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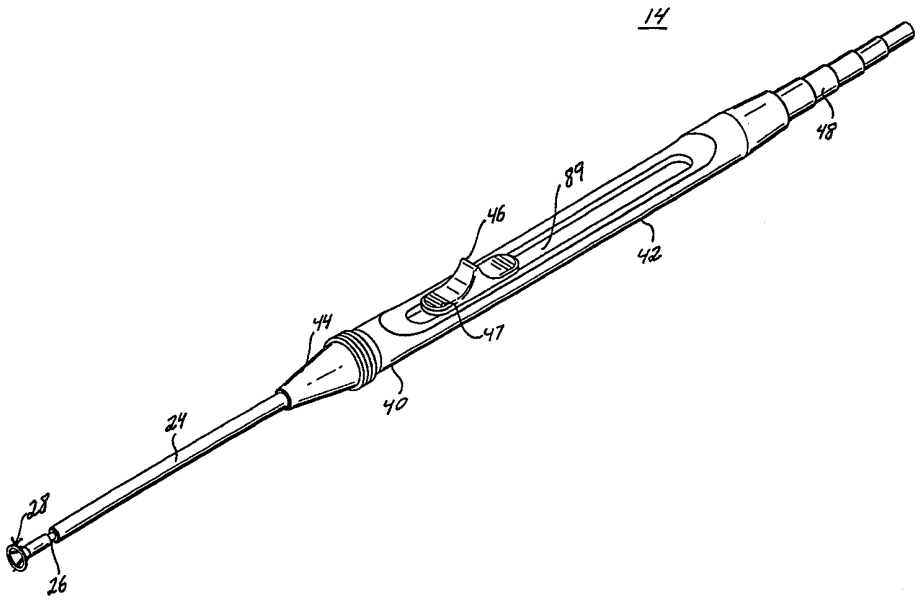

(57) Abstract

A laser ablation device (10) is provided with a handpiece (14) having an extender (28) at the distal end of an articulating tube (26) from where the optical fiber (12) exits the handpiece (14) for inhibiting blood, debris from being deposited between the articulating tube (26), and the optical fiber (12) during a TMR procedure. The laser ablation device (10) allows for longitudinal movement of an optical fiber (12) at a controlled rate coordinated with the laser energy generator (18) output to ablate heart tissue. Additionally, the laser ablation device (10) allows for effortless withdrawal of the optical fiber (12) into the articulating tube (26) after the TMR procedure.

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LASER HANDPIECE FOR PERFORMING TRANSMYOCARDIAL REVASCULARIZATION

BACKGROUND

Technical Field

The present disclosure relates generally to a laser ablation device for surgical use. More specifically, the present disclosure relates to a laser ablation handpiece designed to inhibit blood and debris from being deposited adjacent the distal end. The laser ablation device is particularly suited for use in performing transmyocardial revascularization (TMR).

Background of the Related Art

A variety of procedures and apparatus have been developed to treat cardiovascular disease. For example, minimally invasive surgical procedures such as balloon angioplasty and atherectomy have received extensive investigation and are in wide use. In some patients, however, circumstances still require conventional open heart bypass surgery to correct or treat advanced cardiovascular disease. In some circumstances patients may be too weak to undergo the extensive trauma of bypass surgery or repetitive bypasses may already have proved unsuccessful. An alternative procedure to bypass surgery is transmyocardial revascularization (TMR).

TMR is a procedure for producing channels of small diameters within the myocardium, which channels extend into the ventricle. Such channels are believed to facilitate delivery of blood directly from the ventricle to oxygen starved areas of the heart. TMR is typically used on patients with ischemic heart disease who are not candidates for coronary artery bypass or percutaneous transluminal angioplasty.

During a conventional procedure, typically dozens of channels are created from the epicardium, through the myocardium and endocardium and into the ventricle, with each channel being of sufficiently small diameter such that the end portions of the channels at the epicardium can be closed by blood clotting. The channels are preferably created by employing either a mechanical coring apparatus or an advancing lasing device, such as an optical fiber. In the case of the latter, the optical fiber is advanced through a handpiece in proximity to the heart tissue and a laser is fired to transmit laser energy through the fiber to ablate the heart tissue.

As TMR channels are created, blood and debris generally fills up in the distal end of the handpiece between an articulating tube from where the optical fiber exits the handpiece and the optical fiber. This blood/debris causes excessive friction at the distal end of the articulating tube

resulting in a force on the optical fiber directed away from the surgeon. This force is generally greater than the force supplied by the fiber advancing and withdrawing mechanism to withdraw the fiber. As a result, the step of withdrawing the fiber into the articulating tube, after having created the TMR channel and withdrawn the fiber from the heart tissue, is often difficult or impossible.

Accordingly, a need exists for a TMR laser ablation device which inhibits blood and debris from being deposited into the distal end of the handpiece, i.e., between the articulating tube and the optical fiber, thereby allowing the optical fiber to be easily withdrawn into the articulating tube after a TMR procedure.

SUMMARY

In accordance with the present disclosure, a laser ablation device is provided with a handpiece having an extender at the distal end of an articulating tube from where the optical fiber exits the handpiece for inhibiting blood and debris from being deposited between the articulating tube and the optical fiber during a TMR procedure. The laser ablation device allows for longitudinal movement of an optical fiber at a controlled rate coordinated with the laser energy generator output to ablate heart tissue. Additionally, the laser ablation device allows for effortless withdrawal of the optical fiber into the articulating tube after the TMR procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to the drawings:

FIG. 1 is a perspective view of a laser ablation device in accordance with the present disclosure;

FIG. 2 is a perspective view of a laser ablation control module and optical fiber advancing assembly combined into a single unit;

FIG. 3 is an enlarged perspective view of the handpiece of the laser ablation device shown in FIG. 1;

FIG. 4 is an enlarged perspective view with parts separated showing the various components of the handpiece;

FIG. 5 is an enlarged perspective view of the distal end of the handpiece shown in FIG. 1;

FIG. 6 is an enlarged perspective view of the distal end of the handpiece shown in FIG. 1 with the articulating tube being in the articulating position;

FIG. 7 is a side view showing the articulating tube moved into the articulating position;

FIG. 8 is a side view showing distal translation of an optical fiber through the articulating tube to extend the optical fiber beyond the distal end of the handpiece;

FIG. 9 is an enlarged side view in partial cross-section illustrating the fiber piercing the epicardium;

FIG. 10 is an enlarged side view in partial cross-section illustrating the formation of a channel through heart tissue;

FIG. 11 is an enlarged side view in partial cross-section illustrating the fiber withdrawn from the heart tissue;

FIG. 12 is an enlarged side view of the handpiece illustrating the fiber retracted back into the articulating tube and the articulating tube retracted back into the elongated, rigid tube;

FIG. 13 is cross-sectional view of an alternate handpiece for operating with the laser ablation device shown by FIG. 1; and

FIG. 14 is an enlarged cross-sectional view of the area of detail circled in FIG. 13.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Preferred embodiments of the laser ablation device will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements.

Referring to FIG. 1, a laser ablation device designated generally as 10 is employed to perform a TMR procedure in accordance with the present disclosure.

Lasing device 10 is similar to lasing devices disclosed in copending, commonly assigned U.S. Patent Application Serial No. 08/648,638 to Pacala et al., filed May 13, 1996, the subject matter of which is incorporated herein by reference. Device 10 is capable of advancing a laser ablation member 12, e.g., an optical fiber, optical fiber bundle or other laser energy transmission mechanism, through heart tissue while concomitantly outputting laser energy, where the advancement rate is coordinated with the magnitude of laser energy generated and with the pulsing frequency of the laser source. It is contemplated that the advancement rate, the magnitude of laser energy generated, and the pulsing frequency of the laser source are automatically controlled by feedback control systems.

Laser ablation device 10 includes a handpiece 14, an optical fiber advancing mechanism 16, a laser generator 18, a foot operated actuator 20, and a control module 22. Handpiece 14 includes an elongated, rigid tube 24 having an articulating tube 26 traverse therethrough. An

extender 28 is mounted at a distal end 30 of articulating tube 26 to inhibit blood, ablated tissue and other debris from being deposited between optical fiber 12 and articulating tube 26 as further described below.

Optical fiber advancing mechanism 16 is of the type capable of precisely transmitting longitudinal motion to optical fiber 12. The controlled longitudinal motion can be provided by one or more motors and preferably by one or more stepper motors which can deliver approximately four pounds of pushing force and 1.25 pounds of pull force to a 1.4 mm fiber bundle. Laser generator 18 may be either a continuous wave laser or a pulsed, high energy laser, such as, for example, an excimer, $C0_2$, Yag or an alexandrite laser.

Optical fiber advancing mechanism 16 and laser generator 18 are operably connected to foot actuator 20. By depressing foot actuator 20, laser energy is transmitted through optical fiber 12 by laser generator 18 while fiber advancing mechanism 16 contemporaneously advances optical fiber 12 relative to handpiece 14. An electrical signal from foot actuator 20 actuates control module 22 which communicates with fiber advancing mechanism 16. Control module 22 is programmable and controls the motors or other suitable advancing structure in advancing mechanism 16 upon actuation of foot actuator 20.

With reference to FIGS. 1-4, control module 22 is shown with a programmable computer 74 having a terminal 76 and a keyboard 78 for storing instructions recruited to operate advancing mechanism 16. Control module 22 can be programmed to control the amount of advancement of optical fiber 12 when foot operated actuator 20 is depressed. A toggle switch 35 may also be provided on control module 22 to switch from an operation mode to a test mode. In a particular test mode, when foot actuator 20 is acted upon, flexible optical fiber 12 is moved sequentially from a retracted position, to a predetermined extended position, and back to the retracted position.

Fiber advancing mechanism 16 is equipped with two limit switches which are set to control the amount of advancement of optical fiber 12 within the heart tissue. Preferably, these limit switches are automatic, however manual switches are also contemplated. Both limit switches are preferably preempted by control module 22 during ablation if control module 22 determines that optical fiber 12 has entered the ventricle. The first limit switch is activated when optical fiber 12 is at a desired retracted position (i.e., a "home" position), wherein the mechanism that is retracting the fiber is caused to stop. Optical fiber 12 is in the retracted position unless foot actuator 20 is depressed or the test mode is activated. The exact retracted

position can be selected by means of programming control module 22 or manually setting selector 36 which is a rotatable knob.

The second limit switch limits/controls the maximum distance that optical fiber 12 can extend from handpiece 14. However, control module 22 can be programmed with such information, as noted above, and preempt the second limit switch. External selector 36 is provided so that the operator can manually select the desired maximum extension of the distal end of optical fiber 12 from a distal end 30 of the articulating tube 26. For example, selector 36 is in the form of a rotatable knob that can be set at selectable positions, wherein each position corresponds to a predetermined maximum longitudinal position of optical fiber 12. When the fiber reaches the selected maximum position, the fiber's advancement is automatically terminated. It is contemplated that external selector 36 can be controlled automatically to control the amount of maximum extension of optical fiber 12 beyond handpiece 14.

By way of example, the operator can select or program maximum fiber extension positions so that the distal end of fiber 12 extends from the distal end of extender 28 from between about 3 mm and about 50 mm, with the ability to select in increments of about 2.5 mm to about 5 mm. The maximum extension position is preferably chosen to be slightly longer than the heart wall thickness for the particular patient such that fiber 12 will penetrate into the patient's ventricle. Once the maximum extended position is reached, output of laser energy is automatically suspended.

With reference to FIGS. 3 and 4, handpiece 14 includes housing 40 formed from molded housing half-sections 40a and 40b. Housing 40 has an elongated body 42 with a conically tapered section 44. Tube 24 traverses through housing 40 and rests against channel 80 formed within conically tapered section 44 of housing half-sections 40a and 40b. Articulating tube 26 which guides optical fiber 12, traverses a portion of tube 24 and is held within tube 24 by washers 82 and 84. Washer 84 includes a proximal end 85 which- is press fit to a distal end of inner tube 88 which traverses rigid tube 24. A proximal end of articulating tube 26 is press fit to a distal end 87 of washer 84 for the articulating tube 26 to be held within rigid tube 24.

A proximal end of tube 24 is press fit within a first cavity 86 of slidable lever 46 as shown by broken line "A". Inner tube 88 traverses a second cavity 90, a channel (not shown) within wall 92 of lever 46 and tube 24. A distal end of inner tube 88 rests against channel 91 formed in housing 40 and flange 81 rests against groove 83 to fix inner tube 88 to housing 40.

When lever 46 is moved proximally along slot 89 formed between housing half-sections 40a and 40b, rigid tube 24 is moved proximally over inner tube 88 to cause articulating tube 26

to move into the articulating position as shown by FIGS. 6 and 7. Articulating tube 26 is manufactured from shape memory/alloy. Two ridged surfaces 47 are formed on lever 46 to facilitate grasping and moving of lever 46.

A flexible support tube 48 surrounds the distal end of sheath 50 covering optical fiber 12 to reduce stress at the proximal end of handpiece 14. An elongated tubular portion 92 of metallic washer 94 is inserted within a distal end of support tube 48 to connect support tube 48 with handpiece 14. Washer 94 is housed within elongated body 42 of housing 40.

With reference to FIGS. 5 and 6, extender 28 includes an annular flange 52 dimensioned to matingly engage the distal end of articulating tube 26 and a conic portion 54 having a plurality of buttresses 56, shown here with four buttresses 56 defining four openings 58 therebetween. In a preferred embodiment, extender 28 spaces the distal end of articulating tube 26 approximately 3 mm from the epicardium during a TMR procedure as shown by letter "D" in FIGS. 5 and 7. It is preferred to position the distal end of optical fiber 12 either on the epicardium or to about 0.5 mm from the epicardium prior to firing laser generator 18 to initiate the TMR procedure.

An alternate contemplated procedure is to position optical fiber 12 halfway between the distal end of articulating tube 26 and the epicardium (i.e., 1.5 mm from the epicardium) at time zero. At an advancement rate of about 1 mm per second and a pulse rate of about 30 pulses per second, upon activation of the advancing mechanism 16, there are approximately 45 laser pulses prior to contact of fiber 12 with the epicardium. By firing fiber 12 in air prior to contacting the heart, the shock waves serve to loosen debris that may become deposited on fiber 12. In one method, laser generator 18 is not actuated until the distal end of optical fiber 12 has pierced the epicardium to facilitate the formation of a flap to prevent bleeding as described below.

Extender 28 serves to reduce the amount of material deposited adjacent the distal end of articulating tube 26, and therefore greatly reduces the likelihood of failure during pull back of fiber 12. Extender 28 spaces the distal end of articulating tube 26 from the heart tissue, and therefore less blood and debris are deposited within articulating tube 26. In addition, extender 28 serves to increase the visibility of optical fiber 12 once it exits the distal end of handpiece 14.

It is contemplated to utilize extender 28 as a stabilizer for placement against the epicardium during a TMR procedure to facilitate proper orientation of optical fiber 12 with respect to the heart tissue.

The operation of the laser ablation device 10 will become more apparent from a detailed discussion of a TMR procedure using the presently disclosed laser ablation device. Referring to

FIGS. 7-12, a method for producing a TMR channel utilizing the laser ablation device 10 is illustrated.

As shown in FIG. 7, lever 46 may be moved proximally to advance articulating tube 26 into the articulating position. Advancing mechanism 16 is then actuated to advance optical fiber 12 a predetermined distance beyond the distal end of extender 28. It is preferred that optical fiber 12 is advanced approximately 0-10 mm beyond extender 28 as shown by FIG. 8. During the advancement of fiber 12, fiber 12 may be fired in air to create shock waves which serve to loosen debris that may have deposited on fiber 12 as discussed above. The fiber 12 may be fired continuously or intermittently during the advancement step.

The amount of advancement of fiber 12 is selectable by means of programming control module 22 or properly setting external selector 36 as discussed above (See FIG. 2). The distal end of fiber 12 is then positioned either on the epicardium or to about 0.5 mm from the epicardium. Laser generator 18 is then fired to ablate myocardial tissue while advancing mechanism 16 is actuated to advance fiber 12 to form a TMR channel.

Alternatively, with reference to FIGS. 9 and 10, with the tip of fiber 12 protruding in this manner, and without depressing foot actuator 20 to output laser energy, fiber 12 is brought into contact with epicardium 60 so as to mechanically pierce and thus separate the epicardial outer surface as shown by FIG. 9. The momentum causes the fiber tip to initially advance through the separated epicardium 60 and myocardium 62 without laser energy being generated.

As the tip of fiber 12 penetrates, epicardial and myocardial tissue adjacent to the fiber tip are pushed aside. This tissue 64 will not be ablated with laser energy since foot actuator 20 has not yet been activated. Tissue 64 will substantially return to its natural position following channel formation and act as a cad to reduce bleeding from the channel. At this point, fiber 12 has penetrated approximately 3-10 mm into the heart tissue.

With extender 28 in contact with the epicardium as depicted in FIG. 9, there is approximately 3 mm from the outer surface of epicardium 60 to the distal end of articulating tube 26 to inhibit blood and debris from depositing between articulating tube 26 and fiber 12 during TMR channel formation. Further, extender 28 enhances the surgeon's ability to position and stabilize handpiece 14 with respect to the heart which is beating during the TMR procedure.

With reference to FIG. 10, the surgeon then commences TMR channel formation by depressing foot actuator 20. This initiates operation of laser generator 18 and advancing mechanism 16 to transmit laser energy from the tip of fiber 12 to ablate heart tissue while correspondingly advancing fiber 12. The spacing provided by extender 28 between the heart

tissue and the distal end of articulating tube inhibits blood and debris from entering and/or being deposited between articulating tube 26 and optical fiber 12. Further, openings on extender 28 permit the blood and debris to escape from within extender 28, thereby further preventing these substances from depositing within the distal end of articulating tube 26.

Optical fiber 12 is advanced through the myocardium 62 and endocardium 66 until it reaches its maximum extended position corresponding to a predetermined distance as preset by selector 36 or until its advancement is suspended by control module 22 in response to feedback control signals or other parameters. Optical fiber 12 is preferably advanced at a rate of between about 0.5 mm/sec (0.02 in/sec) to about 12.7 mm/sec (0.5 in/sec) with a laser power level of about 10 mJ/mm^2 to about 60 mJ/mm^2 and a pulsing frequency of about B Hz to about 100 Hz. Preferably, the optical fiber is advanced at a rate of about 1.0 mm/sec to about 2.0 mm/sec with a laser power level of between about 30 mJ/mm^2 to about 40 mJ/mm^2 and a pulse frequency of about 50 Hz. In a most preferred embodiment, the rate of advancement of the optical fiber is no greater than the rate of ablation of tissue in order to minimize mechanical tearing by the fiber. Alternatively, if some degree of mechanical tearing is desired in addition to laser ablation, the advancing mechanism can be manually set to advance the fiber at a rate greater than the ablation rate.

When fiber 12 penetrates slightly into ventricle 68, output of laser energy is suspended and fiber 12 is automatically retracted. Handpiece 14 is then drawn away from the heart wall whereby transmyocardial channel 70 is completed as shown by FIG. 11. The epicardial and myocardial tissue 64 which was pushed aside during channel formation acts as a cap to prevent bleeding from channel 70. Slidable lever 46 is then pushed distally for rigid tube 24 to extend over articulating tube 26 as shown by FIG. 12.

Handpiece 14 is then moved to another location on epicardium 60 to begin forming another channel. The overall procedure wherein dozens of channels are typically formed can thus be performed much faster as compared to prior art methods, since each channel 70 can be provided with a cap to prevent bleeding and fiber 12 is automatically retracted into articulating tube 26.

With reference to FIGS. 13 and 14, there is shown a handpiece for preferably performing TMR designated generally by reference numeral 120 and having a fiber positioning calibration mechanism 122. Calibration mechanism 122 permits a surgeon to manually calibrate the position of the distal end of handpiece 120 relative to fiber 12. With particular reference to FIG. 14, calibration mechanism 122 includes an inner member 124 having an outer threaded

surface 126 and an outer member 128 having an inner threaded bore 130. Inner member 124 includes a bore 132 configured and dimensioned to matingly engage tubing 134 housing fiber 12 therein. Tubing 134 is preferably made from hard plastics.

In operation, the surgeon grasps handpiece 120 with one hand and tubing 134 with the other hand and rotates inner member 124 within outer member 128 to move tubing 134 distally or proximally depending on the direction of rotation. As the tubing 134 moves counter-clockwise relative to handpiece 120, the distal end of handpiece 120 moves proximally relative to fiber 12. It is preferred that the maximum distance fiber 12 can be exposed by calibration mechanism 122 is 3 mm, such that the distal end of fiber 12 is flush with the distal end of conic portion 54. It is contemplated that the calibration mechanism 122 or a similar mechanism can be provided at the proximal end of tubing 134, such as at or near advancing mechanism 16. It is further contemplated to provide a marking on the distal end of tubing 134 to provide a reference point to easily determine the amount of displacement of fiber 12 with respect to handpiece 120.

What is Claimed is:

1. A laser ablation device, comprising:

a laser ablation member;

a handpiece having a proximal end and a distal end, the laser ablation member located within the handpiece and being advanceable and retractable within the handpiece; and

an extender having a proximal end and a distal end, the proximal end of the extender coupled to the distal end of the handpiece so that the laser ablation member is advanceable and retractable within the extender;

wherein the distal end of the extender provides spacing between the distal end of the handpiece and the surface of a material to be ablated to reduce the amount of material deposited adjacent the distal end of the handpiece.

2. The laser ablation device of claim 1 wherein the distal end of the extender terminates in a contact member which is coupled to the distal end of the extender by at least one buttress, the buttress being configured to provide at least one opening between the contact member and the distal end of the extender.

3. The laser ablation device of claim 2, wherein the extender further comprises an annular flange having a proximal end dimensioned to matingly engage the distal end of the handpiece and a distal end dimensioned to couple with four buttresses, and wherein the contact member and buttresses are arranged in a conic configuration, the four buttresses defining four openings between the distal end of the handpiece and the contact member.

4. The laser ablation device of claim 1, wherein the handpiece includes an articulating tube for guiding the laser ablation member.

5. The laser ablation device of claim 4, wherein the articulating tube comprises a shape memory alloy such that the articulating tube is curved when extended and substantially straight when retracted.

6. The laser ablation device of claim 5, wherein the articulating member is substantially L-shaped when extended.

7. The laser ablation device of claim 1, wherein the laser ablation member is an optical fiber.

8. A laser handpiece for performing transmyocardial revascularization, comprising:

a hand piece with an elongated tube;

an articulating tube traversing through the elongated tube;

an optical fiber traversing through the articulating tube; and

an extender coupled at a distal end of the articulating tube to inhibit material from being deposited between the optical fiber and the articulating tube, the extender comprising:

an annular flange dimensioned to matingly engage the distal end of the articulating tube; and

a conic portion having a contact member connected to the annular flange by a plurality of buttresses;

wherein a plurality of openings are located between a distal end of the annular flange and the contact member and wherein the extender spaces the distal end of the articulating tube from a surface of a tissue to be ablated so that material is allowed to escape through the openings during ablation to reduce the amount of material deposited adjacent the distal end of the tube; and

wherein the extender stabilizes the placement of the optical fiber to facilitate proper orientation of the optical fiber with respect to the tissue.

9. The laser handpiece of claim 8, further comprising an optical fiber advancing mechanism coupled to the optical fiber for advancing and retracting the optical fiber through the tissue.

10. The laser handpiece of claim 9, further comprising a laser generator to transmit laser energy through the optical fiber, wherein the advancement rate of the optical fiber is coordinated with the magnitude of laser energy and with a pulsing frequency of the laser generator.

11. The laser handpiece of claim 10, further comprising a control module which automatically controls the advancement rate, the magnitude of laser energy generated, and the pulsing frequency of the laser generator by feedback control systems.

12. The laser handpiece of claim 11, wherein the control module includes a programmable computer having a terminal and a keyboard for storing instructions to operate the advancing mechanism.

13. The laser handpiece of claim 12, further comprising a foot actuator coupled to the fiber advancing mechanism and the laser generator, wherein activation of the foot actuator enables laser energy to be transmitted through the optical fiber by the laser generator while the fiber advancing mechanism contemporaneously advances the optical fiber.

14. The laser handpiece of claim 8, wherein the articulating tube comprises a shape memory metal such that the articulating member conforms to the elongated shape of the elongated tube when in a retracted position and the articulating member is curved when in an extended position.

15. The laser handpiece of claim 14, wherein the articulating member is substantially L-shaped when in an extended position.

16. The laser handpiece of claim 8, wherein the extender spaces the distal end of the articulating tube approximately 3 mm from the surface of the tissue, wherein the surface of the tissue is an epicardium of a heart.

17. The laser handpiece of claim 16, wherein a distal end of the optical fiber is positioned on the epicardium prior to firing the laser generator to initiate the transmyocardial revascularization procedure.

18. The laser handpiece of claim 16, wherein a distal end of the optical fiber is positioned approximately 0.5 mm from the epicardium prior to firing the laser generator to initiate the transmyocardial revascularization procedure.

19. The laser handpiece of claim 16, wherein a distal end of the optical fiber is mechanically positioned about 3 mm to 10 mm into the tissue prior to firing the laser generator to initiate the transmyocardial revascularization procedure.

20. A method of performing transmyocardial revascularization, the method comprising the steps of:

providing a laser ablation member;

guiding the laser ablation member through a tube, whereby the laser ablation member is advanced and retracted relative to the tube;

coupling an extender to a distal end of the tube;

wherein the distal end of the extender includes a contact member for contacting a surface of the epicardium, the contact member being coupled to the proximal end of the extender by at least one buttress, the buttress being configured to provide at least one opening between the contact member and the distal end of the tube; and

spacing the distal end of the tube from the surface of the epicardium by placing the contact member on the surface of the material to be ablated.

21. The method of claim 20, further comprising the step of:

advancing the ablation member to mechanically pierce through the epicardium and a portion of a myocardium such that epicardial and myocardial tissue adjacent to the ablation member are pushed aside;

after the step of advancing the ablation member, transmitting laser energy through the ablation member to ablate heart tissue; and

advancing the ablation member while simultaneously transmitting laser energy through the ablation member.

22. The method of claim 20, wherein the ablation member is an optical fiber.

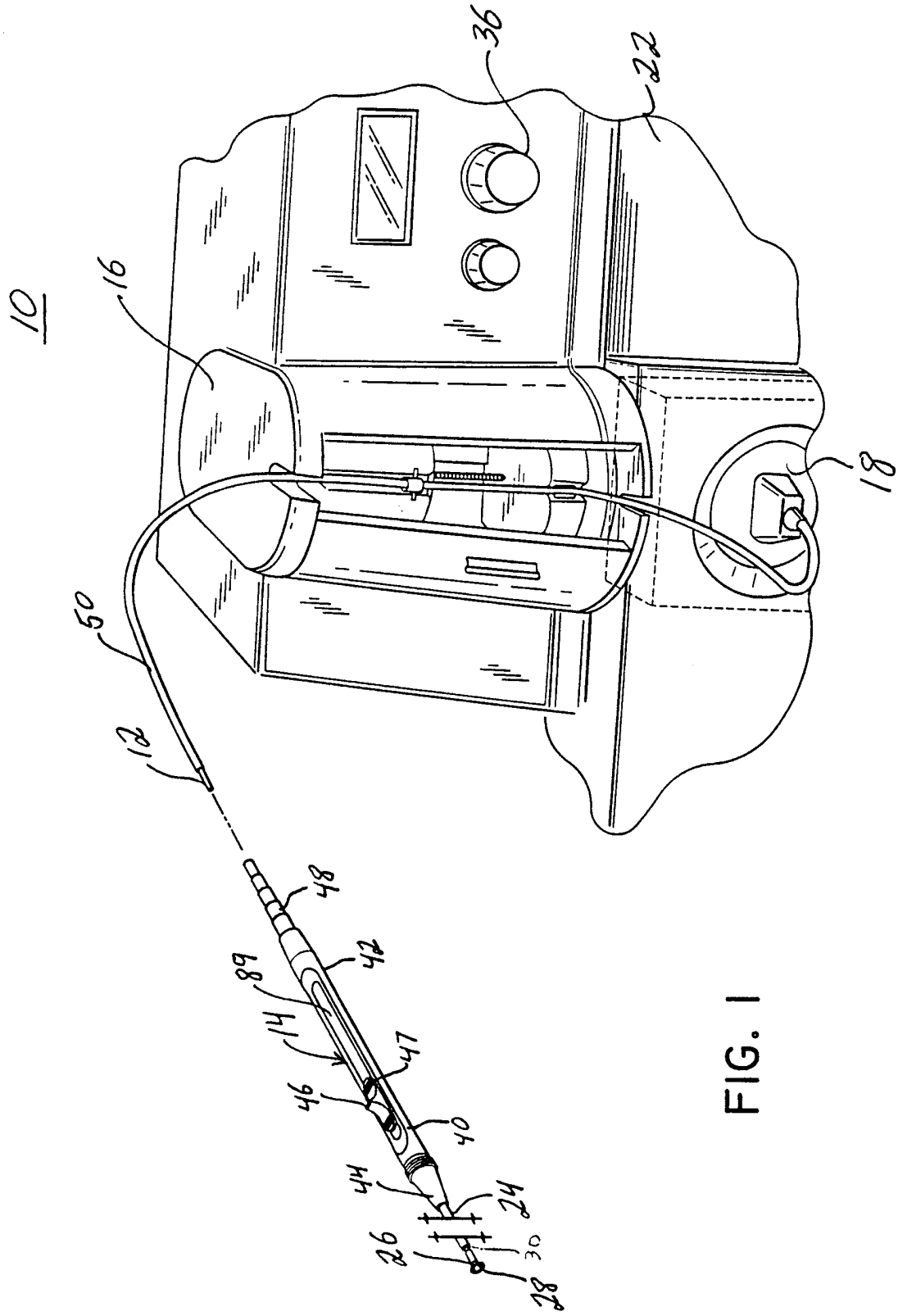


FIG. 1

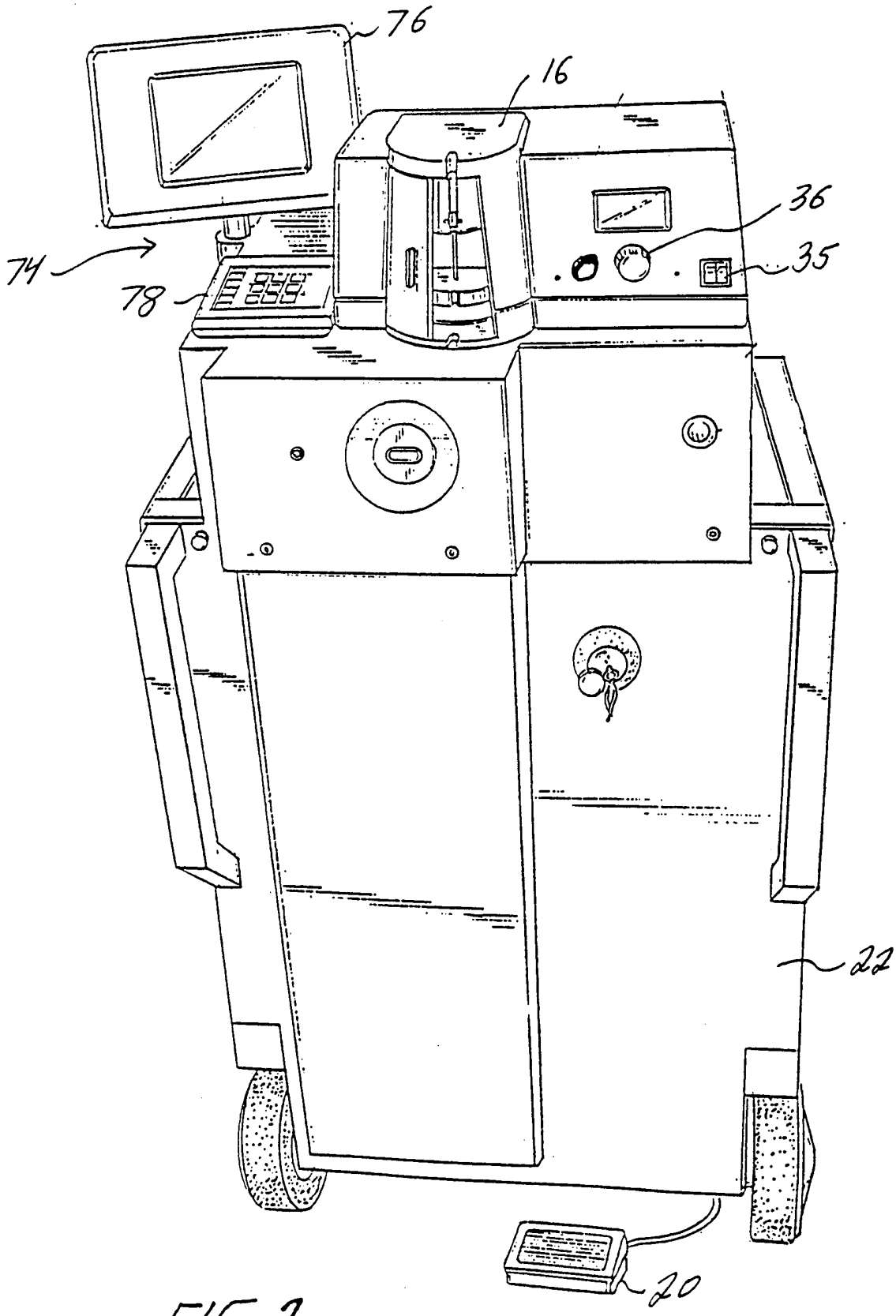


FIG. 2

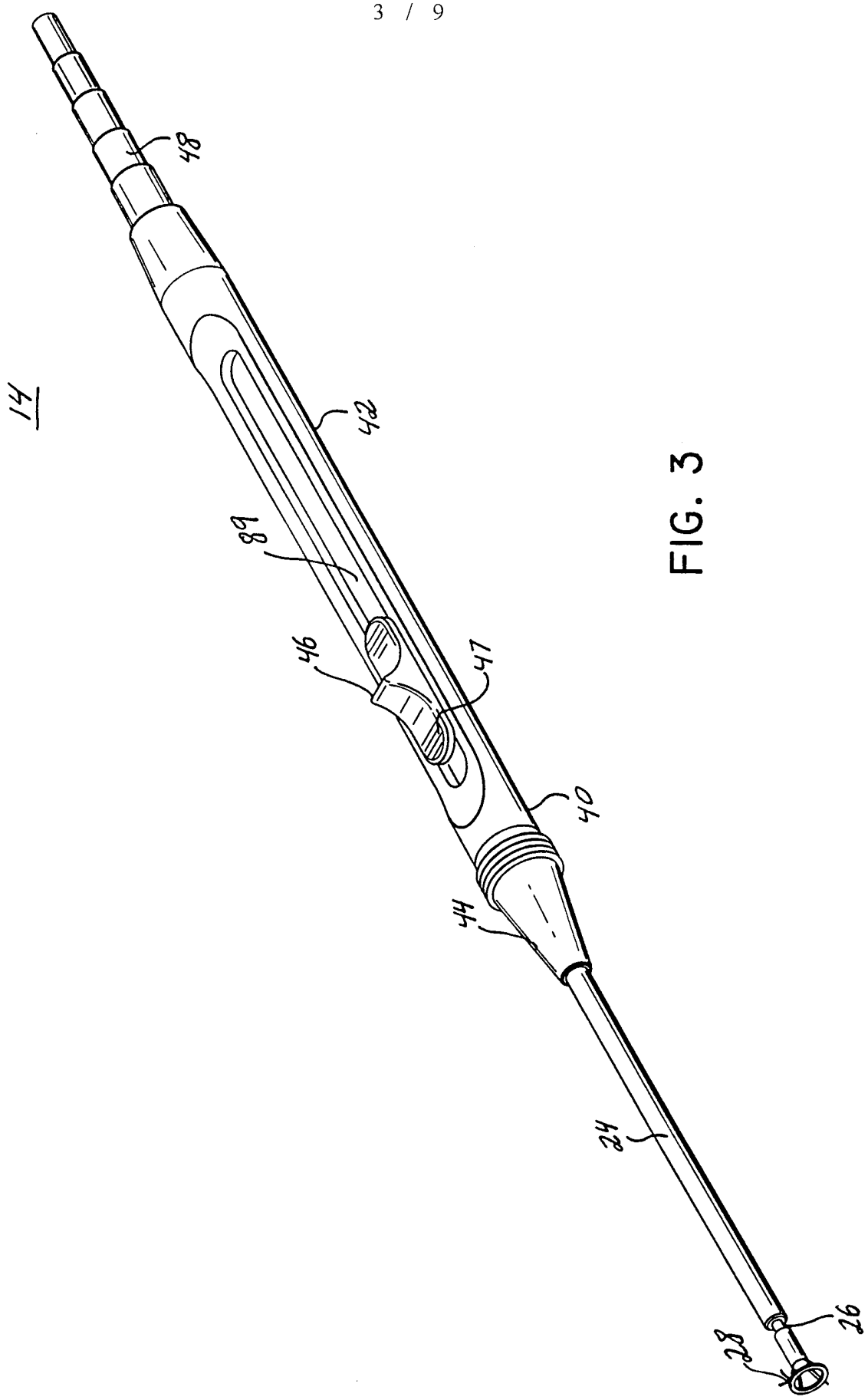


FIG. 3

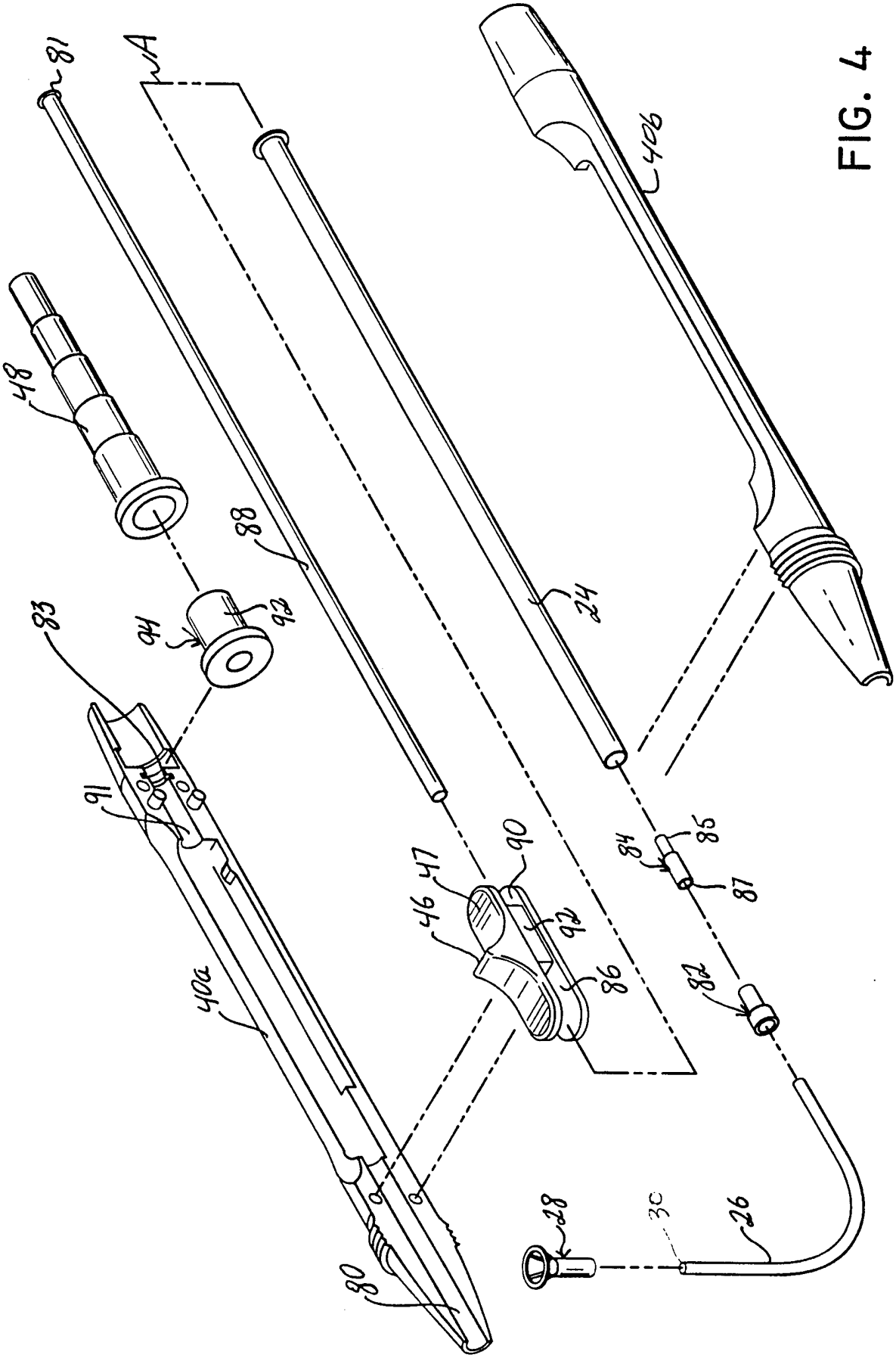
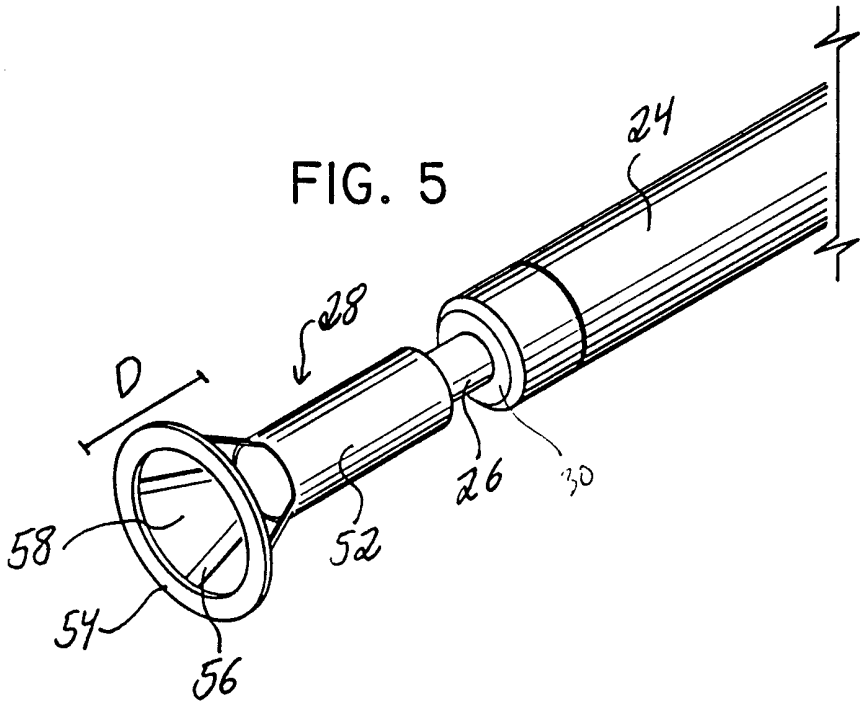


FIG. 4

FIG. 5



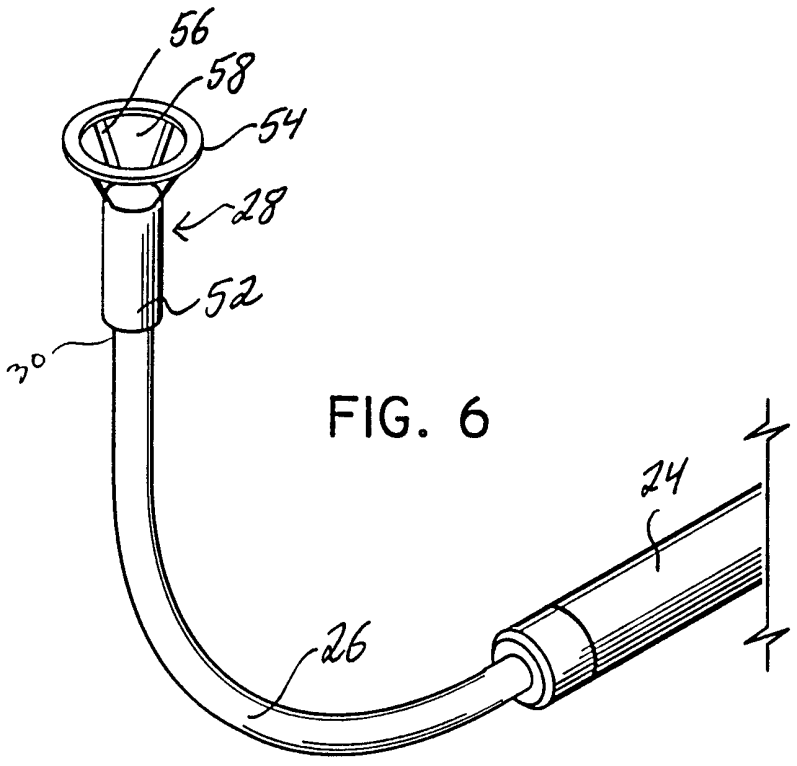


FIG. 6

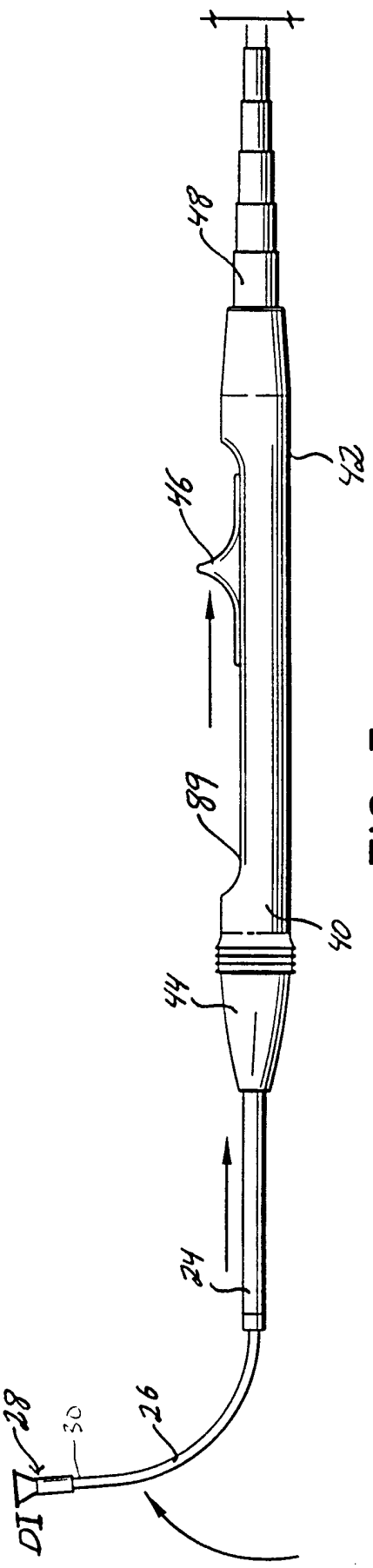


FIG. 7

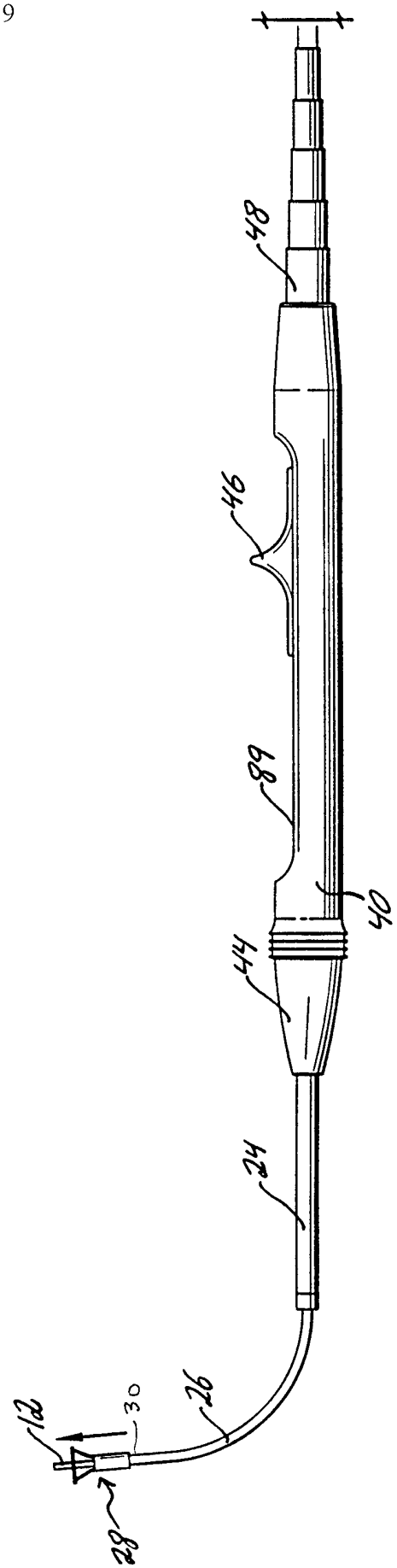


FIG. 8

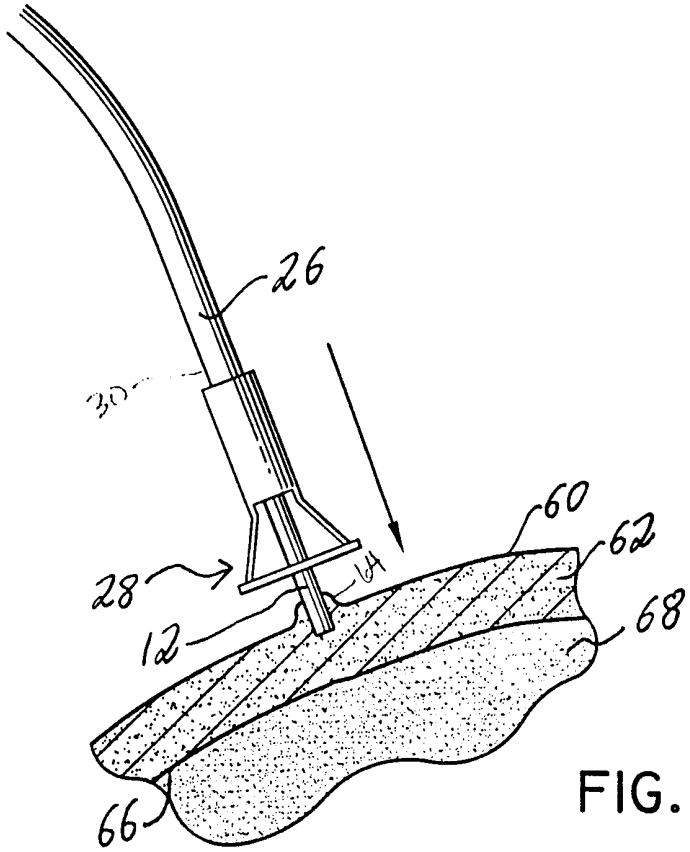


FIG. 9

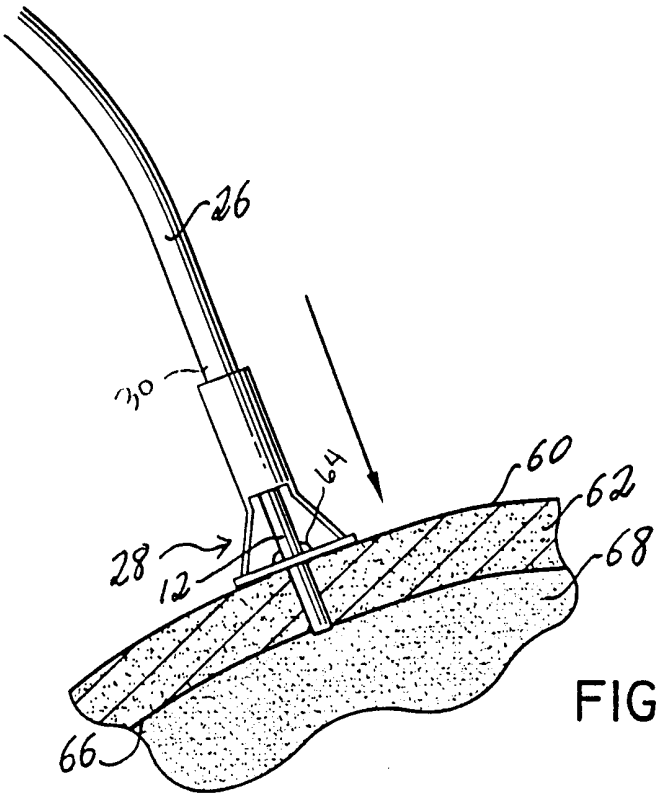


FIG. 10

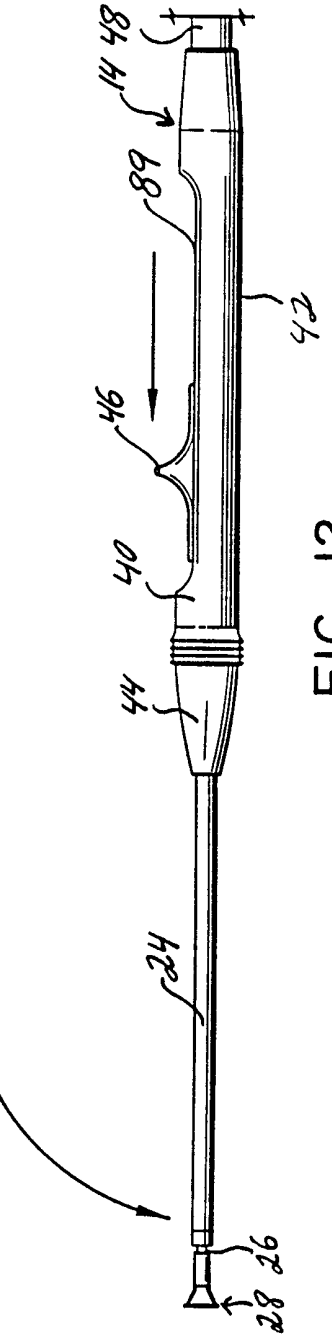


FIG. 12

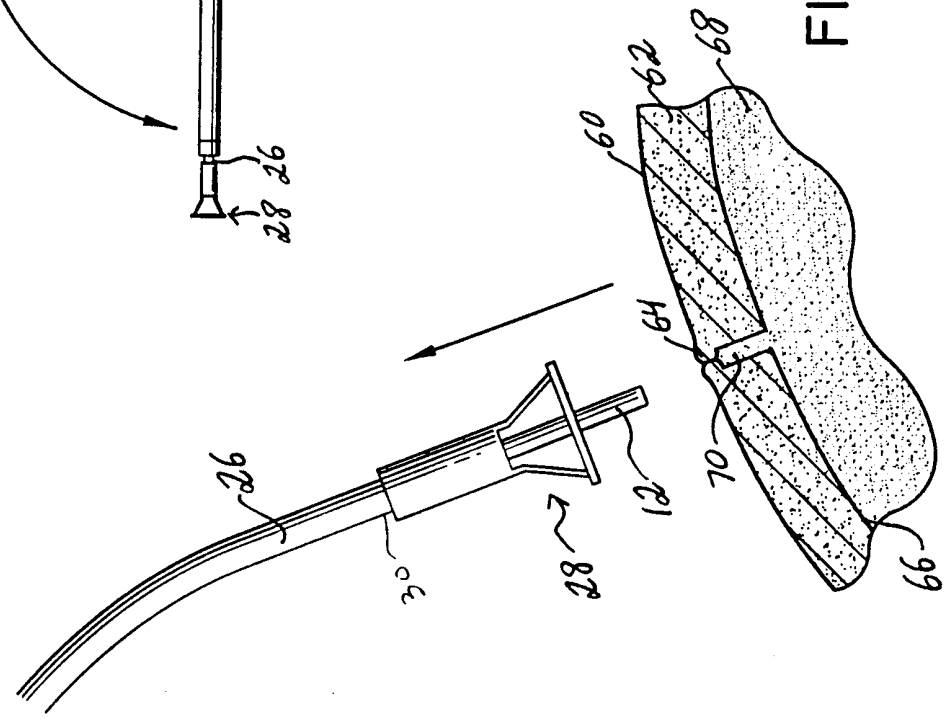


FIG. 11

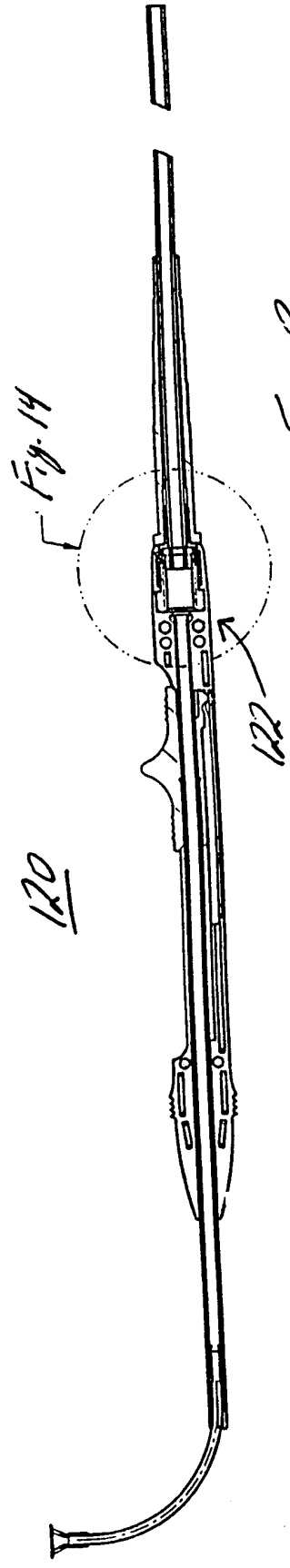


Fig. 13

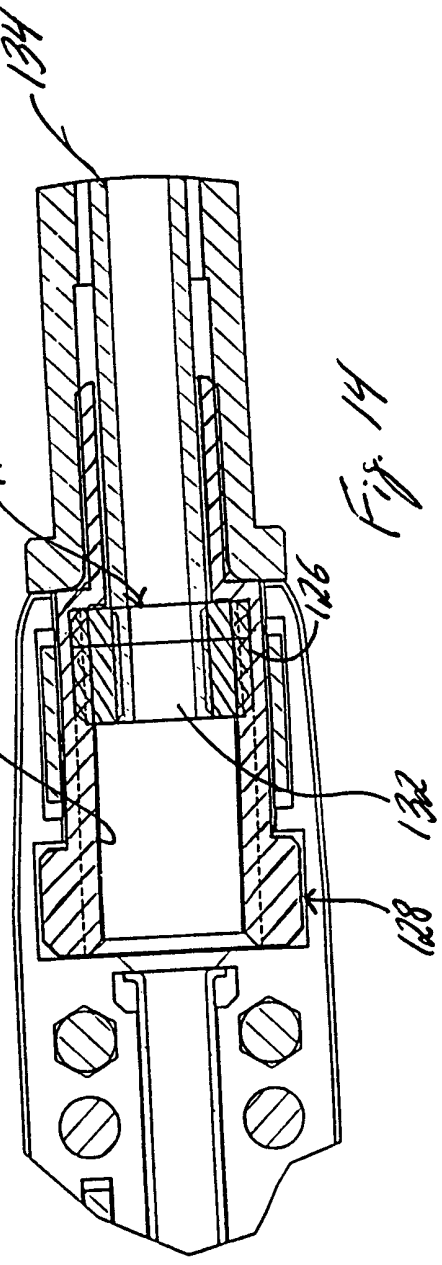


Fig. 14

Fig. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/23268

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/36
US CL :606/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/7, 10, 13-17

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,703,985 A (OWYANG) 30 December 1997, entire document.	1, 2, 7, 20, 22
X	US 5,738,680 A (MUELLER et al.) 14 April 1998, entire document.	1, 2, 7, 20, 22
X	US 5,766,164 A (MUELLER et al.) 16 June 1998, entire document.	1, 2, 4, 7, 20, 22
Y	US 5,807,383 A (KOLESA et al.) 15 September 1998, entire document.	21
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A		1, 8

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

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
06 JANUARY 2000

Date of mailing of the international search report
21 JAN 2000

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