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(54) **ELECTROPHYSIOLOGY/ABLATION CATHETER AND REMOTE ACTUATOR THEREFOR**

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**Related U.S. Application Data**

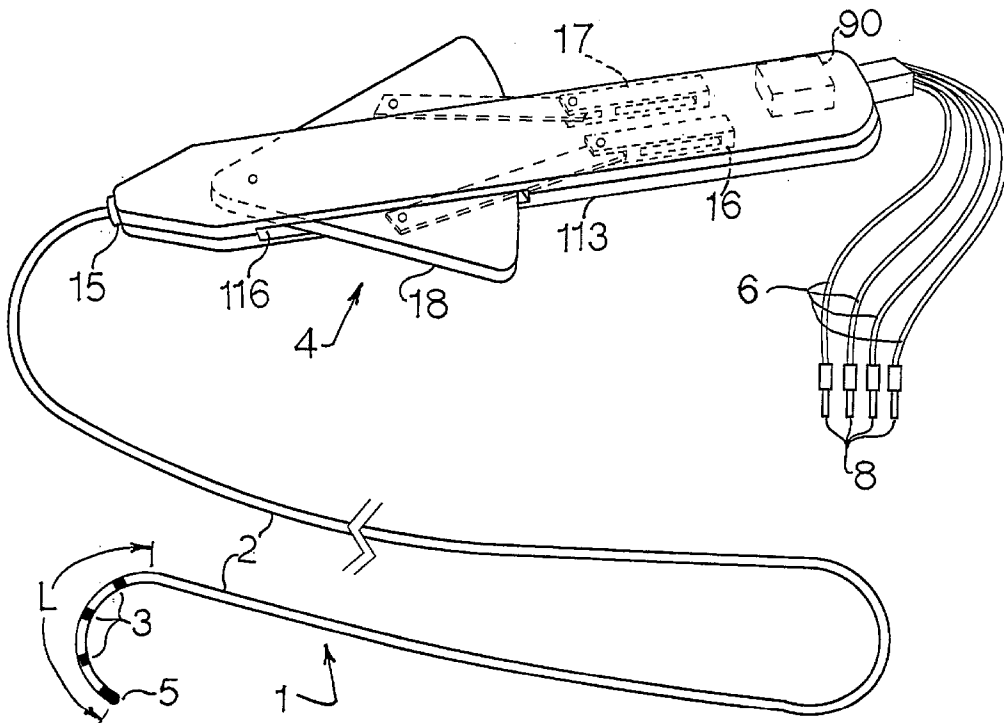
(60) Division of application No. 09/232,866, filed on Jan. 15, 1999, which is a continuation-in-part of application No. 08/880,080, filed on Jun. 20, 1997, now Pat. No. 5,861,024.

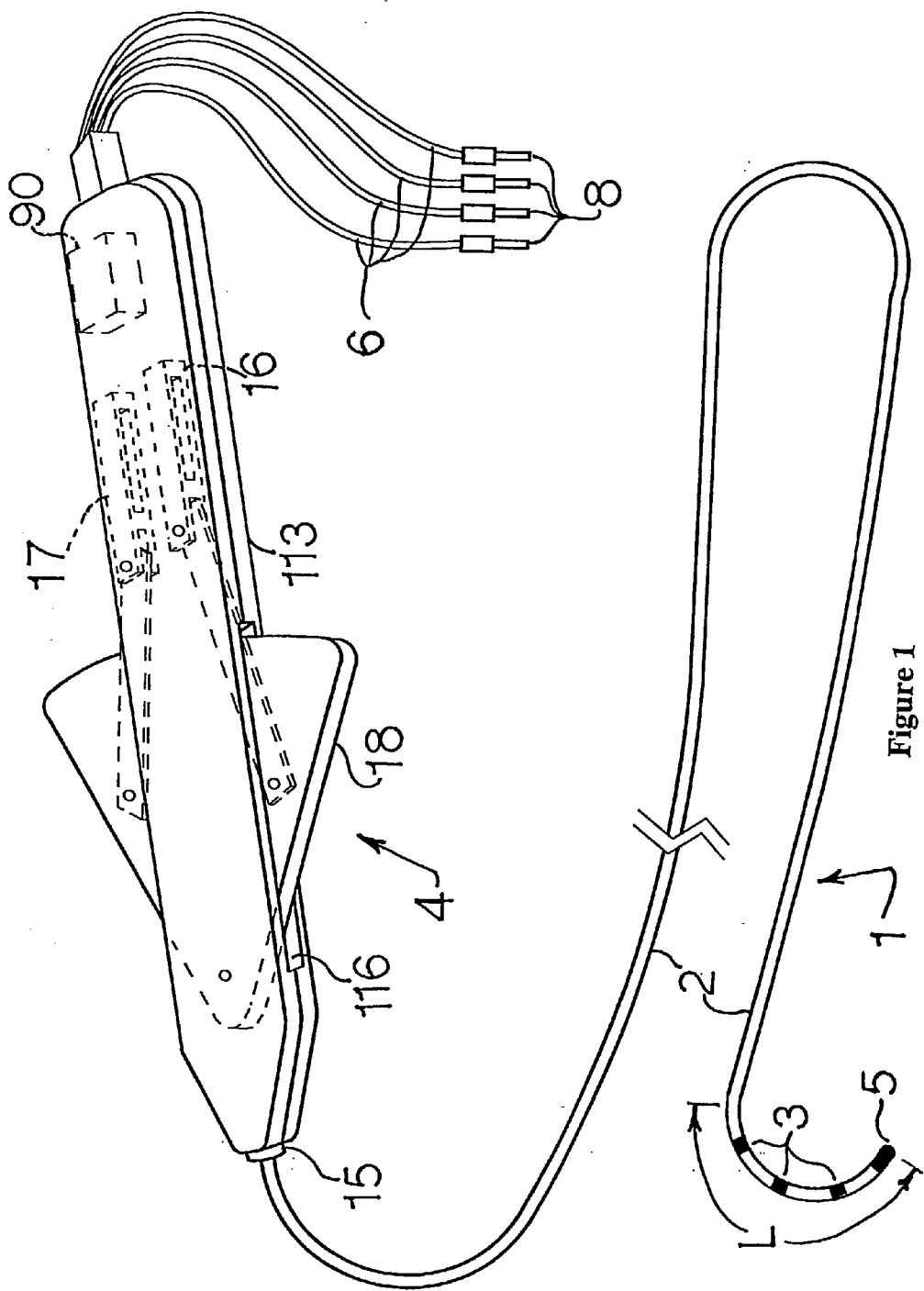
**Publication Classification**

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(52) **U.S. Cl. .... 600/374; 606/41**

(57) **ABSTRACT**

A cardiac catheter employed for minimally invasive cardiac diagnostic electrophysiology and/or cardiac ablation procedures. The catheter of this invention comprises of an elongated cylindrical and electrically non conductive main exterior tube with plurality of surface electrodes disposed on its distal portion, and a handle on its proximal end. The distal portion of this catheter can be curved and the assumed curvature can be retained by a single action on manual actuator of the catheter handle. In one embodiment of this invention an electromechanical drive system is incorporated into the catheter handle for formation of curvatures at the distal portion of the catheter. In a further embodiment an electrical heating element is incorporated within the distal electrode of the catheter for ablation procedures. In another embodiment of this invention a readily removable and disposable blood contacting segment is provided. The non-blood contacting actuator is thus reusable and reduces the cost of the cardiac electrophysiology and/or ablation procedure. The catheter of this invention comprises two tension/compression members for curvature formation at the distal end of the catheter. These tension/compression or pull/push members are wires with circular cross-sections that are integrally formed into ribbon-like configurations at their distal portions for enhanced deflectability. The actuator handle includes a pivoted member movable in one direction by the thumb of the user's hand grasping the handle and in the opposite direction by the other fingers of the same hand.





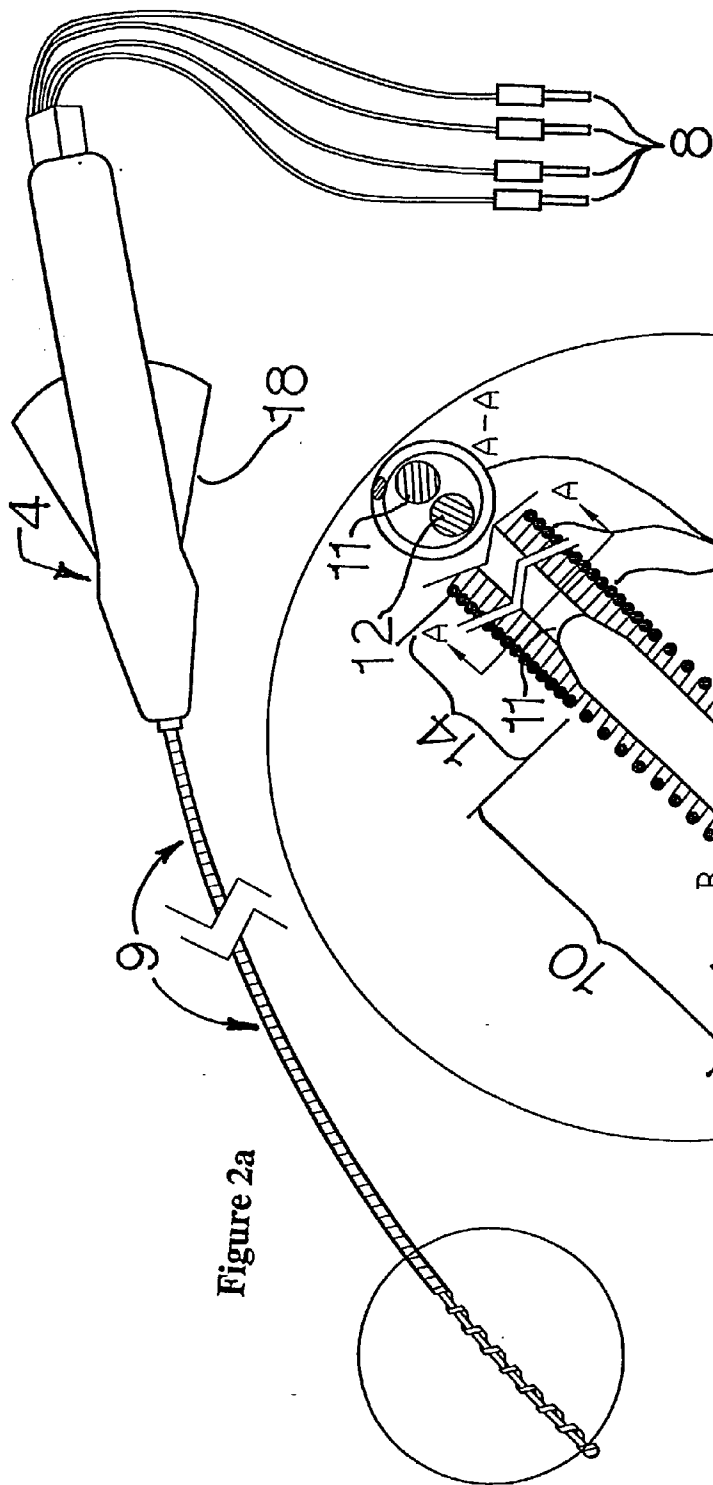


Figure 2a

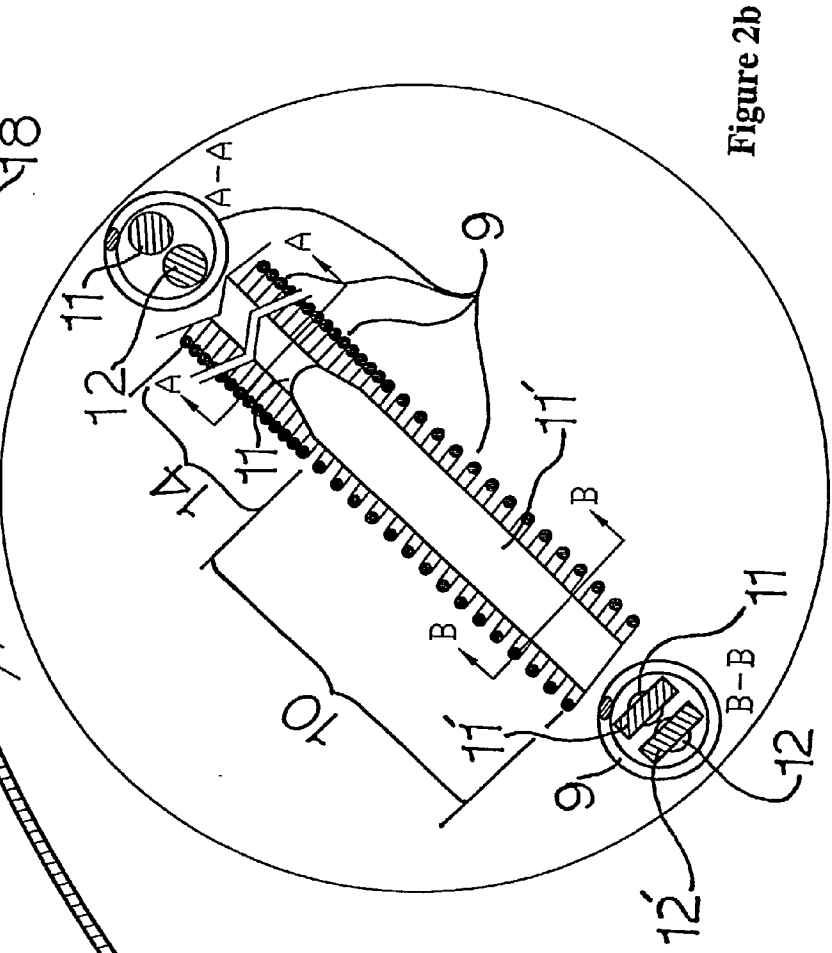


Figure 2b

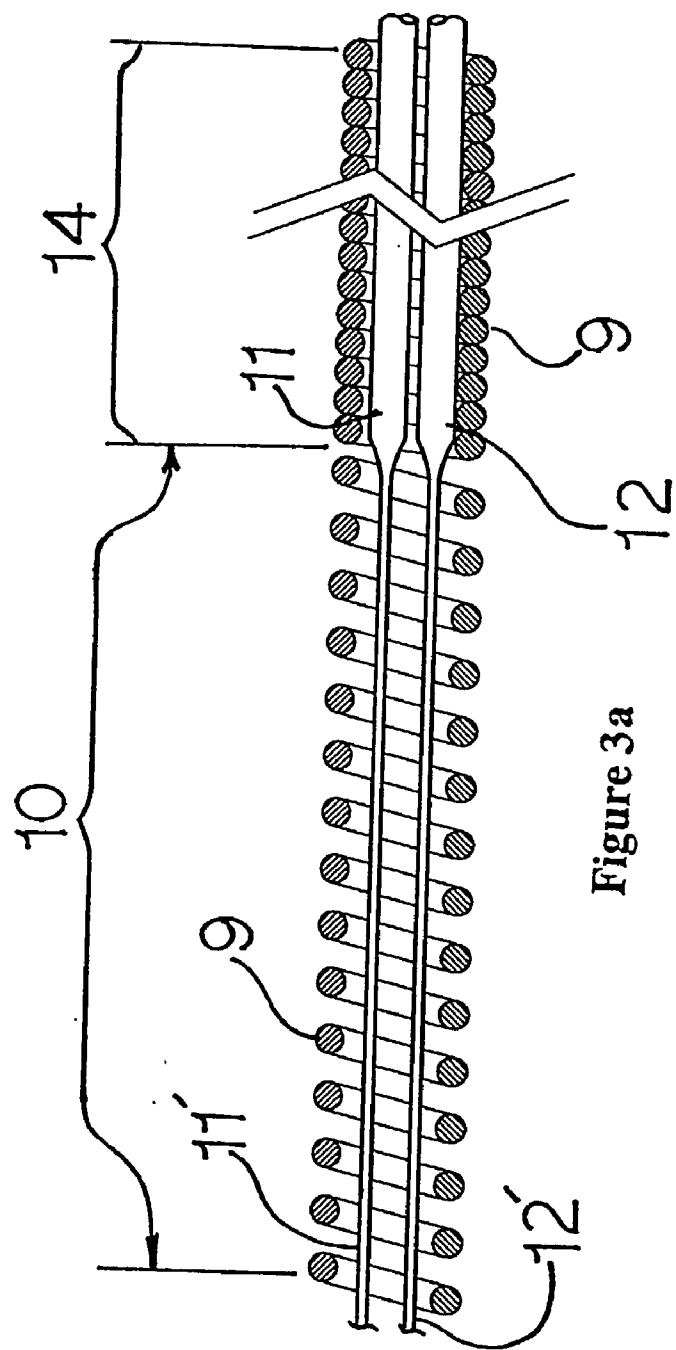


Figure 3a

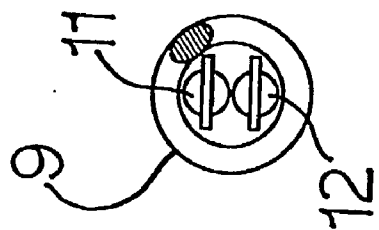


Figure 3b

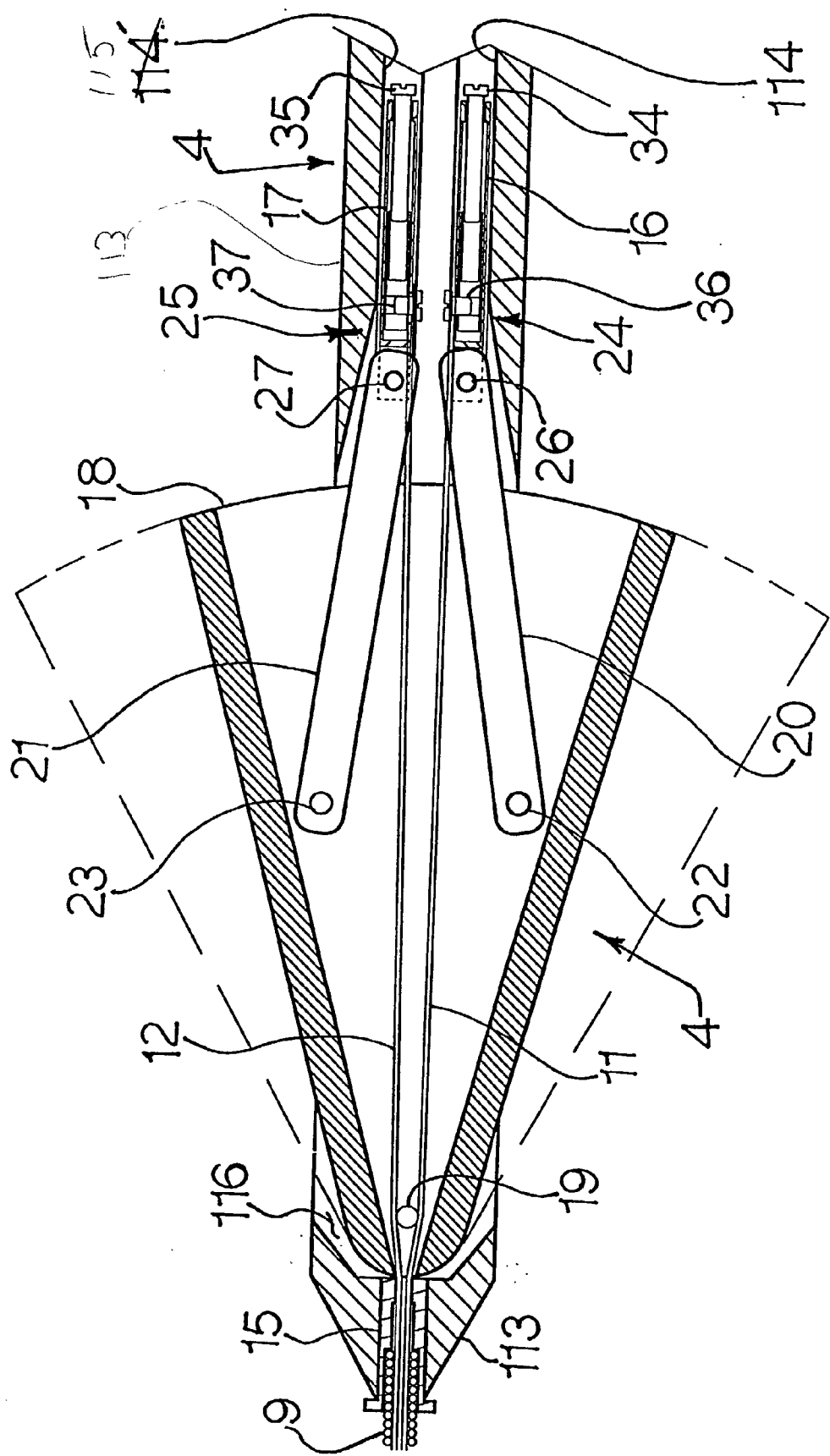
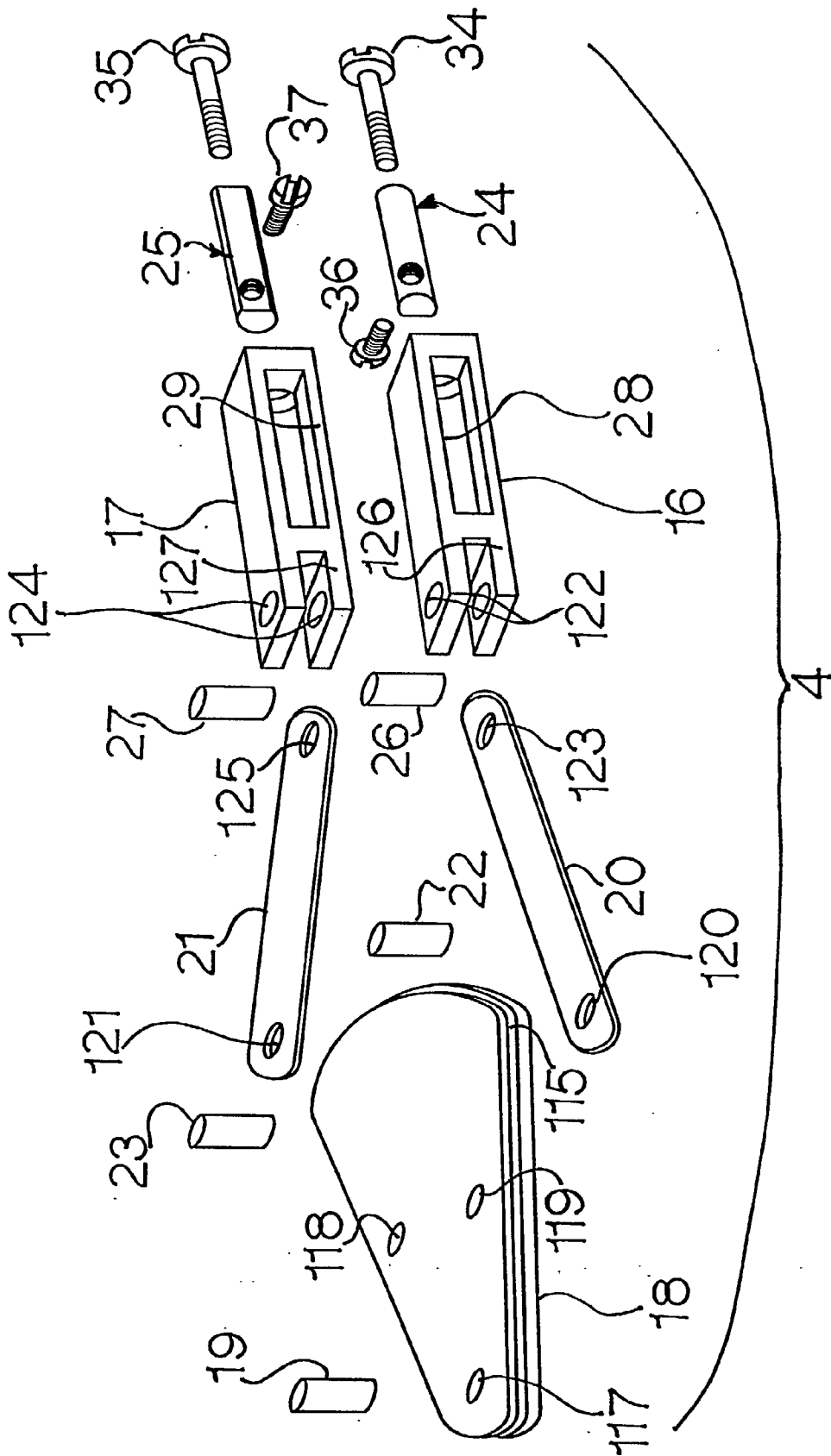


Figure 4



### Figure 5

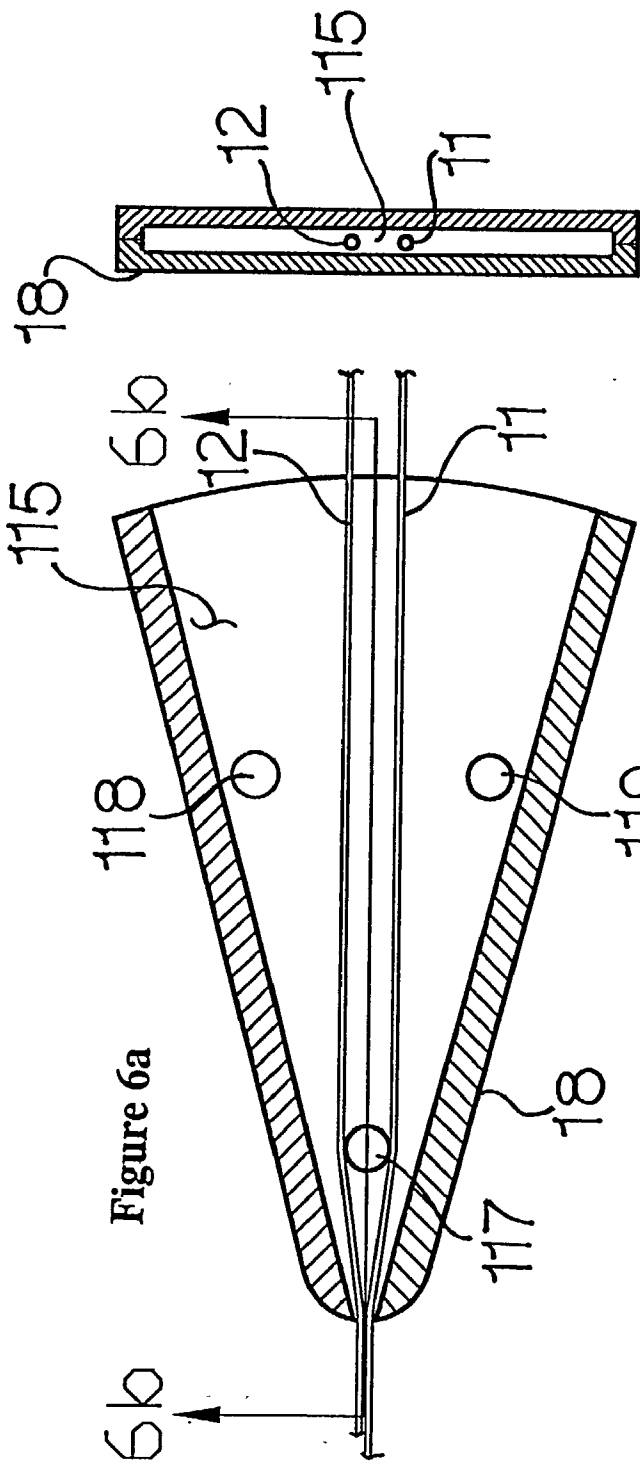


Figure 6a

Figure 6c

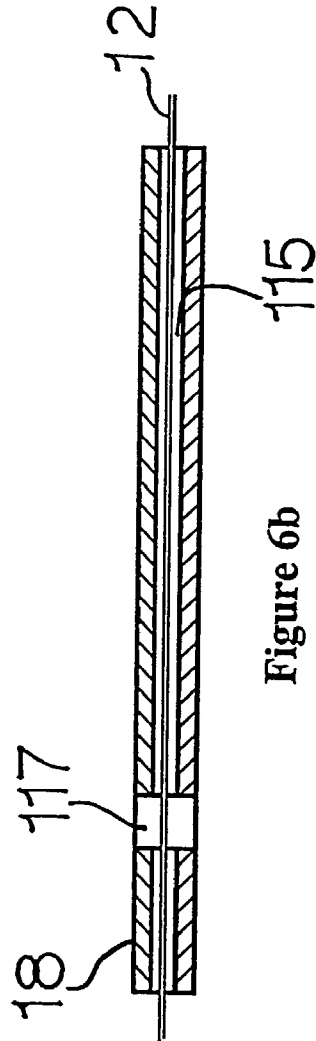
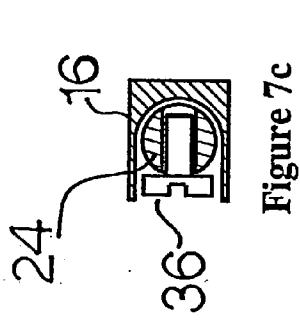
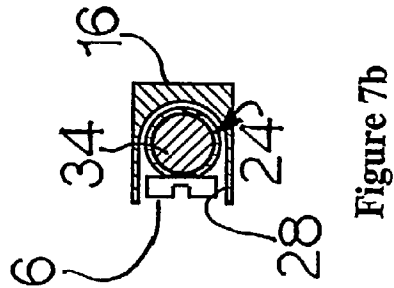


Figure 6b



**Figure 7c**



**Figure 7b**

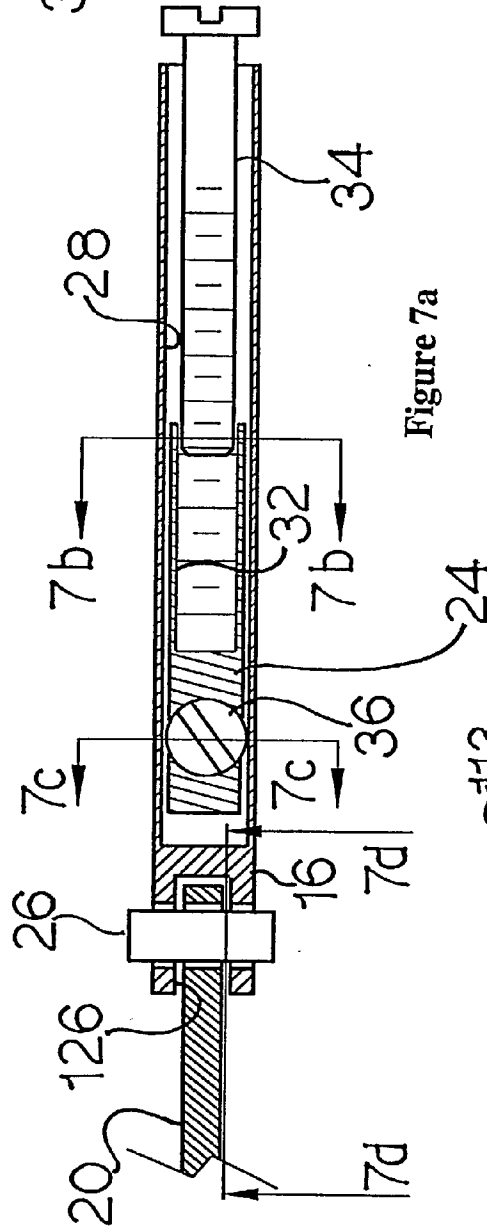
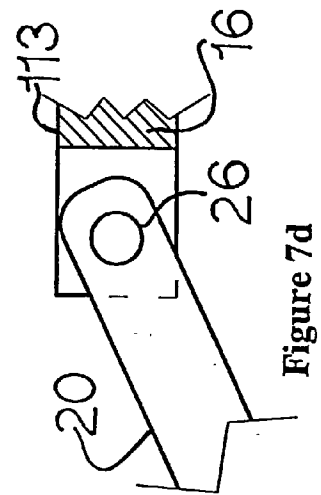


Figure 7a



**Figure 7d**



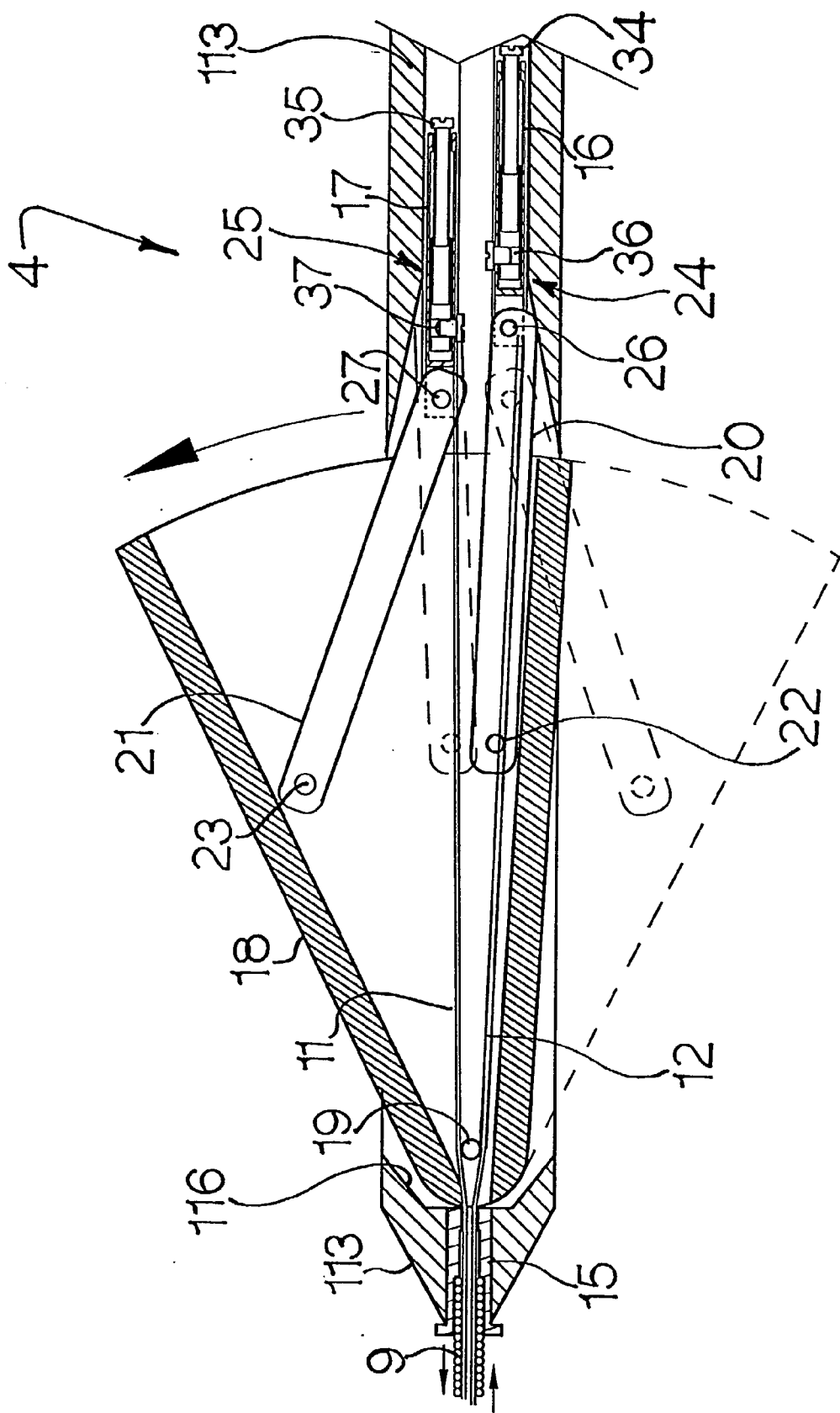


Figure 8

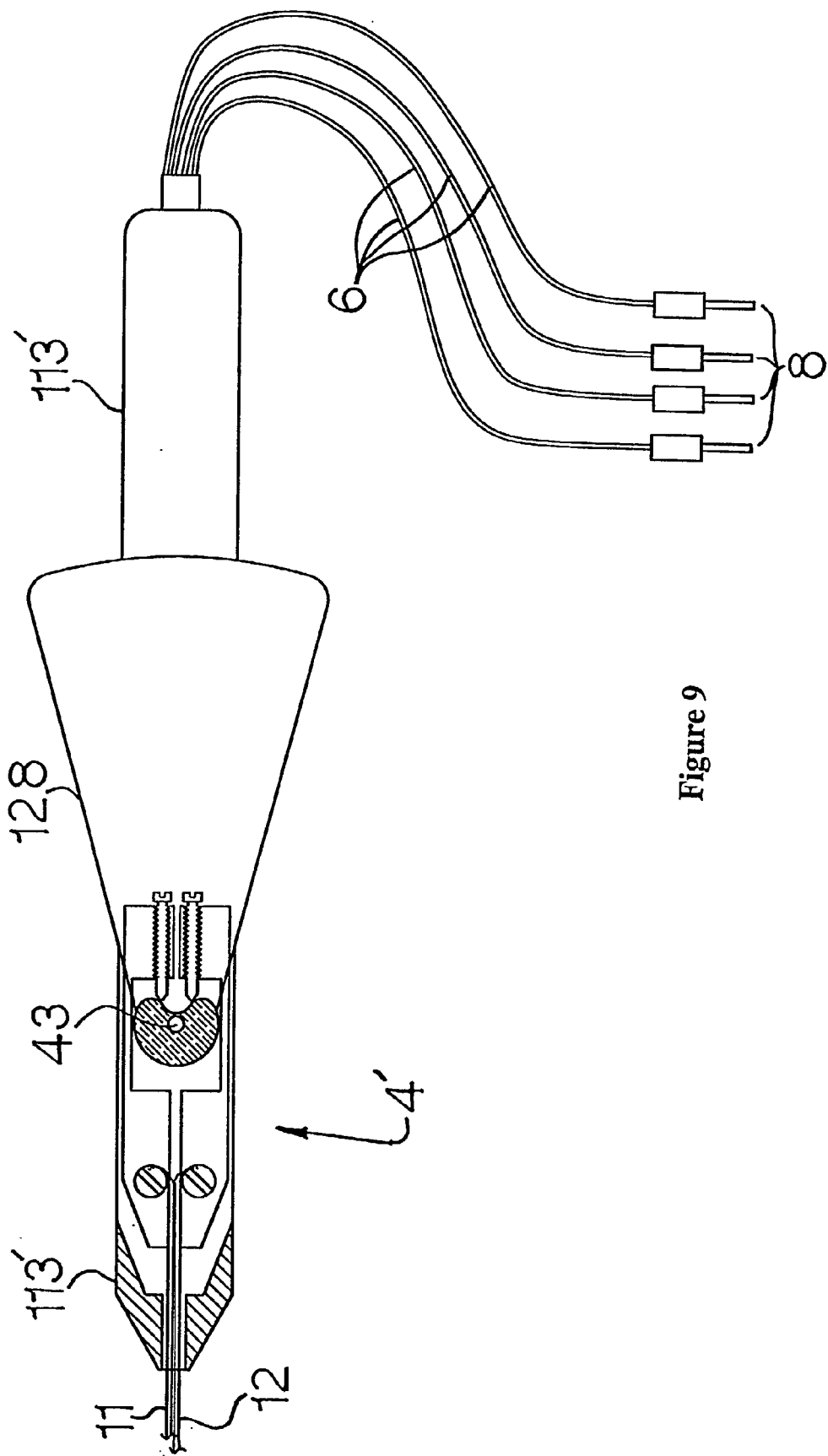


Figure 9

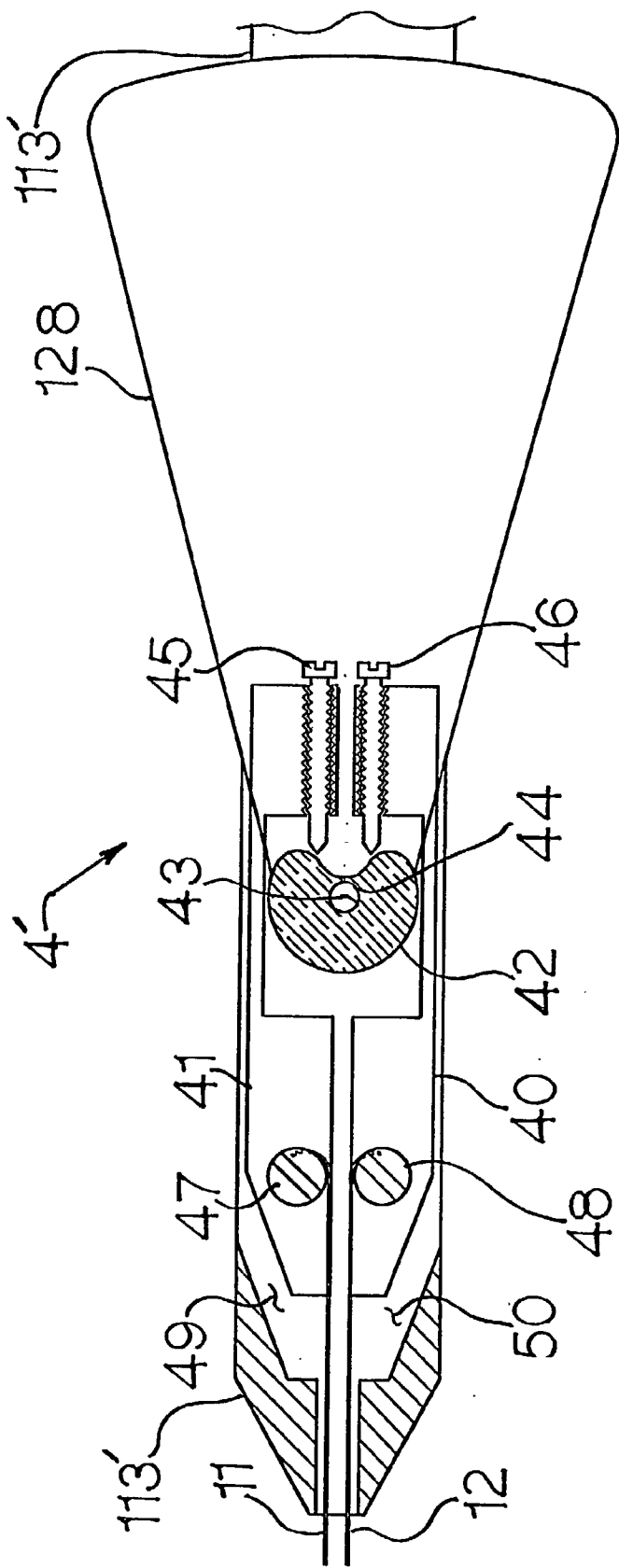


Figure 10



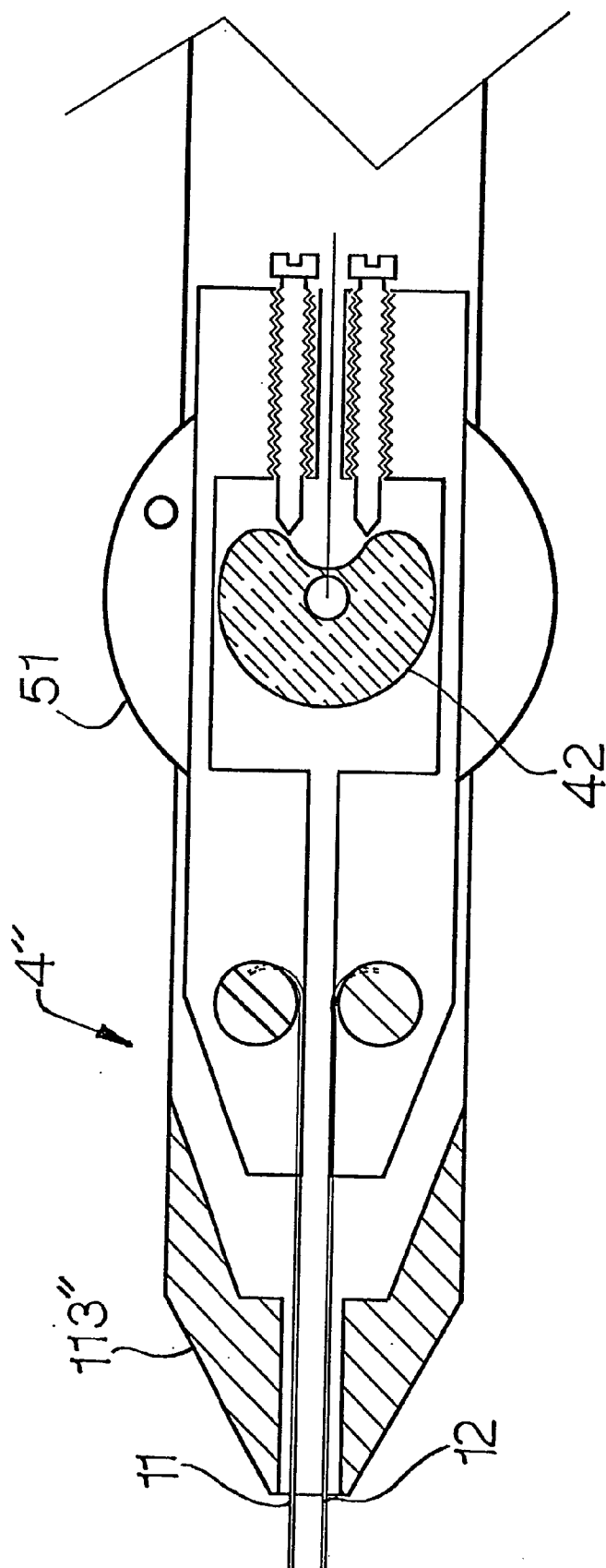


Figure 12

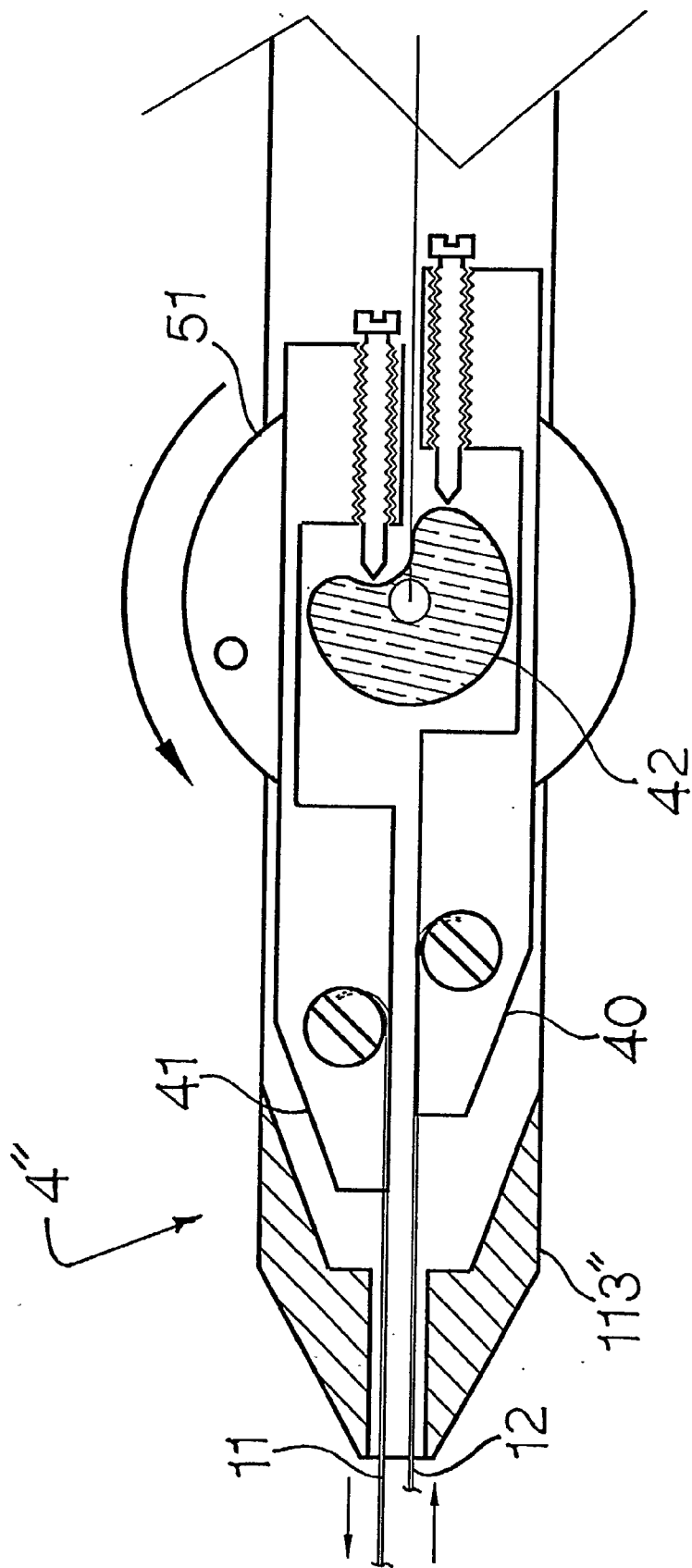


Figure 13



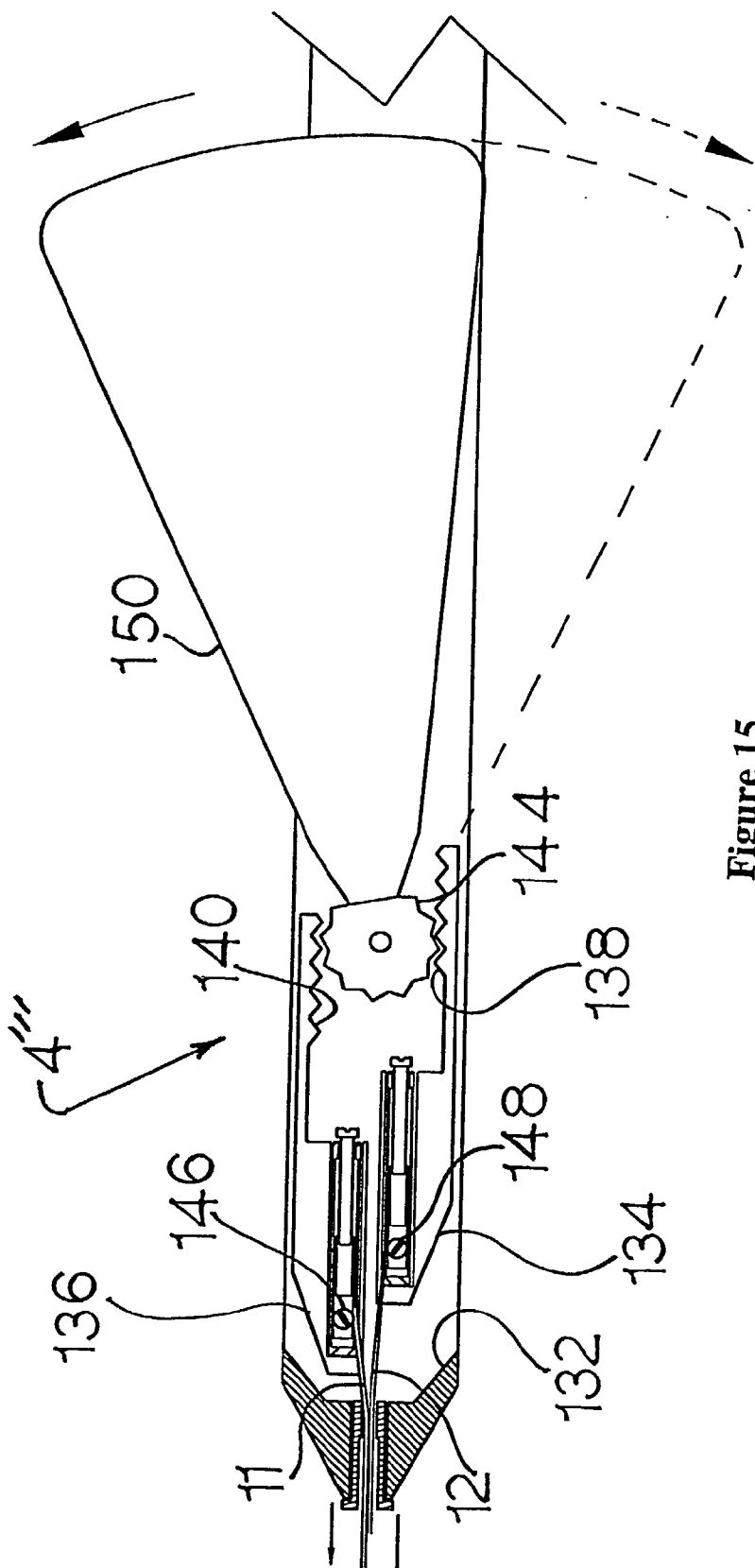


Figure 15



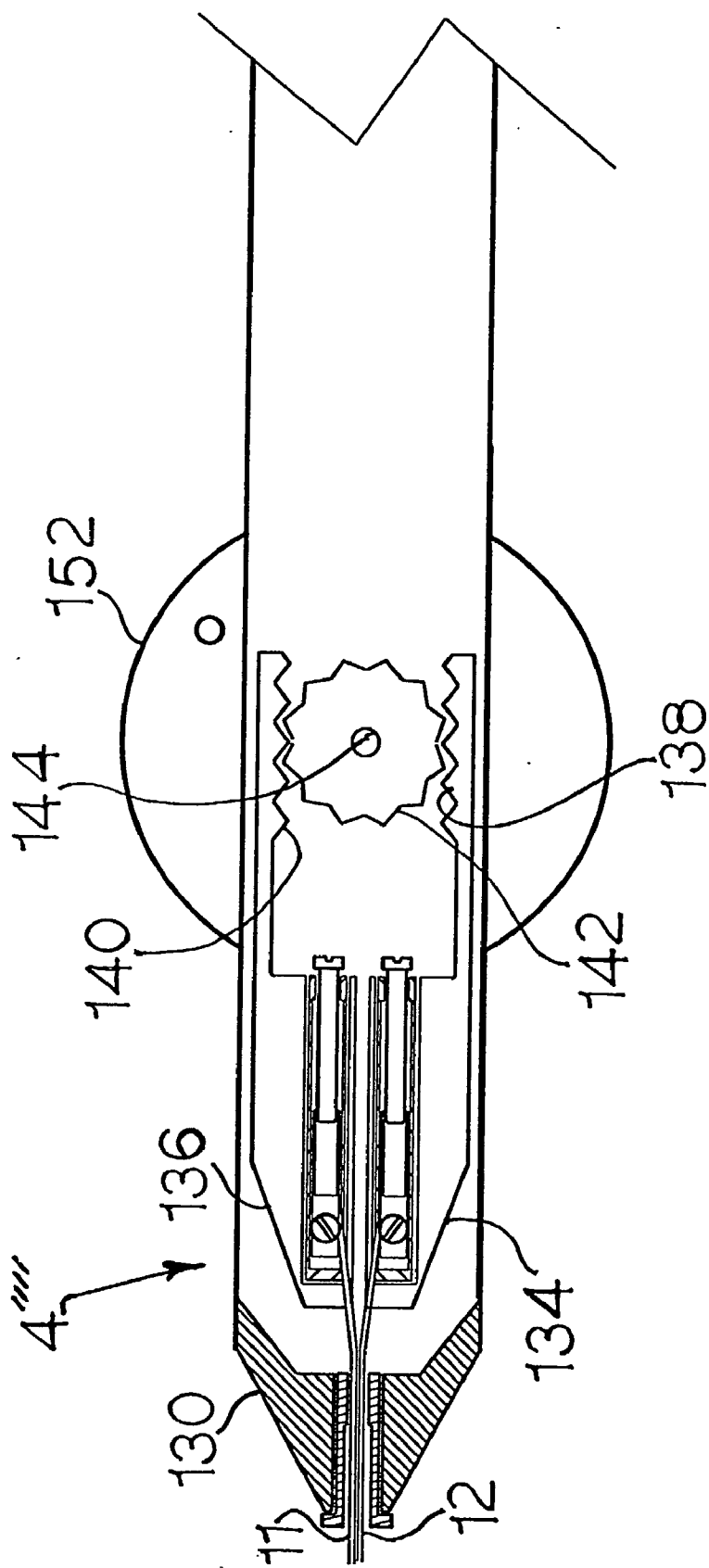


Figure 16a

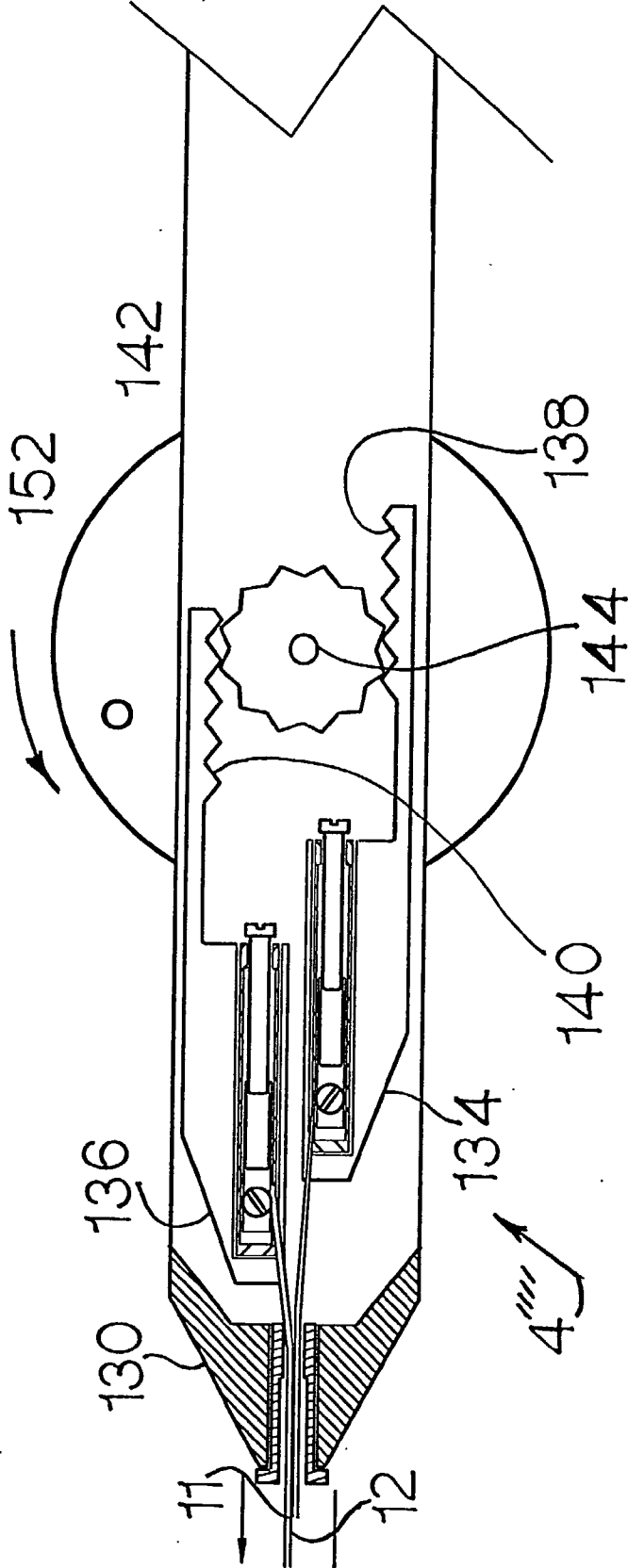


Figure 16b

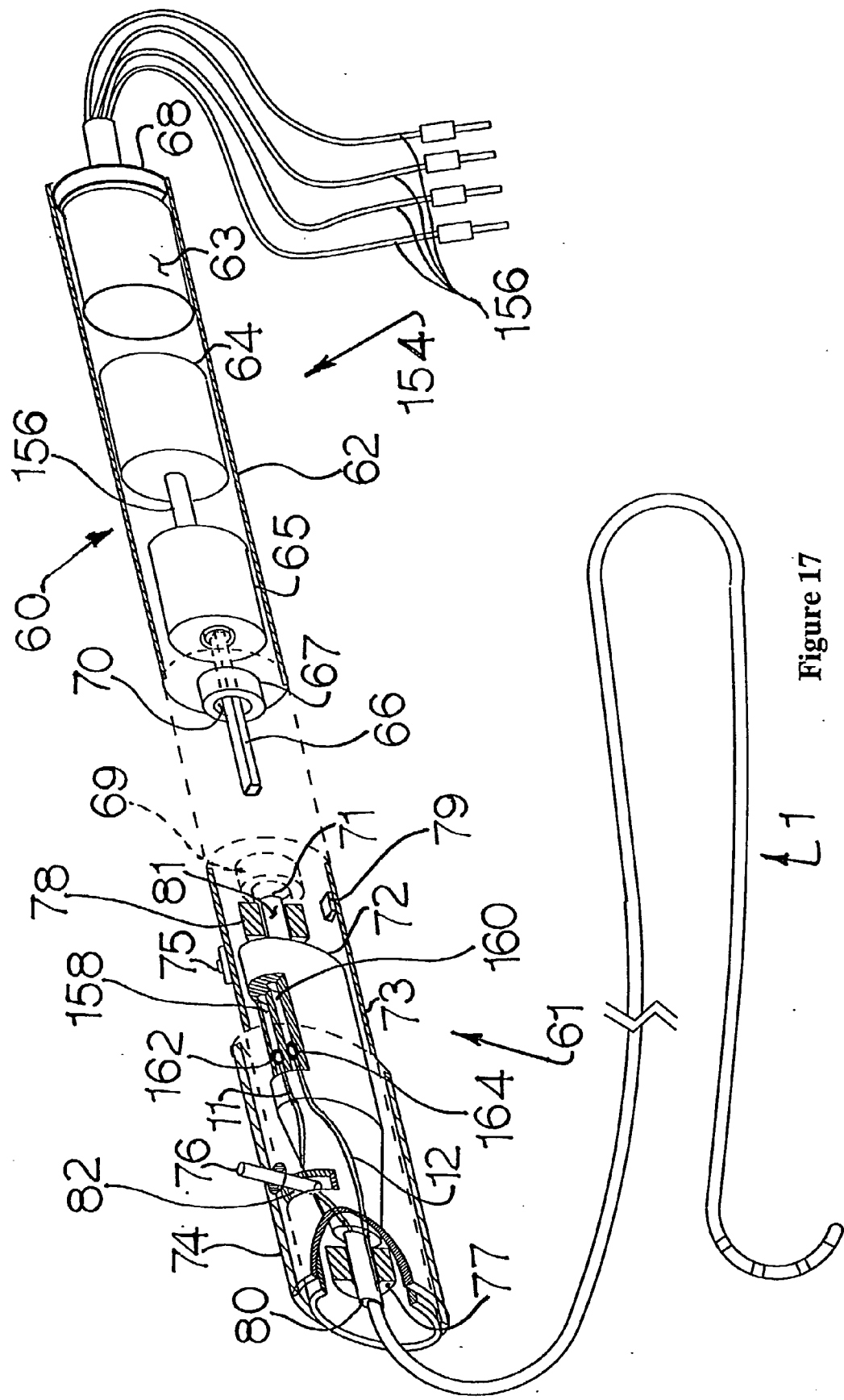
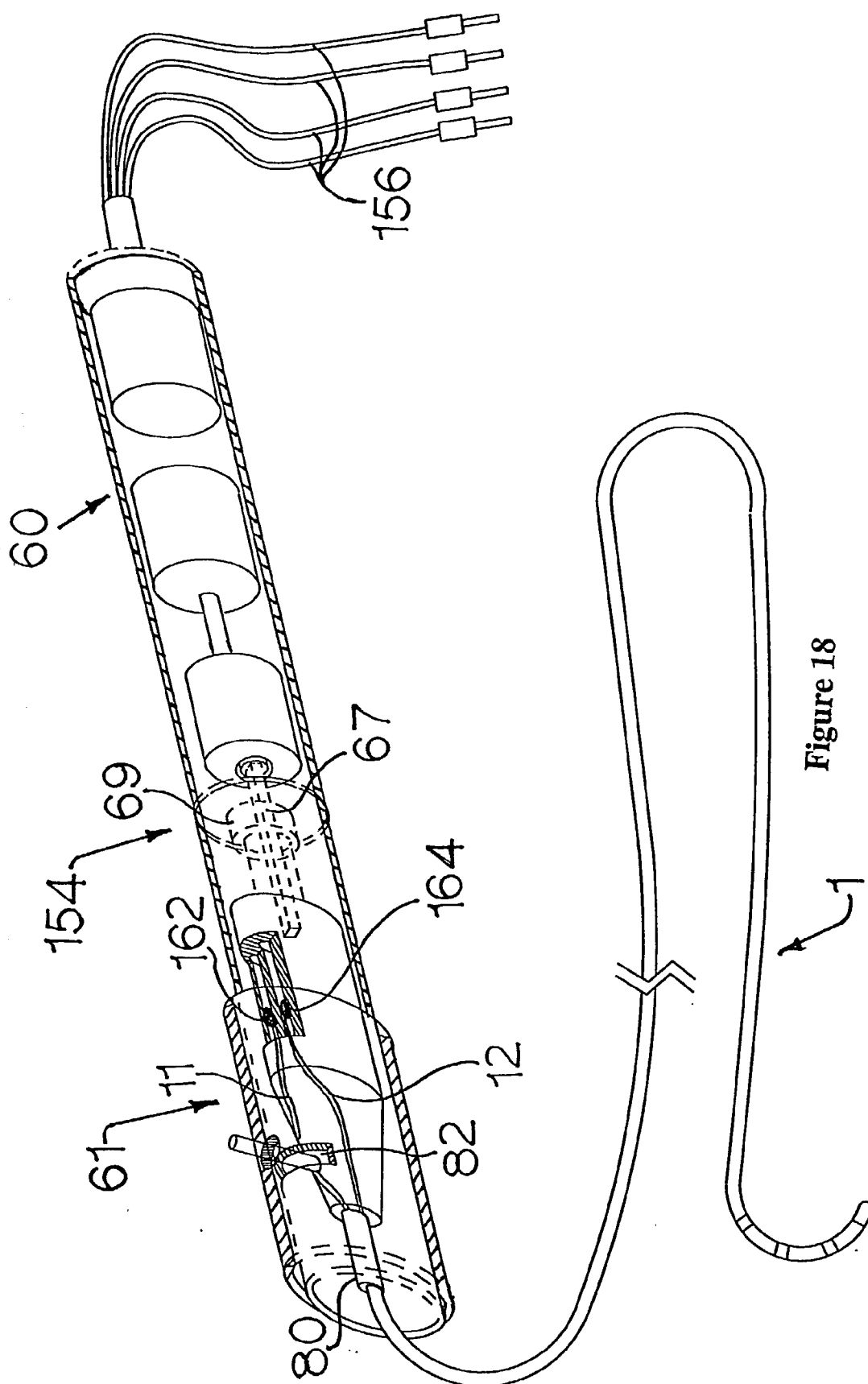


Figure 17



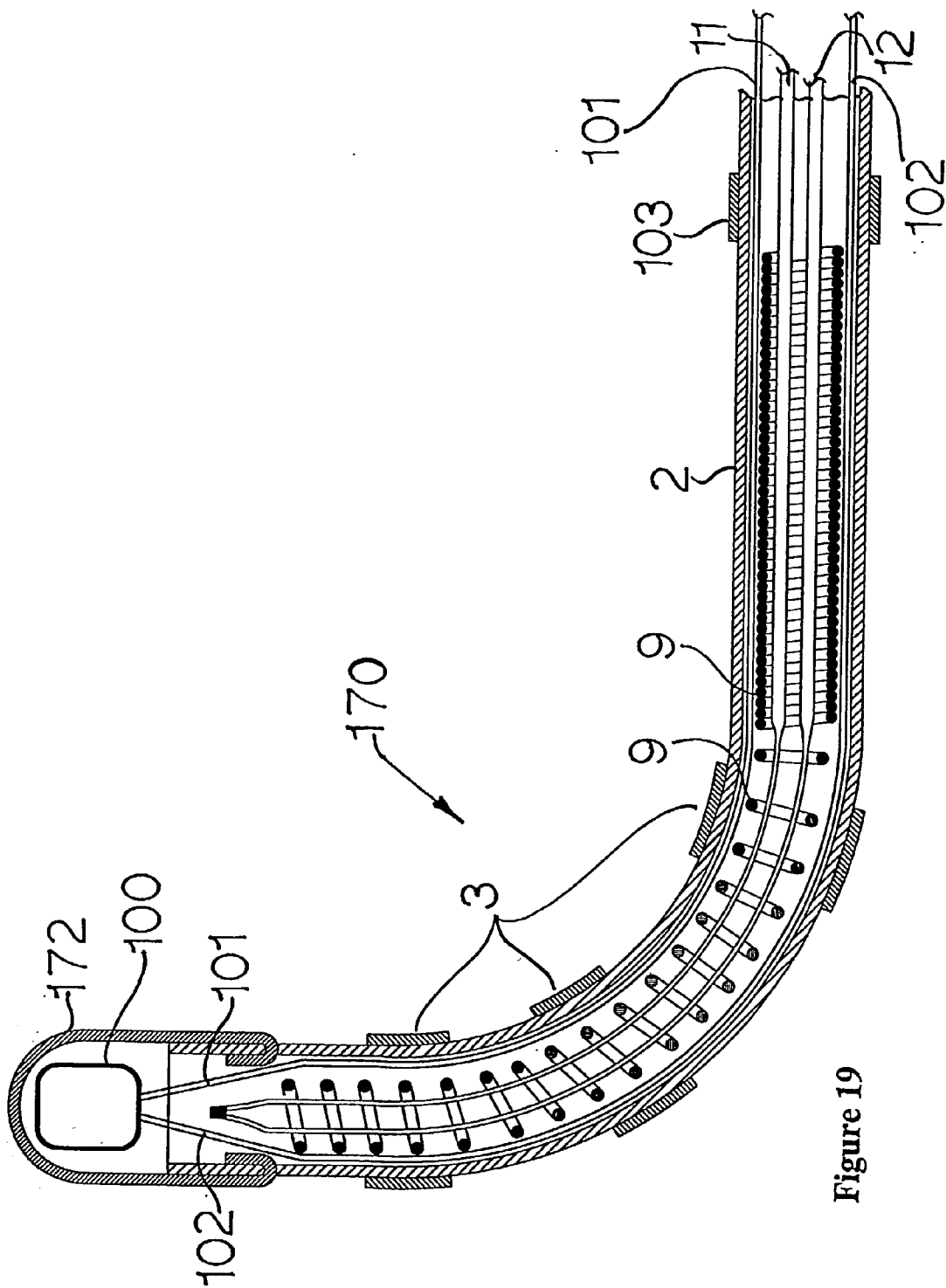
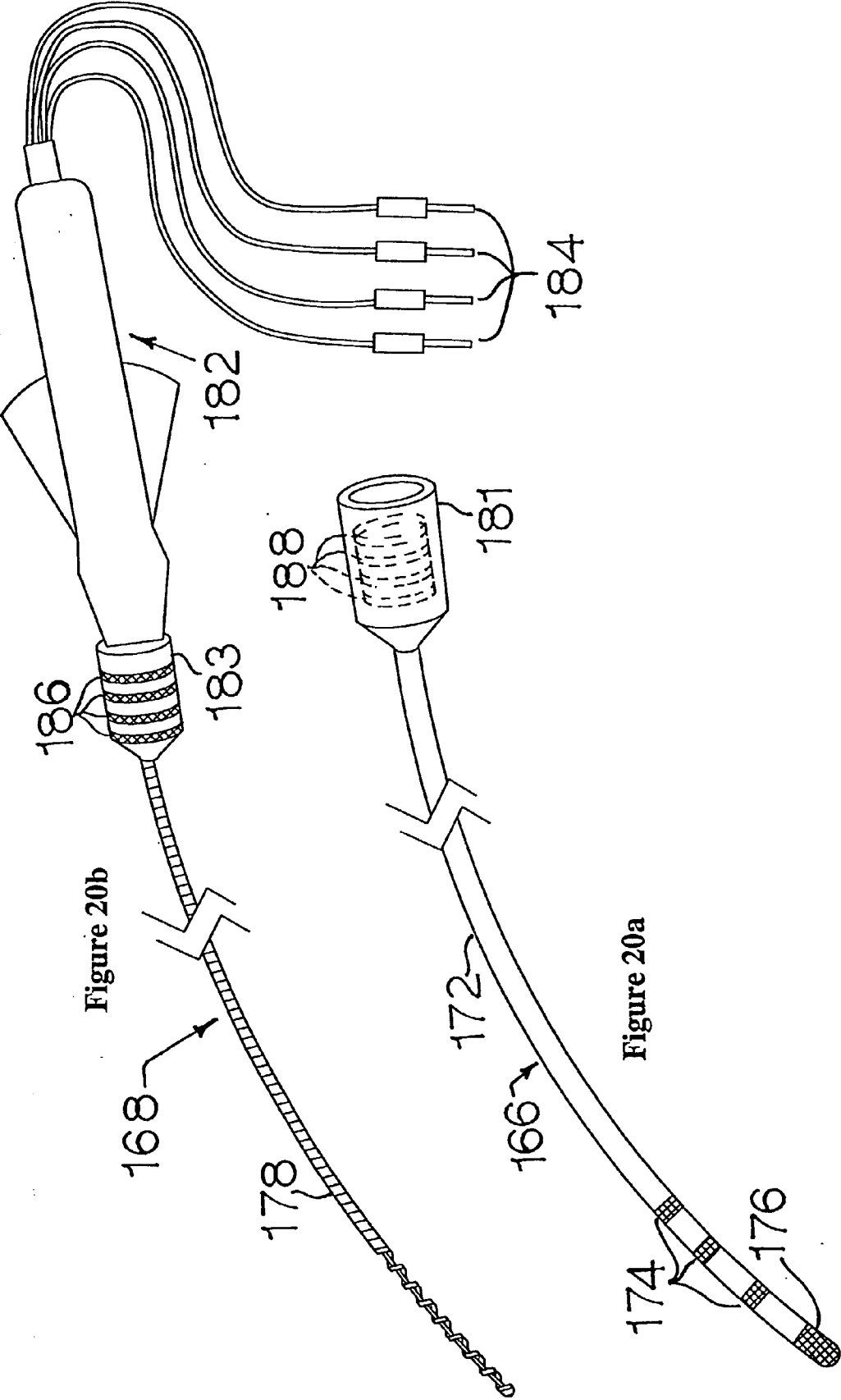


Figure 19



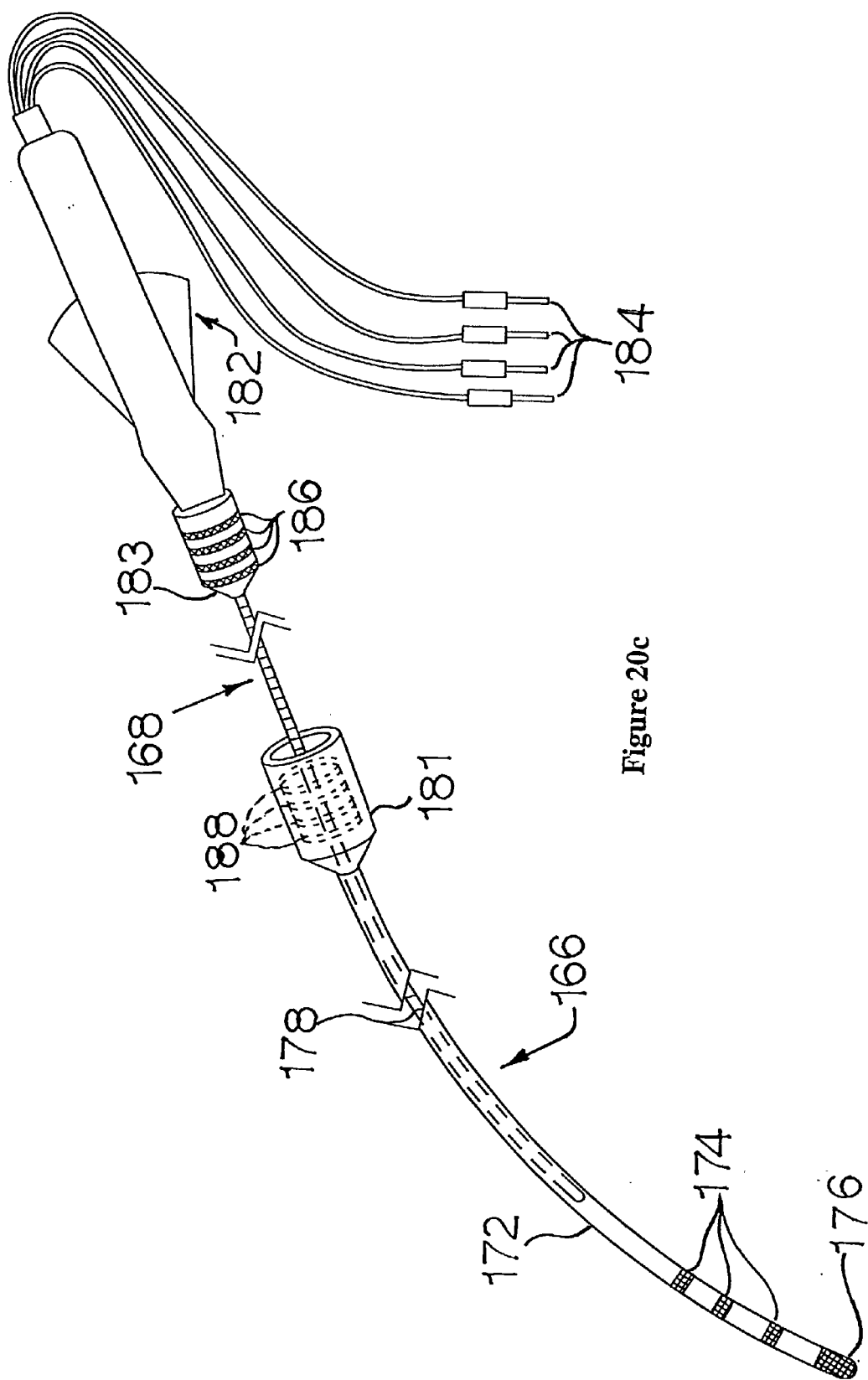


Figure 20c

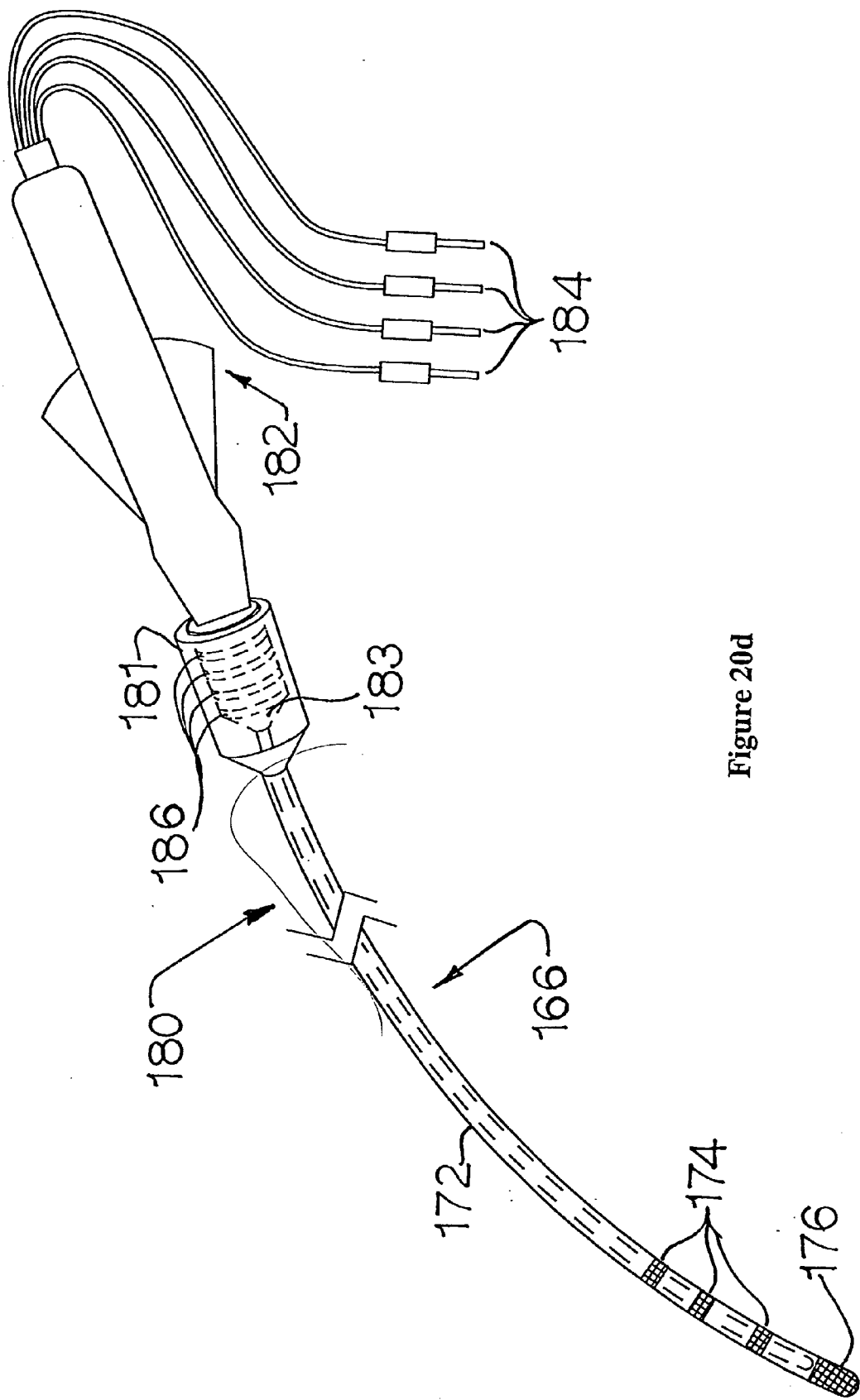


Figure 20d



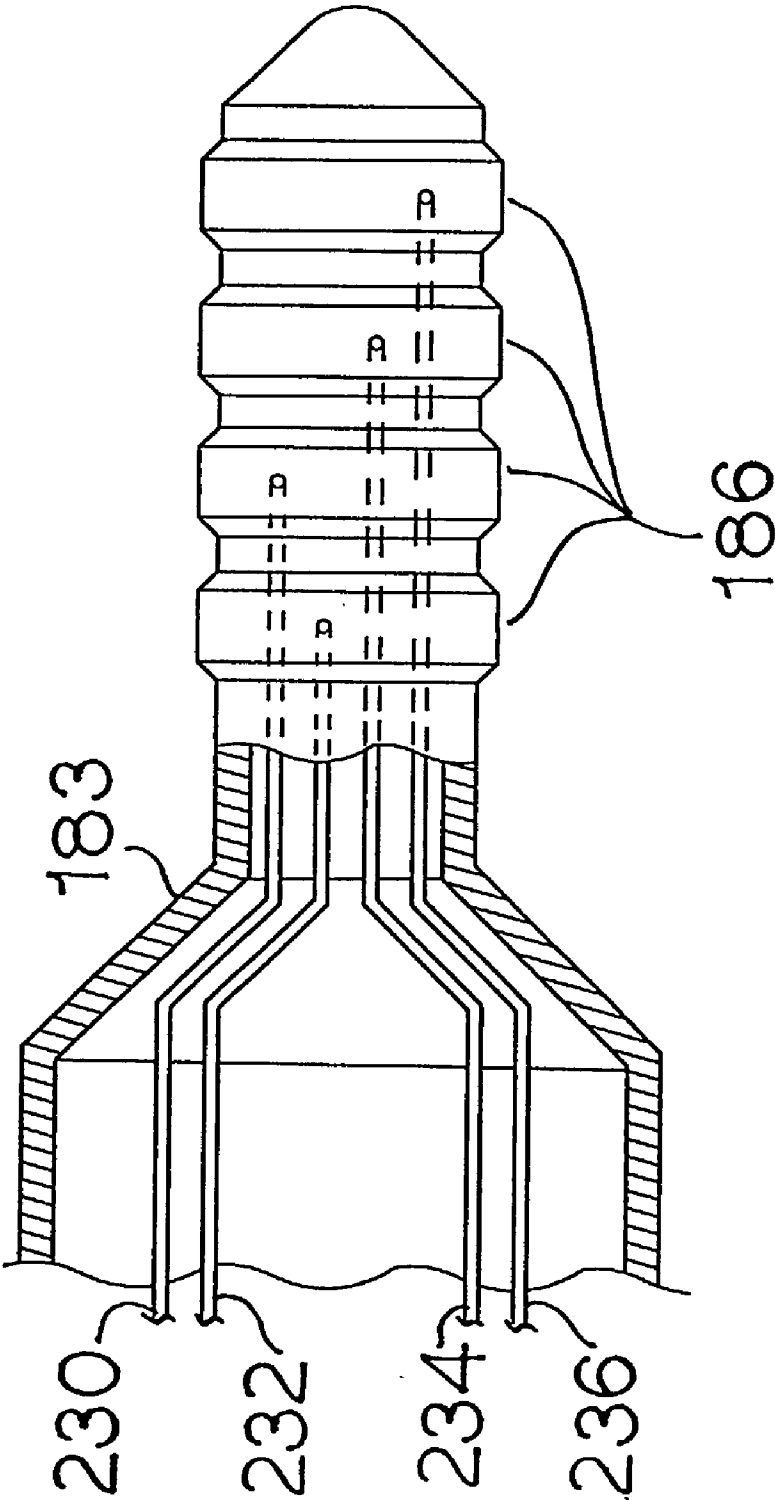
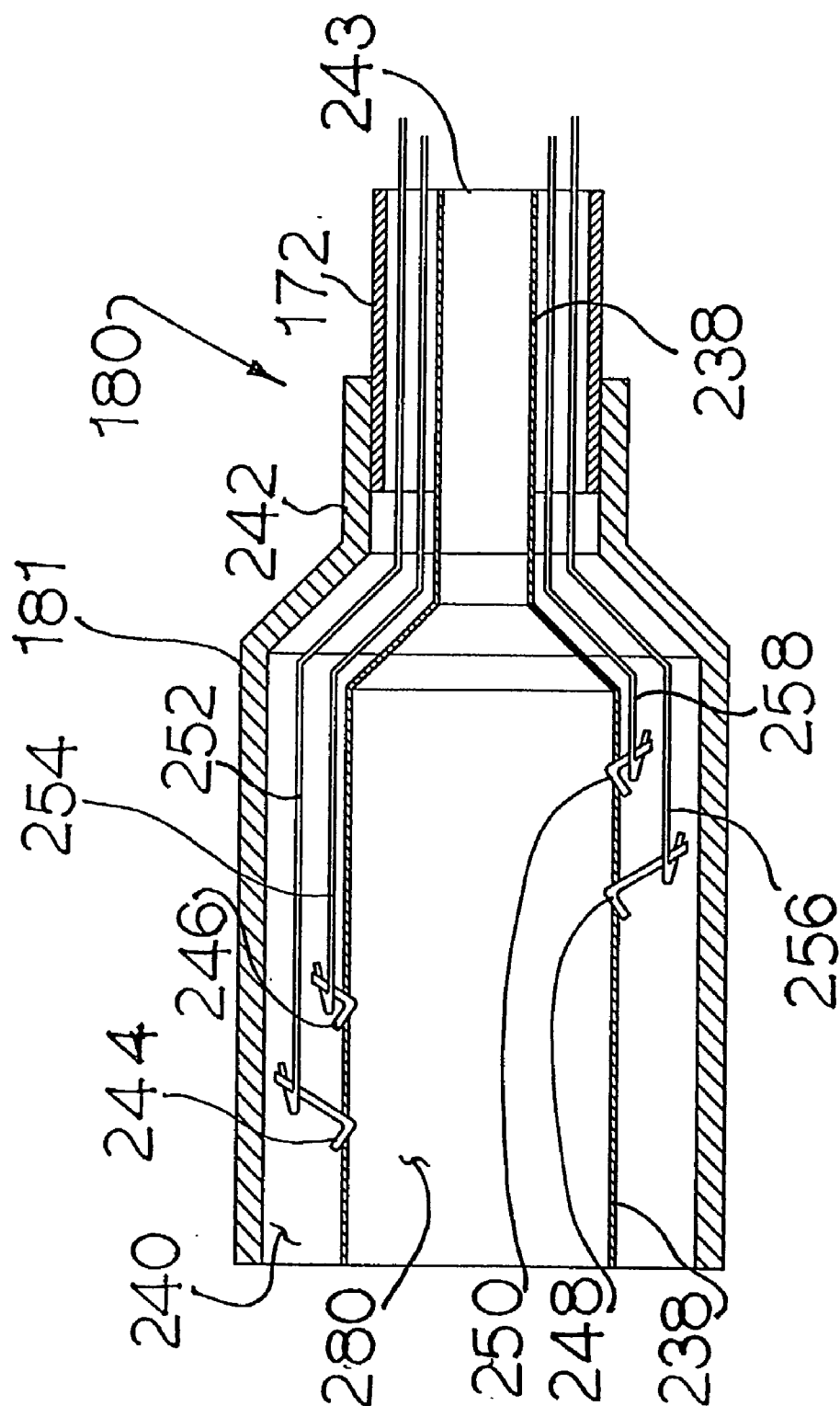
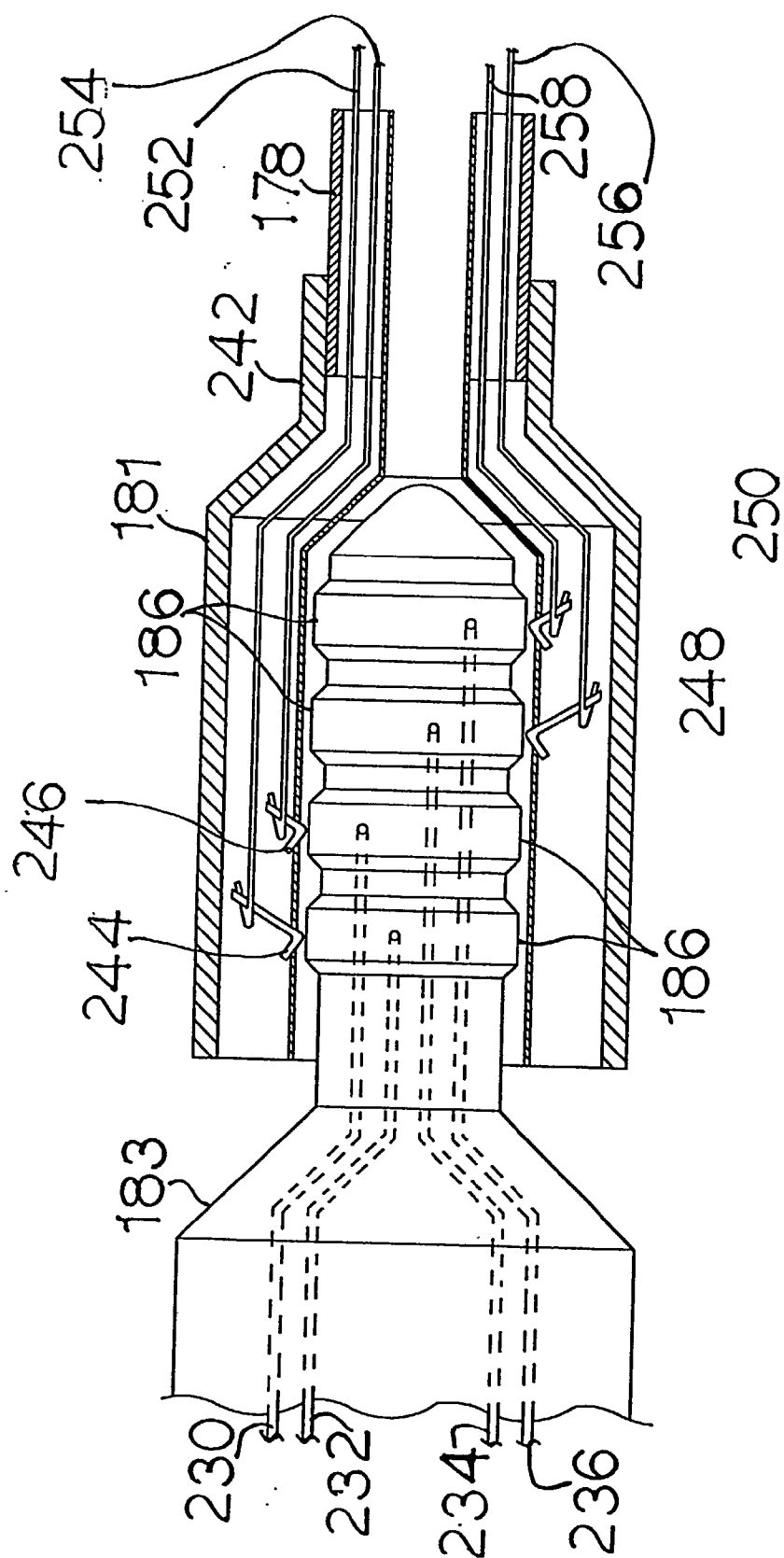


Figure 21



## Figure 22



**Figure 23**

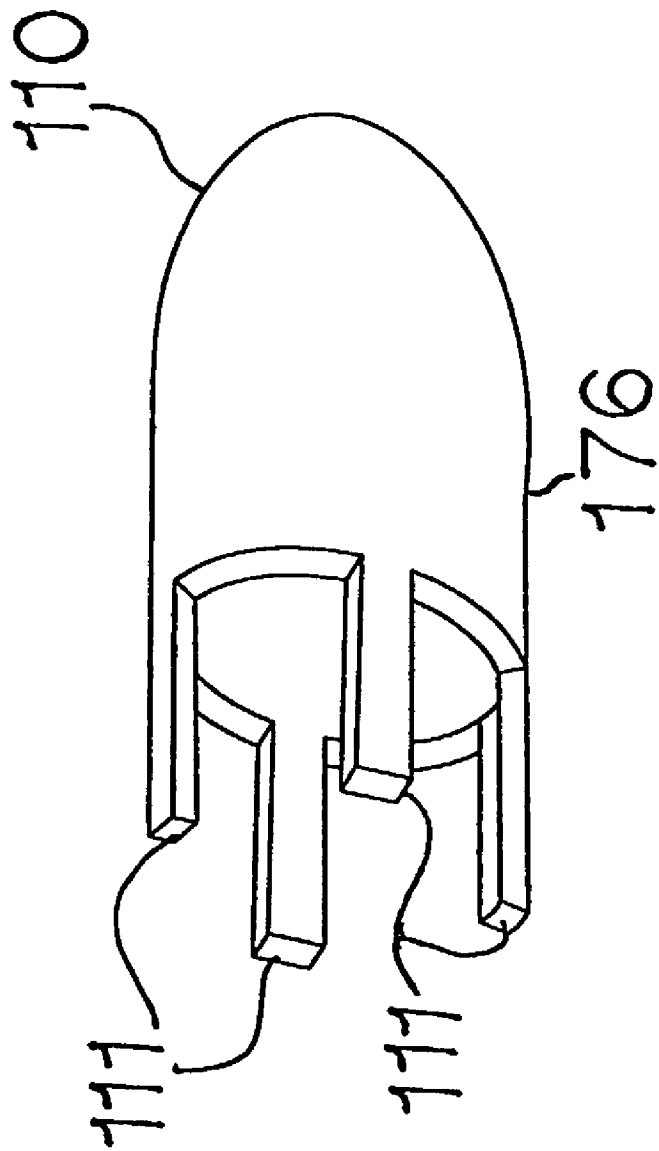


Figure 24

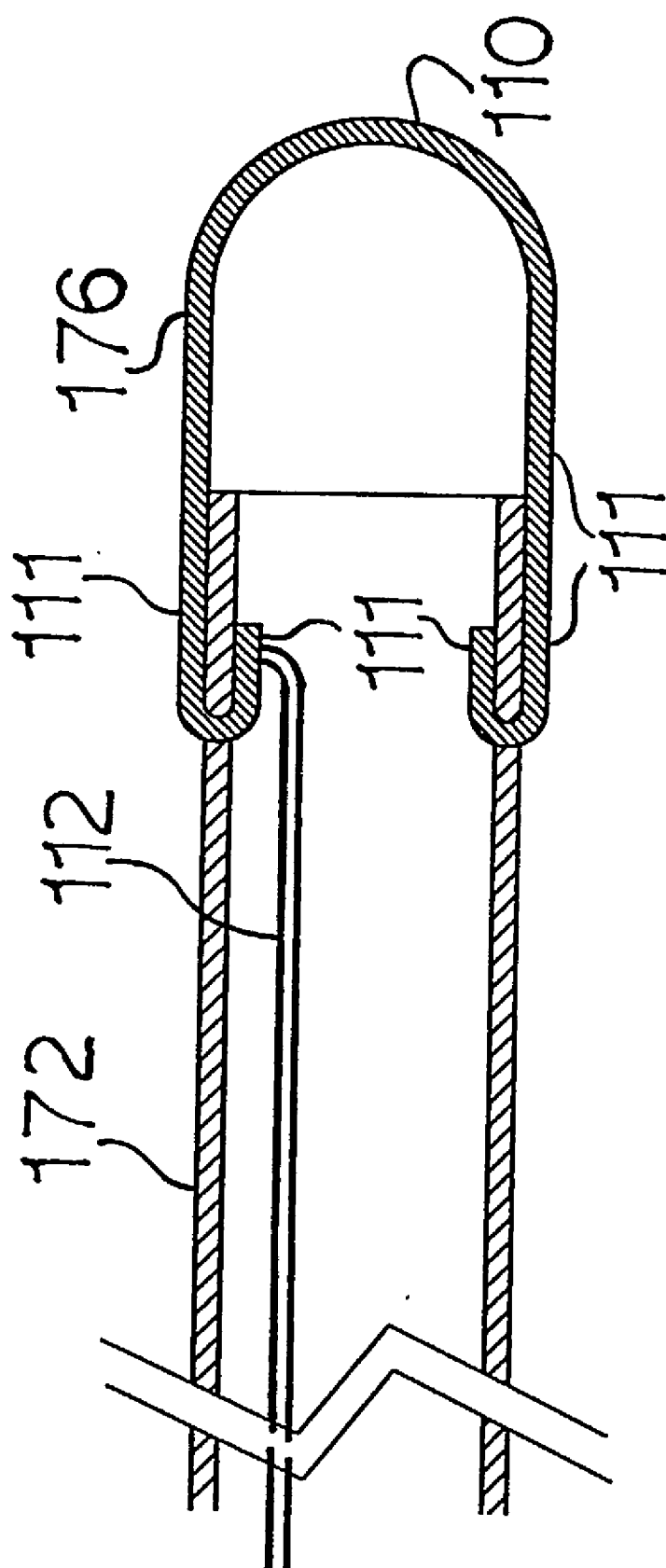
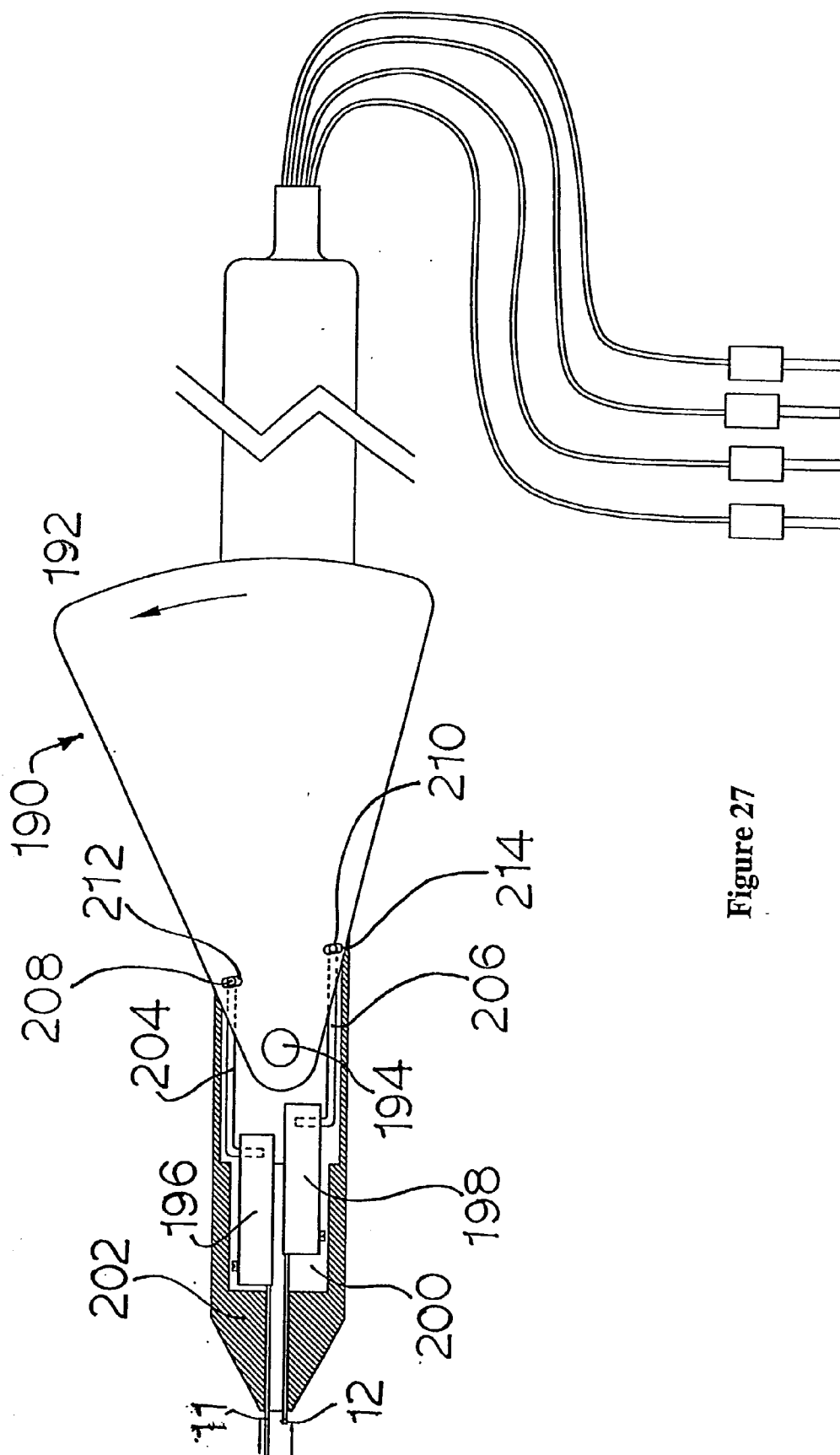


Figure 25





**Figure 27**

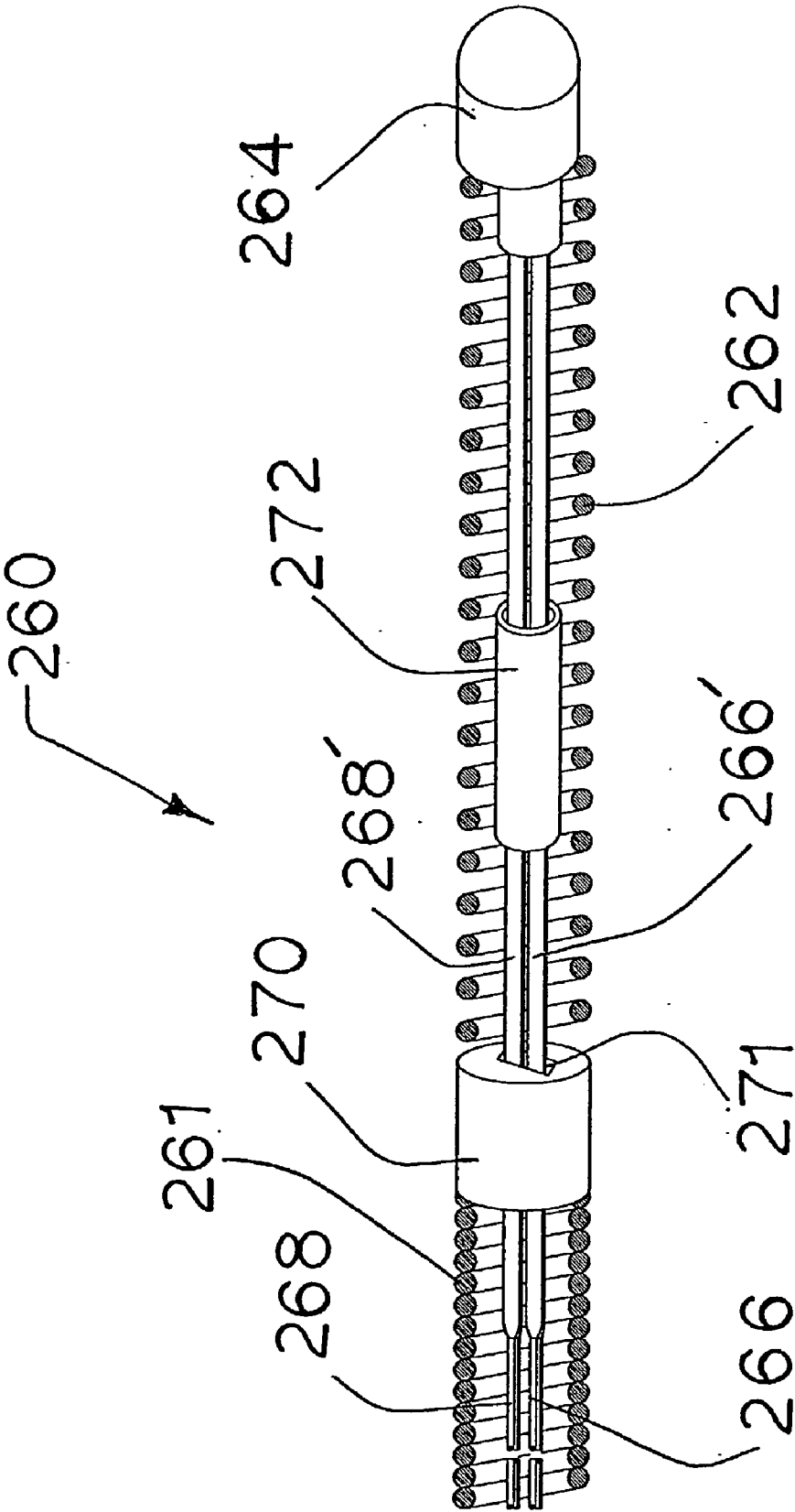


Figure 28





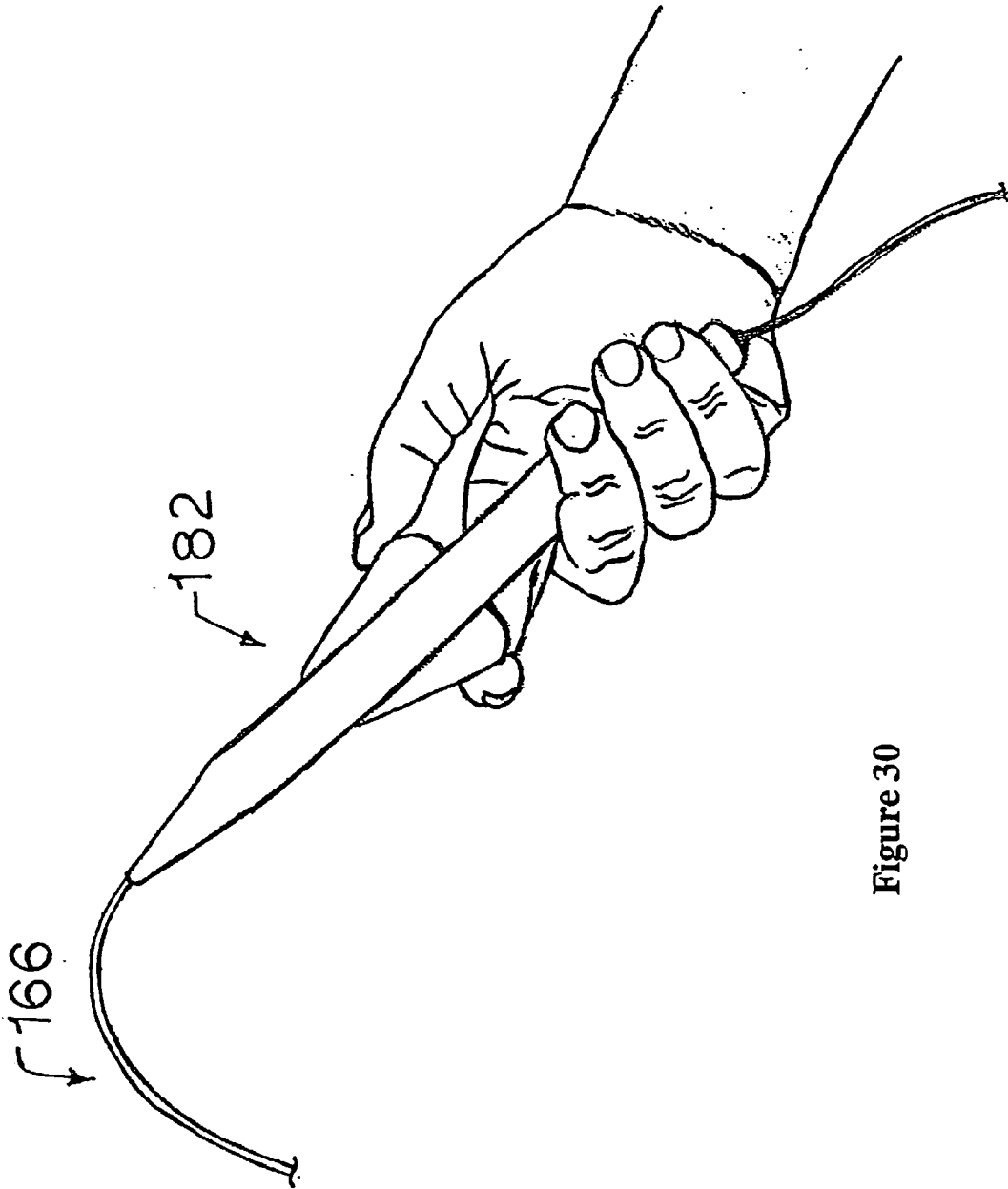
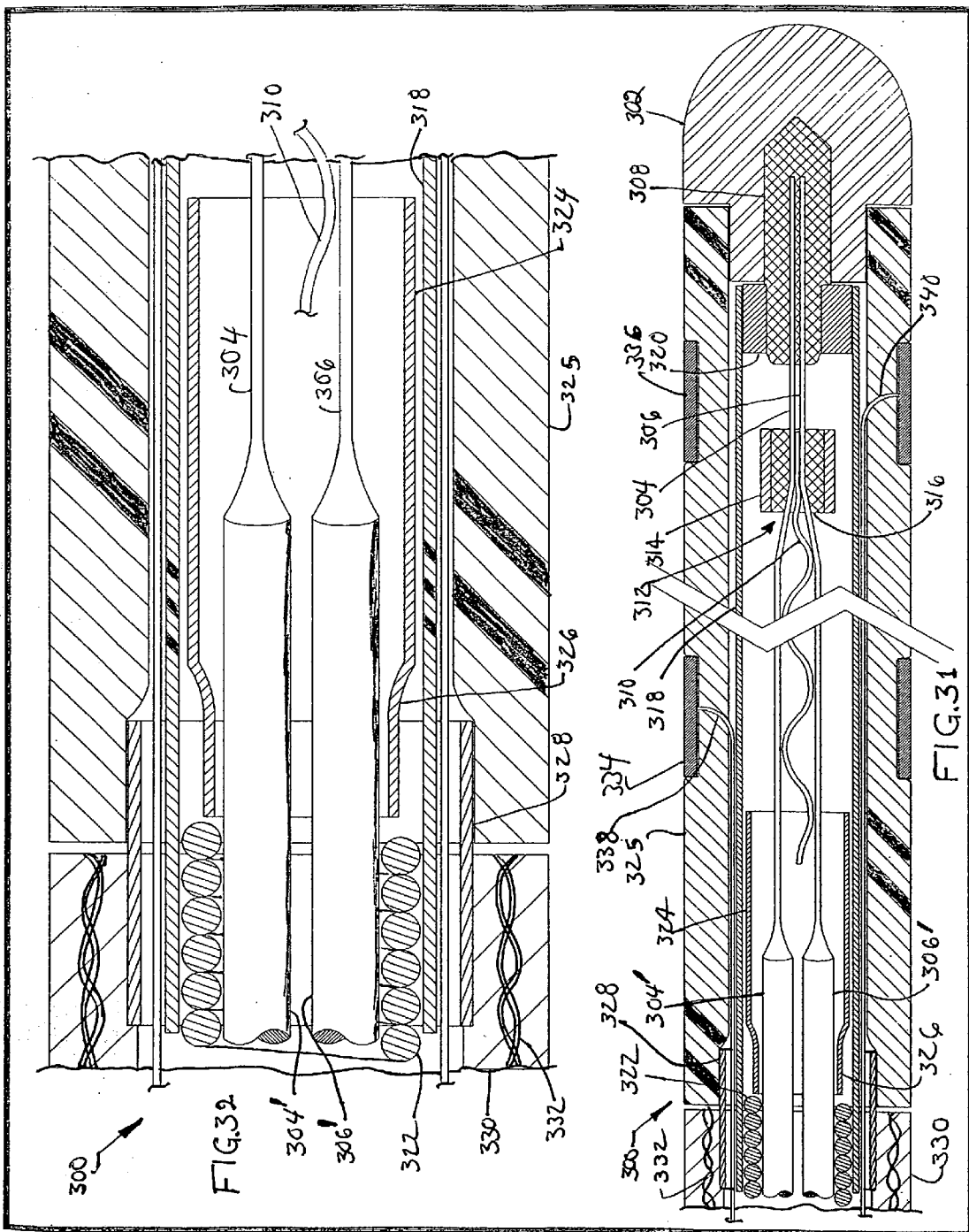
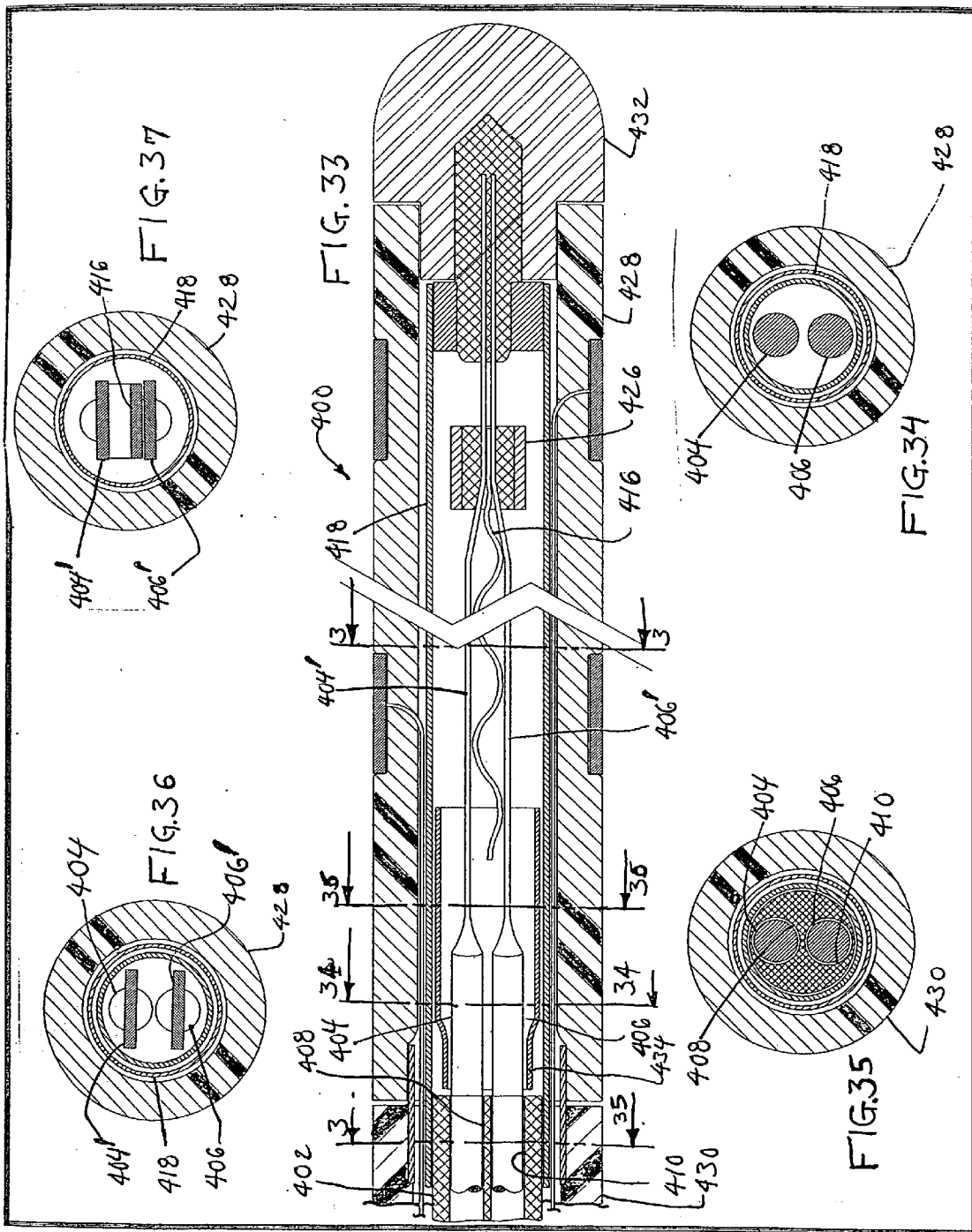
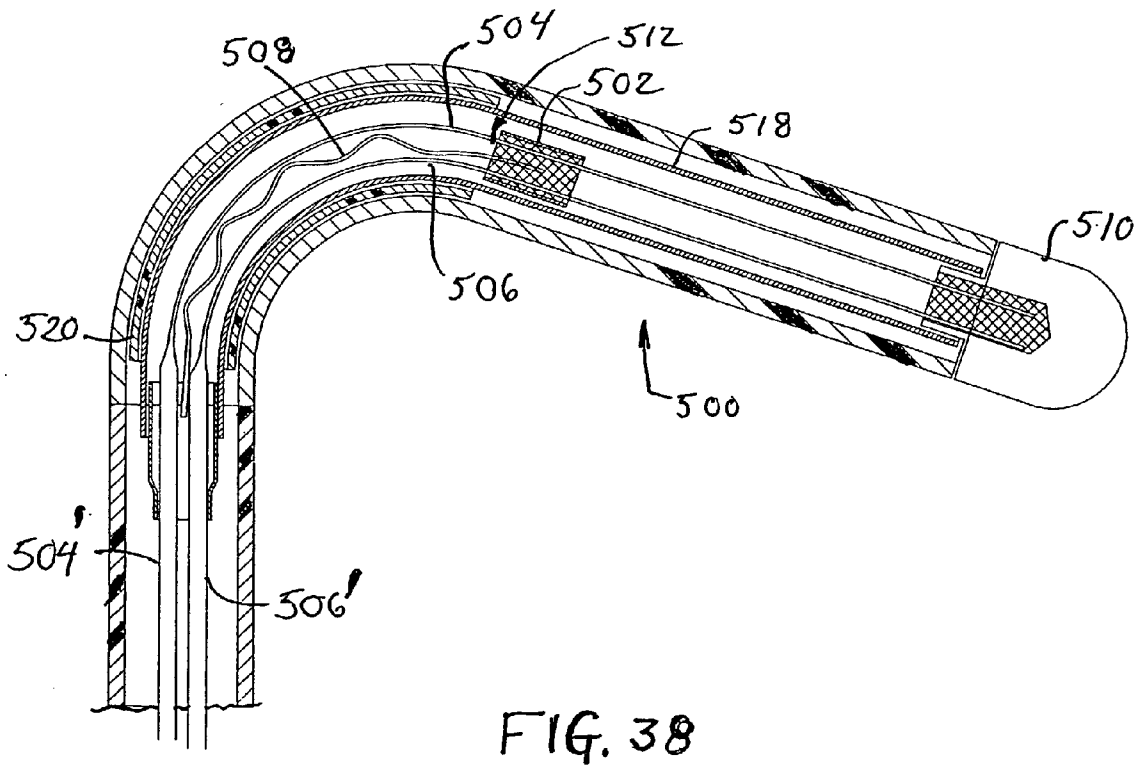
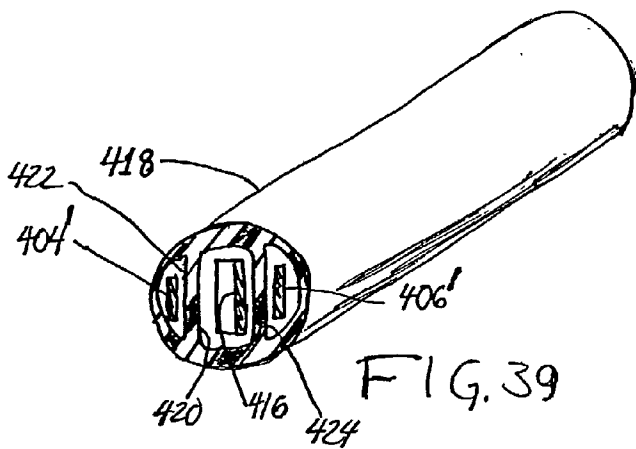


Figure 30







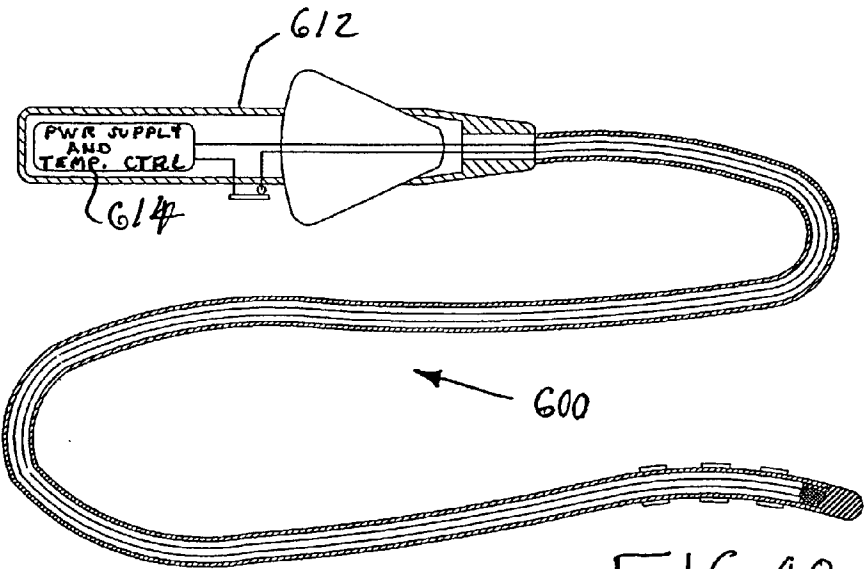


FIG. 40

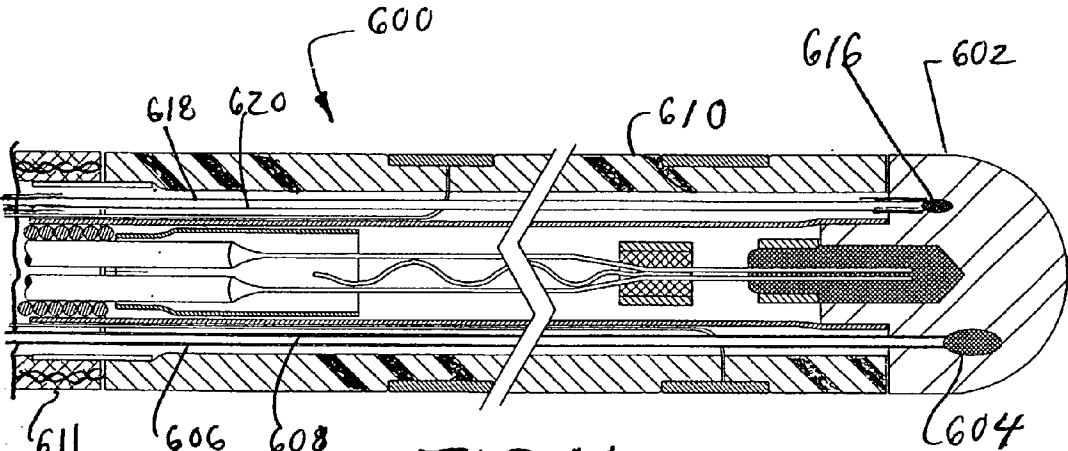
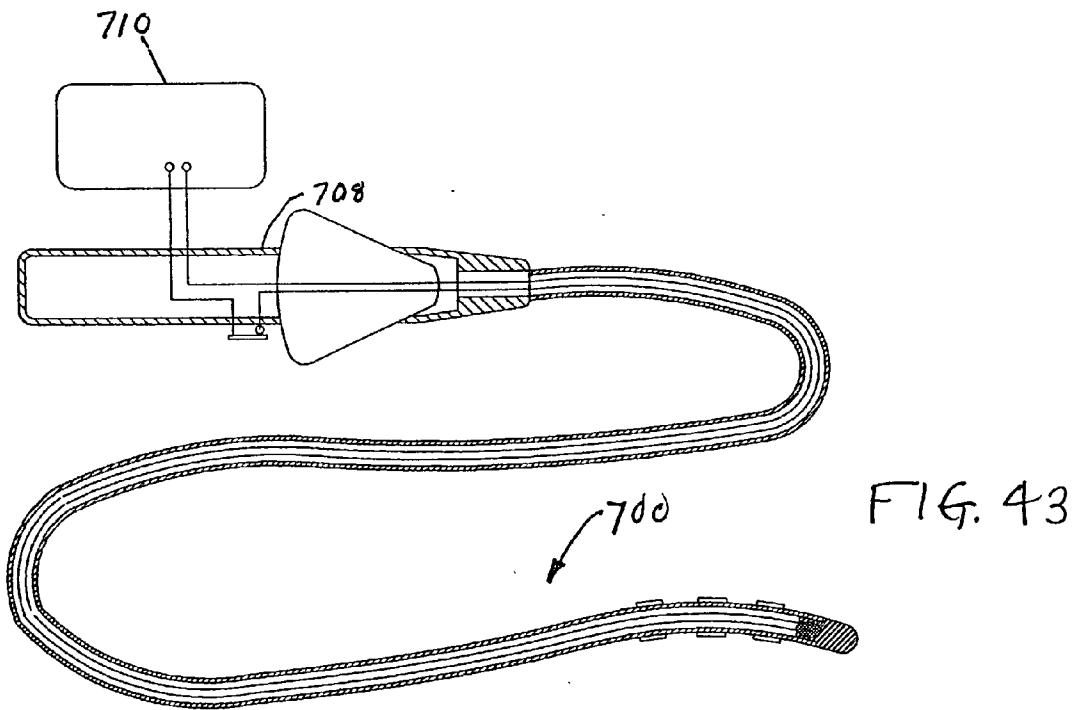
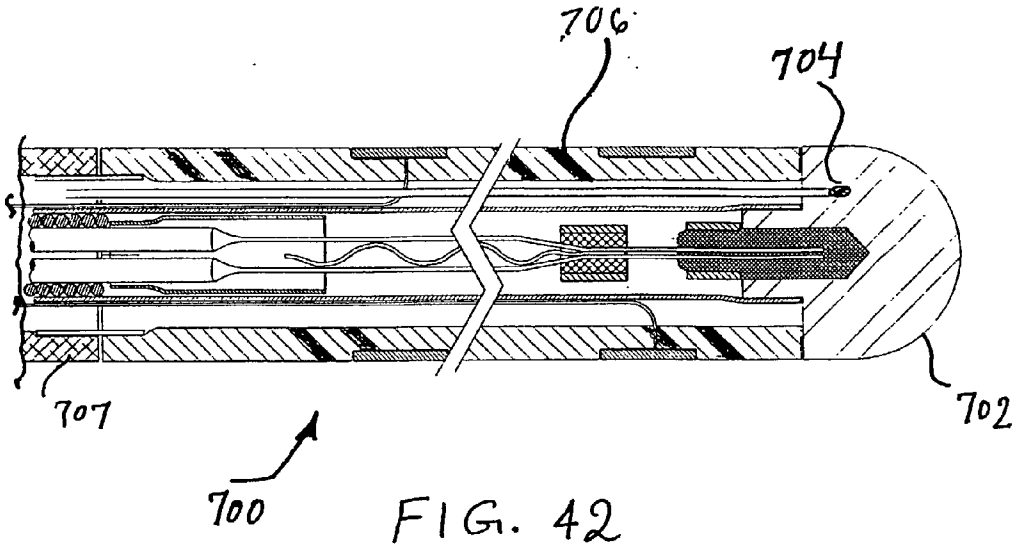


FIG. 41



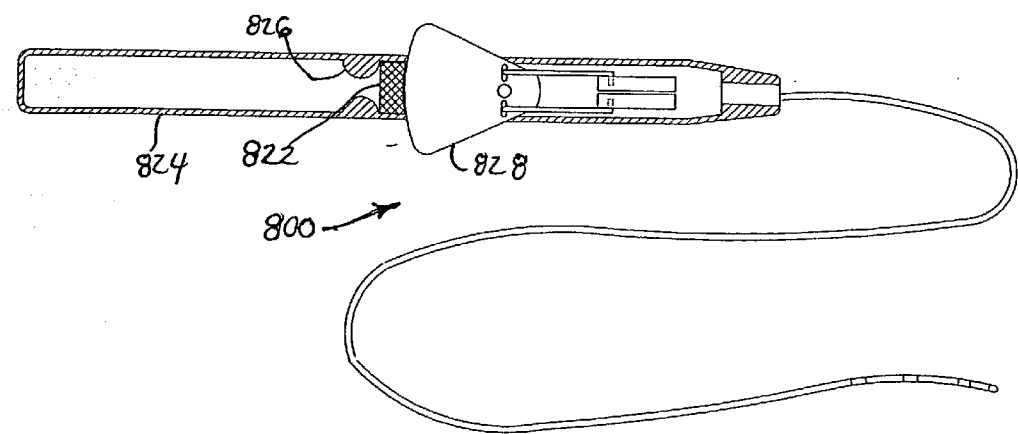


FIG. 45

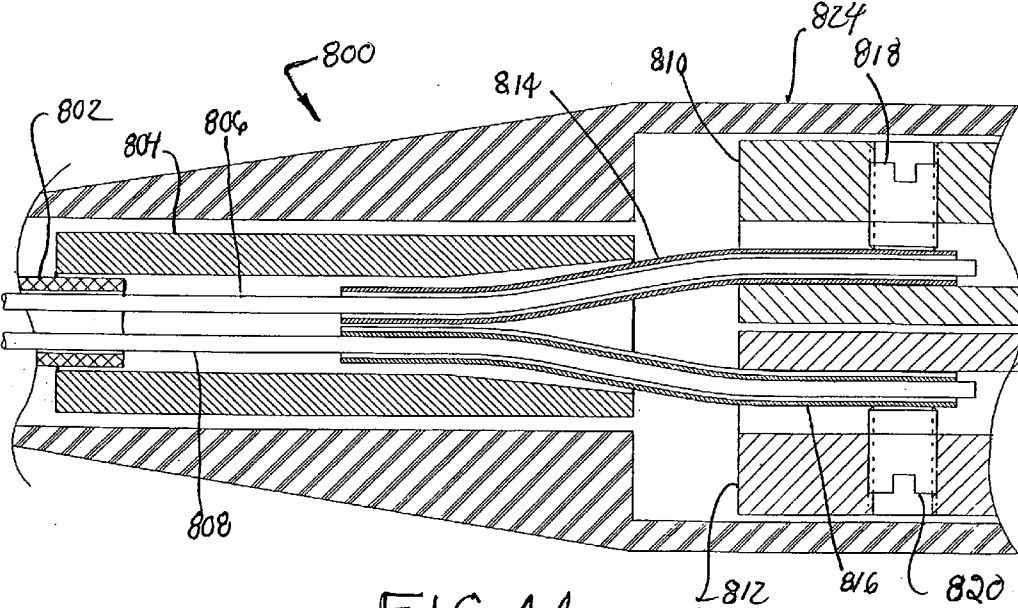
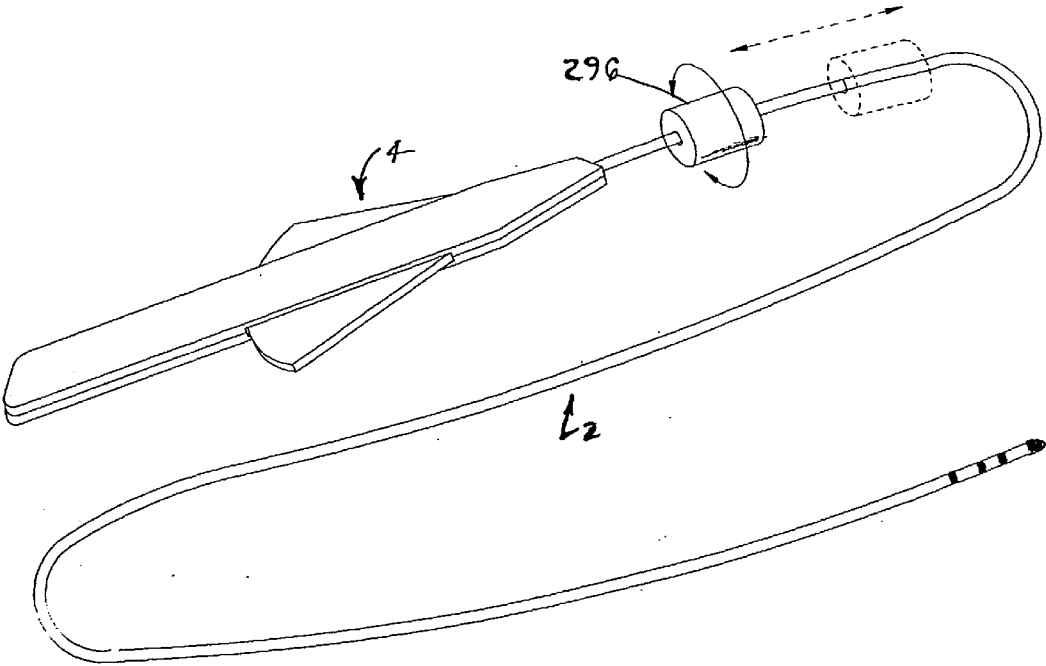
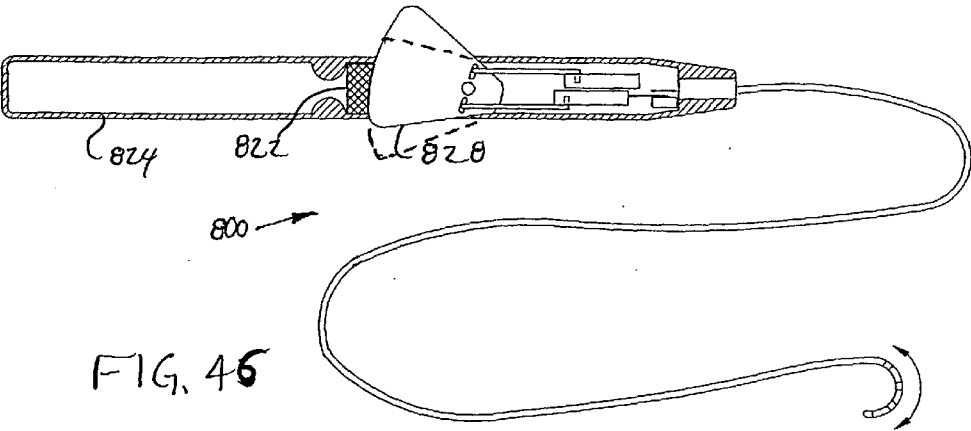
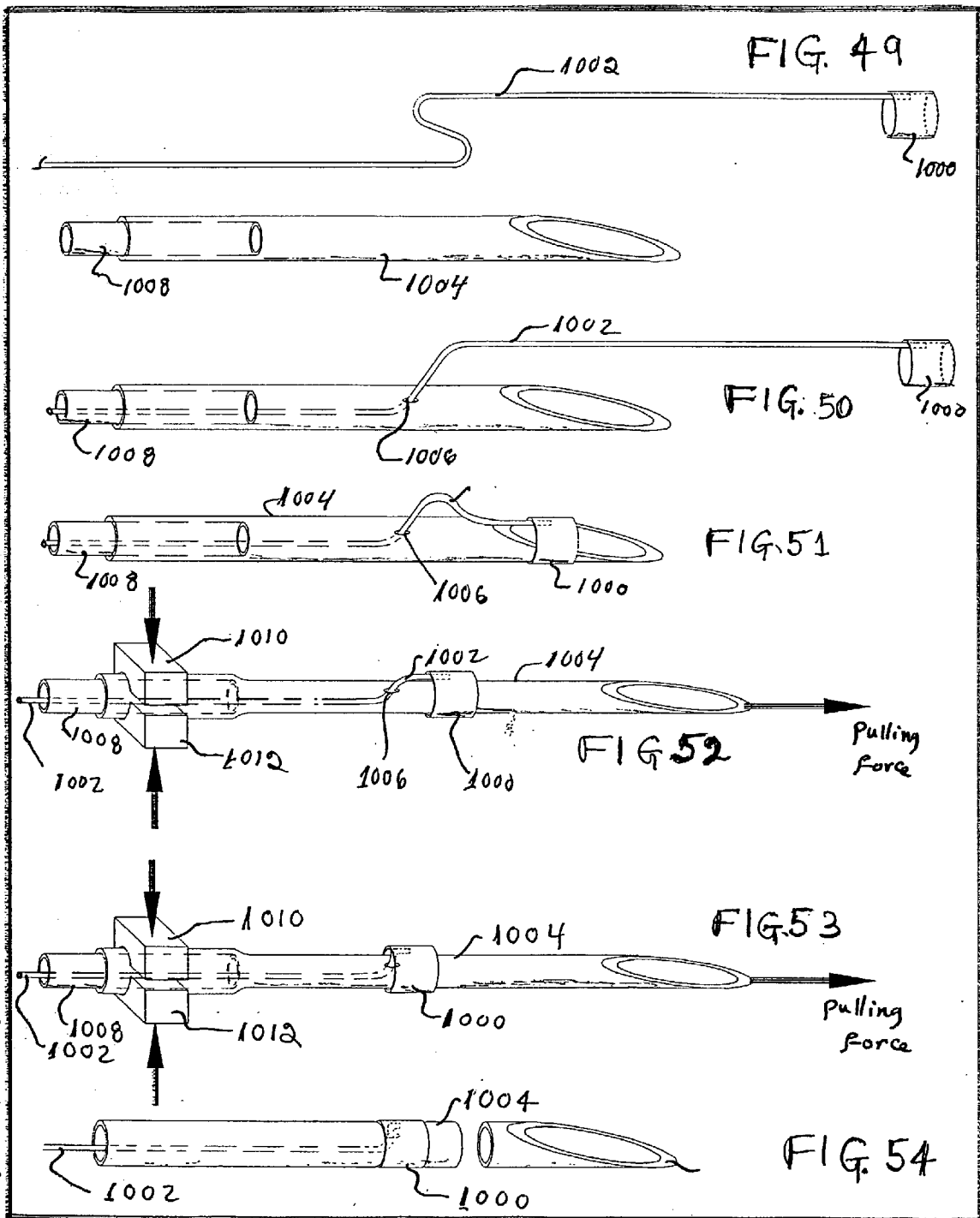
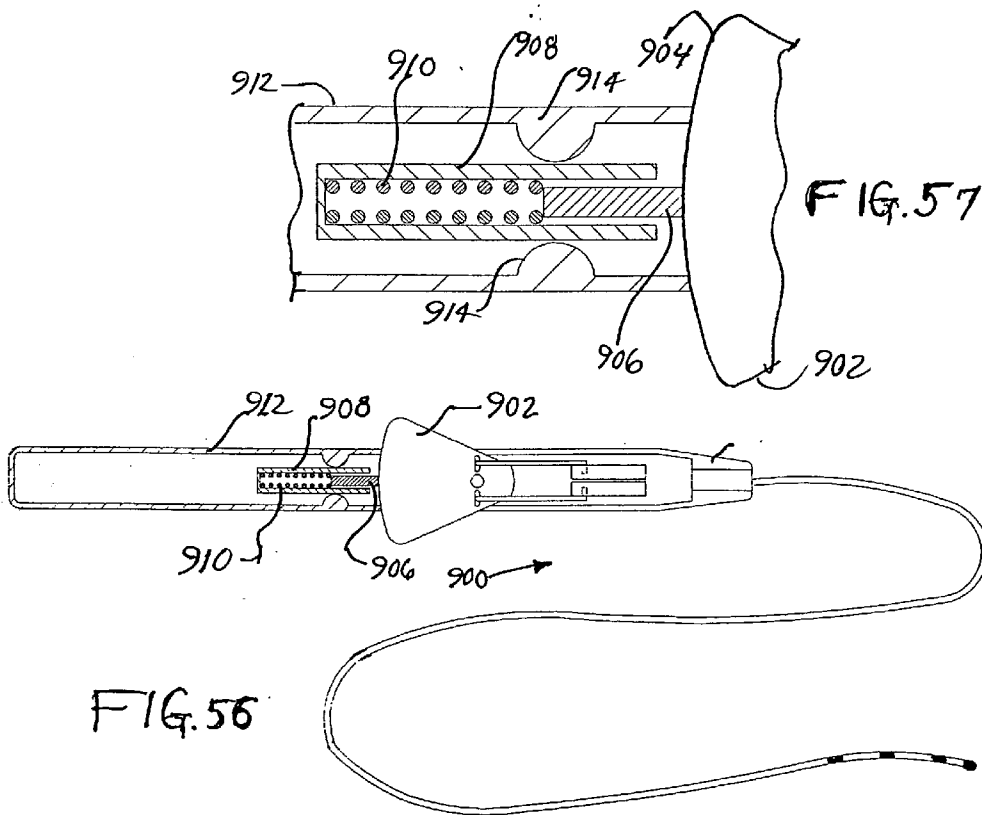
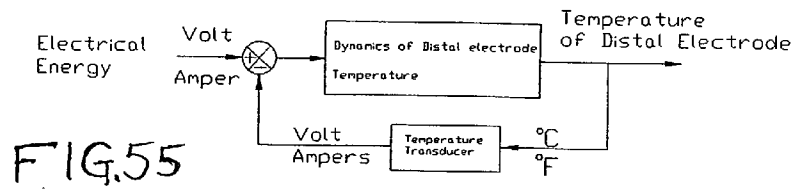
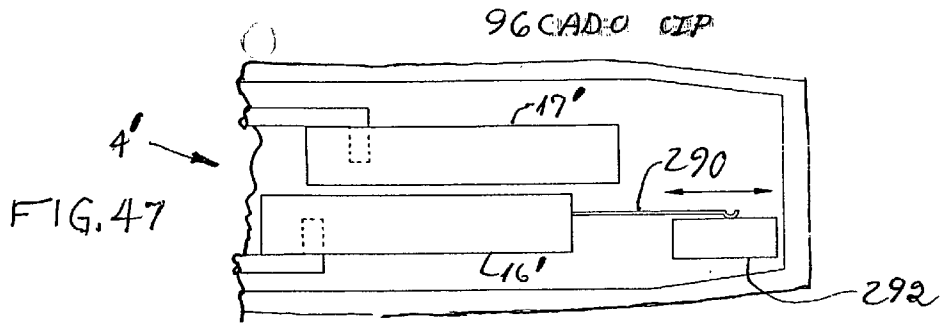


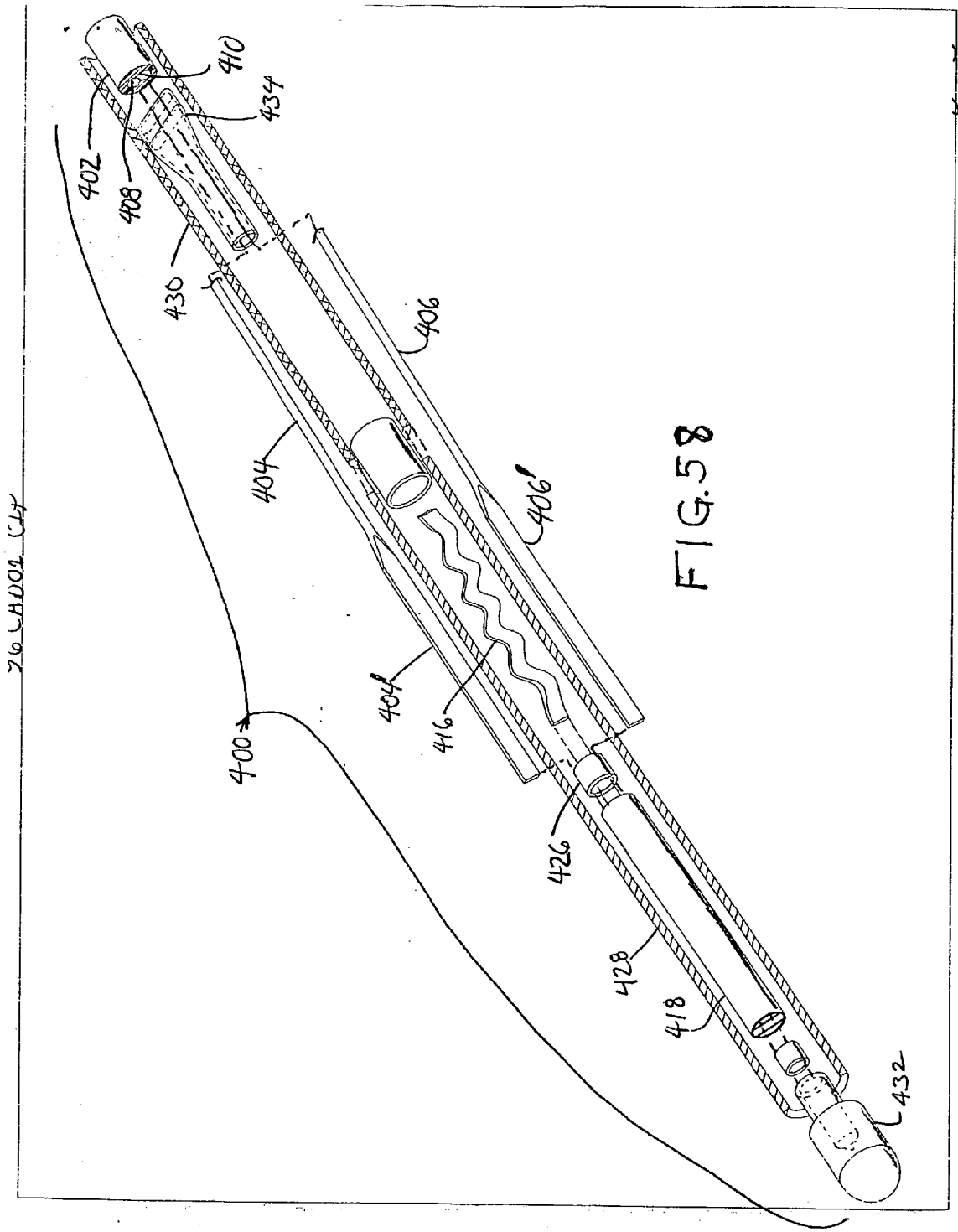
FIG. 44











## ELECTROPHYSIOLOGY/ABLATION CATHETER AND REMOTE ACTUATOR THEREFOR

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation-In-Part of my co-pending application Ser. No. 08/880,080 filed Jun. 20, 1997 entitled: "Electrophysiology Catheter and Remote Actuator Therefor."

### STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

### MICROFICHE APPENDIX

[0003] Not Applicable

### BACKGROUND OF THE INVENTION

[0004] a) Field of the Invention

[0005] The present invention relates to a catheter employed for diagnostic and/or therapeutic procedures in medicine, more specifically in minimally invasive cardiac electrophysiology studies and/or cardiac ablation procedures.

[0006] b) Description of the Prior Art

[0007] The primary device for an intra-cardiac electrophysiology study is a catheter with conductive electrodes at its distal portion [U.S. Pat. Nos. 5,156,151, 5,279,299, 5,415,633, 5,454,370, 5,465,717]. The distal portion of the catheter, where the electrodes are located, is commonly placed transvenously into the heart to monitor and/or record the intra-cardiac electrical signals during electrophysiology studies, or during intra-cardiac mapping. The function of these electrodes on the catheter is to conduct cardiac electrical signals to appropriate monitoring and recording devices.

[0008] During the diagnostic procedures, the catheter is also used as a medium to deliver low energy electrical pulses from a cardiac stimulator to the heart in order to evaluate the heart's response to the cardiac stimulator signals.

[0009] During therapeutic (cardiac ablation) procedures, electrical energy in the form of radio-frequency, microwave or high-voltage pulses is delivered from an appropriate energy source to the heart commonly via the catheter's distal electrode. The intent of this energy delivery is to destroy the site of the cardiac tissue that causes abnormality (arrhythmia) to the normal rhythm of the heart.

[0010] During such a minimally invasive cardiac ablation procedure the distal portion of a catheter, which usually comprises a plurality of spaced annular cylindrical electrodes and a distal electrode, is transvenously placed into the heart. The proximal end of the catheter, remote from the electrodes, has electrical leads which are connected to an appropriate recording and/or monitoring device. The intra-cardiac electrical signals can then be monitored and recorded.

[0011] A surface electrocardiogram, obtained from patient's skin, is concurrently compared with the intra-cardiac electrical signals. Typically, when a known catheter

is employed for ablation procedures, an electrically conductive self adhesive skin patch is also placed on the patient's body. An electrical lead from this patch is connected to an electrical energy source. As the abnormal site of the cardiac tissue is detected with the catheter's distal electrode, its corresponding electrical lead is switched from the monitoring/recording device to the electrical energy source for ablation. At this time, electrical energy can be delivered to the heart from the catheter tip that is in contact with abnormal heart tissue. The self adhesive patch on the patient's body is the return path of the electrical energy to the energy source. This known ablation procedure, using a self-adhesive patch as the return path of electrical energy to the energy source, may result in a significant level of electrical "noise" that is generated by the energy source during the energy delivery period. This "noise" superimposes itself to both surface electrocardiograms and intra-cardiac signals obtained from the catheter. Cardiac signals contaminated with such "noise" have been found difficult to monitor during energy delivery period.

[0012] Intra-cardiac signals are commonly acquired for electrophysiology studies via a selected pair of a catheter's electrodes. The catheter is said to be used as a bi-polar probe when a cardiac signal is obtained between any pair of its electrodes. In some electrophysiology studies or cardiac mapping, however, the catheter is used as a uni-polar probe. When catheters of the prior art have been employed as a uni-polar probe, an additional reference electrode, that is not a part of the inserted catheter, is needed to complete the electrical circuit path. In such an arrangement, a second catheter is transvenously placed into the heart and this second catheter electrode functions as the reference electrode. U.S. Pat. No. 4,920,980 describes uni-polar and bio-polar application of cardiac catheters.

[0013] Currently most widely used and commercially available cardiac diagnostic and ablation catheters are sold for "one-time-use-only", and the entire catheter is discarded after a single use. Catheters of this type are relatively expensive. The catheter price and the convention of its "one-time-use-only" have an impact on the overall cost of cardiac electrophysiology and ablation procedures.

[0014] Typically, known catheters have a generally cylindrical electrically non-conductive body which has a plurality of spaced annular surface electrodes on the distal end with a hemispherically-shaped tip electrode. Each electrode has a relatively fine electrically conductive wire attached thereto and embedded in the catheter's main body (tube) and extending from the distal end to the proximal end (catheter handle) where the electrical connectors such as plugs or jacks are provided to be plugged into a corresponding sockets provided in recording and monitoring devices.

[0015] Typically, the main body of these catheters comprises a flexible tube constructed from polyurethane, nylon or some other electrically non-conductive flexible material with braided steel wires or other non metallic fibers in its wall as re-enforcing elements. An early example of such construction is that shown and described in U.S. Pat. No. 3,416,531 issued to M. L. Edwards. Catheters of this type are available in two general categories: a) those having a non-deflectable distal portion, an example of which is shown and described in U.S. Pat. No. 3,190,286 issued to R. W. Stokes, and b) those having a deflectable distal portion, as

for example the catheter shown and described in U.S. Pat. No. 3,605,725 issued to I. E. Bentov. The distal portion of deflectable type catheters is typically made from non-braided flexible tube. This portion can be deformed into a variety of curved configurations with different radii of curvature by means of user input to a manual actuator on the catheter handle. The actuator is commonly internally linked to the catheter distal portion or the tip electrode by at least one steel tension or pull wire.

**[0016]** The proximal end of the tension or pull wire(s) is connected to a tensioning or puller mechanism in the handle. The distal end of the tension or pull wire(s) is fixed to the catheter distal electrode or anchored to a point on the catheter distal portion.

**[0017]** Catheters of this type also commonly comprise a flexible guide tube within the main body (tube) for bearing, in longitudinal or axial direction, the thrust or compression reaction of the flexible pull wire(s). An example of this latter type of configuration is shown and described in U.S. Pat. No. 3,906,938 issued to J. J. Fleischhacher and U.S. Pat. No. 3,521,620 issued to W. A. Cook. In the catheters of the prior art, such as those described in the aforesaid Cook and Fleischhacher patents, the inner flexible guide tube is formed by winding a tight coil of spring wire with the adjacent turns in contacting or closed relationship so that the inner guide tube will not compress longitudinally, but is freely flexible in bending. The tension wire(s) slides freely through this guide or coil spring type inner tube. The proximal end of the inner guide tube, in the aforesaid type catheters, is fixed to the catheter handle. The distal end of the inner guide tube is disposed in the distal portion of the catheter tubular main body. In one known catheter construction, one end of a bendable compression strut is seated on the distal end of the inner guide tube; and, the distal end of the pull wire(s) is fixed to the distal end of a bendable strut. Catheters employing such a strut are shown and described in the aforementioned Cook and Fleischhacher patents. See also U.S. Pat. No. 5,108,368 issued to Hammerslag for a catheter with a strut. In such known catheters, as tension is applied to the pull wire by the manual actuator on the catheter handle, the catheter distal portion assumes a curved configuration.

**[0018]** One of the distinctive parts of deflectable distal portion catheters is the pull wire mechanism that is commonly located in the proximal end (handle) of the catheter. This mechanism usually includes a manual actuator by which the catheter distal portion can be deflected. The primary difference among the designs of deflectable distal portion catheters is in the catheter handle, more specifically, the tension or pull wire mechanism. This mechanism transmits the manual force applied to the actuator on the handle to the catheter distal portion via the pull wire(s), for formation of a desirable radius of curvature at the distal portion of the catheter. A catheter employing a partially rotating "wheel" or "cam" mechanism for pull wire(s) is disclosed in U.S. Pat. No. 5,273,535 issued to S. D. Edwards et al. A rectilinearly moving arrangement for the pull wire is disclosed in U.S. Pat. No. 4,960,134 issued to W. W. Webster, Jr. A shapeable or bendable catheter handle for curvature formation on the distal portion of the catheter is disclosed in U.S. Pat. No. 5,318,525 issued to Scott West et al. A rotating collar or thumb-wheel type actuator is disclosed in U.S. Pat. No. 3,416,531, issued to M. L. Edwards.

**[0019]** The primary desirable performance features of the deflectable distal portion catheters are:

**[0020]** Ease of operation: ergonomic design to provide for the best use of physician's hand anatomy for catheter handling and usage;

**[0021]** A relatively low force requirement on the manual actuator of the catheter handle for formation of curvature at the catheter distal portion;

**[0022]** A comfortable range of displacement of the manual actuator to provide for a full range of curvature formation at the distal portion of the catheter; and,

**[0023]** A simultaneous curvature formation and curvature retention at the distal portion of the catheter by a single action of the physician's finger(s).

**[0024]** The above desirable performance features for the catheters with deflectable distal portion have not been met by known commercially available catheters. The catheters of the prior art referenced in this document have not satisfied all of the desirable performance features mentioned above. For example, in the aforesaid U.S. Pat. No. 4,960,134, issued to Webster Jr., the sliding pull wire arrangement does not satisfy the low force requirement on the manual actuator of the catheter handle for formation of curvature at the catheter distal portion.

**[0025]** In the aforesaid U.S. Pat. No. 5,273,535, issued to Edward et al, a catheter is disclosed with two manual actuators on the catheter handle; one actuator is employed for formation of curvature at the distal portion of the catheter; and, the other actuator is used for retention of curvature or locking. This catheter requires two independent manual actions on both actuators in order to form and retain a desirable radius of curvature on the distal portion of the catheter. Therefore, the Catheter of U.S. Pat. No. 5,273,535 (Edwards et al) fails to satisfy a simultaneous curvature formation and curvature retention at the distal portion of the catheter by a single action of the operators hand.

**[0026]** Attempts have been made in the prior art catheters to provide a relatively laterally flexible distal portion for ease of its navigation through the vascular branches of the heart. In U.S. Pat. No. 5,203,772, issued to Gary R. Hammerslag et al, a steerable tip guide wire is disclosed for percutaneous transluminal insertion into the coronary vascular branches. The structure of the guide wire of the '772 Hammerslag et al, catheter comprises a spring coil wherein adjacent loops of the spring coil are "closed" or normally in contact with each other, except the loops that form the deflectable distal portion of the guide wire. The closed or contacting loops and the open or non-contacting loops of the guide wire of the '772 Hamemerslag et al construction provide an axially relatively non-compressible structure in the region of the stacked loops, with a relatively laterally flexible distal portion formed in the region of the open loops.

**[0027]** U.S. Pat. No. 3,521,620 issued to William Cook discloses a similar guide wire structure having contacting and non-contacting portions with a deflectable tip for the same intended use as the aforementioned Hammerslag '772 guide wire.

**[0028]** The cardiac catheters of the prior art are not only expensive but are solely for "one-time-use-only". The cath-

eter price and the convention of "one-time-use-only" increases the overall cost of electrophysiology and ablation procedures.

[0029] Presently employed known methods of cardiac ablation procedure and presently employed known ablation catheters have the disadvantage of requiring an electrically conductive patch on the patient skin during the procedure. The function of this patch is to return the delivered electrical charge, from the catheter electrode inside the heart, to the ablation energy source.

#### BRIEF SUMMARY OF THE INVENTION

[0030] It is an objective of the present invention to provide an electrophysiology catheter with a deflectable distal portion having the following features:

[0031] An ergonomically comfortable range of motion of the manual actuator for a full range of curvature formation at the distal portion of the catheter;

[0032] A low manual force requirement, applied by a single hand of the user, on the handle actuator for formation of curvature at the distal portion of the catheter;

[0033] A simultaneous curvature formation and curvature retention capability at the distal portion of the catheter by a single action of the operator's hand;

[0034] It is another objective of this invention to provide a catheter with a manual actuator on the catheter handle that is operated with the joint actions of index finger and the thumb in order to make the most efficient use of the anatomy of the operator's hand.

[0035] A further objective of this invention is to provide an electrophysiology and/or ablation catheter incorporating a sensor in the catheter handle to detect the longitudinal displacement of the pull/push wires and which can be correlated to the radius of curvature at the distal portion of the catheter for monitoring purposes.

[0036] Another objective of this invention is to provide an electromechanical drive system in the catheter handle to substitute the manual effort for formation of curvature at the distal portion of the catheter. The electromechanical drive system can also be controlled and manipulated via telecommunicated commands. The electromechanical system can also be over-ridden manually in the event of the failure of the drive unit.

[0037] A further objective of this invention is to provide an electrophysiology catheter having a disposable blood contacting portion comprising the catheter main body and electrodes with a deflectable distal segment. A re-useable portion comprising the actuator handle with its associated tip deflecting mechanism which is easily attachable/detachable from the blood contacting portion.

[0038] Another objective of the present invention is to provide an electrophysiology catheter incorporating an extra electrode on the catheter's exterior tube that can be employed as a reference electrode if desired for a uni-polar application of the catheter.

[0039] A further objective of this invention is to provide an electrophysiology catheter having a deflectable distal

portion with a self contained heating element within its distal electrode that can be employed for ablation procedures

[0040] Another objective of this invention is to provide a stand-alone electrophysiology catheter having deflectable distal portion with a self contained heating element within its distal electrode and a self contained power supply in its proximal handle portion that can be employed for cardiac mapping and cardiac ablation procedures.

[0041] A further objective of this invention is to provide an electrophysiology and/or ablation catheter with deflectable distal portion that can easily be manufactured in smallest possible size that can offer desirable bending characteristics at the catheter distal portion.

[0042] A further objective of this invention is to provide an electrophysiology catheter having independent pull/push wire length adjuster units for each pull/push wire in the catheter handle for independent removal of slack from each individual pull/push wire.

[0043] This invention provides a catheter employed for cardiac electrophysiology studies and/or cardiac ablation procedure. The catheter of this invention comprises of two main sub-structures. The first sub-structure is the blood contacting segment that includes: a) the catheter elongated tubular body, and b) the electrodes. The second sub-structure is the mechanism for formation of curvatures at the distal portion of the catheter. This mechanism includes: the catheter handle and its associated components.

[0044] The catheter presented in this invention offers the following desirable features:

[0045] A simultaneous curvature formation and curvature retention at the distal portion of the catheter by a single action of one hand of the user.

[0046] An ergonomic handle for curvature formation at the distal portion of the catheter that makes the most comfortable and efficient use of the user's hand anatomy.

[0047] A sensing unit within the catheter handle to be employed for displaying the radius of curvature at the catheter distal portion.

[0048] In one embodiment of the present invention the blood contacting portion is disposable, i.e. used only once, thereby maintaining all safety and effectiveness requirements, yet the overall catheter use cost is significantly reduced by allowing re-use of the non-blood contacting portions.

[0049] In one embodiment of this invention an ablation catheter with a self-heating element at its distal electrode is disclosed. Ablation with this catheter eliminates the need for a self-adhesive patch on the patient's body.

[0050] In one embodiment of the present invention an additional electrode, that can be employed as a reference electrode, is incorporated in the catheter for enabling uni-polar application of the catheter, thereby eliminating the need for the placement of a second catheter in the patient's heart.

[0051] The present invention offers the following additional attribute:

[0052] An electromechanical battery operated drive system in the catheter handle as an alternative for the manual drive components of the distal portion curvature formation mechanism.

[0053] The present invention utilizes a novel catheter construction which eliminates the compression loading of the inner guide tube and provides design flexibility and economies in construction.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0054] FIG. 1 is a perspective view of the cardiac catheter presented in this invention;

[0055] FIG. 2a is a overall view of the non-blood contacting segments of the catheter of FIG. 1;

[0056] FIG. 2b is an enlarged view of the encircled distal portion of the non-blood contacting segment of the catheter of FIG. 1;

[0057] FIG. 3a is an enlarged cross-section through the axis of inner guide tube of the catheter of FIG. 1;

[0058] FIG. 3b is a left end view of FIG. 3a;

[0059] FIG. 4 Shows a top sectional view of the slider-crank pull/push wire mechanism of the catheter handle of FIG. 1;

[0060] FIG. 5 Shows an exploded view of the slider-crank pull/push wire mechanism of the catheter of FIG. 1;

[0061] FIG. 6a is a plan view of the delta-shaped actuator of the catheter of FIG. 1;

[0062] FIG. 6b is a section view taken along section-indicating line 6b-6b of FIG. 6a;

[0063] FIG. 6c is a right end view of FIG. 6a;

[0064] FIG. 7a Shows an enlarged view of the slider block and the length adjuster of

[0065] the pull/push wire mechanism of the catheter of FIG. 1;

[0066] FIG. 7b is a section view taken along section-indicating lines 7b-7b of FIG. 7a;

[0067] FIG. 7c is a section view taken along section-indicating lines 7c-7c of FIG. 7a;

[0068] FIG. 7d is a section view taken along section-indicating lines 7d-7d of FIG. 7a;

[0069] FIG. 8 Shows a plan sectional view of the catheter handle with the actuator partially rotated counterclockwise, thereby pulling one tension/compression member and pushing the other tension/compression member;

[0070] FIG. 9 Shows a plan sectional view of an alternative embodiment for the catheter handle with a cam-follower mechanism;

[0071] FIG. 10 Shows an enlarged view of the cam-follower mechanism of FIG. 9;

[0072] FIG. 11 Shows a plan sectional view of the catheter handle with the cam-follower mechanism and the actuator

partially rotated counterclockwise, thereby pulling one tension/compression member and pushing the other tension/compression member;

[0073] FIG. 12 Shows a plan sectional view of the cam-follower mechanism with a circular disc actuator;

[0074] FIG. 13 Shows the cam-follower mechanism with a circular disc actuator partially rotated counterclockwise, thereby pulling one tension/compression member and pushing the other tension/compression member;

[0075] FIG. 14 Shows a plan sectional view of a further embodiment of a rack-pinion mechanism of the catheter handle;

[0076] FIG. 15 Shows a plan sectional view of the catheter handle with the rack-pinion mechanism and the actuator partially rotated counterclockwise, thereby pulling one tension/compression member and pushing the other tension/compression member;

[0077] FIG. 16a Shows a plan sectional view of the catheter handle with rack-pinion mechanism having a circular disc actuator;

[0078] FIG. 16b is a view similar to FIG. 16a showing the disk actuator rotated in a counterclockwise direction from the position of FIG. 16a;

[0079] FIG. 17 Shows a perspective view of yet another embodiment of the catheter handle with an electromechanical drive system and associated control components in two main segments 60 and 61;

[0080] FIG. 18 Shows a perspective view of catheter handle of FIG. 17 with the two main segments attached together;

[0081] FIG. 19 Shows a sectional view of the ablation catheter with a heating element within its distal electrode;

[0082] FIG. 20a Shows the blood contacting segment of the partially disposable catheter with a quick attachment/detachment plug;

[0083] FIG. 20b is a view of the non-blood contacting segments of the catheter with a quick attachment/detachment jack;

[0084] FIG. 20c Shows the process of attachment/detachment of the blood contacting and

[0085] non-blood contacting segments of the partially disposable catheter;

[0086] FIG. 20d Shows the segments of FIG. 20c fully assembled;

[0087] FIG. 21 is an enlarged view of the electrical connector of handle 182 of FIGS. 20b and 20c;

[0088] FIG. 22 is an enlarged view of the electrical connector of the disposable blood contacting portion 166 of FIGS. 20a, 20c, and 20d;

[0089] FIG. 23 is an enlarged view of the assembly of the connectors of FIGS. 21 and 22;

[0090] FIG. 24 Shows a perspective view of a cup-shaped distal electrode;



[0091] FIG. 25 Shows a sectional view of the distal portion of the catheter main body and its connection to the cup-shaped distal electrode;

[0092] FIG. 26 is an exploded view of another embodiment of the catheter handle with a Scotch-Yoke mechanism for moving the tension/compression members;

[0093] FIG. 27 is a section view of the assembled mechanism of FIG. 26;

[0094] FIG. 28 is a cross-section similar to FIG. 2b of an alternate embodiment of the non-blood contacting inner guide tube and its associated components;

[0095] FIG. 29 is a view showing the embodiment of FIG. 28 in the deflected condition; and,

[0096] FIG. 30 is a view showing the actuator handle assembly as grasped by the user's hand.

[0097] FIG. 31 is a longitudinal cross-section of the distal portion of another embodiment of the electrophysiology/ablation catheter of the present invention;

[0098] FIG. 32 is an enlarged view of a portion of FIG. 31;

[0099] FIG. 33 is a longitudinal section view similar to FIG. 31 of an alternate embodiment of the invention of FIG. 31;

[0100] FIG. 34 is a section view taken along section indicating lines 34-34 of FIG. 33;

[0101] FIG. 35 is a section view taken along section indicating lines 35-35 of FIG. 33;

[0102] FIG. 36 is a section view taken along section indicating lines 36-36 of FIG. 33;

[0103] FIG. 37 is a section view taken along section indicating lines 37-37 of FIG. 33;

[0104] FIG. 38 is a longitudinal section view of the catheter of FIG. 33 in a modified embodiment with the distal portion thereof undeformed during curvature;

[0105] FIG. 39 is an enlarged view of the distal guide tube of the embodiment of FIGS. 33 and 38;

[0106] FIG. 40 is a longitudinal section of an ablation catheter embodying the present invention and having a self contained power source and temperature control in the handle;

[0107] FIG. 41 is an enlarged detail section view of the distal end of the ablation catheter of FIG. 40;

[0108] FIG. 42 is a view similar to FIG. 40 showing an alternate embodiment of the distal end of the ablation catheter of FIG. 40;

[0109] FIG. 43 is a longitudinal section view of an alternate embodiment of the ablation catheter of FIG. 40;

[0110] FIG. 44 is an enlarged section view of the proximal end of the catheter of the present invention illustrating the attachment of the tension/compression members to the sliders;

[0111] FIG. 45 is a longitudinal section view of an embodiment of the invention employing a self positioning friction brake for the actuator of the handle;

[0112] FIG. 46 is a view similar to FIG. 45 showing the actuator in a position for causing curvature at the distal portion of the catheter;

[0113] FIG. 47 is a schematic view of the sliders of the handle of the present invention showing a displacement transducer;

[0114] FIG. 48 is a perspective view of the catheter of the present invention employing a collar thereon for enabling user to apply torque to the braided outer casing tube of the catheter;

[0115] FIG. 49 is a view of the components prior to commencing assembly of the annular electrodes at the distal portion of the catheter;

[0116] FIG. 50 is a view of the first step of assembly of the annular electrodes;

[0117] FIG. 51 is a view of the step subsequent to the step of FIG. 50;

[0118] FIG. 52 indicates a further step from the assembly of FIG. 51;

[0119] FIG. 53 indicates a subsequent step from FIG. 52;

[0120] FIG. 54 indicates the final step in assembling annular electrodes onto the catheter casing;

[0121] FIG. 55 is a schematic for the temperature control of the ablation catheter of FIG. 40;

[0122] FIG. 56 is a longitudinal section view of the positioning brake for the actuator of the handle of the catheter;

[0123] FIG. 57 is an enlarged view of a portion of FIG. 56;

[0124] FIG. 58 is an exploded view of the embodiment of FIG. 33

#### DETAILED DESCRIPTION OF THE INVENTION

[0125] Referring now to the drawings, which are not intended to limit the invention, FIG. 1 illustrates a perspective view of one embodiment of the catheter assembly including the elongated flexible main body indicated generally at 1. The catheter of this invention is comprised of two main components: i) a blood contacting segment that includes the catheter elongated exterior tubular body 2 with a plurality of spaced electrodes 3 and a distal electrode 5; and ii) a sub-assembly comprising the actuator mechanism for affecting the catheter distal curvature which includes a catheter handle and its associated components which is indicated generally at 4. The blood contacting segment 2 comprises of an elongated cylindrical electrically non-conducting preferably braided main exterior tube 2 with a plurality of spaced annular surface electrodes 3 on its distal portion and a hemispherically shaped solid or hollow cup-shaped distal electrode 5. The distal portion of the catheter denoted by the reference character "L" is a non-braided tube that is significantly more flexible or softer than the rest of main exterior tube 2. Each of the electrodes 3,5 has a fine electrical conductor wire 6 attached thereto, which extends within the length of the catheter and through handle 4 and

outwardly to a corresponding one of the plugs/jacks 8 disposed at the proximal end of the catheter handle sub-assembly 4.

[0126] FIG. 2a shows the catheter assembly 1 of the present invention with the tubular body 2 removed, thereby exposing the non-blood contacting segment of the catheter generally denoted by reference numeral 9.

[0127] When the first sub-structure 2 is assembled over the inner guide tube 9 of the catheter handle 4, the distal portion 10 of the inner guide tube 9 is situated or disposed in the distal non-braided portion of the catheter exterior tube 2. The catheter distal portion L of FIG. 1 assumes the same curved configurations as that of the distal portion 10 of the inner guide tube 9 in response to the user manipulations of the actuator 18 on the catheter handle 4.

[0128] Referring to FIGS. 2a and 2b the non-blood contacting segment of the catheter of this invention includes:

- [0129] an inner guide tube indicated generally at 9,
- [0130] a pair of tension/compression members 11,12 comprising flattened portions 11' and 12',
- [0131] a catheter handle 4,
- [0132] and a plurality of electrical plugs 8

[0133] Referring to FIG. 2b, the entire length of the inner guide tube 9 and its distal portion along the length 10 is disposed within the tubular body 2 of FIG. 1. FIGS. 3a and 3b show the area of FIG. 2b in further enlargement wherein the inner guide tube 9 is a flexible body made from spring wire in the region denoted by reference numeral 14; and, is preferably formed as a tightly wound spring with adjacent coils contacting or closed windings. The inner guide tube 9 has disposed therein at least two tension/compression members in the form of wires 11 and 12. The tension/compression members 11, 12 have a generally circular cross-section and extend preferably along the length of the elongated inner guide tube 9 and have a generally flattened ribbon-like configuration 11', 12' in the region 10 of guide tube 9. The inner guide tube 9 is formed to have generally circular cross-section. The windings of the distal portion 10 of the inner guide tube 9 are permanently stretched or wound in the opened condition to provide an easily bendable structure.

[0134] FIG. 4 shows an enlarged sectional view of the pull/push mechanism of the catheter handle 4. The proximal end of the inner guide tube 9 is seated on the catheter handle nose 15 which is attached to an end of block or body 113 of handle 4. The tension/compression members 11 and 12 are each fixed at one end to the distal end of the guide tube 9 in the region 10. The other end of each of the tension/compression members 11 and 12 is attached to one of the pull/push length adjuster units 16 and 17 which are slidably mounted in grooves or slots 114, 115 mounted in block 113. With this arrangement, the distal portion 10 of the inner guide tube 9 can be formed into a curved configuration by user movement of the manual actuator member 18 in either transverse direction as indicated by the dashed outline in FIG. 4 about pivot pin 19 by which actuator 18 is mounted to block 113 in a through-slot 116.

[0135] FIG. 5 shows an exploded view of the pull/push mechanism removed from the catheter handle block 113. Upon movement of actuator 18 the mechanism 4 is operative

for applying tension to one of the tension/compression members 11, 12, and thereby affecting curvature formation at the distal portion L of the catheter of this invention. In one embodiment, this pull/push mechanism comprises two symmetrically coupled slider-crank linkages, hereinafter described, that share the actuator member 18 which is preferably formed into a circular segment or delta shape with a hollowed out portion 115 formed therearound.

[0136] Referring to FIGS. 4 and 5, the actuator 18 is disposed freely within slot 116 of the handle block 113. The proximal apex of this actuator 18 is hinged within the proximal front end of the handle housing block 113 by a pin 19 received through aperture 117 in actuator 18. A pair of connecting rods 20 and 21 are received in the hollowed-out portion 115 formed in actuator 18 and are independently and symmetrically hinged each at one end through aperture 120, 121 respectively to the actuator 18 by pins 22 and 23 respectively, received through aperture 118, 119 formed in actuator 18. The opposite ends of the connecting rods 20 and 21 are each independently hinged each to an end of two separate and identical slider links 16 and 17 by pins 26 and 27 respectively. Pin 26 is received in aperture 122 in slider 16, with pin 26 passing through aperture 123 in rod 20; and, pin 27 is received in aperture 124 in slider 17, and pin 27 passes through aperture 125 in rod 21. The end of rod 20 pivoted by pin 26 is received and articulated in a slot 126 formed in slider 16; and, the end of rod 21 pivoted about pin 27, is received and articulated in a slot 127 formed in slider 17.

[0137] Referring to FIGS. 4 and 5 the slider links 16 and 17 each contain a pull/push member length adjuster unit indicated generally at 24 and 25 respectively.

[0138] Referring to FIGS. 4, 6b, and 6c, one of the pull/push or tension/compression members 12 is shown as extending through hollow 115 in actuator 18 and is connected to slider 17; and, pull/push member 11 extends through hollow or slot 115 and is connected to slider 16.

[0139] Referring to FIGS. 7a 7b, 7c, and 7d, one of the slider blocks 16 is illustrated with its associated pull/push member length adjuster unit 24 and its sub-components. The pull/push member length adjuster 24 is disposed in a slider block 16 having a longitudinally extending blind cylindrical cavity 28.

[0140] A generally cylindrical rod or adjusting member indicated generally at 24 with an internally threaded hole or bore 32 formed in the right end thereof is slidably disposed freely within the cavity 28 formed therein. The longitudinal position of rod 24 with respect to the slider block 16 can be adjusted by the adjusting screw 34 threaded into bore 32. A pull/push member fastener 36 fixes the proximal end of a pull/push member 12 (not shown in FIGS. 7a-7d) to rod 24. FIG. 7d shows an enlarged view of the typical hinged attachment between one end of the connecting rod 20 and slider block 16 by pin 26. The function of each individual and independent pull/push member length adjusters such as adjuster 24 is to independently remove the slack from the corresponding pull/push member 11, 12 that extends from catheter distal portion to the catheter handle 4.

[0141] Referring to FIG. 8, actuator member 18 is shown in solid outline and moved counterclockwise from the neutral position of FIGS. 1 and 4. In the position shown in

**FIG. 8**, rod **20** has moved slider **16** rightward pulling on tension/compression member **12**. Rod **21** has moved slider **17** leftward pushing on member **11**. The distal portion of the catheter of this invention can simultaneously be curved to different radii of curvature and retained at the desired curvature by a single action of the operator's finger. The slider-crank pull/push mechanism of the catheter handle of this invention operates near its "top-dead-center" or aligned position. An inherent property of a slider-crank mechanism operating near its top-dead-center position is a high-gain force amplification between the input force on the crank link or actuator **18**, and the output force on the slider link. Therefore, catheter of this invention requires a low actuating force on the actuator **18**, transmitted through the crank link, for assuming a full range of pull on one of the members **11**, **12** for affecting curvature at the distal portion of the catheter. Any curvature formed at the catheter distal portion by this mechanism will retain its configuration. This is because the elastic potential energy stored in the deflected distal portion of the catheter cannot provide a sufficient pull on the tensioned members **11** or **12** as the case may be to move the crank link and thus actuator **18** to disturb the assumed configuration of the slider-crank mechanism which is near the "top-dead-center".

[0142] The geometric shape and dimensions of the delta-shaped actuator **18** are designed to comfortably fit between the thumb and index fingers of an operator's hand. The relative magnitudes of these geometric dimensions, crank length (distance between pin **19** and pins **22**, **23**) and the length of the connecting rods **20** and **21** are determined such that a comfortable range of actuator **18** rotation in two opposite directions results in formation of the full range of curvature, in opposite directions, at the distal portion of the catheter. It will be understood that rotation of actuator **18** in one direction is affected by the user's thumb of the hand grasping the handle **113**; and, rotation of actuator **18** in the opposite direction is affected by at least one other finger of the same grasping hand.

[0143] Referring to **FIG. 8** the rotation of link **18** in a counterclockwise direction to the position shown in solid outline has caused the rectilinear displacements of slider blocks **16** and **17** in two opposite directions, i.e. slider **17** has moved to the left and slider **16** has moved to the right. The movement of actuator **18** by the user to the position shown in solid outline **FIG. 8** affects formation of a curvature in a counterclockwise direction, at the distal portion of the catheter, as the result of tension in the pull/push member **12**. It will be understood that a clockwise curvature formation can be achieved at the distal portion of the catheter when the manual actuator **18** is rotated in a clockwise direction to the position shown in dashed outline in **FIG. 8** which causes slider block **16** to be moved to the left and slider block **17** to be moved to the right when links or rods **21**, **20** are moved to the positions shown respectively in dashed line.

[0144] Referring to **FIGS. 9, 10, 11, 12**, and **13** an alternative embodiment **4'** of the catheter handle is shown with a cam-follower type pull/push mechanism for affecting formation of curvature at the distal portion of the catheter upon movement of actuator **128**. The pivoted delta shaped actuator **128** is disposed to pivot freely about pin **43** within the handle **113'**.

[0145] Referring to **FIG. 10**, the mechanism of handle **4'** comprises two symmetrically coupled followers **40** and **41**

disposed for sliding movement on block **113'** and with a single rotating cam **42** as the driver. The cam **42** is rigidly attached to the apex of the delta-shaped actuator **128** for rotation therewith. The center **44** of cam **42** is pivoted within the catheter handle body **113'** about a pin **43**.

[0146] The two sliding followers **40** and **41** are driven by cam **42**. Each of the sliding followers **40** and **41** includes an adjusting screw **45** and **46** respectively. The tip of each of these adjusting screws **45**, **46** are anchored to the cam profile and provides the contacting point between the followers **40** and **41** and the profile of the cam **42**. The distal ends of pull/push members **11** and **12** are individually fastened to the corresponding followers **40** and **41** respectively by the screws **47**, **48** threaded respectively into followers **41**, **40**. The slack in each pull/push member can independently be removed by adjusting the screws **47** and/or **48**.

[0147] Each of the two followers **40** and **41** slides freely, in one of the straight grooves **49** and **50** respectively, provided in the catheter handle **113'**.

[0148] Referring to **FIG. 11** the actuator member **128** is shown rotated counterclockwise from the position shown in **FIG. 10**, wherein cam **42** has caused rectilinear displacements of the two followers **40** and **41** in opposite directions. Follower **40** has been moved rightward tensioning pull/push member **12**; and follower **41** has been moved leftward pushing on pull/push member **11**. This movement of followers **40**, **41** results in formation of a curvature, in a counterclockwise direction, at the distal portion of the catheter. It will be understood that a clockwise curvature formation can be achieved at the distal portion of the catheter when the manual actuator **128** is rotated in a clockwise direction to the position shown in dashed outline in **FIG. 11**.

[0149] Referring to **FIG. 12** an alternative arrangement of the actuator handle is shown generally at **4''**, having a handle **113''** and wherein the user actuator member comprises a circular disk-shaped actuator **51** which is attached to cam **42** in a torque-transmitting arrangement. Cam **42** is shown in the neutral position in **FIG. 12**. It will be understood that user rotation of actuator disk **51** rotates cam **42**.

[0150] Referring to **FIG. 13**, the actuator disk **51** has been rotated in a counterclockwise direction as indicated by the arrow to place cam **42** in the position shown in solid outline in **FIG. 13**. In **FIG. 13**, follower **40** has been moved rightward from the position of **FIG. 12**, tensioning or pulling member **12**; and follower **41** has been moved leftward from the **FIG. 12** position, resulting in pushing on member **11**.

[0151] Referring to **FIG. 14** a further alternative embodiment of the actuator handle is shown generally at **4'''** for the catheter of this invention wherein handle or body **130** has a groove or through-slot **132** with a pair of parallel oppositely disposed sliders **134**, **136**, disposed therein, each having a rack gear formed thereon as denoted respectively by reference numerals **138**, **140**. Rack gears **138**, **140** are engaged on opposite sides of a common pinion gear **142**. Pinion **142** rotates freely within the catheter handle **130** about pin **144** secured through body **130**. Each slider **134**, **136** includes a pull/push member anchoring or attachment screw **146**, **148** to which one end of pull/push members **11**, **12** are attached respectively. The apex of a delta-shaped manual actuator

**150** is fixed to the pinion **142** in torque transmitting arrangement and is shown in the neutral position in **FIG. 14**.

[0152] Referring to **FIG. 15** the manual actuator **150** is shown rotated counterclockwise from the position of **FIG. 14**, resulting in the rectilinear displacements of the slider **136** to the left and slider **134** to the right, pulling on pull/push member **12** and pushing on pull/push member **11**. The proximal ends of the pull/push member **11** and **12** are fixed to the sliders **136**, **134** respectively by fasteners such as screws **146** and **148**. It will be understood that the distal end of the pull/push members **11** and **12** are fixed to the distal ends of the elongated inner guide tube **9**. It will be also understood that the actuator **150** may also be moved in the clockwise direction to the position shown in dashed outline in **FIG. 15**, resulting in opposite movement of slider **134**, **136**. With either counterclockwise or clockwise rotations of actuator **150** the rectilinear displacement of the slider racks **134**, **136** is in opposite directions and results in formation of curvature at the distal portion of the catheter.

[0153] Referring to **FIG. 16(a)**, another embodiment of the actuator handle is indicated generally at **4'''**, wherein pinion gear **142** is attached to a circular actuator **152** in torque transmitting arrangement.

[0154] Referring to **FIG. 16(b)**, as the user rotates actuator disk **152** in a counterclockwise direction as shown by the arrow slider **136** is moved leftward, and slider **134** is moved rightward from the neutral position shown in **FIG. 16(a)**.

[0155] Referring to **FIG. 17**, another alternative embodiment has the handle assembly that is indicated generally at **154**. Handle assembly **154** includes an electromechanical battery operated drive system that is substituted for the manually actuated pull/push mechanism of the embodiments **4-4'''**. The embodiment **154** comprises two main subsystems indicated generally at **60** and **61**. The first sub-system **60** of the embodiment **154** is the "lower" portion of the catheter handle that includes:

- [0156] a cylindrical housing **62**, having disposed therein a battery **63**;
- [0157] an electrical motor **64**, which is connected to battery **63** disposed at the right hand end of housing **62**;
- [0158] a speed reduction gear box **65**, driven by motor shaft **156**, and which has an output drive shaft **66**;
- [0159] a multi connector junction plug **67** is disposed on the front end of the housing **62**; and,
- [0160] an electronic module **68** is provided on this end of housing **62** adjacent to battery **63** for receiving computer and/or tele-communication signals. Battery **63** can either be disposable or re-chargeable.

[0161] The second sub-system **61** has a multi connector proximal end jack **69** disposed in the right hand end of housing **73**. All electrical wires of the catheter, including the electrode conductors are terminated to the terminals (not shown) of jack **69**. The corresponding electrical leads of sub-system **60** are terminated at terminals (not shown) of plug **67**.

[0162] The electrical motor **64** and motor speed reduction gear box **65** are disposed within the cylindrical housing **60**

adjacent the left hand end. The coupling drive shaft **66** extends from the gear box **65** through a cylindrical collar **70** in the left end of the housing **62**. The drive shaft **66** can freely rotate within the front end collar **70** of the housing **62**. The end of the drive shaft **66** is coupled to the left hand end **71** of the core **72** of the sub-system **61**. In operation either clockwise or counterclockwise rotation of the drive shaft **66** results in driving core mechanism **72** and a corresponding curvature formation respectively at the catheter distal portion.

[0163] The second sub-system **61** of the embodiment **154** comprises the front or left hand portion of the catheter handle end and includes:

- [0164] a cylindrical housing **73**;
- [0165] a manual back-up actuator **74** in the form of a tubular member disposed concentrically over housing **73**;
- [0166] a motor control switch **75**;
- [0167] the multi connector junction jack **69** is disposed inside the right hand end of the cylindrical housing **73**;
- [0168] a connecting rod or pin **76** interconnects manual drive actuator **74** to core **72** through a slot **82** formed in housing **73**;
- [0169] a front bearing support **77** is disposed in housing **73** adjacent the left end thereof;
- [0170] a rear bearing support **78** is disposed in housing **73** adjacent the right hand end thereof; and,
- [0171] an angular displacement sensor **79** is disposed in housing **73** and located at the right hand end thereof for sensing rotation of core **72** with respect to housing **73** of sub-system **61**.

[0172] The core **72** of sub-system **61** includes two identical pull/push member length adjusters **158**, **160** which are each respectively connected to one of the pull/push members **11**, **12** of the catheter **1**. These adjusters are disposed, side-by-side, and parallel to the longitudinal axis of the housing **73**, within and near the surface of the cylindrical solid portion of the core **72**. The core **72** of the sub-system **61** has a left end shaft **80** extending therefrom and a right end shaft **81** extending therefrom in a direction opposite shaft **80** and aligned therewith. Shaft **80**, **81** are supported by rotary bearings **77** and **78** respectively disposed in housing **73**; and thus, the core **72** can freely rotate within the housing **73** about its longitudinal axis.

[0173] A backup manual actuator **74** comprises a short cylindrical tube that is disposed over the front portion of the housing **73** and can freely rotate about the longitudinal axis of the housing **73**. An actuator slot **82**, extending circumferentially and perpendicular to the longitudinal axis of housing **73**, is provided on the upper half of the housing **73**. The backup manual actuator **74** is linked to the front portion of the core **72** with connecting rod or pin **76** through slot **82**. The width of the slot **82** is chosen to guide but permit free movement of pin **76**. The core **72** can thus be rotated about its longitudinal axis with respect to housing **73** of sub-system **61** by the rotation of the backup manual actuator about the same axis.

[0174] It will be understood that the proximal end of each pull/push member 11 and 12 is fastened to a corresponding one of the pull/push member length adjusters 158, 160 by screws 162, 164 respectively.

[0175] Rotation of core 72 about its longitudinal axis will pull one of the pull/push members 11 or 12, and compresses the other one, resulting in formation of curvature at the distal portion of the catheter 1.

[0176] The multi connector junction jack 69 and multi connector junction plug 67 serve as both the mechanical and electrical coupling between the sub-systems 60 and 61.

[0177] When sub-systems 60 is connected to sub-system 61, the left end of the drive shaft 66 is engaged with the right hand end of core 72. The motor can be energized and controlled for forward and reverse rotation by a switch 75 provided on the exterior of housing 73. As the motor 64 is activated, the drive shaft 66 will rotate the core 72 which results in formation of curvature at the distal portion of the catheter. Angular displacement sensor 79, disposed in the housing 61, is employed to provide predetermined limits for the angular rotation of core 72 as an indication of the radius of curvature at the distal portion of the catheter. The actuator or servomotor driven cardiac catheter handle 154 of FIG. 17 can also be controlled remotely via computer and/or telecommunication systems and thus has application for various other cardiac catheter procedures.

[0178] Referring to FIG. 18 the servomotor operated electromechanical catheter handle 154 is shown as a complete assembly with its two subassemblies 60 and 61 connected together with plug 67 engaging jack 69 as shown in dashed line.

[0179] Referring to FIG. 19 the distal portion of a further embodiment of the catheter of this invention indicated generally at 170 and is shown in the curved condition. The embodiment of FIG. 19 is configured such that it can be employed for cardiac ablation and intra-cardiac mapping procedures.

[0180] This embodiment indicated generally at 170 in FIG. 19 is a modified version of the catheter 1 presented in FIG. 1 of this invention. The modification is applied on the catheter distal tip electrode 5 of the FIG. 1 embodiment and is described as follows.

[0181] Referring to FIG. 19 an electrical heating element 100 is disposed within the distal tip cup-shaped electrode 172. The heating element 100 is energized by a battery disposed in the catheter handle 4 or by an external electrical power supply (not shown). The temperature of the distal electrode is controlled by adjusting the electrical current flow through the heating element 100. Electrical lead wires 101 and 102 are connected to the heating element 100 and extend from the heating element 100 within the interior of tubular body 2 to the proximal end and outwardly to the power supply and temperature control switch (not shown).

[0182] The embodiment 170 includes an additional annular reference electrode 103 on the catheter main exterior tube 2 for a uni-polar application of the catheter during intra-cardiac mapping procedures. In addition, the catheter 170 may include a blood-clot sensor or detector (not shown) and a temperature indicator (not shown) in the catheter handle 4.

The purpose of blood clot sensor is to stop or reduce the delivery of electrical energy to the heating element during ablation procedures.

[0183] Referring to FIGS. 20a through 20d a further embodiment 180 of the catheter of the present invention is illustrated and has the feature that the blood contacting portions are disposable; and, thus, the embodiment 180 is particularly suitable for cardiac electrophysiology/ablation procedures. The embodiment 180 is a modified version of the catheter presented in FIG. 1 of this invention. The modification is applied in two parts. The first modification pertains to the shape of the distal tip electrode 176 and its connection to the main exterior tube 172 of the catheter which, along with a proximal end connector 181 having internal connector rings 188 comprises the blood contacting components or sub-assembly indicated generally at 166. The second modification involves the method of connecting the subassembly 166 of blood contacting components i.e. a main exterior tube 172, spaced electrodes 174 and distal electrode 176 to the non-blood contacting components indicated generally at 168 comprising an inner guide tube 178 and catheter handle indicated generally at 182.

[0184] The first modification is illustrated in FIG. 20a. FIG. 24 shows the modified distal electrode 176 employed in the FIG. 20a embodiment as having a cup-shaped configuration. The distal electrode 176 is formed as a cylindrical shell with a hemispheric dome 110 on the closed end and a plurality, preferably four, of circumferentially spaced prongs 111 extend outwardly in an axial direction from the other open end of the cup-shaped distal electrode 176.

[0185] Referring to FIG. 25 the cup-shaped electrode 176 is sleeved partially over the distal portion of the main exterior tube 172 of the catheter. The prongs 111 are bent inwardly perforating the wall of the main exterior tube 172, extending inwardly and again bent over the inner wall of the main exterior tube 172 to form a "stapled-type" connection between the cup-shaped distal electrode 176 and the main exterior tube 172. At least one wire 112 is wrapped around one of the prongs 111 and secured to the inner wall of the main exterior tube 172 to provide electrical connection to electrode 176 and also provides a redundant securement to tube 172.

[0186] Referring to FIGS. 20a-20d, the second modification for the disposable catheter 180 is described as follows. The two sub-assemblies, namely the blood contacting sub-assembly 166 and non-blood contacting sub-assembly 168 of catheter 180 of this invention are individually fabricated such that they can function independently as intended.

[0187] Referring to FIG. 20a, the first sub-assembly or blood contacting unit 166 of this embodiment 180 comprises of the main exterior tube 172 of the catheter, the spaced surface electrodes 174 and distal electrode 176, the electrical wires of the surface electrodes and the combined electric coupling and structural connector 181. All electrical wires of the catheter tip electrodes 174, 176 terminate to the coupling 181.

[0188] Referring to FIG. 20b the second non-blood contacting sub-assembly 168 of embodiment 180 is illustrated. Second sub-assembly 168 comprises the inner guide tube 178, a combination electrical connector and structural coupling 183, a catheter handle indicated generally at 182 and

catheter electrical lead connector end plugs **184**. The non blood contacting sub-assembly **168** can readily be coupled to the blood contacting subassembly **166**; and, the two can be locked together by the couplings **181** and **183** which may be threaded or quick-lock type to form an assembly **180** that can function as a complete catheter.

[0189] Referring to **FIG. 20c** the coupling of the two sub-assemblies of the catheter of this invention is shown with guide inner tube **178** of subassembly **168** partially inserted into tubular casing **172** of sub-assembly **166**. The coupling action of the two sub-assemblies **166, 168** can also be done during the cardiac electrophysiology/ablation procedures by the physician. This allows the physician to select from variety of second non-blood contacting actuator sub-assemblies **168** that offer different distal portion curvature configurations for the same blood contacting sub-assembly **166**. In the embodiment **180**, the disposable segment of the catheter comprises only the blood contacting sub-assembly **166** shown respectively in **FIG. 20a**.

[0190] Referring to **FIG. 20d**, the catheter of embodiment **180** is fully assembled with connector **181** engaged with connector **183**. It will be understood that the electrical lead from each of the electrodes **174, 176** is connected to one of the electrical terminal rings **186** on connector **183**. Each of the rings **186** makes electrical contact with a correspondingly located terminal annular **188** provided in connector **181** of sub-assembly **166**.

[0191] The catheter of this embodiment **180** can thus significantly reduce the price of cardiac catheters and thus an overall cost reduction of the cardiac electrophysiology and ablation procedures.

[0192] Referring to **FIG. 21** the external electrical connector **186** of actuator handle sub-assembly **182** of **FIGS. 20b, 20c, and 20d** is shown where each of the electrical connector **186** has an end of one of the lead wires **230, 232, 234, 236**, attached thereto. It will be understood that each of the leads **230-236** has its opposite end connected to one of the connectors **184** externally of handle **182**.

[0193] Referring to **FIG. 22** the electrical connector **181** of disposable blood contacting subassembly **180** of **FIGS. 20a, 20c, and 20d** is shown enlarged with an internal tubular sheath or liner **238** defining an annular space **240** between liner **238** and the body of connector **181**. The proximal end of the main exterior tube **172** is received and retained, as for example by weldment into a reduced diameter neck **242** formed on connector body **181**. Liner **238** has a reduced diameter neck **243** which extends a predetermined distance into main exterior tube **172**. A plurality of axially spaced electrical terminals **244, 246, 248, 250** are disposed on the inner periphery of liner **238** with each of its terminals **244-250** having portions thereof extending outwardly through the wall of liner **238** and into the annular space **240**. A plurality of electrical leads **252, 254, 256, 258** is received in the annular space **240** and each has respectively one end thereof connected to one of the terminals **244-250**. Each of the leads **252-258** extends through annular space between liner **238** and the inner periphery of main exterior tube **172** and continues to the distal portion of tube **172**. It will be understood that each of the leads **252-258** is respectively connected to one of the electrodes **174, 176** on the blood contacting sub-assembly **166**.

[0194] Referring to **FIG. 23**, connectors **181, 183** are shown assembled with the ring. electrical connectors **186** of

connector **183** each making contact with one of the connector terminals **244-250** for providing electrical continuity between electrical leads pairs **230** and **254, 232** and **252, 234** and **256, 236** and **258** thereby connecting each of the external connectors **184** with one of the electrodes **176, 174** on the distal portion of the disposable blood contacting subassembly **166**.

[0195] Referring to **FIG. 26** an alternative embodiment indicated generally at **190** of the catheter handle sub-assembly is shown in exploded view without the handle body with a Scotch-Yoke type pull/push mechanism for affecting formation of curvature at the distal portion of the catheter upon movement of the actuator member **192**. The preferably delta shaped actuator **192** is disposed to pivot freely about pin **194** within the handle's body (not shown). It will be understood that member **192** may be disposed for pivoting in a handle slot in a manner similar to actuator member **18** of **FIG. 1**.

[0196] Referring to **FIGS. 26 and 27**, the mechanism of handle **190** comprises two symmetrically coupled sliders **196** and **198** disposed for sliding movement in groove **200** formed in handle body **202** and with the single rotating actuator **192** as the driver thereof. The sliders **196** and **198** are linked to the delta-shaped actuator **192** by non-articulating pins or links **204** and **206**.

[0197] Referring to **FIG. 26** pins or links **204, 206** are formed generally at a right angle at one end, with the ends each received in a transverse bore provided in the side of sliders **196, 198** with links **204, 206** extending from sliders **196, 198** outwardly in the direction of sliding movement. The opposite or free ends of links **204, 206** are also formed at right angles in a common direction orthogonal to the links-receiving bores in the sliders **196, 198** and as denoted by reference numerals **208, 210**. The links **204, 206** are thus non-articulatable in a center plane passing through both sliders **196, 198**.

[0198] The actuator **192** has a pair of spaced slots **212, 214** elongated in a direction transverse to delta-shaped actuator **192**. Link end **208** is received in slot **212**; and, link end **210** is received in slot **214**. It will be understood that user movement of the actuator **192** in the direction of the block arrows in **FIG. 26** will cause relative movement of the link ends into slots **212, 214** and will result in pulling one and pushing the other of the sliders **196, 198** in groove **200** of body **202**.

[0199] The proximal ends of tension/compression (pull/push) members **11** and **12** are individually received in a closely fitting tubular sleeve denoted respectively **216, 218** which are in turn received individually in a longitudinal bore denoted respectively **220, 224** provided in each of the sliders **196, 198**. The sleeves **216, 218** may be secured to pull/push members **11, 12** respectively by weldment if desired, as, for example by soldering or brazing. The sleeves **216, 218** and the proximal ends of members **11, 12** are secured respectively in slider bores **220, 224** by engagement with set screws torqued into threaded cross holes provided in sliders **196, 198**, one such cross hole is visible in **FIG. 26** at **230**.

[0200] Each of the two sliders **196** and **198** slides freely, in the straight groove **200** provided in the catheter handle **202**.

[0201] Referring to **FIG. 27** the actuator member is shown rotated counterclockwise from the position shown in **FIG.**

26, wherein actuator 192 has caused rectilinear displacements of the two sliders 196 and 198 in opposite directions. Slider 196 has been moved leftward pushing member 11; and slider 198 has been moved rightward pulling member 12. This movement of sliders 196, 198 results in formation of a curvature, in a counterclockwise direction, at the distal portion of the catheter. It will be understood that a clockwise curvature formation can be achieved at the distal portion of the catheter when the manual actuator 192 is rotated in a clockwise direction to the position shown in dashed outline in FIG. 27.

[0202] Referring to FIGS. 28 and 29, an alternative preferred embodiment of the non-blood contacting actuator 168 of FIG. 20b is shown generally at 260 with an inner guide tube 262 formed of helically wound wire similar to inner guide tube 178 of FIG. 20b. The distal end of inner guide tube 262 has a tip plug or member 264 attached securely thereto, such as by weldment. A pair of pull/push or tension/compression members 268, 266 are received in tube 260, with a portion of each denoted 266', 268' integrally flattened to a ribbon-like configuration, with the end of each ribbon secured to tip 264 as by weldment. A guide bushing 270 has a rectangular through bore 271 formed therein has the ribbons 266', 268' slidably received therein, with guide bushing 270 adjacent to the proximal end of ribbon-like portions 266', 268'. The guide bushing 270 is secured, such as by weldment, to the distal end of the inner guide tube 261 with contacting coils (closed windings).

[0203] An annular collar or sleeve member 272 is received over ribbon-like portions 266', 268' and serves as a kinematic junction of the ends of 266', 268'. The collar 272 is secured, such as by weldment, to both ribbons 266', 268' at a predetermined distance between the guide bushing 270 and tip plug 264. The actuator 260 is shown in relaxed or neutral condition in FIG. 28.

[0204] Referring to FIG. 29, tension has been applied to member 266 causing ribbon 266' to pull on collar 272 bending the 262 between guide bushing 270 and collar 272; however the portion of tube 262 between collar 272 and tip 264 remains straight or un-deflected.

[0205] It will be understood that the inner guide tube 261 of FIG. 29 or 9 of FIG. 3a of the present invention is not loaded in compression when one of the members 266, 268 of FIG. 29 or 11, 12 of FIG. 3a is tensioned. Unlike the known catheters, the catheter of the present invention transmits the compression loading of the kinematic junction directly to the one of push/pull members 266, 268 of FIG. 29 that is not being tensioned by the manual actuator and does not use a separate compression strut member to transmit compression load to the inner guide tube as in the case of known catheters. It will be understood that in the embodiment of FIGS. 28 and 29 the kinematic junction comprises of the weldment of collar 272 to 266', 268'; and in the embodiment of FIG. 3a the kinematic junction comprises the attachment of the pull/push or tension/compression members 11', 12' to the distal end of portion 10 of inner guide tube 9.

[0206] The present invention thus provides a low cost cardiac catheter which has a disposable blood-contacting segment removable from the actuator assembly which is re-useable. The actuator utilizes a pair of tension/compression members which are flattened integrally at the distal end

region for improved deflection characteristics. The actuator handle is grasped in the user's hand and catheter distal region deflection in one direction is affected by movement of a handle actuator member in one direction by the user's thumb; and catheter deflection in the opposite direction is affected by movement of the handle actuator member in the opposite direction by the other finger(s) of the same hand.

[0207] FIG. 30 is a view showing the actuator handle assembly as grasped by the user's hand.

[0208] Referring to FIGS. 31 and 32, another embodiment of the catheter of the invention is indicated generally at 300 and has a solid distal electrode that in the present practice of the invention has been formed satisfactorily from platinum material and is denoted by reference numeral 302. The electrode 302 has the distal ends of a pair of tension/compression members 304, 306 secured therein as for example by weldment which in the present practice of the invention comprises a brazed joint 308. It will be understood that the distal portions of the tension/compression members 304, 306 have a generally flattened rectangular transverse cross-sections as illustrated in FIG. 32.

[0209] A spacer means 310 is disposed between the flattened ends of tension/compression members 304, 306 in the present practice of the invention. The spacer means 310 comprises a wave-shaped flat spring having a generally rectangular transverse cross-section with an end thereof secured between the tension/compression members 304, 306 in a kinematic junction indicated generally at 312. The kinematic junction 312 is formed by a sleeve 314 which in the present practice of the invention is formed of stainless steel tubing received over the tension/compression members at the kinematic junction having the end of the wave-shaped spring 310 and is secured and formed by weldment which in the present practice of the invention comprises brazing as denoted by reference numeral 316. It will be understood that the spacer 310 serves only to maintain the transverse or lateral spacing of the tension/compression members 304, 306 on the side of kinematic junction 312 away from the distal electrode 302. It will be understood that except for the end of spacer 310 which is brazed into sleeve 314, the wave-shaped flat spring 310 is otherwise free-floating between the tension/compression members 304, 306.

[0210] It will be understood that the tension/compression members' transition to a round or wire-like configuration is denoted by reference numerals 304', 306' in a manner similar to the embodiment of FIGS. 2b and 3a of the present invention. In the embodiment of FIGS. 31 and 32, a thin wall plastic tubing 318 is received over the distal flattened portions of the tension/compression members 304, 306 and the plastic tube is received over, in closely fitting engagement, an annular sleeve or collar 320 secured to the weldment or brazed joint of the distal electrode. In the present practice of the invention, the collar 320 is formed of stainless steel material. The plastic tube 318 extends over the round cross-section portions 304', 306' of the tension/compression members; and, the tube 318 also extends over the distal end of an inner guide tube 322 which in the present practice of the invention comprises a closed coil stacked helical spring member.

[0211] A thin wall preferably stainless steel tubular member 324 is received over the tension/compression members 304', 306' and the tube 324 has one end thereof crimped to

a flattened cross-section as denoted by reference numeral **326** and the member **324** serves to constrain the tension/compression members from twisting or rotation with respect to the outer casings **325** and **330** during flexing of distal portion of the catheter. An outer blood-contacting casing comprising a tubular flexible plastic member **325** has the distal end thereof is attached to a reduced diameter portion distal electrode **302** and extends over the tube **318** and has the opposite end thereof received over a thin-wall short annular sleeve member **328** which serves to join the outer casing member **325** with the outer casing **330** which is re-enforced with braided material as denoted by reference numeral **332**. With reference to **FIG. 31**, a plurality of annular electrodes are received over the outer periphery of the casing member **325** and are disposed in spaced arrangement therealong with each of the electrodes having an electrical wire lead member connected thereto as denoted by reference numeral **334,336** for the electrodes and **338,340** for the wire leads in **FIG. 31**.

[0212] It will be understood that the catheter **300** is intended to be operated by the handle mechanism illustrated in **FIG. 1** wherein the slider members are connected to the tension/compression members **304, 306** such that movement of the actuator causes one slider to tension one of the members **304, 306** and the other of the members is placed in compression; and, reversed movement of the actuator wherein the handle causes the other of the tension/compression members to be tensioned and the one to be placed in compression.

[0213] Referring to **FIGS. 33 through 37**, another embodiment of the electrophysiology/ablation catheter of the present invention is indicated generally at **400** and has a construction generally identical to that of the catheter **300** of **FIG. 31** with the exception that the inner guide tube **302** is formed of plastic material and has two generally circular longitudinally extending lumens **404, 406** formed thereto to which are received the tension/compression members **408, 410**.

[0214] It will be understood that in the embodiment **400**, a tension/compression members **404, 406** have flattened distal portions **404'** and **406'** as illustrated in detail in **FIGS. 36 and 37**; and, the embodiment **400** also employs the spacer means comprising a wave-shaped flat spring **416** with one end thereof secured in a kinematic junction **426** in a manner identical to that of embodiment **300** of **FIG. 31**.

[0215] It will be understood that in the embodiment **400**, the inner guide tube is received in the end of the thin wall plastic tube **418** which corresponds to the tube **318** in the embodiment of **FIG. 31**.

[0216] Referring to **FIGS. 39 and 58**, the embodiment **400** of the present invention is illustrated in exploded view in the preferred form wherein the flexible plastic tube **418** has three (3) lumens formed therethrough with wave-shaped flat spring spacer **416** received through the central lumen and each of the tension/compression members' flattened portions **404', 406'** received through a lumen disposed respectively on opposite sides of the central lumen.

[0217] Referring to **FIG. 39**, the central lumen is denoted by reference numeral **420** and the side lumens are denoted by reference numerals **422** and **424**. In the embodiment **400**, the annular tube member forming the kinematic junction is

denoted by reference numeral **426**; and, the outer casing portion having the electrodes thereon is denoted by reference numeral **428** and the braided portion of the outer casing is denoted by reference numeral **430** and the distal electrode is denoted by reference numeral **432**.

[0218] In the embodiment **400**, the flattened tube portion denoted by reference numeral **434** is optional in as much as the construction of the inner guide tube **402** is operative to prevent twisting of the tension/compression members with respect to the outer casings **428** and **430**.

[0219] Referring to **FIG. 38**, another embodiment of the catheter of **FIG. 33** is illustrated in longitudinal cross-section in its distal portion and denoted generally at **500**. The catheter **500** is identical to the catheter **400** of **FIG. 33** with the exception that sleeve or annular member **502** forming the kinematic junction of the ends **504, 506** of the tension/compression members **505', 506'** and the end of the wave-shaped flat spring spacer **508** is spaced a distance further from the distal electrode **510**.

[0220] The kinematic junction **512** is formed by brazing in distal ends of the tension/compression members **504, 506** and the distal end of the wave shaped flat spring spacer **508** in the annular member **502**. By virtue of the distance between the distal electrode **510**, and the kinematic junction **512** a region is created, between the electrode **510** and kinematic junction **512**, which remains un-deformed during lateral deflection of the catheter by operation of the actuator for pulling and pushing on the tension/compression members **504'** and **506'**. In the embodiment **500**, an additional flexible tube is inserted over the flexible tube **518** (which corresponds to the tube **418**) and the additional tube denoted by reference numeral **520** which provides additional stiffness to the region of the catheter between kinematic junction **512** and the end of the tube **518** remote from electrode **510**.

[0221] Referring to **FIGS. 40 and 41**, another embodiment of the invention is indicated generally at **600**; and, the distal portion of the catheter **600** is identical to the embodiment **300, 400** as described hereinabove except the distal electrode of the catheter **600**, denoted by reference numeral **602**, has embedded therein a heating element **604** to enable the catheter to be employed as an ablation catheter. It will be understood that the heating element **604** has a pair of electrical power leads **606, 608** attached thereto and which extend within the outer casing **610** to the proximal end of the catheter and into the handle **612** for connection to a power supply and temperature control module provided therein and denoted by reference numeral **614** in **FIG. 40**.

[0222] The embodiment **600** of **FIG. 41** also includes a temperature sensor **616** embedded in the distal electrode **602**, which is the present practice of the invention may be a solid state junction device which has leads **618, 620** extending within the casing **610** to the proximal end of the catheter. The sensor **616** is intended for use in remote monitoring of the temperature of the distal electrode **602** during ablation procedures.

[0223] Referring to **FIGS. 42 and 43**, an alternate version of the embodiment **600** is illustrated wherein the catheter assembly indicated generally at **700** as the construction thereof, identical to the embodiment **600** with the exception that catheter of **700** does not include a heating element in its distal electrode **702**; and instead, the temperature of the



distal electrode **702** is controlled by a radio-frequency power supply/control module that is external to the catheter of **700**.

[0224] It will be understood that a fiber optic temperature sensor can be used instead of the solid state junction **716** in an alternate embodiment of catheter **700**; and, a fiber optic cable extends within outer casings **706** and **707** to the proximal end of the catheter.

[0225] Referring to **FIG. 44**, another embodiment of catheter handle is indicated generally at **800** and has the proximal end of the guide tube **802** received in a tubular member **804** in a closely fitting arrangement with the tension/compression members **806**, **808** extending from the proximal end of the guide tube **802** and through the tube member **804** for connection to a pair of slider blocks **810** and **812** which corresponds in shape and function to the sliders **16** and **17** of **FIG. 5**. The proximal ends of each of the tension/compression members **806**, **808** each have a closely fitting thin wall preferably stainless steel tube **814**, **816** received respectively thereover.

[0226] The proximal ends of the tension/compression members **806**, **808** with their respective tubes **814**, **816** are each secured in one of the slider blocks **810**, **812** by a set screw **818**, **820** respectively which deforms the thin wall of tubing **814**, **816** and clamps the tubing and the respective tension/compression members **806**, **808** to the slider blocks **810**, **812**.

[0227] Referring to **FIG. 45**, the embodiment **800** of catheter embodies a friction brake member **822** contained in the handle **824** by interior projection **826** which maintains the member **822** in frictional contact with the curved edge of the actuator **828** which corresponds in shape and function to actuator **18** of embodiment of **FIG. 1**. In the present practice of the invention the member **822** is formed of elastomeric material to provide inherent spring compression of the material against the curved edge of the actuator **828**; and, the member **822** by virtue of the sliding friction on the curved edge of the actuator **828** serves to retain the actuator **828** in its user selected position after movement from the neutral position shown in **FIG. 45**.

[0228] Referring to **FIG. 46**, the embodiment of catheter **800** illustrated in **FIG. 45** is shown with the actuator moved to a user selected position for curving the distal portion of the catheter wherein the member **822** has deformed resiliently to the position of the curved edge of the actuator **828** but is maintaining frictional contact therewith.

[0229] Referring to **FIGS. 56 and 57**, another version of the frictional retaining member is illustrated in the embodiment indicated generally at **900** wherein the actuator **902** corresponds to the actuator member **828** of the embodiment **800**; and, the curved edge portion **904** of the actuator **902** has engaged therewith the end of a spring loaded plunger **906** which is received in a tubular housing **908** which in turn has a compression spring **910** received therein for biasing the plunger **906** in contact with the curved edge **904** of the actuator **902**. The tubular member **908** is disposed in the handle **912** between guide projections **914**. It will be understood that the plunger **906** serves the same function as the member **822** of the embodiment **800** of **FIG. 45**.

[0230] Referring to **FIG. 47**, another embodiment of the catheter handle is indicated generally at **4'** wherein the slider **16'** and **17'** have a wiper tube **290** attached thereto which is

operative to vary the electrical resistance in a potentiometer **292** for providing an electrical indicator signal corresponding to the position of the sliders **16'**, **17'** from which the curvature of the distal portion of the catheter may be calibrated for a catheter of known parameters.

[0231] Referring to **FIG. 48**, a compressible collar or spool **296** is received over the proximal portion of the braided exterior casing **2** wherein the collar **296** is in frictional sliding engagement with braided exterior casing **2**. The collar **296** is preferably formed of soft elastomeric or spongy material. The user may press the collar **296** onto the braided outer casing for readily applying torque thereon for twisting the braided outer casing. As shown by the dashed outlines of **FIG. 48**, the member **296** may be moved by the user longitudinally along the braided outer casing tube **2** of the catheter for selecting the point of application of the user's applied torque to the catheter's braided outer casing tube.

[0232] Referring to **FIGS. 48 through 54**, the technique for installing one of the annular electrodes over the outer casing at the distal portion of catheter is illustrated and will be described hereinafter with respect to **FIGS. 49 through 54**. Referring to **FIG. 49**, an annular electrode **1000** has an electrical conductive lead **1002** attached to the interior periphery thereof and extending outwardly therefrom. The flexible outer casing tubing **1004** has an end thereof received over a rigid tubing such as **1008** which serves as a part of a holding vise for the tubing **1004**. The free end of the electrical lead **1002** is then passed through an aperture **1006** on the flexible outer casing tube **1004** and then is passed outwardly through the end of the tubing **1008** as shown in **FIG. 50**.

[0233] Referring to **FIG. 51**, the electrode **1000** is then assembled over the end of tube **1004** over a tapered portion as shown in **FIG. 51**.

[0234] The end of the tube **1004** received over tube **1008** is then clamped and secured thereon by suitable clamping fixtures **1010**, **1012** as shown in **FIG. 52**. The tube **1004** is then stretched such that the electrode **1000** may be passed thereover and located over aperture **1006** with the lead **1002** being fed through the end of tubing **1008**. It will be understood that the stretching or pulling of tube **1004** as indicated by the arrow in **FIG. 52** causes a reduction in diameter of the tube **1004** which permits the electrode **1000** to be slipped thereover and be positioned over the aperture **1006**. When the electrode **1000** is located at the desired position over the aperture **1006**, the electrical lead **1002** is pulled through the end of the tube **1008** as shown in **FIG. 53**. When the electrode **1000** has been positioned at the desired position the pulling force on the tubing **1004** is then released, the tubing **1004** expands to engage the interior of the annular electrode **1000** and maintains the electrode **1000** in a desired position on the tube **1004**. The clamping load of members **1010**, **1012** are then released; the excess material on the end of tube **1004** is then removed as shown in **FIG. 54**.

[0235] Referring to **FIG. 55**, a schematic view of the temperature control of the distal electrode of the ablation catheter **600** of **FIG. 40** is illustrated in a standard feedback control flow-chart.

[0236] Referring to **FIG. 31**, all electrodes disposed on the distal portion of the catheter of this invention may be formed of electrically conductive elastomeric material(s)

[0237] Although the present invention has been described hereinabove with respect to the illustrated embodiments, it will be understood that the invention is capable of modification and variation and is limited only by the scope of the following claims.

What is claimed:

- 1) An electrophysiology/ablation catheter comprising:
  - a) an elongated flexible hollow tubular casing having a proximal end and distal end and a plurality of spaced electrodes disposed at the distal end thereof;
  - b) a pair of flexible tension/compression members disposed in side by side relationship and extending in the hollow of said casing from a point of attachment adjacent said distal end to said proximal end of said tubular casing;
  - c) an electrical lead connected to each of said electrodes and extending through the hollow of said tubular casing to the proximal end thereof, said lead adapted for external connections thereto;
  - d) spacer means disposed between said pair of flexible tension/compression members at said distal end for maintaining lateral spacing between said members, said spacer means being flexible; and,
  - e) wherein longitudinal tensioning of a first of said tension/compression members and simultaneously longitudinal compressing of the second of said tension/compression members with respect to said casing effects lateral displacement of said distal end of said casing in one direction and longitudinal tensioning of the said second of tension/compression members and simultaneously longitudinal compressing of the said first of said tension/compression members with respect to said casing effects lateral displacement of said distal end of said casing in a direction opposite said one direction.
- 2) The catheter defined in claim 1, wherein said pair of tension/compression members each have a portion thereof adjacent said distal end formed to have a flattened transverse section.
- 3) The catheter defined in claim 1, wherein said spacer means comprises a blade spring member.
- 4) The catheter defined in claim 1, wherein said spacer means comprises a wave shaped spring member.
- 5) The catheter defined in claim 1, wherein each of said tension/compression members has substantially rectangular transverse section in the region adjacent said distal portion with the balance thereof having a generally circular cross-section.
- 6) The catheter defined in claim 1, further comprising an elongated flexible tubular guide member disposed in said casing, said guide member having a pair of spaced parallel lumens formed therein with one of said pair of tension/compression members disposed in each lumen.
- 7) The catheter defined in claim 1, further comprising a sleeve received over said flattened portion of said tension/compression members and spaced a preselected distance from said distal end, said tension/compression members secured therein and forming a kinematic junction at said sleeve, wherein the portion of said tubular casing distal said sleeve remains substantially un-deformed upon simultaneous tensioning and compressing of said tension/compression members.
- 8) The catheter defined in claim 7, wherein said spacer means has an end thereof secured in said sleeve with the other end of said spacer floating in the space between said tension/compression members.
- 9) The catheter defined in claim 1, further comprising an elongated flexible tubular guide member disposed in said casing with said tension/compression members received therethrough; and, a rigid collar attached to the distal end of said guide member and extending over a portion of said tension/compression members having said spacer means therebetween.
- 10) The catheter defined in claim 9, wherein said rigid collar has a flatted cross-section on one end and a generally circular cross-section on an end opposite said one end.
- 11) The catheter defined in claim 1, further comprising an annular reference electrode disposed on said tubular casing at a station therealong remote from said plurality of spaced electrodes, wherein said reference electrode is located such that it remains exterior to the heart cavity upon insertion of the said plurality of spaced electrodes into a heart cavity.
- 12) A method of making an electrophysiology/ablation catheter comprising:
  - a) disposing at least one electrode on a distal portion of an elongated flexible tubular member and connecting an electrode lead to said electrode and extending said electrode lead to a proximal end of said tubular member;
  - b) disposing a pair of elongated tension/compression members in said tubular member and fixing an end of each of said pair in the distal portion of said tubular member and extending said pair to the proximal end of said tubular member;
  - c) disposing a flexible spacer intermediate said tension/compression members in the region of the distal portion thereof and spacing said tension/compression members laterally;
  - d) disposing an actuator movably on a handle and connecting said handle to the proximal end of said tubular member; and,
  - e) connecting said actuator to the proximal ends of said tension/compression members.
- 13) The method defined in claim 12, wherein said of fixing includes securing by weldment.
- 14) The method defined in claim 12, wherein said step of disposing a flexible spacer includes securing an end of said spacer to said tension/compression members by weldment.
- 15) The method defined in claim 12, wherein said step of disposing a flexible spacer includes flattening a portion of the distal end of said tension/compression members and securing an end of said spacer thereto by weldment.
- 16) The method defined in claim 12, further comprising disposing a sleeve over said tension/compression members and positioning said sleeve a preselected distance from said distal end and securing said sleeve to said tension/compression members and forming a kinematic junction thereof at said sleeve
- 17) The method defined in claim 12, wherein said fixing includes disposing an additional flexible tube within said casing a certain distance from said distal end and partially stiffening a portion of said tubular member.
- 18) A method of installing a distal electrode to an electrophysiology/ablation catheter comprising:

- a) providing a generally cup-shaped member of electrically conductive material and forming a plurality of spaced fingers extending axially from the rim of said cup-shaped member;
- b) disposing the open end of said cup-shaped member over an end of a tubular catheter casing member and deforming said fingers radially inwardly and passing at least one said fingers through the wall of said tubular member and securing said cup-shaped member to said tubular member with said finger; and,
- c) attaching an electrical lead to said at least one finger and extending said lead through said tubular member.

**19)** The method defined in claim 18, wherein said step of securing includes further deforming said fingers and extending said at least one finger along the inner surface of said tubular member.

**20)** The method defined in claim 18, wherein each step of securing includes further deforming said at least one finger to fold back on itself along the inner surface of the said tubular member.

**21)** The method defined in claim 18, wherein said step of passing said at least one finger through said tubular member includes piercing said wall with said at least one finger.

**22)** A motorized electrophysiology/ablation catheter actuating assembly comprising:

- a) an elongated flexible tubular member having a distal end and a proximal end and having a pair of tension/compression members disposed therein and kinematically joined in said distal end, said tension/compression members extending through the proximal end of said tubular member;
- b) hollow handle structure attached to the proximal end of said tubular member, said handle structure having therein a motor drive including means for connecting motor rotation to linear movement with the proximal ends of said tension/compression members connected to said means for connecting,
- c) a source of electrical power disposed in said handle structure and user operated switch means disposed on said handle structure for energizing said motor drive, wherein said motor drive is operative, upon being energized for rotation in one direction, to cause said means for converting rotation to simultaneously pull and push said first and second tension/compression members respectively and effect curvature of said tubular member in one direction; and said motor drive is operative, upon being energized for rotation in a direction opposite said one direction to cause said means for converting rotation to simultaneously pull and push said second and first tension/compression members respectively and effect curvature of said tubular member in the opposite direction.

**23)** The assembly defined in claim 22, wherein said handle structure includes a position sensor for sensing the position of a member of said means for converting motor rotation to linear motion as an indication of the radius of curvature of the distal portion of said tubular member.

**24)** The assembly defined in claim 22, wherein said handle structure includes connector means adapted for external electrical connection; and, said tubular member includes

lead means connected to at least one distal electrode, said lead means having the proximal end thereof connected to said connector means.

**25)** The assembly defined in claim 22, wherein said connector means includes connections for remote control of said motor drive.

**26)** The catheter defined in claim 1 further comprising a solid state temperature sensor disposed in said distal electrode and sensing lead means connected to said sensor, said sensing leads means extending through said casing to the proximal end thereof for connection to a sensing circuit.

**27)** The catheter defined in claim 1 further comprising a fiber optic temperature sensor received through said casing, having an end thereof connected to said distal electrode for conducting a temperature sensing signals to the proximal end thereof.

**28)** The catheter defined in claim 1 further comprising:

- a) heating element disposed in said distal electrode;
- b) electrical supply lead means connected to said distal electrode, said supply lead means extending through said casing to the proximal end thereof wherein upon powering said lead means, said distal electrode is heated.
- c) electric power supply and temperature control module disposed in said handle to control the temperature of said distal electrode for ablation procedures.

**29)** The catheter defined in claim 28 further comprising a solid state temperature sensor disposed in said distal electrode and sensing lead means connected to said sensor, said sensing leads means extending through said casing to the proximal end thereof for connection to a sensing circuit disposed in said handle.

**30)** The catheter defined in claim 1, wherein said distal portion of said tension/compression members are received in a flexible guide tube disposed within said casing, said guide tube having an end engaging said distal electrode.

**31)** The catheter defined in claim 28, wherein said flexible guide tube has a pair of internal septum formed therein extending the length thereof for separating said tension/compression members and said spacer means

**32)** The catheter defined in claim 1, wherein the proximal end of each of said tension/compression members is received in a closely fitting metal tube; and, said metal tube is deformed by clamping and said tube and tension/compression member are secured to a reciprocating member operationally connected to said actuator member.

**33)** The catheter defined in claim 1, wherein said handle includes a pair of reciprocating members operationally connected to said actuator member, with each reciprocating member connected to one of said tension/compression members; and, said handle includes a displacement sensor operative to sense the motion of at least one of said reciprocating members.

**34)** The catheter defined in claim 1, wherein said handle includes means operable for frictionally securing said actuator in a user selected position.

**35)** The catheter of claim 34, wherein said means for frictionally securing includes an elastic rubber.

**36)** The catheter defined in claim 32, wherein said means for frictionally securing includes a spring loaded plunger.

**37)** The catheter defined in claim 1 further comprising an elastic collar received over the proximal end of said casing,

said collar operable to grip said casing upon user grasping thereof for enabling the user to readily apply torque to said casing.

**38)** The catheter defined in claim 37, wherein said collar is axially moveable along said casing for permitting user selection of the region of torque application therealong.

**39)** A method of installing an annular electrode on a flexible catheter casing comprising:

- a) attaching an end of an electrical lead to said electrode;
- b) forming an aperture in said casing and passing the remote end of said lead through said aperture;
- c) securing the proximal end of the casing over a rigid tube;

d) stretching said casing axially, necking said casing and sliding said electrode over said casing and positioning said electrode over said aperture with said lead there-through;

e) releasing said stretching to expand said necking and securing said electrode on said casing; and,

f) removing excess casing material.

**40)** The catheter defined in claim 1, wherein said distal electrode and said plurality of spaced annular electrodes are made from electrically conductive rubber-like material.

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