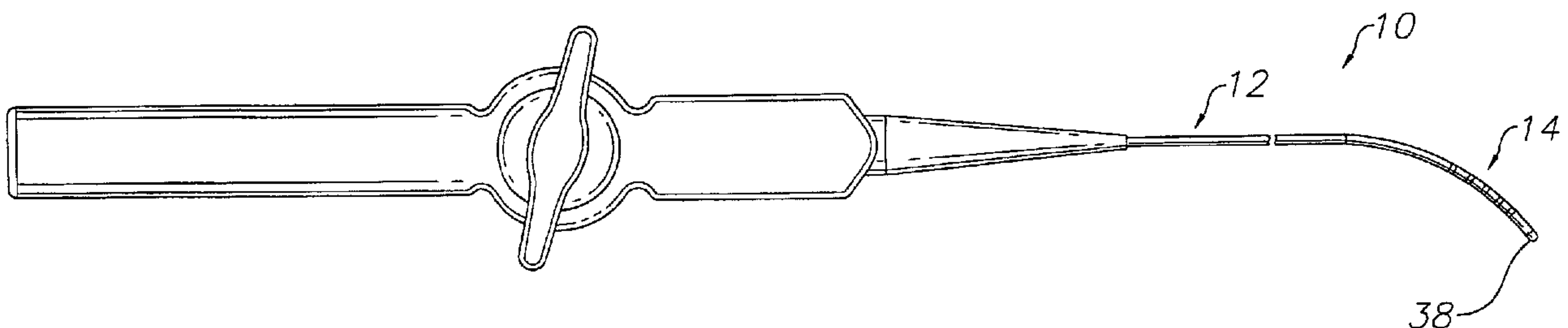
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(54) Titre : MECANISME AMELIORE D'ORIENTATION POUR CATHETER BIDIRECTIONNEL

(54) Title: IMPROVED STEERING MECHANISM FOR BI-DIRECTIONAL CATHETER



(57) **Abrégé/Abstract:**

The present invention provides a bi-directional catheter with nearly double the throw in its catheter tip deflection. In particular, the travel path of each the puller wire includes a U-turn or doubling-back around a pulley which minimizes the offset angle between the pulley wire and the longitudinal axis of the control handle while maximizing the travel distances of that puller wire for any given distance traveled by the pulley drawing the puller wire. In one embodiment, the catheter has an elongated catheter body, a catheter tip section with first and second diametrically-opposed off-axis lumens, and a control handle which includes a steering assembly having a lever structure carrying a pair of pulleys for simultaneously drawing and releasing corresponding puller wires to deflect the tip section of the catheter.

1 ABSTRACT OF THE DISCLOSURE

5 The present invention provides a bi-directional catheter with nearly double the throw in its catheter tip deflection. In particular, the travel path of each the puller wire includes a U-turn or doubling-back around a pulley which minimizes the offset angle between the puller wire and the longitudinal axis of the control handle while maximizing the travel distance of that puller wire for any given distance traveled by the pulley drawing the puller wire. In one
10 embodiment, the catheter has an elongated catheter body, a catheter tip section with first and second diametrically-opposed off-axis lumens, and a control handle which includes a steering assembly having a lever structure carrying a pair of pulleys for simultaneously drawing and releasing corresponding
15 puller wires to deflect the tip section of the catheter.

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1 IMPROVED STEERING MECHANISM FOR BI-DIRECTIONAL CATHETER

FIELD OF INVENTION

5 The present invention relates to improved bidirectional steerable catheters, and more particularly to a catheter having a bidirectional control handle.

BACKGROUND OF INVENTION

10 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. 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
15 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 Bidirectional catheters have been designed to be deflectable in one direction by one puller wire and in the opposite direction within the same plane by a second puller wire. In such a construction, the puller wires extend into opposing off-axis lumens within the tip section of the catheter. So that the tip section can bend in both directions in the same plane, the puller wires and their associated
25 lumens must be located along a diameter of the tip section. For ablation catheters, electrode lead wires must also be provided within the distal end. Typically, an additional lumen is used to contain the electrode lead wires. For example, U.S. Pat. No. 6210407, the disclosure of which is incorporated
30 herein by reference, is directed to a bi-directional catheter comprising two puller wires and a control handle having at least two moveable members longitudinally movable between first and second positions. The proximal end of each puller wire is connected to an associated movable member of the
35 control handle. Proximal movement of a movable member

relative to the catheter body results in proximal movement of the puller wire associated with that movable member relative to the catheter body, and thus deflection of the tip section in the direction of the lumen in which that puller wire extends.

5 As another example, U.S. Pat. No. 6171277, is directed to a bidirectional steerable catheter having a control handle that houses a generally-circular spur gear and a pair of spaced apart rack gears. Each rack gear is longitudinally movable between first and second positions, whereby proximal movement of one rack
10 gear results in rotational movement of the spur gear, and correspondingly distal movement of the other rack gear. Two puller wires extend from the control handle whose the distal ends are fixedly attached to the tip section, and whose proximal ends are each anchored to a separate associated rack gear in the
15 control handle. Proximal movement of a rack gear and its associated puller wire relative to the catheter body results in deflection of the tip section in the direction of the off axis lumen into which that puller wire extends.

Also known is U.S. Pat. No. 6198974 is directed to a
20 bidirectional electrode catheter comprising a control handle. At their proximal ends, two pairs of puller wires are attached to movable pistons in the control handle. Each piston is controlled by an operator using a slidable button fixedly attached to each piston. Movement of selected buttons results in deflection of the
25 tip section into a generally planar "U"- or "S"-shaped curve.

Further known is U.S. Pat. No. 5,891,088 directed to a steering assembly with asymmetric left and right curve configurations. Proximal ends of left and right steering wires are adjustably attached to a rotatable cam housed in a control
30 handle. The rotatable cam

1 has first and second cam surfaces which may be configured
differently from each other to accomplish asymmetric steering.

While the aforementioned catheters provide bi-directional
steering, the mechanical efficiencies of the steering or
5 deflection mechanism can be improved upon. Because the
control handle has limited interior space in which to house
the steering mechanism, a need exists for a compact yet
mechanically-efficient design to accomplish bi-directional
steering. Moreover, a greater degree of deflection in the
10 catheter tip is also desirable, particularly if it can be
accomplished without requiring greater exertion on the part of
the user. The steering assembly of aforementioned U.S. Pat.
No. 5891088 employs a configuration whereby the puller wires
extend to the cam surfaces of the rotatable cam at a greater
15 than generally desirable angle from the longitudinal axis of
the catheter shaft, which decreases the efficiency of the
steering lever and increases friction losses in the operation
of the steering assembly. In addition, the steering assembly
therein generally limits the amount of longitudinal movement
20 of the puller wires for deflecting the catheter tip to only
the circumference of the rotatable cam. An improved catheter
with bi-directional deflection is therefore desired.

SUMMARY OF THE INVENTION

25 The present invention provides a bi-directional catheter
with nearly double the throw in its catheter tip deflection.
In particular, the travel path of each the puller wire
includes a U-turn or doubling-back around a pulley which
minimizes the offset angle between the puller wire and the
30 longitudinal axis of the control handle while maximizing the
travel distance of that puller wire for any given distance
traveled by the pulley drawing the puller wire.

In one embodiment, the catheter has an elongated catheter
body, a catheter tip section with first and second
35 diametrically-opposed off-axis lumens, and a control handle

1 which includes a steering assembly having a lever structure
carrying a pair of pulleys for simultaneously drawing and
releasing corresponding puller wires to deflect the tip
section of the catheter. In particular, the pulleys are
5 rotatably mounted on opposing portions of the lever structure
such that one pulley is moved distally as the other pulley is
moved proximally when the lever structure is rotated. Because
each puller wire is trained on a respective pulley, rotation
of the lever structure causes the pulley that is moved
10 proximally to draw its puller wire to deflect the tip section
in the direction of the off-axis lumen in which that puller
wire extends.

In a detailed embodiment of the invention, each puller
wire is trained about its respective pulley for about 180-187
15 degrees. Moreover, each puller wire may extend from the
distal end of the control handle to its respective pulley at
an angle no greater than about 10 degrees, or more preferably
between 7 and 8 degrees, from the longitudinal axis of the
control handle. Furthermore, the range of rotation of the
20 lever structure in deflecting the catheter tip can be
predetermined through a predetermined profile or curvature in
the housing of the control handle.

In another embodiment of the invention, the control
handle of the catheter includes a pair of constant force
25 springs to draw up slack in a released puller wire when the
tip is deflected. The catheter may also include a pair of
adjustable stops that are configured to stop the proximal ends
of the puller wires from proximal movement beyond a
predetermined stop location along the longitudinal axis.
30 Fine, if not nearly infinitesimal, adjustment in the operating
position of the puller wires is accomplished by selectively
adjusting the placement of the stops distally or proximally
within the catheter housing.

In another embodiment, the control handle of the catheter
35 includes a deflection knob that is rotationally coupled to the

lever structure which enables the user to control deflection of the tip section with, preferably, a thumb and an index finger, when grasping the control handle. The catheter may also include a tension adjustment mechanism for adjusting the tightness of the deflection knob. In one embodiment, the adjustment mechanism includes a cap and a dial rotationally coupled to each other, a friction nut, and a screw rotationally coupled to cap, whereby rotation of the dial selectively increases or decreases the frictional bearing on the lever structure.

In yet another embodiment, the control handle of the catheter is operational for deflection of the tip section without both housing halves of the control handle being joined together. In that regard, the steering assembly is configured to be operational when assembled within one housing half not yet joined with the other housing half. A port formation enables the catheter body to be releasably held in the one housing half such that the puller wires extending from the catheter body can be manipulated by the steering assembly so assembled.

More particularly, there is provided a bi-directional catheter comprising: an elongated catheter body having proximal and distal ends; a catheter tip section at the distal end of the catheter body and first and second diametrically-opposed off-axis lumens; a control handle at the proximal end of the catheter body, the control handle having a longitudinal axis and comprising at least a steering assembly having a lever structure rotatable about an axis substantially perpendicular to the longitudinal axis, the steering assembly including at least two pulleys rotatably mounted on opposing portions of the lever structure; first and second puller wires, each puller wire having proximal and distal ends and extending from the control handle through the catheter body, wherein the first puller wire extends into the first lumen in the tip section and the second puller

wire extends into the second lumen in the tip section, and wherein the distal end of each puller wire is anchored to the tip section; wherein each puller wire is trained on a respective pulley and rotation of the lever structure results in proximal
5 movement of one of said pulleys relative to the control handle thereby drawing proximally at least a segment of its respective puller wire for deflecting the tip section in the direction of the off-axis lumen in which that puller wire extends; and the control handle further comprises a rail configured such that it
10 defines a channel extending between the pulley and the distal end of the handle.

BRIEF DESCRIPTION OF THE DRAWINGS

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

FIG. 1 is a side view of an embodiment of the catheter of the invention.

FIG. 2 is a side cross-sectional view of the junction of the
20 catheter body and tip section of an embodiment of a catheter according to the invention.

FIG. 3 is a transverse cross-sectional view of the catheter body shown in FIG. 2 taken along line 3--3.

FIG. 4 is a side cross-sectional view of the distal end of
25 the tip section shown in FIG. 2.

1 FIG. 5 is a transverse cross-sectional view of the tip section along line 5--5.

5 FIG. 6 is a transverse cross-sectional view of a catheter tip section according to the invention where the puller wires are anchored to the side walls of the tip section.

 FIG. 7 is a longitudinal cross-sectional view of a preferred puller wire T-bar anchor.

10 FIG. 8 is a longitudinal cross-sectional view of the puller wire T-bar anchor of FIG. 7 rotated 90.degree. to show the cross-piece on end.

 FIG. 9 is a top exploded view of a control handle of the catheter of FIG. 1.

15 FIG. 10 is a view of a housing half of control handle and selected components of the steering assembly of the catheter of FIG. 1.

 FIGS. 11a and 11b are views of a lever structure.

20 FIGS. 12a-12c show components of the steering assembly, respectively, as without deflection in the tip section of the catheter, with deflection of the tip section to the right, and with deflection of the tip section to the left.

 FIGS. 13a and 13b are views of different embodiments of a fastener fastening a free end of an embodiment of a constant force spring to a proximal end of a puller wire.

25 FIGS. 14a, 14c and 14e are perspective views of different embodiments of a stop member.

 FIGS. 14b, 14d and 14f are cross-sectional views of the stop members of FIGS. 14a, 14c and 14e, respectively, as situated in a housing half of the control handle.

 FIG. 15 is a view of a deflection knob.

30 FIG. 16 is a view of the housing half of FIG. 10 with parts broken away and a friction nut.

 FIG. 17. is a cross-sectional view of the control handle of the catheter of FIG. 9 taken generally along the axis 75 parts broken away.

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1 FIG. 18. is a view of components of a tension adjustment assembly.

FIG. 19 is a view of a first housing half joined with a second housing half.

5 FIG. 20 is a view of a cap of the tension adjustment assembly.

FIG. 21 is a view of a finger dial of the tension adjustment assembly.

FIG. 22 is a view of a pulley.

10 FIG. 23 is a view of an embodiment of another housing half of the control handle.

FIG. 24 is a cross sectional view taken along Lines W-W in FIG. 10.

15 DETAILED DESCRIPTION OF THE INVENTION

In an embodiment of the invention, there is provided a steerable bidirectional electrode catheter. As shown in FIG. 1, the catheter 10 comprises an elongated catheter body 12 having proximal and distal ends, a tip section 14 at the distal end of the catheter body 12, and a control handle 16 at the proximal end of the catheter body 12.

As shown in FIGS. 2 and 3, the catheter body 12 comprises an elongated tubular construction having a single axial or central lumen 18. The catheter body 12 is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body 12 can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall 20 made of polyurethane or PEBAX. The outer wall 20 preferably comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body 12 so that when the control handle 16 is rotated the tip section 14 will rotate in a corresponding manner.

The overall length and diameter of the catheter 10 may vary according to the application. A presently preferred

1 catheter 10 has an overall length of about 48 inches. The
outer diameter of the catheter body 12 is not critical, but is
preferably no more than about 8 french. The inner surface of
the outer wall 20 is preferably lined with a stiffening tube
5 22, which can be made of any suitable material, preferably
nylon or polyimide. The stiffening tube 22, along with the
braided outer wall 20, provides improved flexural and
torsional stability while at the same time minimizing the wall
thickness of the catheter body 12, thus maximizing the
10 diameter of the central lumen 18. The outer diameter of the
stiffening tube 22 is about the same as or slightly smaller
than the inner diameter of the outer wall 20. A particularly
preferred catheter 10 has an outer diameter of about 0.092
inch and a lumen 18 diameter of about 0.052 inch.

15 As shown in FIGS. 4 and 5, the tip section 14 comprises a
short section of flexible tubing 24 having a first off-axis
lumen 26 and a second off-axis lumen 28. The flexible tubing
24 is made of a suitable non-toxic material that is preferably
more flexible than the catheter body 20. A presently preferred
20 material for the tubing 24 is braided polyurethane, i.e.,
polyurethane with an embedded mesh of braided stainless steel
or the like. The outer diameter of the tip section 14, like
that of the catheter body 12, is preferably no greater than
about 7 french, more preferably about 6-1/2 french or less.

25 The off-axis lumens 26, 28 extend through diametrically
opposed halves of the tip section 14. The off-axis lumens 26,
28 are asymmetrical and therefore non-interchangeable. The
first off-axis lumen 26 is smaller than the second off-axis
lumen 28. In an 8 french or 7 french diameter catheter, where
30 the tip section is 6-1/2 french, it is preferred that the
first off-axis lumen 26 has a diameter ranging from about
0.018 inch to about 0.025 inch, more preferably from about
0.018 inch to about 0.022 inch. Preferably, the second off-
axis lumen 28 has a diameter ranging from about 0.022 inch to

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about 0.030 inch, more preferably from about 0.026 inch to about 0.028 inch.

By using two rather than three lumens along a single diameter, the present design retains the simplified construction of the unidirectional deflectable steerable catheter described in U.S. Pat. No. Re 34,502. However, it is understood that additional lumens may be provided in the tip section. As described in U.S. Pat. No. 6,171,277 the tip section **14** may contain four lumens, two of which have a greater diameter of about 0.029 inch and two of which have a lesser diameter of about 0.018 inch. Lead wires for the electrodes, thermocouple wires and/or electromagnetic sensor cable may extend through different lumen(s) from those through which each of puller wires extends. As such, the present invention may employ two or more lumens in the tip section **14**.

A preferred means for attaching the catheter body **12** to the tip section **14** is illustrated in FIG. 2. The proximal end of the tip section **14** comprises an outer circumferential notch **34** that receives the inner surface of the outer wall **20** of the catheter body **12**. The tip section **14** and catheter body **12** are attached by glue or the like. Before the tip section **14** and catheter body **12** are attached, however, the stiffening tube **22** is inserted into the catheter body **12**. The distal end of the stiffening tube **22** is fixedly attached near the distal end of the catheter body **12** by forming a glue joint with polyurethane glue or the like. Preferably a small distance, e.g., about 3 mm, is provided between the distal end of the catheter body **12** and the distal end of the stiffening tube **22** to permit room for the catheter body **12** to receive the notch **34** of the tip section **14**. A force is applied to the proximal end of the stiffening tube **22**, and, while the stiffening tube **22** is under compression, a first glue joint (not shown) is made between the stiffening tube **22** and the outer wall **20** by a fast drying

1 glue, e.g. Super Glue.RTM.. Thereafter a second glue joint is
formed between the proximal ends of the stiffening tube 22 and
outer wall 20 using a slower drying but stronger glue, e.g.,
polyurethane.

5 A spacer 36 lies within the catheter body 12 between the
distal end of the stiffening tube 22 and the proximal end of
the tip section 14. The spacer 36 is preferably made of a
material that is stiffer than the material of the tip section
14, e.g., polyurethane, but not as stiff as the material of
10 the stiffening tube 22, e.g. polyimide. A spacer made of
Teflon.RTM. is presently preferred. A preferred spacer 36 has
a length of from about 0.25 inch to about 0.75 inch, more
preferably about 0.50 inch. Preferably the spacer 36 has an
outer and inner diameter about the same as the outer and inner
15 diameters of the stiffening tube 22. The spacer 36 provides a
transition in flexibility at the junction of the catheter body
12 and the tip section 14 to bend smoothly without folding or
kinking.

20 In the depicted embodiment, the distal end of the tip
section 14 carries a tip electrode 38 (see FIGS. 1 and 4).
Mounted along the length of the tip section 14 is a ring
electrode 40 (see FIG. 4). The length of the ring electrode
40 is not critical, but is preferably about 1 mm to about 3
mm. Additional ring electrodes can be provided if desired. If
25 multiple ring electrodes are used, they are spaced apart in
any fashion as desired so long as their edges do not touch.

As shown in FIGS. 2-5, the tip electrode 38 and ring
electrode 40 are each connected to a separate lead wire 30.
Each lead wire 30 extends through the second off-axis lumen 28
30 in the tip section 14 (Fig. 5), through the central lumen 18
in the catheter body 12 (Fig. 3) and through the control
handle 16. The proximal end of each lead wire 30 extends out
the proximal end of the control handle 16 and is connected to
an appropriate connector, which can be plugged into or
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1 otherwise connected to a suitable monitor, source of energy,
etc.

The lead wires 30 are connected to the tip electrode 38
and ring electrode 40 by any conventional technique.
5 Connection of a lead wire 30 to the tip electrode 38 is
preferably accomplished by solder or the like. Connection of a
lead wire 30 to the ring electrode 40 is preferably
accomplished by first making a small hole through the tubing
24. Such a hole can be created, for example, by inserting a
10 needle through the tubing 24 and heating the needle
sufficiently to form a permanent hole. The lead wire 30 is
then drawn through the hole by using a microhook or the like.
The end of the lead wire 30 is then stripped of any coating
and welded to the underside of the ring electrode 40, which is
15 then slid into position over the hole and fixed in place with
polyurethane glue or the like.

As also shown in FIGS. 2-5, two puller wires 32 extend
through the catheter 10. Each puller wire 32 extends from the
control handle 16, through the central lumen 18 in the
20 catheter body 12 (Fig. 3) and into one of the off-axis lumens
26 and 28 of the tip section 14 (Fig. 5). As described in more
detail below, proximal movement of the proximal end of each
puller wire 32 is predeterminedly limited within the control
handle 16 and the distal end of each puller wire 32 is
25 anchored within the tip section 14.

Each puller wire 32 is made of any suitable metal, such
as stainless steel or Nitinol. Preferably each puller wire 32
has a coating, such as a coating of Teflon.RTM. or the like.
Each puller wire 32 has a diameter preferably ranging from
30 about 0.006 inch to about 0.0010 inch. Preferably both of the
puller wires 32 have the same diameter.

Each puller wire 32 is anchored near the distal end of
the tip section 14. In the embodiment depicted in FIG. 4, the
puller wires 32 are both anchored to the tip electrode 38 by a
35 welding or the like.

1 Alternatively, the puller wire 32 in the first off-axis
lumen 26 can be anchored to the side wall of the tip section
14. As shown in FIGS. 7 to 9, the puller wire 32 is preferably
attached by means of an anchor 44 fixedly attached to the
5 distal end of the puller wire 32. The anchor 44 is formed by a
metal tube 45, e.g., a short segment of hypodermic stock, that
is fixedly attached, e.g. by crimping, to the distal end of
the puller wire 32. The tube has a section that extends a
short distance beyond the distal end of the puller wire 32. A
10 cross-piece 47 made of a small section of stainless steel
ribbon or the like is soldered or welded in a transverse
arrangement to the distal end of the metal tube which is
flattened during the operation. This creates a T-bar anchor
44. A notch is created in the side of the tip section 14
15 resulting in an opening in the off-axis lumen 26 carrying the
puller wire 32. The cross piece 47 lies transversely within
the notch. Because the length of the ribbon forming the cross-
piece 47 is longer than the diameter of the opening into the
off-axis lumen 26, the anchor 44 cannot be pulled completely
20 into the off-axis lumen 26. The notch is then sealed with
polyurethane glue or the like to give a smooth outer surface.
The glue flows into the off-axis lumen 26 to fully secure the
anchor. A tunnel, in the form of polyimide tubing or the like,
can be provided to permit passage of the lead wire 30 through
25 the glue so that this same puller wire anchor construction can
be used in the second off-axis lumen 28. Other means for
anchoring the puller wires 32 in the tip section 14 would be
recognized by those skilled in the art and are included within
the scope of the invention.

30 Referring back to Figs. 1 and 2, the catheter 10 further
comprises two compression coils 46, each in surrounding
relation to a corresponding puller wire 32. Each compression
coil 46 is made of any suitable metal, such as stainless
steel. Each compression coil 46 is tightly wound on itself to
35 provide flexibility, i.e., bending, but to resist compression.

1 The inner diameter of each compression coil 46 is slightly
larger than the diameter of its associated puller wire 32. For
example, when a puller wire 32 has a diameter of about 0.007
5 inch, the corresponding compression coil 46 preferably has an
inner diameter of about 0.008 inch. The coating on the puller
wires 32 allows them to slide freely within the compression
coil 46. The outer surface of each compression coil 46 is
covered along most of its length by a flexible, non-conductive
10 sheath 48 to prevent contact between the compression coil 46
and the lead wires 30 within the central lumen 18. The non-
conductive sheath 48 made of thin-walled polyimide tubing is
presently preferred.

As shown in Fig. 2, at the distal end of the catheter
body, the two compression coils 46 are positioned in diametric
15 opposition within the stiffening tube 22 and spacer 36 so that
they can be aligned with the two off-axis lumens 26, 28 in the
tip section 14. The compression coils 46 and stiffening tube
22 are sized so that the compression coils 46 fit closely and
slidably within the stiffening tube 22. With this design, the
20 lead wires 30 distribute themselves around the two compression
coils 46 without misaligning the coils.

The compression coils 46 are secured within the catheter
body 12 with polyurethane glue or the like. Each compression
coil 46 is anchored at its proximal end to the proximal end of
25 the stiffening tube 22 in the catheter body 12 by a glue joint
(not shown). When a stiffening tube 22 is not used, each
compression coil is anchored directly to the outer wall 20 of
the catheter body 12.

Still referring to Fig. 2, the distal end of each
30 compression coil 46 is anchored to the distal end of the
stiffening tube 22 in the catheter body 12 by a glue joint 52,
or directly to the distal end of the outer wall 20 of the
catheter body 12 when no stiffening tube 22 is used.
Alternatively, the distal ends of the compression coils 46 may
35 extend into the off-axis lumens 26, 28 of the tip section 14

1 and are anchored at their distal ends to the proximal end of
the tip section 14 by a glue joint. In the depicted
embodiment, where the compression coils 46 are each surrounded
by the sheath 48, care should be taken to insure that the
5 sheath is reliably glued to the compression coil. The lead
wires 30 can also be anchored in the glue joint. However, if
desired, tunnels in the form of plastic tubing or the like can
be provided around the lead wires at the glue joint to permit
the lead wires to be slidable within the glue joint.

10 Both glue joints preferably comprise polyurethane glue or
the like. The glue may be applied by means of a syringe or the
like through a hole made between the outer surface of the
catheter body 20 and the central lumen 18. Such a hole may be
formed, for example, by a needle or the like that punctures
15 the outer wall 18 and the stiffening tube 22 that is heated
sufficiently to form a permanent hole. The glue is then
introduced through the hole to the outer surface of the
compression coil 46 and wicks around the outer circumference
to form a glue joint about the entire circumference of each
20 sheath 48 surrounding each compression coil 46. Care must be
taken to insure that glue does not wick over the end of the
coil so that the puller wire cannot slide within the coil.

As best shown in FIGS. 2 and 5, within the off-axis
lumens 26, 28, each puller wire 32 is surrounded by a plastic
25 sheath 42, preferably made of Teflon.RTM. The plastic sheaths
42 prevent the puller wires 32 from cutting into the wall of
the tip section 14 when the tip section is deflected. Each
sheath 42 ends near the distal end of each puller wire 32.
Alternatively, each puller wire 32 can be surrounded by a
30 compression coil where the turns are expanded longitudinally,
relative to the compression coils extending through the
catheter body, such that the surrounding compression coil is
both bendable and compressible.

Longitudinal movement of the puller wires 32 relative to
35 the catheter body 12, which results in deflection of the tip

1 section 14, is accomplished by manipulation of the control
handle 16. A suitable bidirectional control handle for use in
the present invention is illustrated in FIGS. 9-24.

5 As shown in FIGS. 9 and 10, the control handle 16
comprises a generally elongated handle housing 60, which can
be made of any suitable rigid material. The housing 60 can be
of a unitary construction or of two opposing halves 64, 66
that are joined by glue, sonic welding or other suitable means
along a longitudinal peripheral seam 59 around the housing.

10 The control handle 16 comprises a steering assembly 68 that
controls deflection of the tip section 14 in response to
manipulations by the user. The steering assembly comprises a
lever structure 70 having a pair of coordinated pulleys 72
that act on the puller wires to deflect the tip section, a
15 pair of constant force springs 74 that are attached to the
proximal ends of the puller wires, and a pair of adjustable
stops 76 which prevent the proximal ends of the puller wires
from moving proximally past a selected stop position within
the control handle 16. The steering assembly 68 is

20 advantageously configured to provide a relatively shorter
angular throw while increasing, if not at least generally
doubling, the throw capacity of the catheter. In particular,
the steering assembly has a minimized moment of inertia about
its throw axis 75, while generally doubling the travel
25 distance of a puller wire in relation to the travel distance
of the respective pulley drawing that puller wire, despite the
relatively small interior of the housing. Moreover, the
steering assembly provides a minimal angle between a
longitudinal axis 77 of the control handle 16 and a segment of
30 the puller wire drawn to accomplish deflection, for more
efficient use of the force applied by the user in operating
the control handle.

As better shown in FIGS. 10, 11a and 11b, the lever
structure 70 is somewhat elongated along an axis 84, having a
35 wider center portion 78 between two narrower end portions 80.

1 To deflect the tip section of the catheter, the lever
structure is rotatable at its center about the throw axis 75,
which is generally perpendicular to the longitudinal axis 77
of the control handle 16. A neutral position along axis 79 is
5 defined for the lever structure when its longitudinal axis 84
is generally perpendicular to the longitudinal axis 77 of the
control handle 16. The lever structure is rotatable from its
neutral position in the clockwise direction by angle $+\alpha$ and in
the counterclockwise direction by angle $-\alpha$. The end portions
10 80 are configured with apertures 86, at a radial distance R
from the throw axis 75, in which the pulleys 72 (of which
only one is illustrated in FIGS. 10, 11a and 11b) are
situated. As shown in FIGS. 12a-12c, with rotation of the
lever structure 70, one pulley 72 is translated distally as
15 the other pulley 72 is translated proximally. Moreover, the
lever structure and the pulley are configured such that each
pulley can rotate counterclockwise or clockwise within its
aperture about its own axis. To that end, each pulley has a
core 73 (FIG. 22) about which a puller wire is trained.

20 Referring more to FIG. 10, the housing 60 is configured
at its distal end with a port 90 through which the puller
wires (now designated as 32a and 32b for more clarify) enter
the control handle 16. In the housing half 66 that is shown
in FIG. 10, a divider 92 is configured in the inner surface
25 and proximal of the port to extend linearly between the port
and the lever structure 70. A distal end 94 of the divider is
tapered to define diverging puller wire pathways from the port
toward a respective pulley 72 in the lever structure. For
ease of discussion, the housing half 66 may be described as
30 divisible along the divider 92 into top and bottom housing
quarters 96a, 96b, which are more or less mirror counterparts
of each other in terms of physical layout and operation.
Accordingly, the following description uses similar reference
numerals for similar structures except the numerals are
35 followed by the letter a or the letter b.

1 The top housing quarter 96a is configured with a rail
100a that extends parallel with the divider 92. The rail and
an adjacent side 102a of the housing 60 define a channel 104a
that extends between the pulley 72a and the distal end of the
5 housing quarter which is configured with a well 106a that is
in communication with the channel. Fixedly situated in the
well is the spring 74a whose free end 109a extends proximally
into the channel. Releasably and hence adjustably mounted
onto the rail 100a is the stop 76a.

10 Correspondingly, the bottom housing quarter 96b is
configured with a rail 100b that extends parallel with the
divider 92. The rail and an adjacent side 102b of the housing
define a channel 104b that extends between the pulley 72b
(not shown) and the distal end of the housing quarter which is
15 configured with a well 106b that is in communication with the
channel. Fixedly situated in the well is the spring 74b whose
active end 109b extends proximally into the channel.
Releasably and hence adjustably mounted onto the rail 100b is
the stop 76b.

20 The inner surface of the housing half 64 has formations
in structural correspondence with the aforementioned
formations of the housing half 66. Accordingly, as shown in
FIG. 23, the inner surface is formed with a counterpart
divider 93, counterpart rails 101, counterpart sides 103, and
25 counterpart wells 107.

 In view of the foregoing, the travel path within the
housing of each puller wires is as follows: a first generally
linear path, a non-linear (including, e.g., a U-turn or
doubling back) path, and a second generally linear path, each
30 leg of which is described below in further detail.

 Referring to FIGS. 10 and 12a, the puller wire 32a, whose
distal end is affixed to the tip section 14, enter the control
handle 16 in a proximal direction via the port 90. At the
tapered distal end 94 of the divider 92, the puller wire 32a
35 diverges from the puller wire 32b and continues proximally in

1 a minimally diagonal direction toward the pulley 72a in the
lever structure 70. This section of the travel path, as
defined between the tapered end 94 and the pulley 72a, is
generally linear. This linear segment of the puller wire 32a
5 is hereinafter generally referred to by the numeral 108a (FIG.
12a).

The puller wire 32a then enters the lever structure 70
proximally through a slit opening 110 (best seen in FIG. 11a)
on the distal side of the lever structure and is trained
10 counterclockwise about the pulley 72a before exiting the lever
structure distally through the same slit opening. The puller
wire is trained about the pulley for a predetermined degree
ranging between about 172-195, preferably 177-190, or more
preferably about 180-187. As such, the travel path of the
15 puller wire 32 also includes a section having a U-turn or a
doubling-back at the pulley. This nonlinear segment of the
puller wire is designated by the numeral 111a (FIG. 12a).

The puller wire 32a then veers inwardly and continues
generally distally to enter the channel 104, which defines yet
20 another section of the travel path. Within the channel, the
proximal end of the puller wire (so designated despite its
being physically distal of a preceding segment) is attached to
the free end 109a of the spring 74a. The linear segment of
this travel path is designated by the numeral 112a (FIG. 12a).

25 Correspondingly, the puller wire 32b travels a similar
path having a first linear segment 108b, followed by a
nonlinear segment 111b and further followed by a second linear
segment 112b, except that the segment 111b is trained
clockwise on the pulley 72b. Moreover, the proximal end of
30 the puller wire 32b (so designated despite its being
physically distal of a preceding segment) is attached to the
free end 109b of the spring 74b (not visible in FIG. 10).

In the disclosed embodiment, the constant force springs
74a, 74b are flat coil springs as best seen in FIG. 10. Each
35 spring member exerts a force in the distal direction ranging

1 between about 0.50 ounces and 9.0 ounces, and preferably of
about 1.0 ounce. As shown in FIGS. 13a and 13b, free ends
109a, 109b of the springs 74a, 74b are attached to the
proximal ends of the puller wires 32a, 32b by a fastener 111,
5 e.g., a crimp fastener 113 (FIG. 13a), a welded joint 114
(FIG. 13b).

Configured to act on the free ends 109 are the stops 76
which limit extension of the ends 109 in the proximal
direction (and hence proximal movement of the proximal ends of
10 the puller wires 32) past a predetermined stop location along
the rails 100. Accordingly, each stop 76a, 76b is positioned
proximally of the respective free end 109 and/or fastener 111.
As shown in FIGS. 14a and 14b, each stop can comprise a
generally U-shaped spring clip member 76i (e.g., constructed
15 from a shaped piece of sheet metal) having a base 116 and legs
118 that releasably straddle the rail. The member 76i is
shaped such that one of its legs 118 sits deep in the channel
104 and projects minimally into the channel so as to avoid
interfering with the distal or proximal movement of the puller
20 wires 32 but sufficiently to stop the free ends 109 of the
springs or the fastener 111 from passing proximally.

As shown in FIGS. 14c-14d, each stop can also comprise a
generally S-shaped spring clip member 76j (e.g., constructed
from a piece of shaped sheet metal) which has a first arm 117
25 that wraps around either the rail 100 or the side 102 and a
second arm 119 that sits deep in the channel 104 to adjustably
anchor the member 76j to the rail 100, the side 102 and/or in
the channel 104. Again, the member 76j has a profile that
projects minimally into the channel 104, but sufficiently so
30 as to block the free ends 109 of the springs 74 or the puller
wire fastening means from passing proximally.

Each stop can further comprise a hollow elongated member
76k (e.g., a cylinder formed from a rolled piece of sheet
metal) whose an interior space or volume along the length is
35 generally constant until at its proximal end 121 which can

1 flare when the circumference is unrestrained. A
corresponding, thus close-fitting tubular cross section 123 is
provided in facing surfaces of the rail 100 and the side 102
such that the member 76k can slide or move distally within the
5 channel 104 but is generally restricted against proximal
movement by the frictional engagement of the flared proximal
end 121 against the rail and the wall within the cross section
123. It is understood that the configuration or form of the
stops 76a, 76b is limited by only its function and purpose to
10 adjustable set a stop position and the stops may therefore
take on other forms not expressly described herein.

It can be seen from FIGS. 12a-12c. that rotation of the
lever structure 70 causes deflection in the catheter tip
section 14. That is, when the lever structure is rotated in
15 the clockwise rotation (namely, in the $+\alpha$ direction) (FIG.
12b), the pulley 72a is translated proximally. Because the
puller wire 32a trained on the pulley 72a is stopped against
proximal movement at its proximal end by the stop 76a, the
proximal translation of the pulley 72a causes it to rotate
20 counterclockwise thereby drawing proximally the wire segment
108a, which results in deflection of the tip section 14 to the
right. Facilitating this deflection is the release of the
segment 112b as the pulley 72b is coincidentally translated
distally by the lever structure 70. The resulting slack in
25 the segment 112b is taken up by the spring 74b as the pulley
72b rotates clockwise.

Correspondingly, when the lever structure is rotated in
the counterclockwise rotation (namely, in the $-\alpha$ direction)
(FIG. 12c), the pulley 72b is translated proximally. Because
30 the puller wire 32b trained on the pulley 72b is stopped
against proximal movement at its proximal end by the stop 76b,
the proximal translation of the pulley 72b causes it to rotate
clockwise thereby drawing proximally the wire segment 112b,
which results in deflection of the tip section 14 to the left.
35 Facilitating this deflection is the release of the segment

1 112a as the pulley 72a is coincidentally translated distally
by the lever structure 70. The resulting slack in the segment
112a is taken up by the spring 74a as the pulley 72a rotates
counterclockwise.

5 Although each of the actuating pulley has translated
proximally only a distance x (FIGS. 12b and 12c) along the
longitudinal axis 75 as a result of the rotation of the lever
structure 70, the length of the puller wire drawn by that
pulley proximally from the port in deflecting the tip section
10 is about $2x$. Consequently, the present invention provides a
catheter with nearly double the throw in tip deflection,
despite the small interior space of the control handle.

Because of the repeated cycles of bending each puller
wire can experience around its pulley, the proximal segment(s)
15 of each puller within the control handle may comprise a
flexible braided cable and/or Kevlar® rope which can better
withstand such stress and strain. To that end, the cable or
rope has a length of at least $2x$, with a portion thereof
trained around the pulley. Its distal and proximal ends may
20 be attached to the puller wire and the spring, respectively,
by crimp fasteners. Accordingly, it is understood that the
proximal end of the puller wire and the proximal end of the
cable or rope are used interchangeably herein as appropriate.

Also in accordance with the present invention, as shown
25 in FIGS. 12a-12c, an angle of alignment of the segments 108a,
108b deviates only minimally from the longitudinal axis 77
which provides greater operating efficiency in the force
required to deflection the tip section 14. In the disclosed
embodiment, a deviation angle θ may range between about 5 to
30 12 degrees, preferably between 6 and 10 degrees and more
preferably between 7 and 8 degrees, when the lever structure
is in the neutral position (namely, when α is at or near 0)
(FIG. 12a). Because the pulleys 72 each travel a circular
path when translated by the lever structure 70, the angle θ
35 can be further decreased by up to about 2-4 degrees (that is,

1 decreases down to about $\theta=3$) during this translation (FIGS.
12b and 12c). In any case, given such a minimal range of
angle θ , most of the force that is applied to draw a puller
5 wire proximally along the longitudinal axis 77 for deflecting
the tip section in the direction of the off axis lumen in
which that puller wire extends is advantageously met by the
proximal translation of the pulley drawing that puller wire
along the angle θ .

In accordance with the present invention, an initial
10 neutral position (with little or no detectable deflection)
(FIG. 12a) in the tip section 14 can be readily calibrated by
selective placement of each of the stops 76a, 76b distally or
proximally along the rails 100a, 100b. With the lever
structure 70 resting in a neutral position, the operating
15 position of each puller wire 32 can be adjusted so that it is
sufficiently taut in drawing the ends 109 of the springs 74
against the stops 76 without causing any detectable deflection
in the tip section 14. As described above in relation to
FIGS. 11-13, the stop location of each stop 76a, 76b
20 determines how much distance the corresponding pulley needs to
be moved (or the corresponding puller wire needs to travel)
proximally before the tip section 14 begins to deflect in that
direction. In that regard, it is understood that the puller
wires can also be adjusted to provide the catheter with a
25 predetermined amount of free play in the neutral position so
that the catheter body and/or elements surrounding the puller
wires (e.g., the outer wall 20 and/or the stiffening tube 22)
can shrink or stretch, such as during sterilization of the
catheter, without adversely deforming the puller wires. In
30 accordance with the present invention, fine, if not near
infinitesimal, adjustment of a stop position for each puller
wire is enabled in the control handle 16. As such, these
adjustments of the stop position of each puller wire can also
be used to compensate for certain characteristics in the
35 catheter, including puller wires with unequal actual lengths

1 and/or counterpart components in the steering assembly or the
control handle that are not exact duplicates of each other in
terms of size or operating characteristics. Stop adjustments
5 should be performed to attain a neutral position with little
or no detectable deflection in the catheter tip section 14
before the housing halves 64, 66 are joined to each other.

Referring back to FIG. 9, the lever structure 70 of the
steering assembly 68 is enclosed within the housing halves 64,
66 and is manipulated from outside the housing by a deflection
10 knob 128. Deflection of the catheter 10 can therefore be
comfortably controlled by, preferably, the thumb and/or index
finger of the user when grasping the control handle 16.
Rotation of the deflection knob about the throw axis 75 is
directly coupled to rotation of the lever structure 70
15 primarily by means of an annular protrusion 130 (FIGS. 10 and
11b) formed in the lever structure. The protrusion 130 is
centered about an aperture 132 aligned with the throw axis 75
and extends in the direction of the deflection knob 128. The
protrusion 130 has two recesses 134 aligned along a diameter
20 which allows the lever structure to lock in alignment with the
deflection knob. The protrusion also has a dimension along
the throw axis 75 that enables the protrusion to extend
through and beyond an aperture 136 in the housing half 64
(FIG. 23) to reach a facing surface 138 of the deflection knob
25 128 (FIG. 15). The facing surface 138 is formed with
counterpart annular recess 140 and similarly aligned
protrusions 142 that match, respectively, the annular
protrusion 130 and aligned recesses 134 of the lever structure
70. These matching formations are sized such that the
30 deflection knob can be frictionally or snap-fitted (and secure
by glue if appropriate) through the aperture 136 the housing
half 64 onto the protrusion 130 of the lever structure. In
this manner, the deflection knob 128 and the lever structure
70 are joined to the housing half 64 yet coupled for joint
35 rotation relative to the housing half 64 about the throw axis

1 75. Consequently, clockwise rotation of the deflection knob
causes clockwise rotation of the lever structure, and counter-
clockwise rotation of the deflection knob causes
counterclockwise rotation of the lever structure. In the
5 disclosed embodiment, the recesses 134, 140 and protrusions
130, 142 are also conveniently aligned with arms 144 (FIG. 15)
of the deflection knob so as to give the user a visual
indication of the rotational position or orientation of the
lever structure 70.

10 Because the deflection knob 128 and the lever structure
70 are rotational coupled, rotation of the deflection knob may
also be described in terms of the aforementioned angle α . As
illustrated in FIGS. 12a-12c, the range of angle α is
predetermined primarily by the arcuate profile of the housing
15 near the throw axis 75. Concave or generally recessed
sections 150 (see also FIG. 10) of the housing halves 64, 66
abut with the arms 144 of the deflection knob thus preventing
further clockwise rotation beyond the angle $+\alpha$ (FIG. 12b) and
counterclockwise rotation beyond the angle $-\alpha$ (FIG. 12c). It
20 is understood that the range of rotation of the deflection
knob 128 can be varied by altering the profile or curvature of
the sections 150. Moreover, the sections 150 on each side of
the neutral position of the lever structure 70 need not be
identical; a greater counterclockwise rotation angle and/or a
25 lesser clockwise rotation angle are possible, and vice versa.

In the disclosed embodiment, the angle α of the lever
structure 70 (and hence the deflection knob 128) ranges
between about 0 and 70 degrees, preferably between about 30
and 60 degrees and more preferably between about 40 to 50
30 degrees. Accordingly, the disclosed embodiment provides a
total range of rotation (from $-\alpha$ to $+\alpha$) of between about 0 and
140 degrees, preferably between about 60 and 120 degrees and
more preferably between about 80 to 100 degrees.

35 Significantly, the control handle 16 is configured such
that it need not be fully assembled for the steering assembly

1 68 and deflection of the tip section 14 to be effectively
tested and evaluated. In particular, the steering assembly 68
can be tested and evaluated when assembled solely within the
housing half 66 and operated on by the deflection knob 128
5 mounted onto the lever structure without the housing half 64.
To that end, the housing half 66 is configured at or near the
port 90 with a formation 91 (FIG. 24) that releasably holds
the proximal end of the catheter body 12 (whose outer wall 20
and stiffening tube 22 generally terminate proximal of the
10 formation 91 so that the pulley wires 32 and can extend freely
and uncovered into the control handle 16). The formation can
include a pair of tabs 93 defining a space in which the
catheter body can be snapped into and releasably held to
facilitate the testing and evaluation of the deflection
15 operation of control handle without the housing half 64.

In the assembly of the remainder of the control handle,
reference is made to FIGS 9, 11a, and 16-21. A second annular
protrusion 152 on a surface 154 of the lever structure 70
facing the housing half 66 is received in an annular
20 indentation 156 (FIG. 19) formed in the housing half 66. The
annular indentation 156 of the housing half 66 is concentric
with an aperture 158 that is aligned with the throw axis 75
and has a geometric (non-circular) or hexagonal cross-section.
In the illustrated embodiment, the control handle 16 includes
25 a tension adjustment mechanism 160 (FIG. 9) that is mounted
onto the outside of the housing half 66. The mechanism 160
which can be manipulated to adjust the tightness or tension of
the rotational movement of deflection knob 128 includes a cap
162 and a finger dial 164 that are rotationally coupled, a
30 friction screw 166 that is rotationally coupled to the cap,
and a friction nut 167 that is in engagement with the friction
screw 166.

As best shown in FIG. 17, the friction nut 167 is
situated in the aperture 132 of the lever structure 70. The
35 friction nut is configured with a lip 176 at one end that

1 engages with a corresponding diameter 178 in the aperture 132
of the lever structure 70. The lip 176 and the diameter 178
are oriented such that they point toward the deflection knob
128. On an end face of the lip, there are two recesses on a
5 diameter of the outer surface of the lip 179 which can receive
the head of a screwdriver that may be used during assembly of
the control handle 16. At an end 169 of the nut 167, it is
provided with a geometric or hexagonal cross section 177 that
matches the aperture 158 of the housing half 66. The length
10 of the nut 167 allows the end 169 to be received in the
aperture 158 so that the nut is secured with the housing half
66 against rotation about the throw axis 75.

An inner surface 168 of the cap 162 (FIG. 18) facing the
outside of the housing half 66 defines a raised circular
15 portion 170 that fits within a corresponding indented circular
portion 172 (FIG. 19) in the outer face of the housing half
64. With a central aperture 174 (FIG. 18) of the cap
concentric with the hexagonal aperture 158 (FIG. 19) which
leads to a threaded interior of the friction nut 167 (FIG. 17)
20 within the lever structure 70, the screw 166 (not shown in
FIG. 17, but shown in FIG. 9) is inserted through the aperture
174 and the aperture 158 and its end advanced into threaded
engagement with the end 169 of the friction nut 167. As shown
in FIG. 20, the aperture 174 has three depths when viewed from
25 its outside surface. A first depth has a smaller circular
cross section 180 defining a passage for the screw 166
completely through the cap 162. A second depth has a
geometric or hexagonal cross section 182 about mid-depth so as
to anchor a geometric or hexagonal screw head 184 (FIG.
30 9) against axial movement toward the friction nut 167 and to
rotationally couple the cap 162 and the screw 166 to each
other. A third depth 186 has a larger circular cross section
whose depth sufficiently enables the cap to receive a facing
circular portion 188 of the finger dial 164 (FIG. 22).

1 Referring to FIGS. 19-21, covering the screw head 184,
the finger dial 164 is mounted outside of the cap 162 by
prongs 190 (FIG. 21) that protrude from the finger dial in
opposing positions across the portion 188, for frictional snug
5 fitting into (and beyond) apertures 192 (FIGS. 18, 20) form on
a diameter of the cap 162. And, because the cap 162 and the
finger dial 164 have rotational freedom relative to the
housing half 66, the outside surface 194 of the housing half
66 is configured with two curved recesses 196 (FIG. 19) which
10 not only accommodate rotation movement of the ends of the
prongs 190 extending past the cap, but effectively limit such
rotational movement about the throw axis 75 to about 60
degrees, preferably about 50 degrees, or more preferably about
45 degrees. Accordingly, when the finger dial 164 is rotated,
15 the cap 162 (rotationally coupled thereto by the prongs 190)
and the screw 166 (rotationally coupled to the cap 162 by the
hexagonal head 184) are jointly rotated.

Where the dial 167 is rotated to advance the screw 166
into the friction nut, the friction nut 167 is drawn toward
20 the adjustment mechanism 160 thereby drawing the lever
structure 70 toward the inside of the housing half 66 to
increase the frictional contact or bearing between the second
annular protrusion 152 of the lever structure 70 against the
indented circular portion 172 of the inner surface of housing
25 half 66. The tension of the lever structure 70 and hence the
deflection knob 128 against rotational movement is thereby
increased. Correspondingly, where the dial 164 is rotated to
draw the screw 166 out of the friction nut 167, the bearing of
the protrusion 152 of the lever structure 70 against the
30 portion 172 of the housing half 66 is decreased thereby
decreasing the tension of the lever structure 70 and the
deflection knob 128 against rotation. This bearing between
the lever structure 70 and the housing half 66, which can
affect whether the deflection knob is at all rotatable, how
35 much force the user is to apply in deflecting the tip section

1 and whether and/or how quickly the tip section can straighten
after deflection when the deflection knob is released, can
therefore be tightened or loosen as desired by the user in
operating the deflection knob 128.

5 In other embodiments, one or more additional off axis
lumens may be provided through which additional components,
e.g., infusion tube, optic fiber, etc., may extend. Depending
on the intended use of the catheter 10, it can further
comprise additional features such as temperature sensing
10 means, an optic fiber, an infusion tube, and/or an
electromagnetic sensor. Additionally, smaller components, such
as a temperature sensing means, could also extend through the
second lumen in the tip section along with the puller wire and
lead wire(s).

15 In the embodiments described above, the central lumen 18
of the catheter body 12 is used for passage of the electrode
lead wires 30 as well as the two puller wires 32, compression
coils 46 and, if present, thermocouple wires, electromagnetic
sensor cable, optic fiber or infusion tube. It is understood
20 that the catheter body 12 could alternatively comprise a
plurality of lumens. However, the single central lumen 18 is
preferred because it has been found that a single lumen body
permits better control when rotating the catheter 10. The
single central lumen 18 permits the puller wires 32,
25 compression coils 46 and lead wires 30 to float freely within
the catheter body 12. If such wires are restricted within
multiple lumens, they tend to build up energy when the control
handle 16 is rotated, resulting in the catheter body 12 having
a tendency to rotate back if, for example, the handle 16 is
30 released, or if bent around a curve, to flip over, either of
which are undesirable performance characteristics.

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
35 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.

Accordingly, the foregoing description should not be read as
5 pertaining only to the precise structures described and illustrated in the accompanying drawings.

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CLAIMS:

1. A bi-directional catheter comprising:

an elongated catheter body having proximal and distal ends;

a catheter tip section at the distal end of the catheter body and first and second diametrically-opposed off-axis lumens;

a control handle at the proximal end of the catheter body, the control handle having a longitudinal axis and comprising at least a steering assembly having a lever structure rotatable about an axis substantially perpendicular to the longitudinal axis, the steering assembly including at least two pulleys rotatably mounted on opposing portions of the lever structure;

first and second puller wires, each puller wire having proximal and distal ends and extending from the control handle through the catheter body, wherein the first puller wire extends into the first lumen in the tip section and the second puller wire extends into the second lumen in the tip section, and wherein the distal end of each puller wire is anchored to the tip section;

wherein each puller wire is trained on a respective pulley and rotation of the lever structure results in proximal movement of one of said pulleys relative to the control handle thereby drawing proximally at least a segment of its respective puller wire for deflecting the tip section in the direction of the off-axis lumen in which that puller wire extends; and

the control handle further comprises a rail configured such that it defines a channel extending between the pulley and the distal end of the handle.

2. A bi-directional catheter of claim 1, wherein each of the puller wires is trained about its respective pulley for at least about 180 degrees.

3. A bi-directional catheter of claim 1, wherein each puller wire extends from the distal end of the control handle to its respective pulley at an angle of no greater than about 10 degrees from the longitudinal axis of the control handle.

4. A bi-directional catheter of claim 1, wherein each puller wire extends from the distal end of the control handle to its respective pulley at an angle ranging between about 3 and 10 degrees from the longitudinal axis of the control handle.

5. A bi-directional catheter of claim 1, wherein the control handle further comprises a deflection knob, wherein the deflection knob and the lever structure are rotationally coupled to each other.

6. A bi-directional catheter of claim 1, further comprising:

first and second constant force springs;

a first stop positioned proximal a first connection between the first constant force spring and the proximal end of the first puller wire;

a second stop positioned proximal a second connection between the second constant force spring and the proximal end of the second puller wire.

7. A bi-directional catheter of claim 1, wherein the constant force springs are positioned distal of the pulleys.

8. A bi-directional catheter of claim 4, wherein the first and second stops prevent proximal ends of first and second puller wires from moving proximally beyond a respective predetermined location along the longitudinal axis.

9. A bi-directional catheter of claim 1, further comprising a divider extending along the longitudinal axis of the control handle, said divider directing the puller wires at a predetermined angle toward its respective pulley.

10. A bi-directional catheter of claim 1, further comprising an adjustment knob configured to adjust tension of the deflection knob.

11. A bi-directional catheter of claim 10, wherein the adjustment knob comprises a dial.

12. A bi-directional catheter of claim 11, wherein the adjustment knob further comprises a member configured to draw the lever structure toward the housing in response to rotation of the dial.

13. A bi-directional catheter of claim 1, wherein the lever structure rotates within a predetermined range of angles from the perpendicular axis.

14. A bi-directional catheter of claim 1, wherein the predetermined range is dependent on a profile of the control handle.

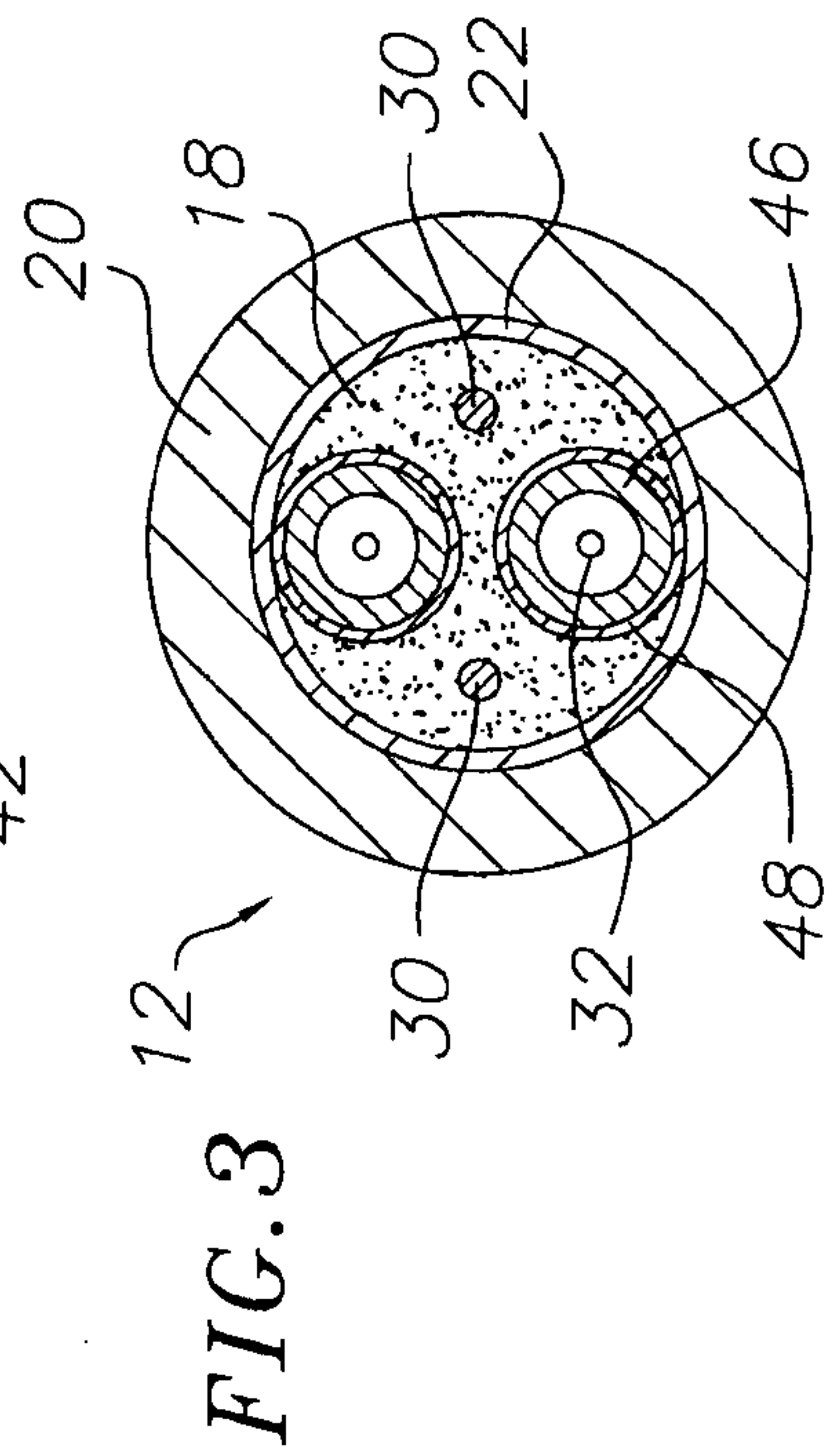
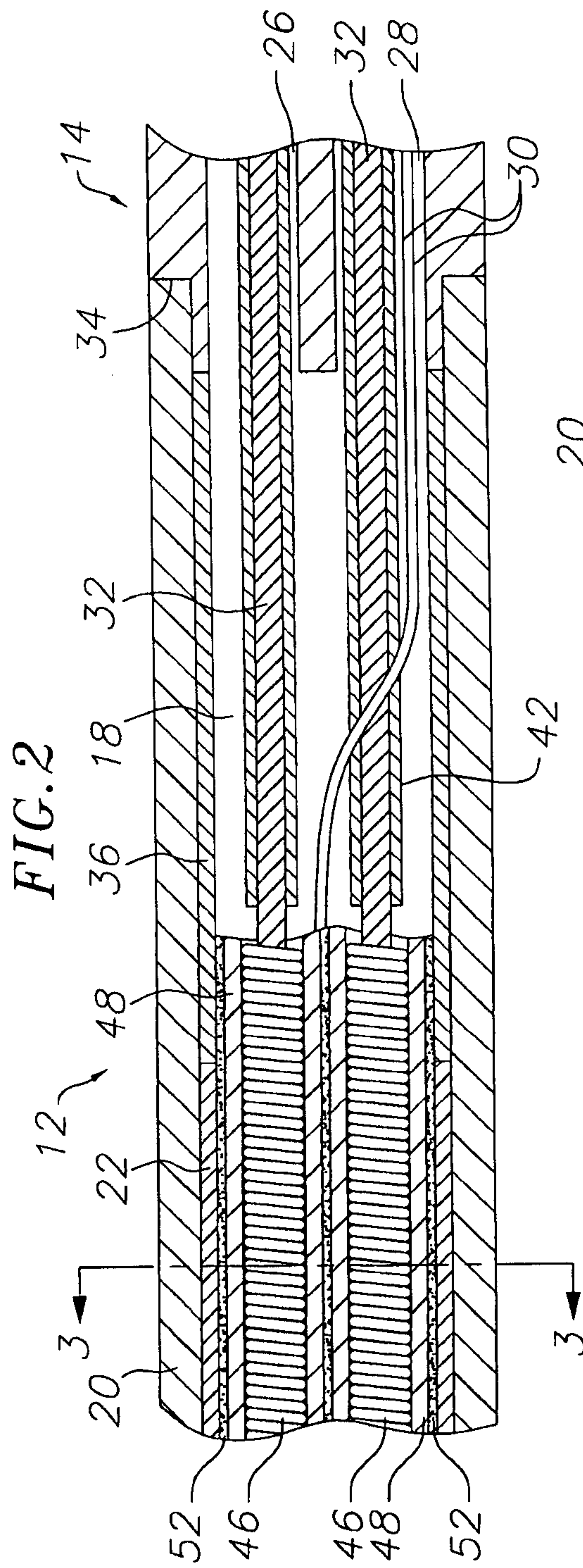
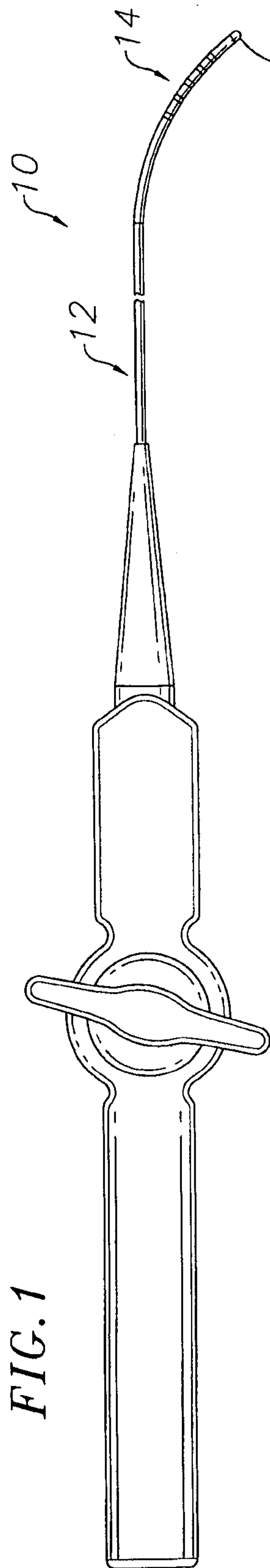
15. A bi-directional catheter of claim 11, wherein the predetermined range is about -50 to +50 degrees.

16. A bi-directional catheter of claim 1, wherein a travel path of each puller wire within the control handle includes a U-turn of at least 180 degrees about a respective pulley.

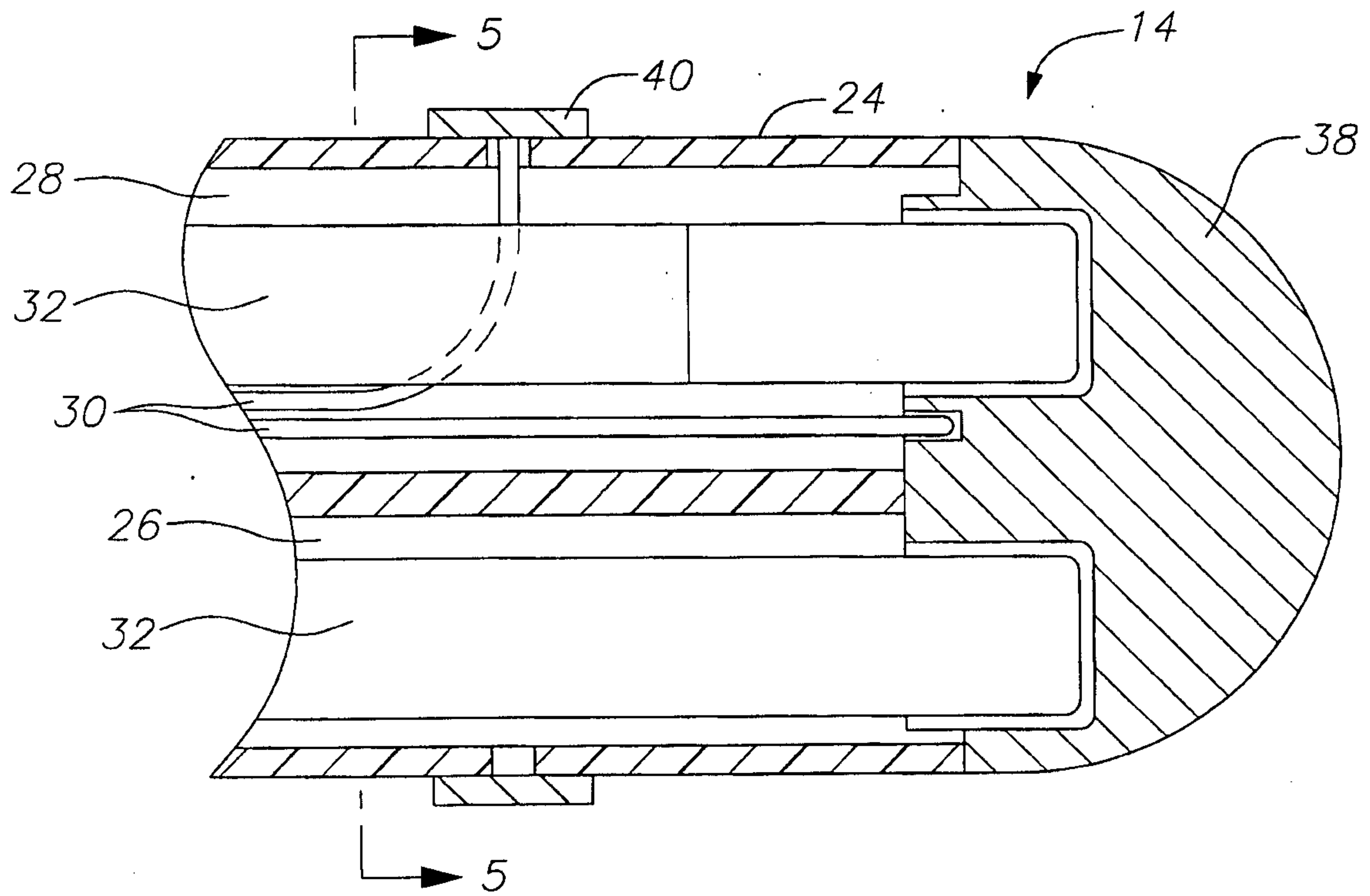
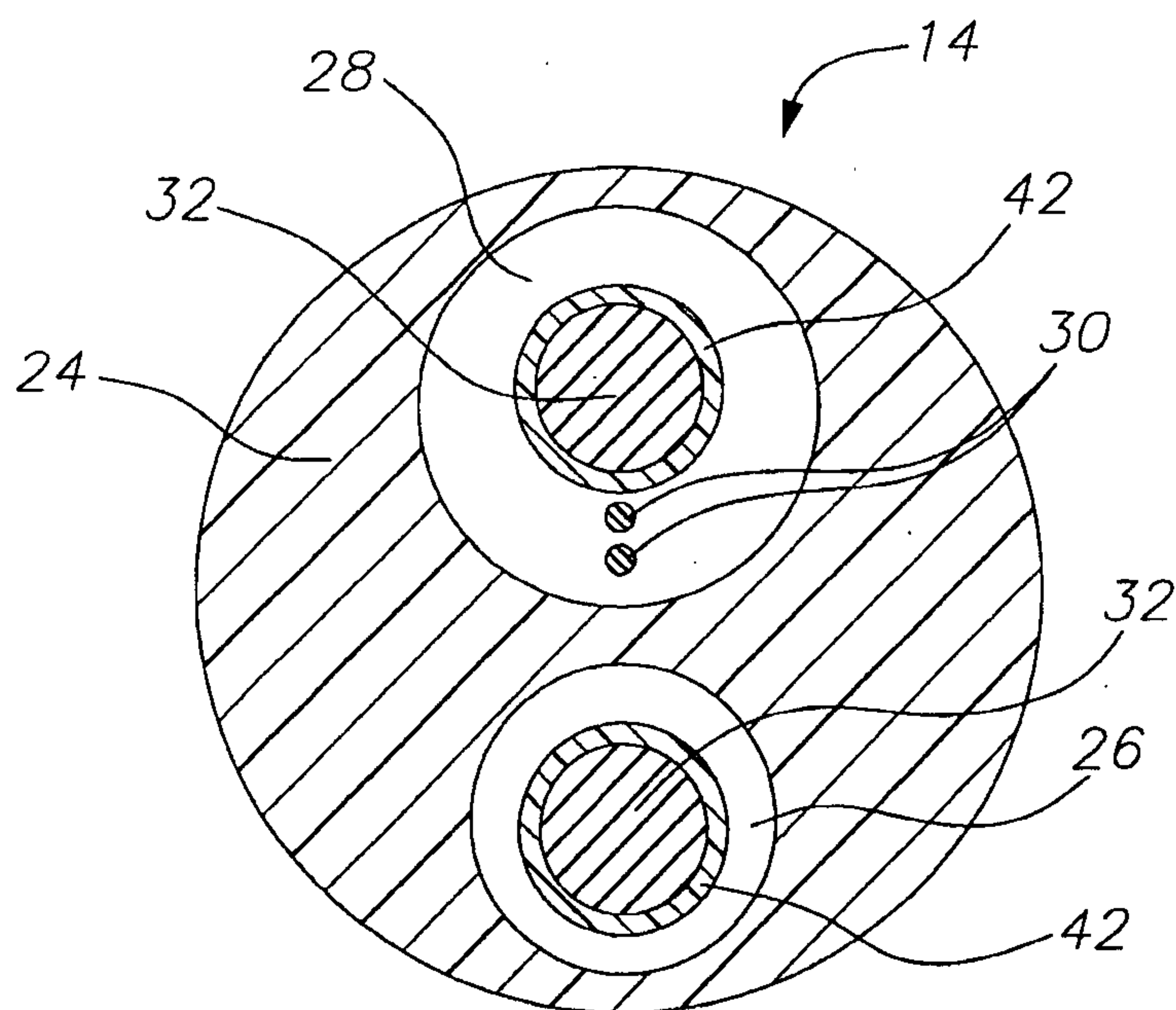
17. A bi-directional catheter of claim 1, wherein

the control handle has two housing members that can be joined to enclose a steering assembly; and

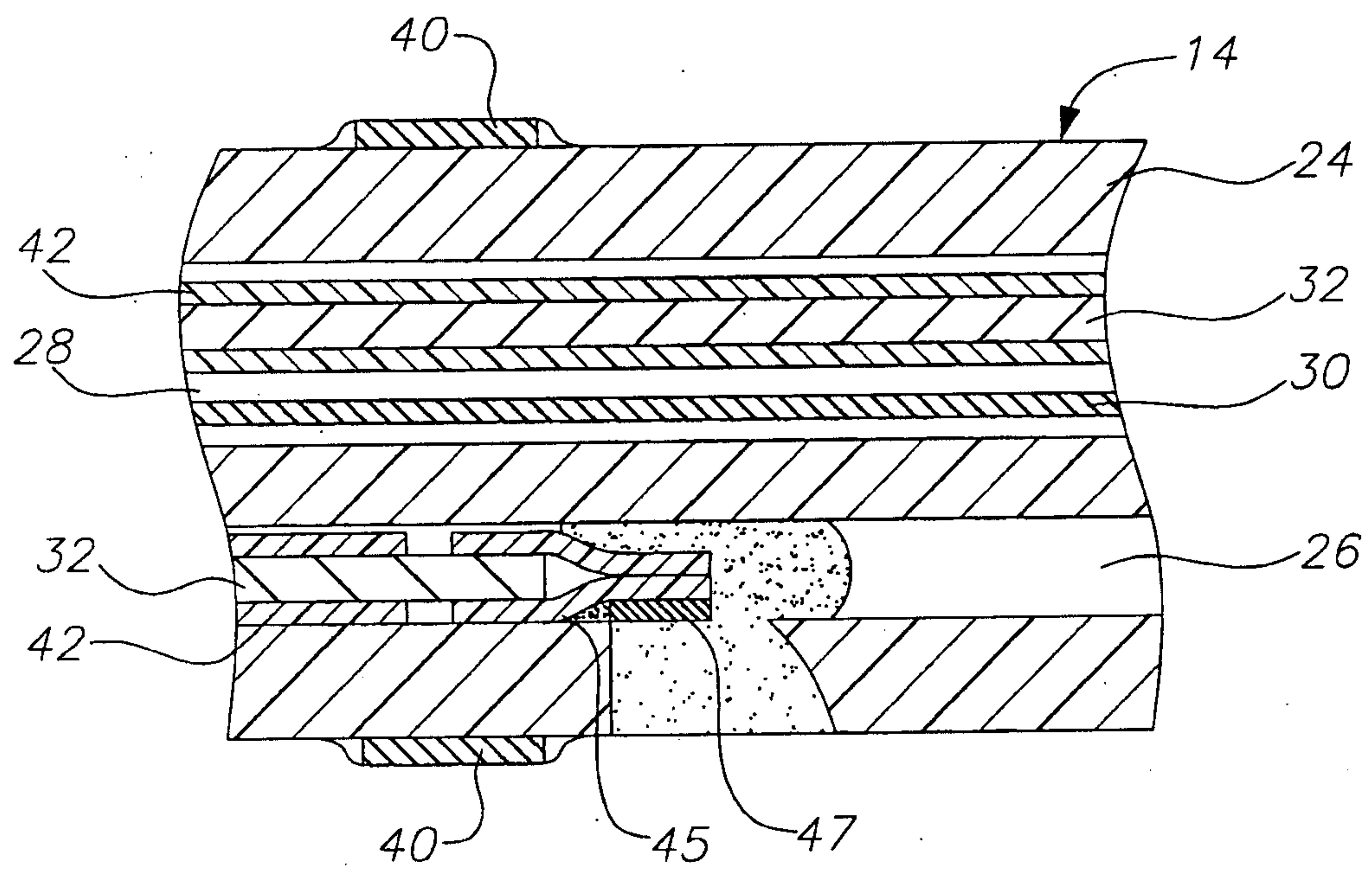
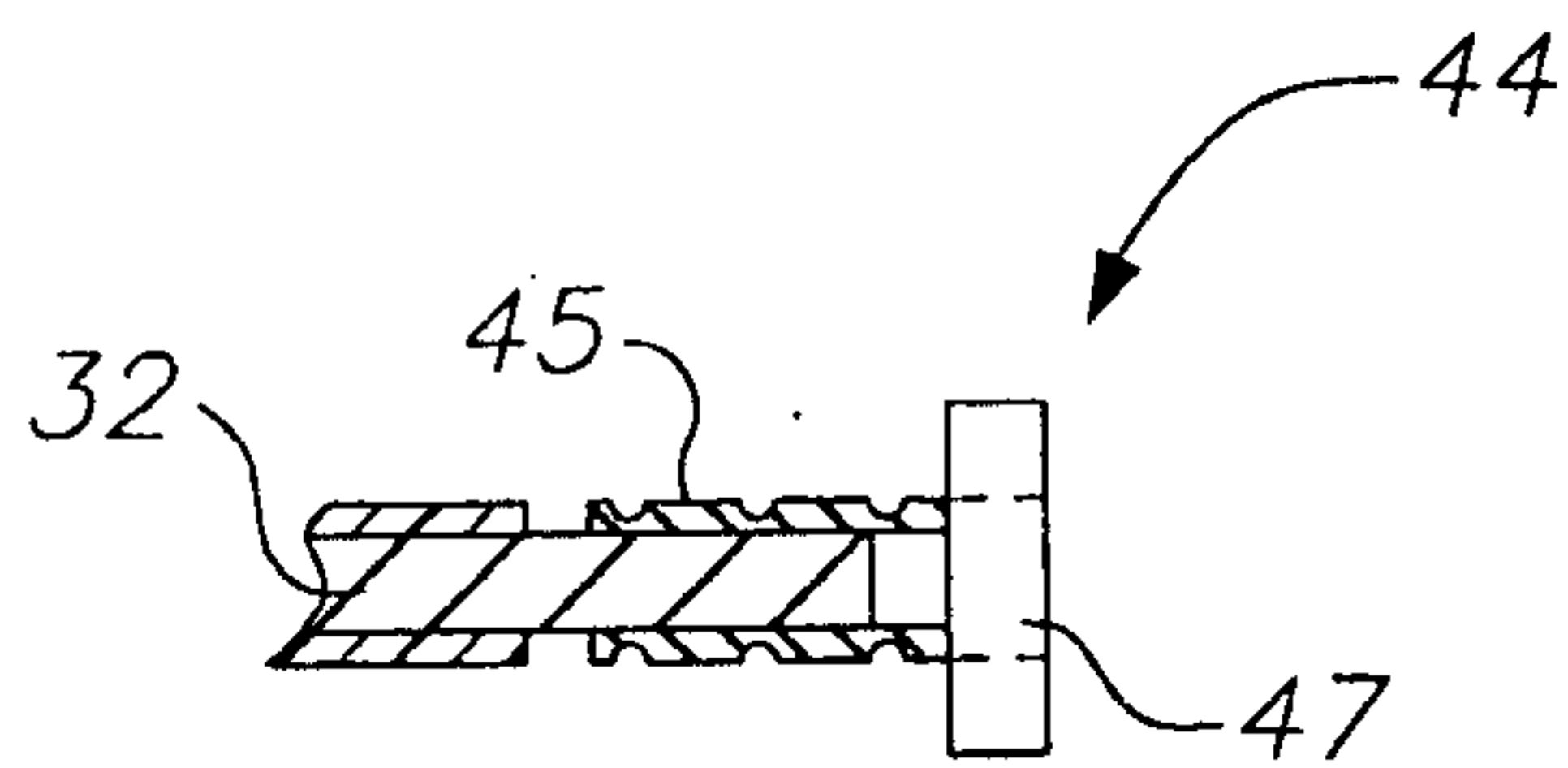
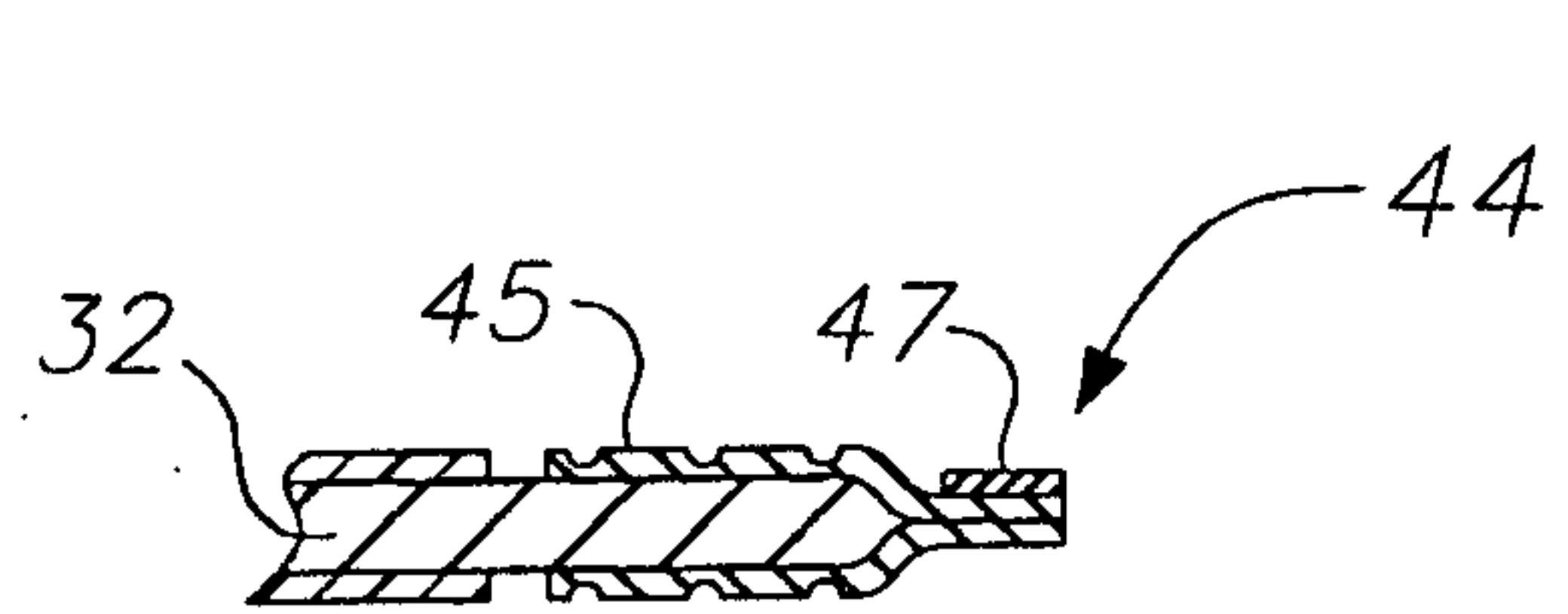
wherein one housing member is configured to releasably hold the proximal end of the catheter body so that the steering assembly is operational on the puller wires to deflect the puller wire without the two housing members being joined.



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FIG. 4*FIG. 5*

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FIG. 6*FIG. 7**FIG. 8*

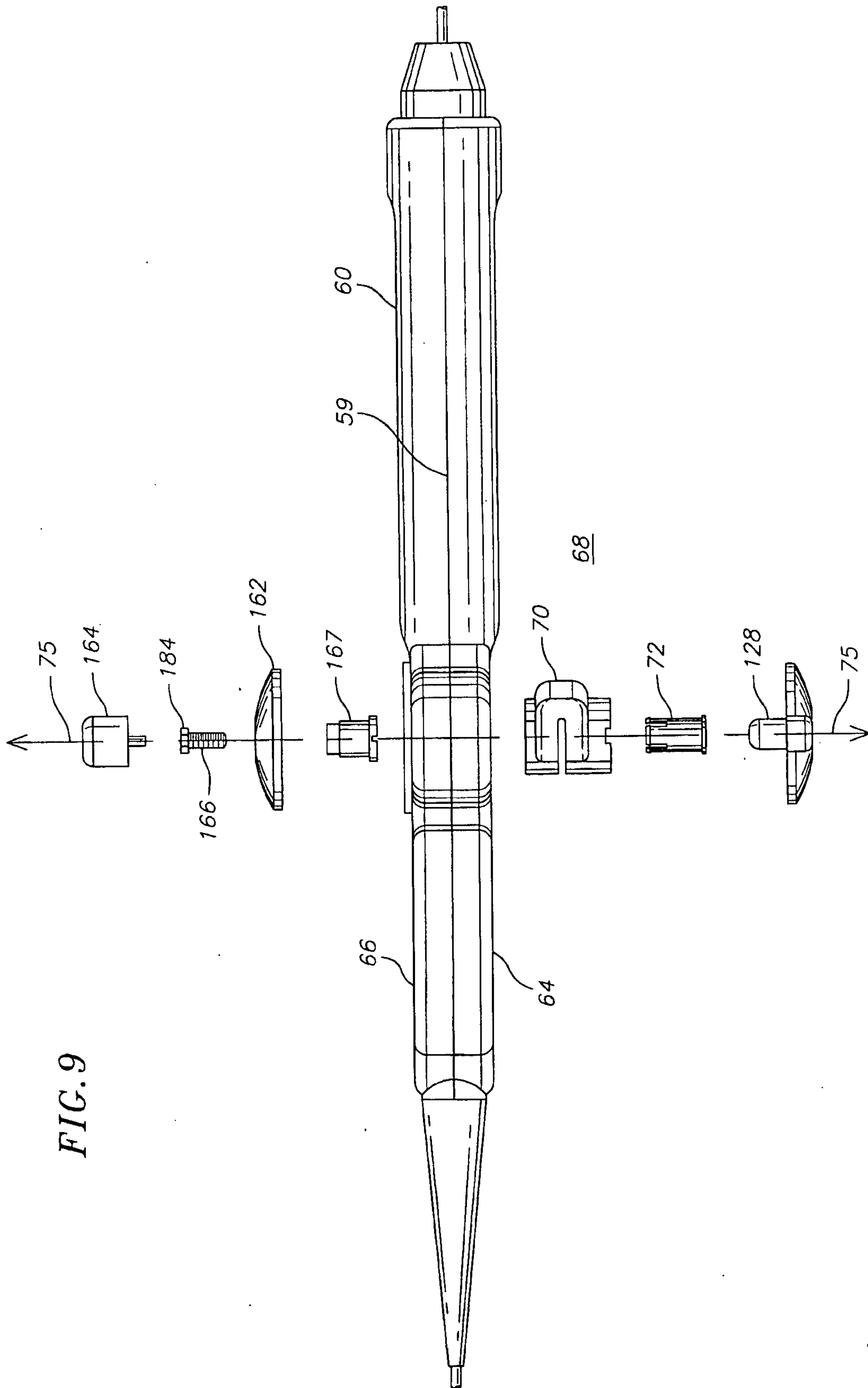


FIG. 10

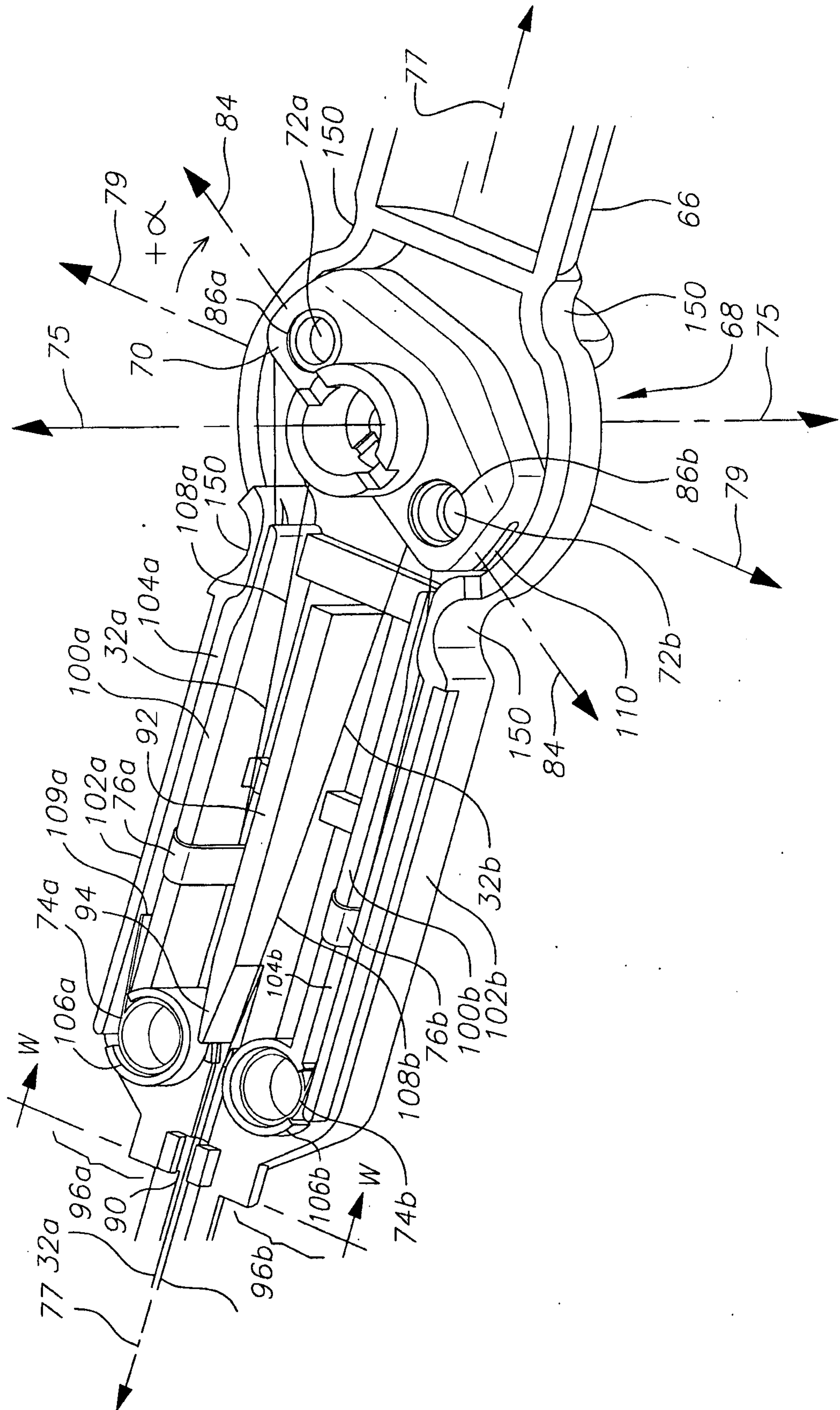


FIG. 11a.

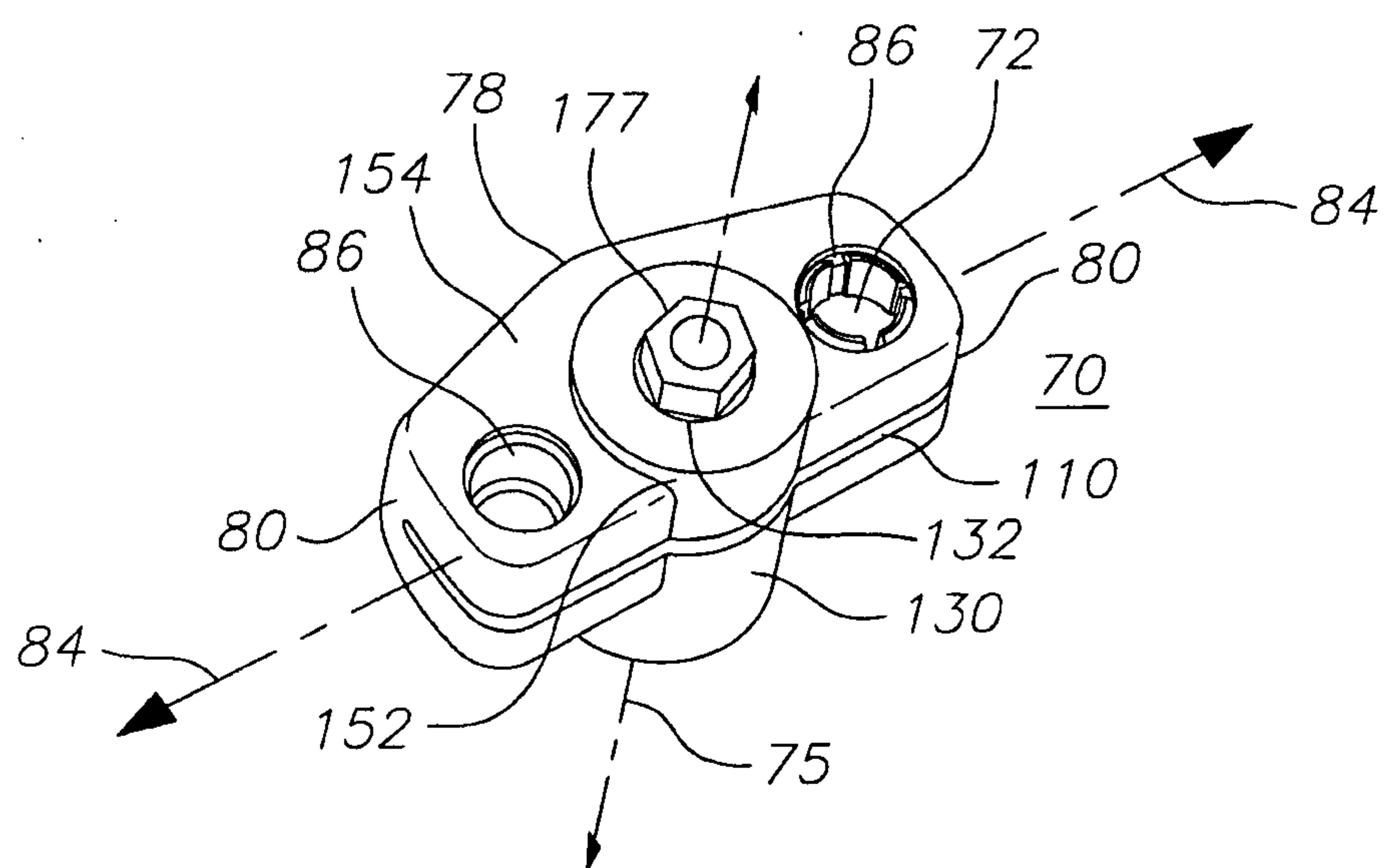
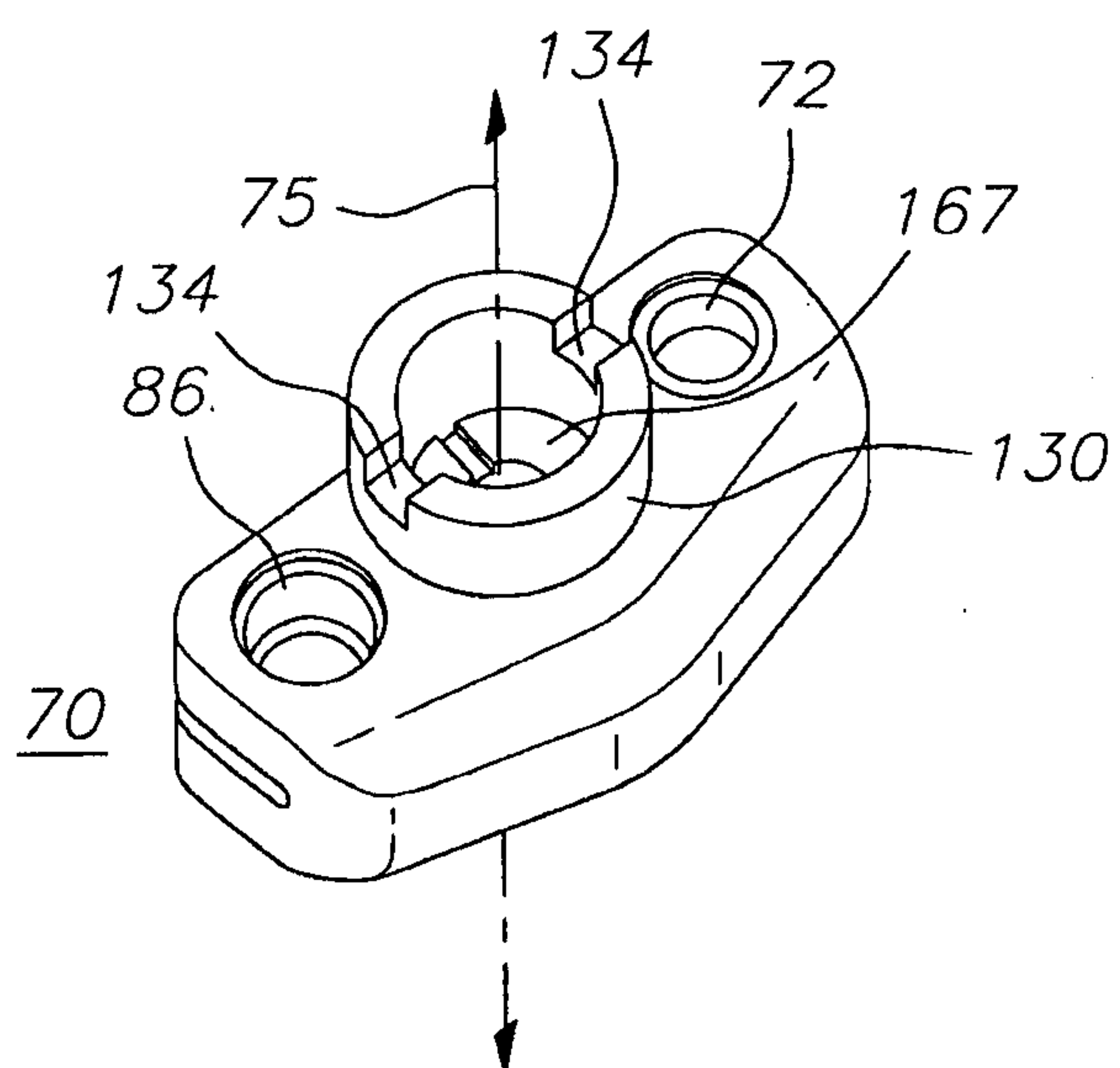


FIG. 11b



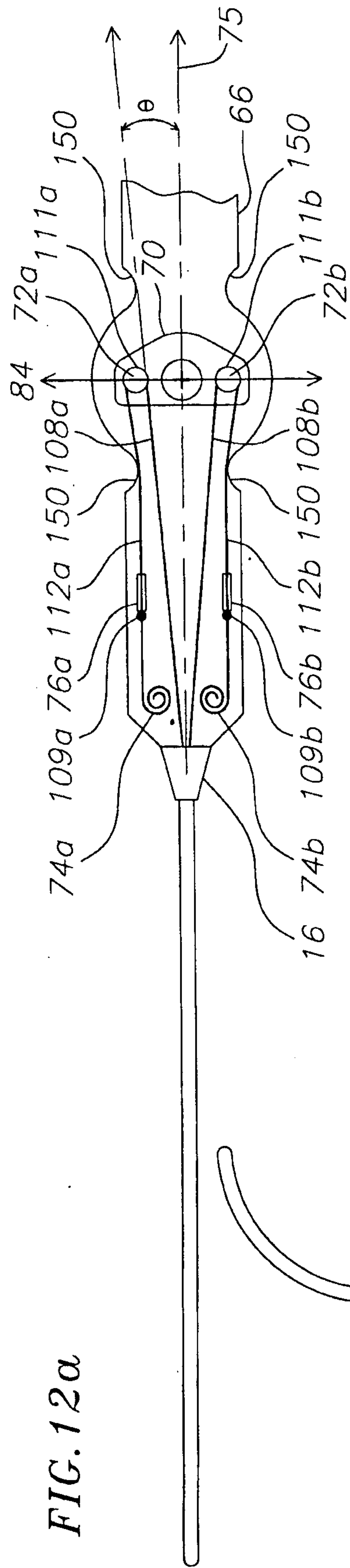


FIG. 12a

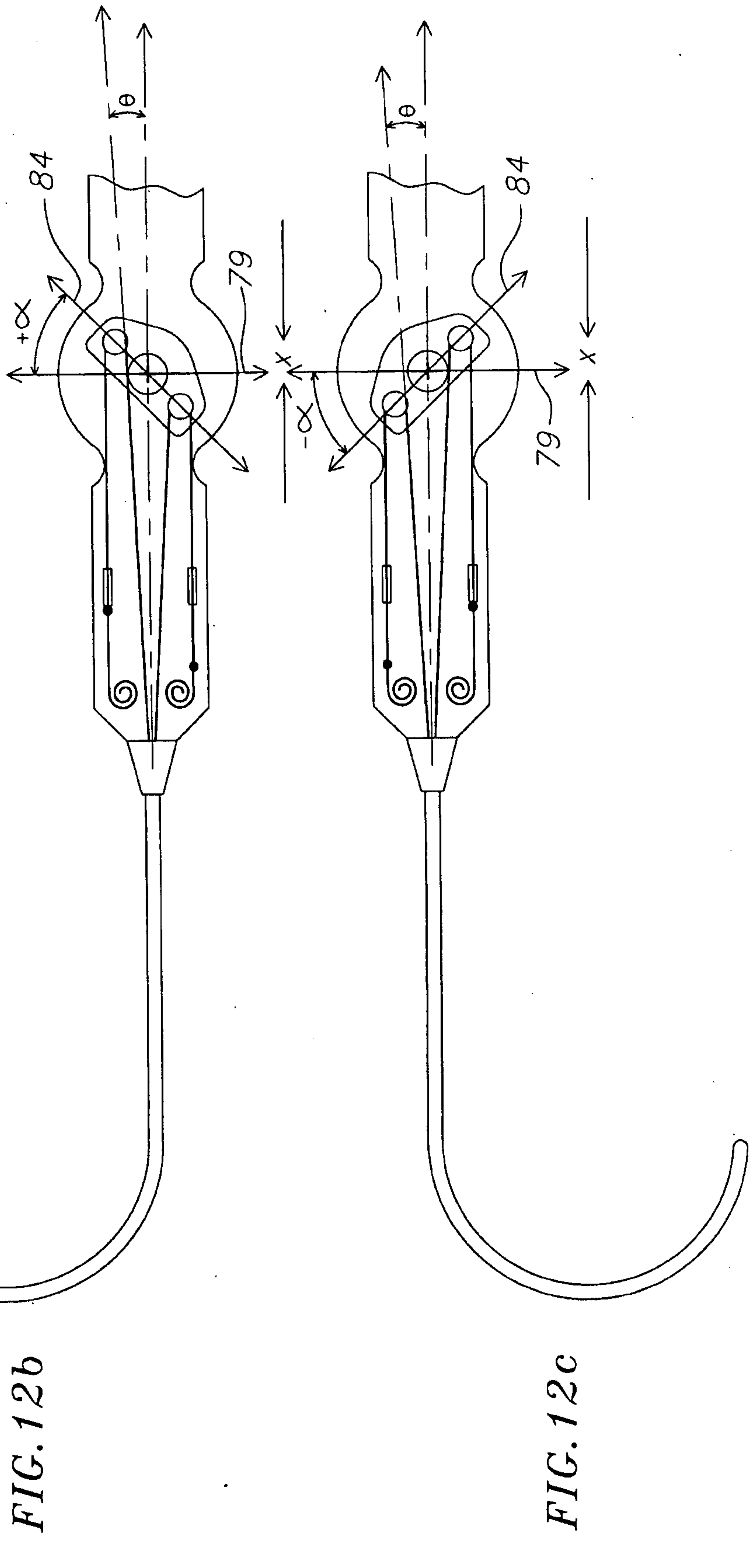


FIG. 12b

FIG. 12c

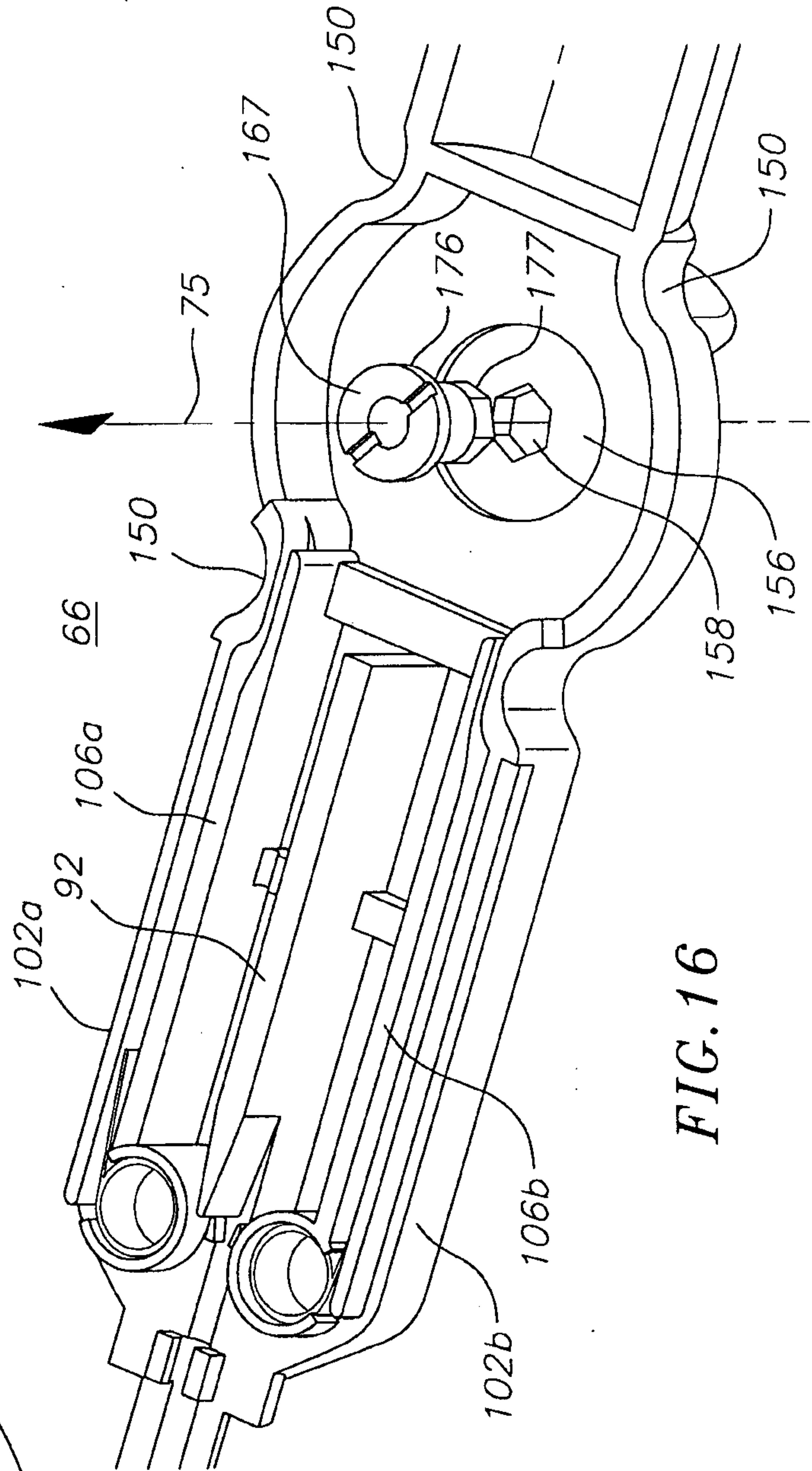
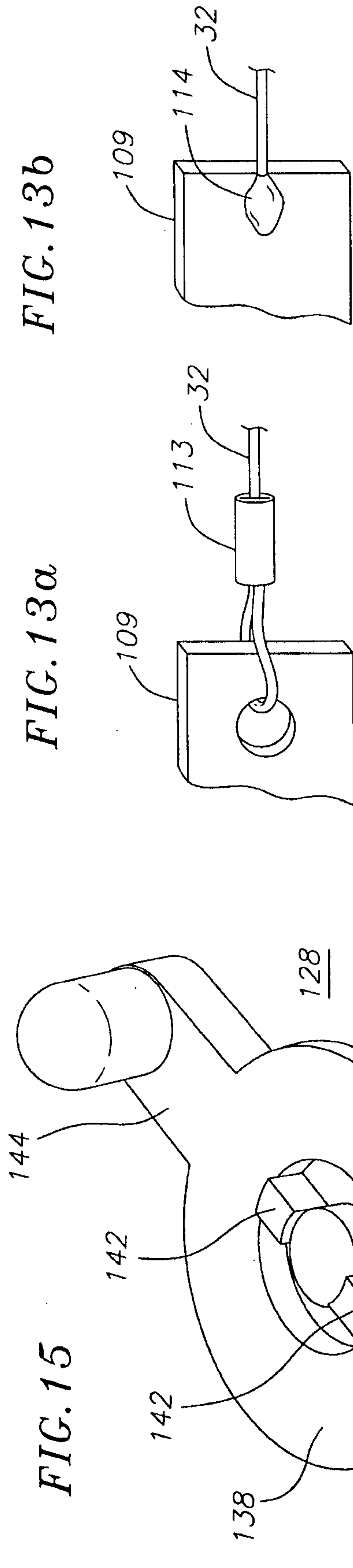
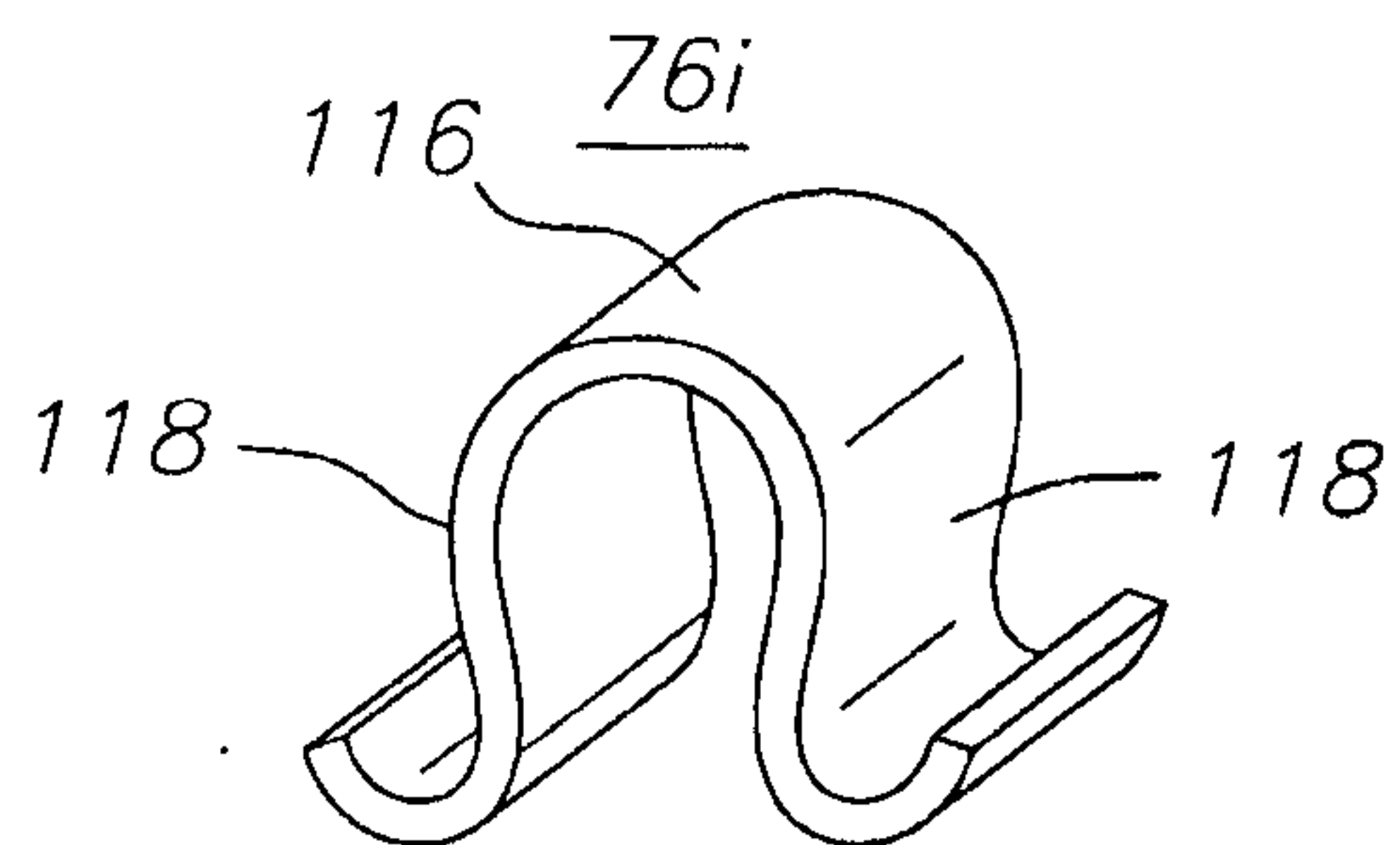
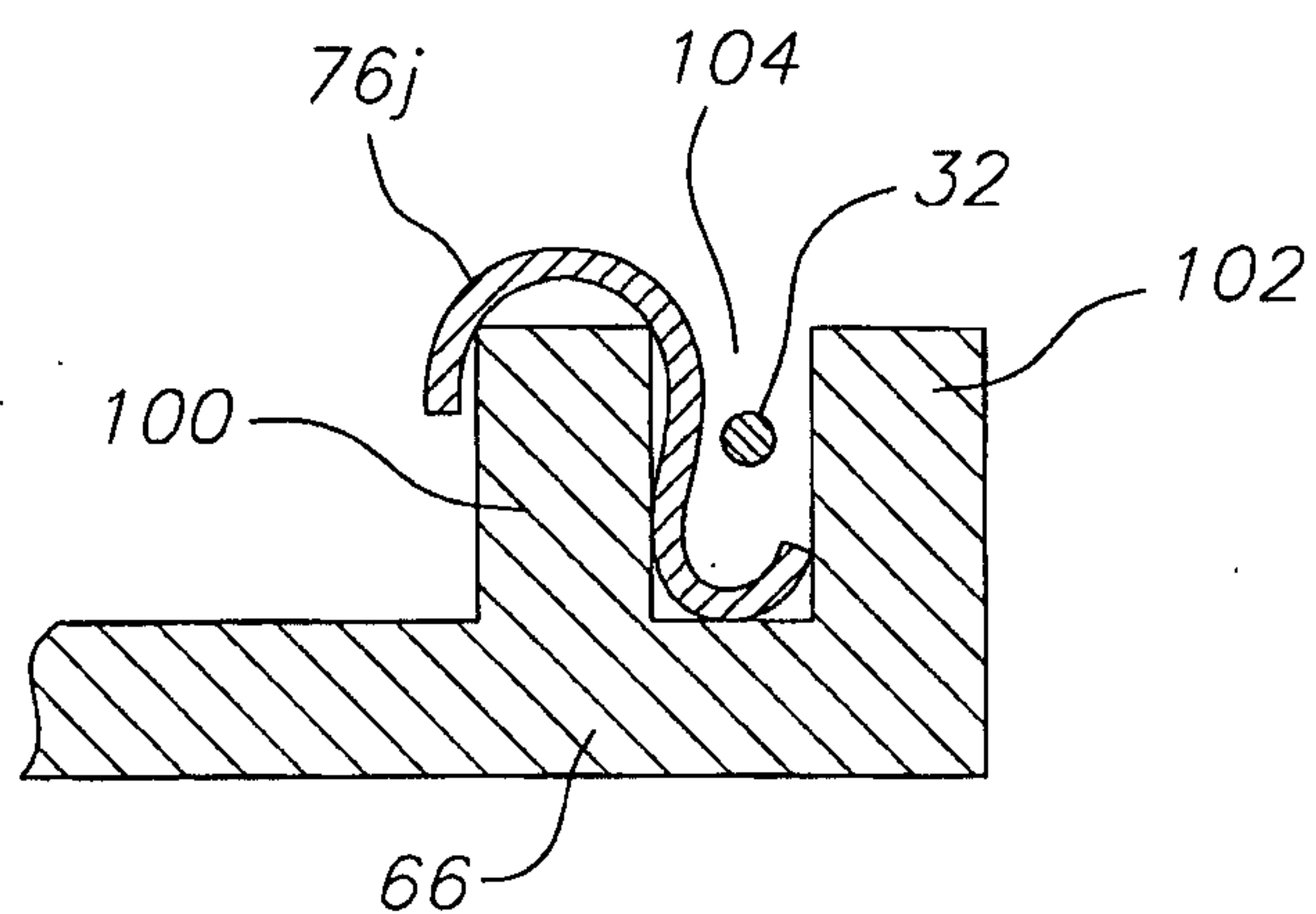
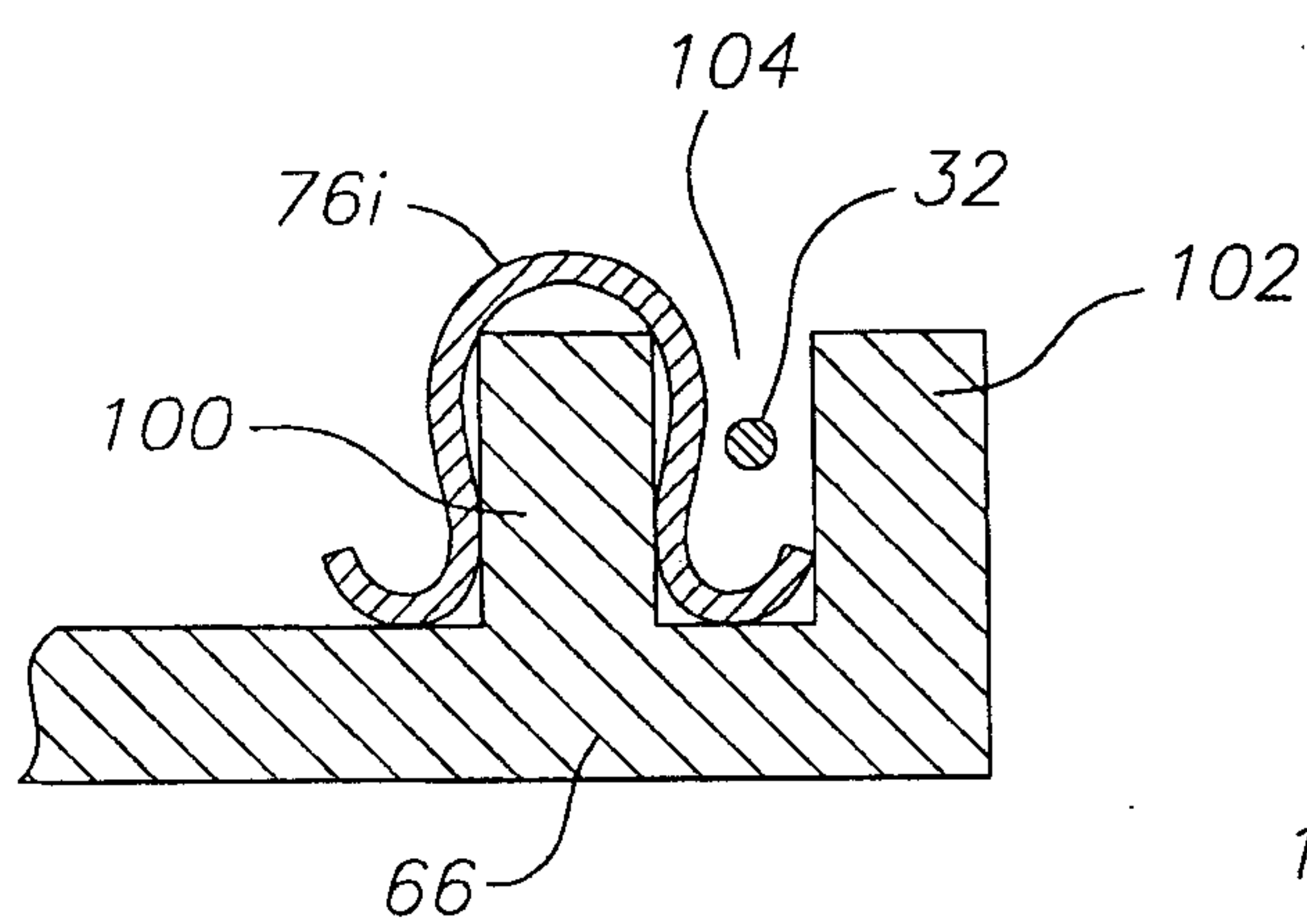
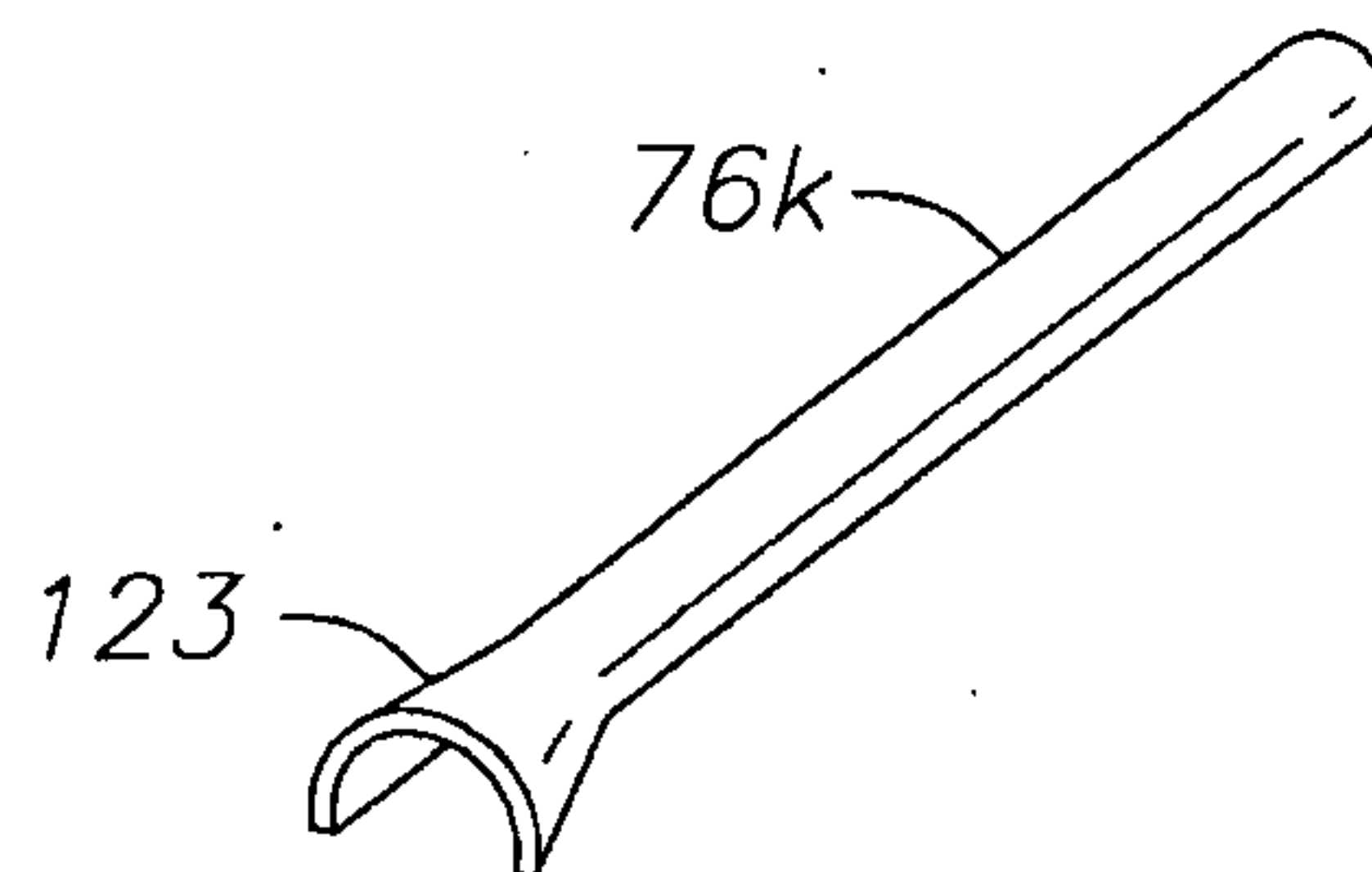
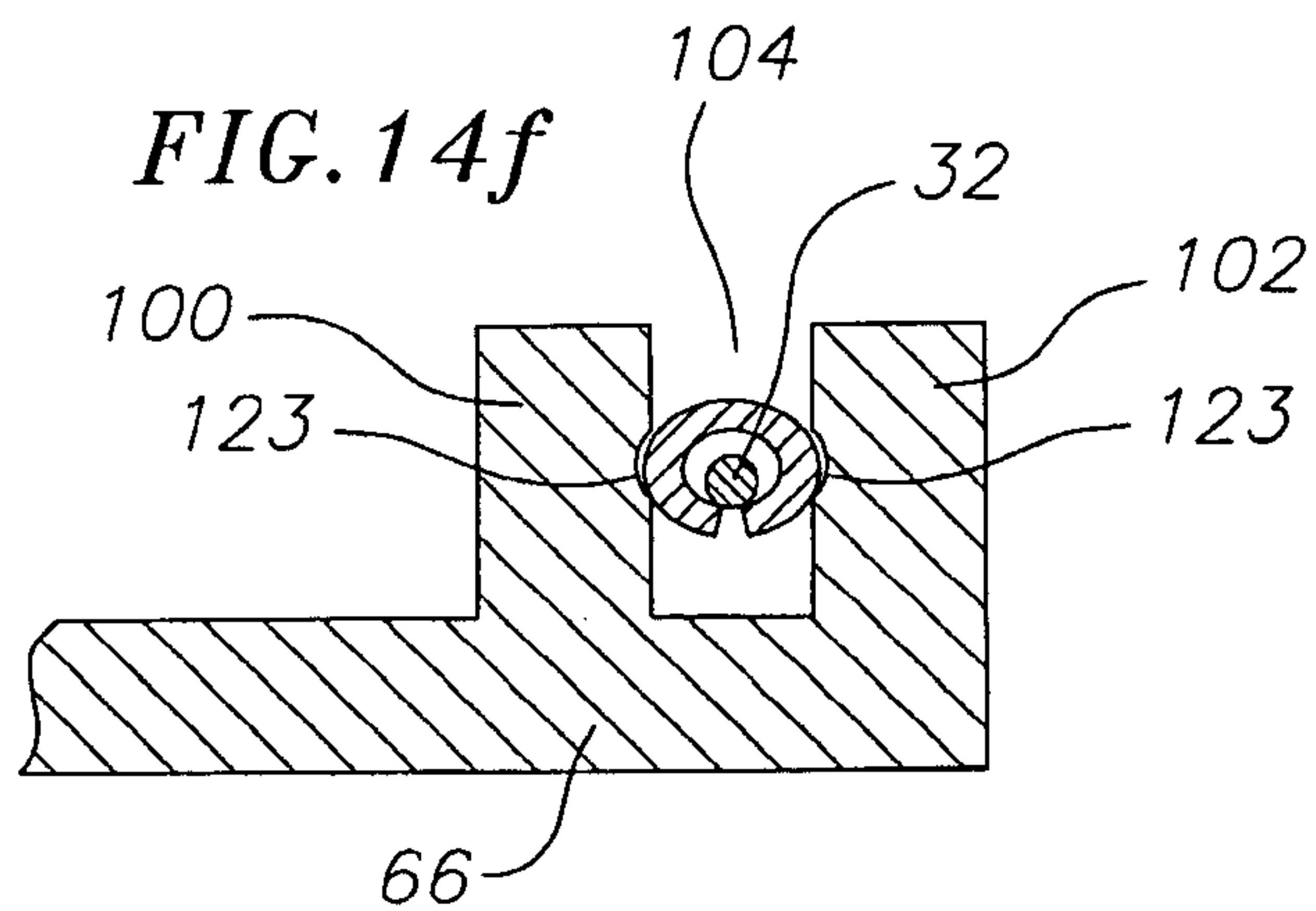
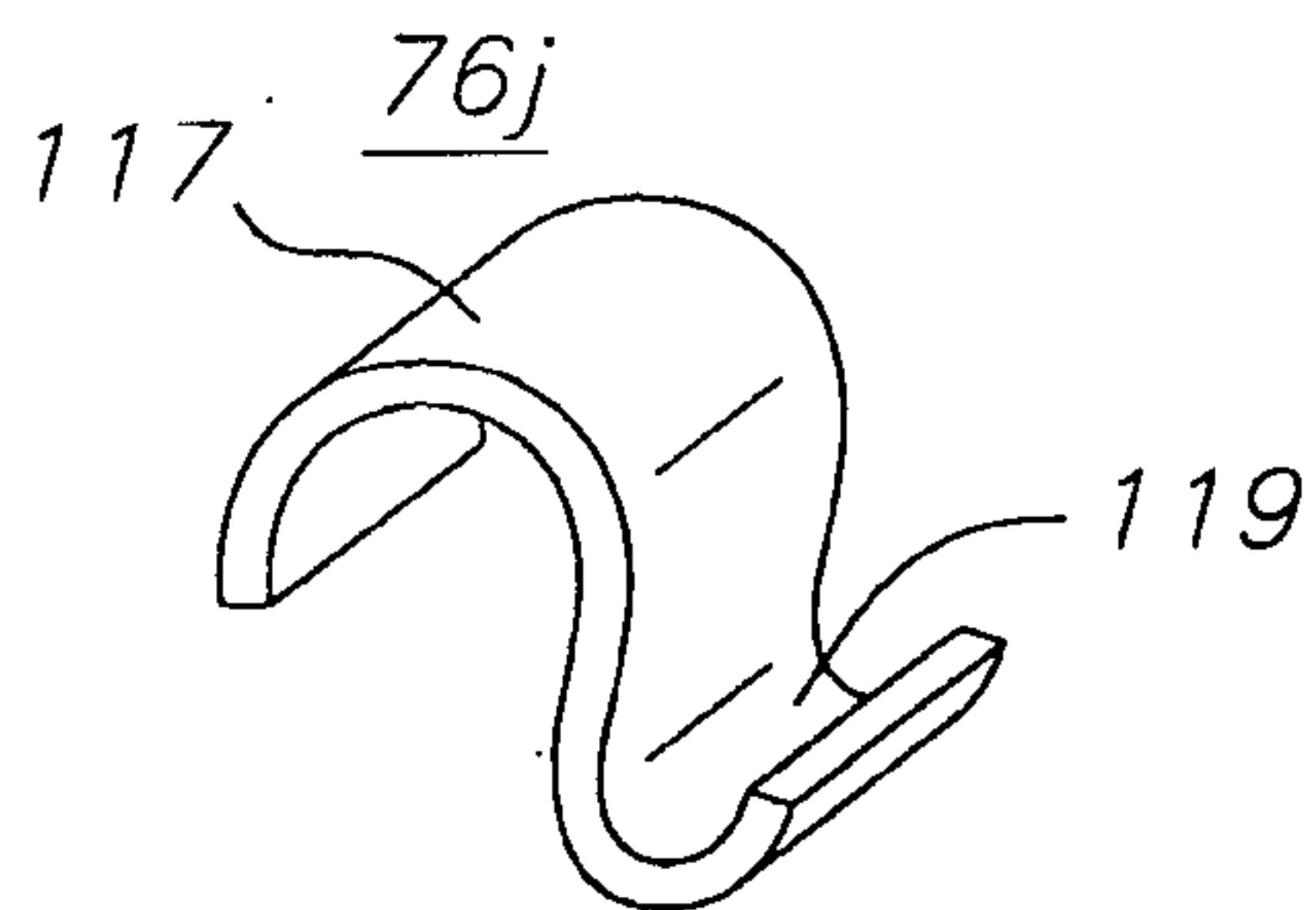
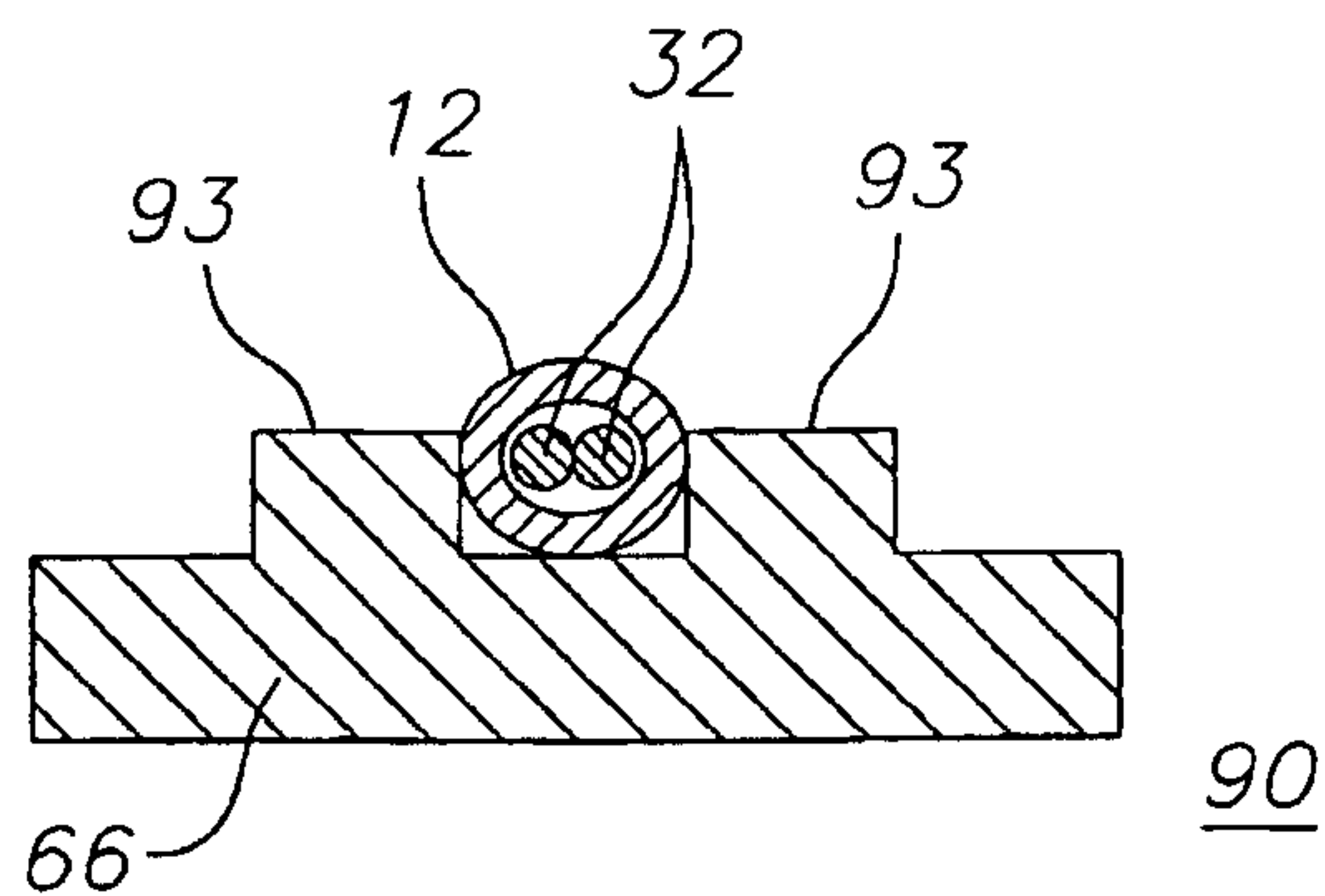
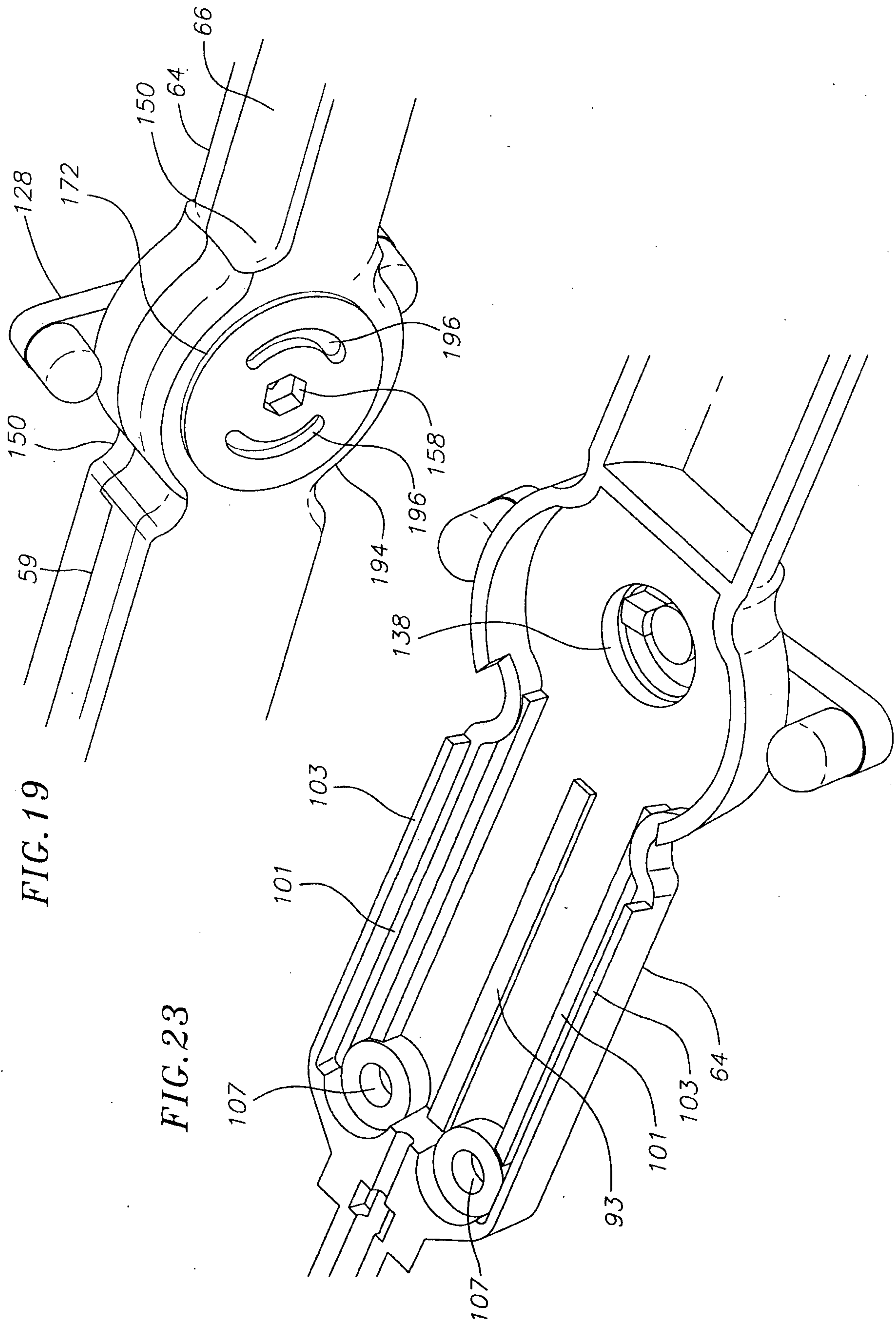
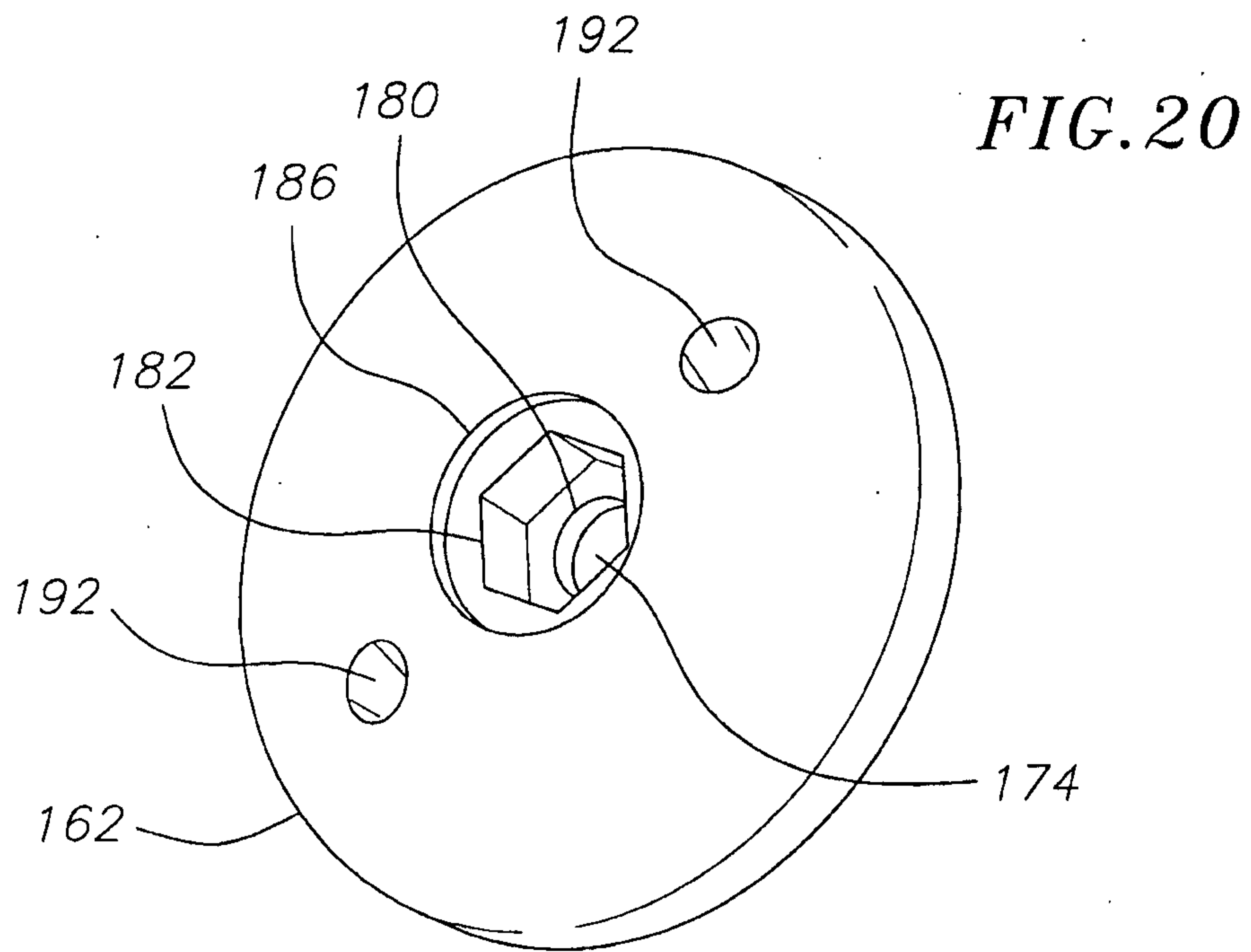
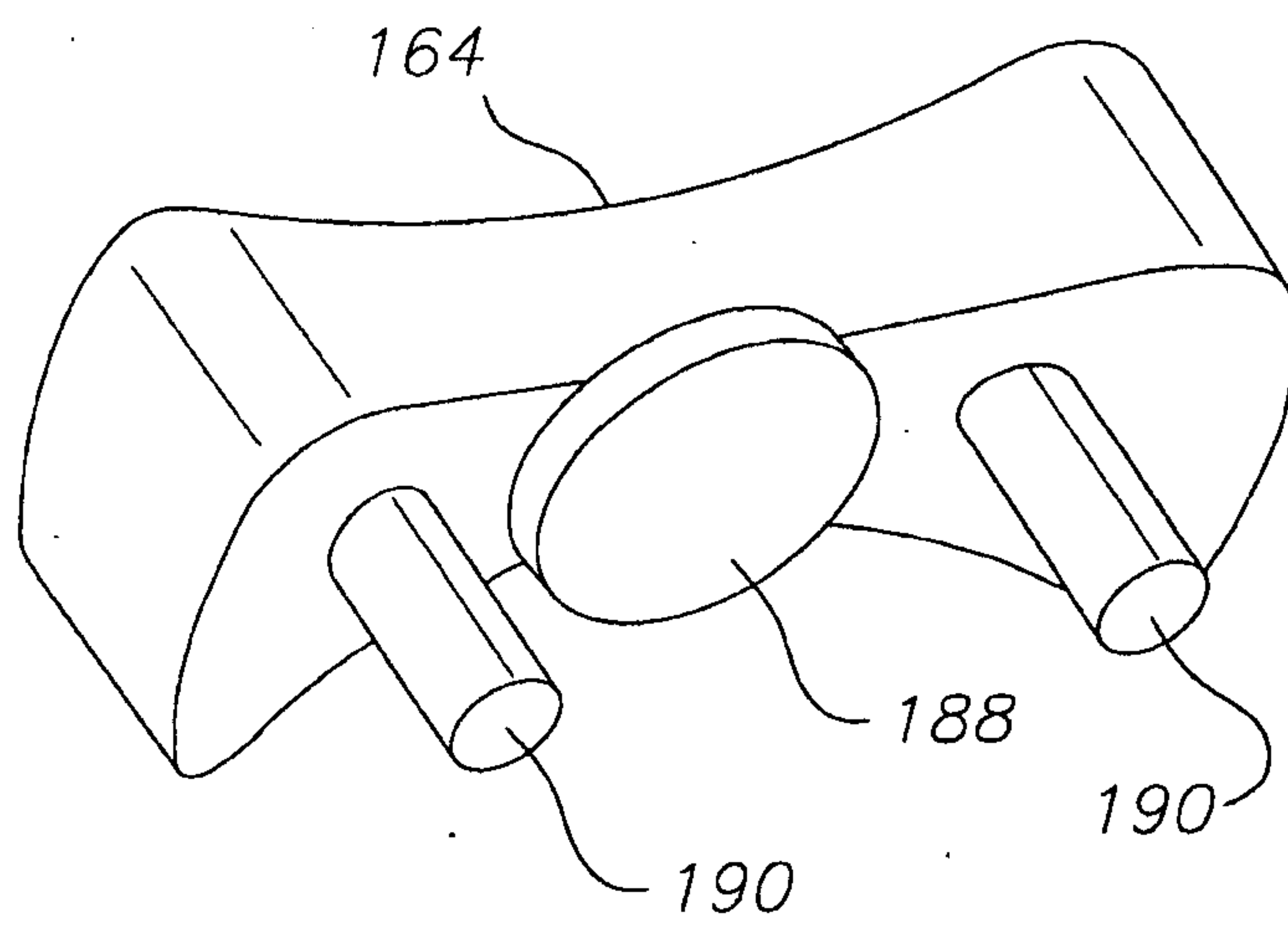


FIG. 14a*FIG. 14d**FIG. 14b**FIG. 14e**FIG. 14f**FIG. 14c**FIG. 24*



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*FIG. 21**FIG. 22*