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Notice Of Entitlement

I, John David O'Connor, of 31 Market Street, Sydney, New South Wales, 2000, Australia, Patent Attorney for the Applicant/Nominated Person in respect of Application No. 68190/94 state the following:-

The Applicant/Nominated Person has entitlement from the actual inventors as follows:-

The Applicant/Nominated Person is the assignee of the actual inventors.

The Applicant/Nominated Person is entitled to rely on the application listed in the Declaration under Article 8 of the PCT as follows:

The Applicant/Nominated Person is the assignee of the basic applicants.

The basic application listed on the Declaration under Article 8 of the PCT is the first application made in a Convention country in respect of the invention.

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(57) Claim

1. A medical probe device for medical treatment of tissue at a treatment site through a natural body opening defined by a wall comprising a guide housing having proximal and distal extremities and having a passageway extending from the proximal extremity to the distal extremity, a stylet slidably mounted in said passageway and including a flexible conductive electrode with a tip and a layer of insulating material coaxially mounted on the electrode but exposing the tip, means carried by the distal extremity of the guide housing and in communication with the passageway for directing the electrode and the layer of insulating material sidewise of the guide housing, handle means coupled to the proximal extremity of the guide housing for introducing the distal extremity of the guide housing into the natural body opening to a position adjacent the treatment site, the handle means including means for advancing the stylet to cause the tip of the electrode to penetrate the wall and extend into the tissue at the treatment site with the layer of insulating material extending through the wall, means for supplying electrical energy to the electrode to cause a thermal effect in the tissue

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at the treatment site while the layer of insulating material protects the wall from the thermal effect caused by the electrical energy and first and second temperature sensing means carried by the layer of insulating material, the second temperature sensing means spaced proximally of the first temperature sensing means whereby when the layer of insulating material is disposed in the wall the first and second temperature sensing means are located on opposite sides of the wall.

8. A medical probe device for medical treatment of tissue of a prostate through a urethra defined by a urethral wall comprising a guide housing having proximal and distal extremities and a passageway extending from the proximal extremity to the distal extremity, the guide housing having a length so that when the distal extremity of the guide housing is in the vicinity of the prostate the proximal extremity of the guide housing is outside the urethra, a stylet slidably mounted in the passageway, the stylet having proximal and distal extremities and a lumen extending from the proximal extremity to the distal extremity, means carried by the distal extremity of the guide housing and in communication with the passageway for directing the stylet sidewise of the guide housing, handle means coupled to the proximal extremity of the guide housing for introducing the distal extremity of the guide housing into the urethra so that the distal extremity of the guide housing is in the vicinity of the prostate, the handle means including means for advancing the stylet from the passageway to cause the distal extremity of the stylet to penetrate the urethral wall and to extend into the tissue of the prostate, means coupled to the guide housing for supplying a liquid to the lumen for delivery into the tissue of the prostate, means for supplying radio frequency energy through the distal extremity of the stylet to cause the temperature of the tissue of the prostate adjacent the distal extremity of the stylet to be raised to cause destruction of cells in the tissue of the prostate and first and second temperature sensing means carried by the stylet, the second temperature sensing means spaced proximally of the first temperature sensing means whereby when the stylet is disposed in the urethral wall the first and second temperature sensing means are located on opposite sides of the urethral wall.

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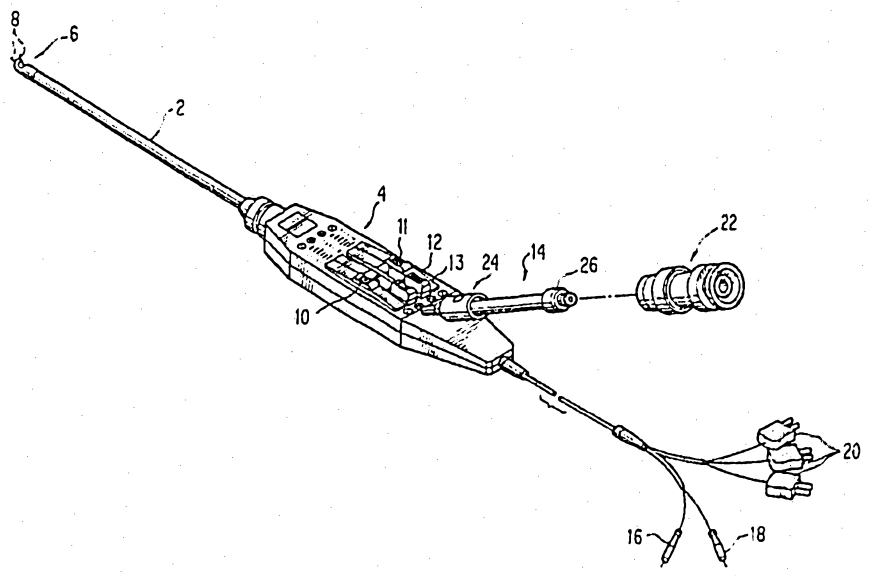

(57) Abstract

A medical probe device of this invention comprising a catheter (2) having a control end and a probe end. The probe end includes a stylet guide housing (6) having at least one stylet port and stylet guide means for directing a flexible stylet (8) outward through at least one stylet port and through intervening tissue to targeted tissues. A stylet (8) is positioned in at least one of said stylet guide means, the stylet comprising a nonconductive sleeve (30) having an RF electrode lumen (50) and an optional fluid supply lumen (60) and a temperature sensor lumen (58) therein. At least one portion of an opposed surface of the electrode lumen and the electrode (32) can be spaced apart to define a liquid supply passageway for delivery of medicament liquid. The RF electrode enclosed within the nonconductive sleeve has a distal length optionally having at least one current focusing groove (70) means thereon and a distal tip shaped to focus current crowding on its terminal end.

MEDICAL PROBE DEVICE

Technical Field

This invention is directed to a unique device and method for penetrating body tissues for medical purposes such as tissue ablation and fluid substance delivery, for example. The device penetrates tissue to the precise targe selected in order to delivery energy to the tissue and/or delivery substance. It limits this treatment to the precise preselected site, thereby minimizing trauma to normal surrounding tissue and achieving a greater medical benefit. This device is a catheter-like device for positioning a treatment assembly in the area or organ selected for medical treatment with one or more stylets in the catheter, mounted for extension from a stylet port in the side of the catheter through surrounding tissue to the tissue targeted for medical intervention.

Background Art

Treatment of cellular tissues usually requires direct contact of target tissue with a medical instrument, usually by surgical procedures exposing both the target and intervening tissue to substantial trauma. Often, precise placement of a treatment probe is difficult because of the location of targeted tissues in the body or the proximity of the target

tissue to easily damaged, critical body organs, nerves, or other components.

Benign prostatic hypertrophy or hyperplasia (BPH), for example, is one of the most common medical problems experienced by men over 50 years old. Urinary tract obstruction due to prostatic hyperplasia has been recognized since the earliest days of medicine. Hyperplastic enlargement of the prostate gland often leads to compression of the urethra, resulting in obstruction of the urinary tract and the subsequent development of symptoms including frequent urination, decrease in urinary flow, nocturia, pain, discomfort, and dribbling. The association of BPH with aging has been shown to exceed 50% in men over 50 years of age and increases in incidence to over 75% in men over 80 years of age. Symptoms of urinary obstruction occur most frequently between the ages of 65 and 70 when approximately 65% of men in this age group have prostatic enlargement.

Currently there is no proven effective nonsurgical method of treatment of BPH. In addition, the surgical procedures available are not totally satisfactory. Currently patients suffering from the obstructive symptoms of this disease are provided with few options: continue to cope with the symptoms (i.e., conservative management), submit to drug therapy at early stages, or submit to surgical intervention. More than 430,000 patients per year undergo surgery for removal of prostatic tissue in the United States. These represent less than five percent of men exhibiting clinical significant symptoms.

Those suffering from BPH are often elderly men, many with additional health problems which increase the risk of surgical procedures. Surgical procedures for the removal of prostatic tissue are associated with a number of hazards including anesthesia related morbidity, hemorrhage, coagulopathies, pulmonary emboli and electrolyte imbalances. These procedures performed currently can also lead to cardiac complications, bladder perforation, incontinence, infection, urethral or

bladder neck stricture, retention of prostatic chips, retrograde ejaculation, and infertility. Due to the extensive invasive nature of the current treatment options for obstructive uropathy, the majority of patients delay definitive treatment of their condition. This circumstance can lead to serious damage to structures secondary to the obstructive lesion in the prostate (bladder hypertrophy, hydronephrosis, dilation of the kidney pelves, chronic infection, dilation of ureters, etc.) which is not without significant consequences. In addition, a significant number of patients with symptoms sufficiently severe to warrant surgical intervention are therefore poor operative risks and are poor candidates for prostatectomy. In addition, younger men suffering from BPH who do not desire to risk complications such as infertility are often forced to avoid surgical intervention. Thus the need, importance and value of improved surgical and non-surgical methods for treating BPH is unquestionable.

High-frequency currents are used in electrocautery procedures for cutting human tissue especially when a bloodless incision is desired or when the operating site is not accessible with a normal scalpel but presents an access for a thin instrument through natural body openings such as the esophagus, intestines or urethra. Examples include the removal of prostatic adenomas, bladder tumors or intestinal polyps. In such cases, the high-frequency current is fed by a surgical probe into the tissue to be cut. The resulting dissipated heat causes boiling and vaporization of the cell fluid at this point, whereupon the cell walls rupture and the tissue is separated.

Destruction of cellular tissues *in situ* has been used in the treatment of many diseases and medical conditions alone or as an adjunct to surgical removal procedures. It is often less traumatic than surgical procedures and may be the only alternative where other procedures are unsafe. Ablative treatment devices have the advantage of using an

electromagnetic energy which is rapidly dissipated and reduced to a non-destructive level by conduction and convection forces of circulating fluids and other natural body processes.

Microwave, radiofrequency, acoustical (ultrasound) and light energy (laser) devices, and tissue destructive substances have been used to destroy malignant, benign and other types of cells and tissues from a wide variety of anatomic sites and organs. Tissues treated include isolated carcinoma masses and, more specifically, organs such as the prostate, glandular and stromal nodules characteristic of benign prostate hyperplasia. These devices typically include a catheter or cannula which is used to carry a radiofrequency electrode or microwave antenna through a duct to the zone of treatment and apply energy diffusely through the duct wall into the surrounding tissue in all directions. Severe trauma is often sustained by the duct wall during this cellular destruction process, and some devices combine cooling systems with microwave antennas to reduce trauma to the ductal wall. For treating the prostate with these devices, for example, heat energy is delivered through the walls of the urethra into the surrounding prostate cells in an effort to ablate the tissue causing the constriction of the urethra. Light energy, typically from a laser, is delivered to prostate tissue target sites by "burning through" the wall of the urethra. Healthy cells of the duct wall and healthy tissue between the nodules and duct wall are also indiscriminately destroyed in the process and can cause unnecessary loss of some prostate function. Furthermore, the added cooling function of some microwave devices complicates the apparatus and requires that the device be sufficiently large to accommodate this cooling system.

Application of liquids to specific tissues for medical purposes is limited by the ability to obtain delivery without traumatizing intervening tissue and to effect a delivery limited to the specific target tissue. Localized chemotherapy, drug infusions, collagen injections, or

injections of agents which are then activated by light, heat or chemicals would be greatly facilitated by a device which could conveniently and precisely place a fluid (liquid or gas) supply catheter opening at the specific target tissue.

It is an object of the present invention to substantially overcome or at least ameliorate one or more of the disadvantages of the prior art.

Disclosure of the Invention

Accordingly, in a first aspect, the present invention discloses a medical probe device for medical treatment of tissue at a treatment site through a natural body opening defined by a wall comprising a guide housing having proximal and distal extremities and having a passageway extending from the proximal extremity to the distal extremity stylet slidably mounted in said passageway and including a flexible conductive electrode with a tip and a layer of insulating material coaxially mounted on the electrode but exposing the tip, means carried by the distal extremity of the guide housing and in communication with the passageway for directing the electrode and the layer of insulating material sidewise of the guide housing, handle means coupled to the proximal extremity of the guide housing for introducing the distal extremity of the guide housing into the natural body opening to a position adjacent the treatment site, the handle means including means for advancing the stylet to cause the tip of the electrode to penetrate the wall and extend into the tissue at the treatment site with the layer of insulating material extending through the wall, means for supplying electrical energy to the electrode to cause a thermal effect in the tissue at the treatment site while the layer of insulating material protects the wall from the thermal effect caused by the electrical energy and first and second temperature sensing means carried by the layer of insulating material, the second temperature sensing means spaced proximally of the first temperature sensing means whereby when the layer of insulating material is disposed in the wall the first and second temperature sensing means are located on opposite sides of the wall.

In a second aspect, the present invention discloses a medical probe device for medical treatment of tissue of a prostate through a urethra defined by a urethral wall comprising a guide housing having proximal and distal extremities and a passageway extending from the proximal extremity to the distal extremity, the guide housing having a length so that when the distal extremity of the guide housing is in the vicinity of the prostate the proximal extremity of the guide housing is outside the urethra, a stylet slidably mounted in the passageway, the stylet having proximal and distal extremities and a lumen extending from the proximal extremity to the distal extremity, means carried by the distal extremity of the guide housing and in communication with the passageway for directing the stylet sidewise of the guide housing, handle means coupled to the proximal extremity of the guide housing for introducing the distal extremity of the guide housing into the urethra so that the distal extremity of the guide housing is in the vicinity of the prostate, the handle means including means for advancing the stylet from the passageway to cause the distal extremity of the stylet to penetrate the urethral wall and to extend into the tissue of the prostate, means coupled to the guide housing for supplying a liquid to the lumen for delivery into the tissue of the prostate, means for supplying radio frequency energy through the distal extremity of the stylet to cause the temperature of the tissue of the prostate adjacent the distal extremity of the stylet to be raised to cause destruction of cells in the tissue of the prostate and first and second temperature sensing means carried by the stylet, the second temperature sensing means spaced proximally of the first temperature sensing means whereby when the stylet is disposed in the urethral wall the first and second temperature sensing means are located on opposite sides of the urethral wall.

Brief Description of the Drawings

Fig. 1 is an isometric view of an RF ablation catheter embodiment of this invention with an fiber optic viewing accessory.

Fig. 2 is a cross-sectional view of a catheter of Fig. 1 showing details of the stylet guide housing.

Fig. 3 is a side view of the stylet and lumen assembly of this invention.

Fig. 4 is a cross-sectional side view of the junction of the stylet and control tube assembly taken along the central axis of the tubing.

Fig. 5 is a cross-sectional view of the junction of the stylet and control tube assembly taken along the line 5-5 of Fig. 4.

Fig. 6 is a cross-sectional view of a trilumen stylet of this invention taken along the line 6-6 in Fig. 3.

Fig. 7 is a cross-sectional side view of the trilumen stylet tip shown in Fig. 3 taken along line 7-7 of Fig. 6.

Fig. 8 is a plane view of the annular groove embodiment of the current density focusing electrode of this invention.

Fig. 9 is a plane view of the spiral groove embodiment of the current density focusing electrode of this invention, position and the sleeve partially retracted therefrom.

Fig. 10 is an exploded view of the RF ablation catheter shown in Fig. 1.

Fig. 11 is an isometric view of the adjuster block and tension tube assembly of the RF ablation catheter shown in Fig. 10.

Fig. 12 is a detailed view "A" of the tension tube connections shown in Fig. 11.

Fig. 13 is an exploded view of the sleeve and electrode

slide block assembly of the embodiment shown in Fig. 10.

Best Mode for Carrying Out the Invention

The device of this invention provides a precise controlled positioning of a treatment stylet in a tissue targeted for treatment, destruction or sampling from a catheter positioned in the vicinity of the target tissue.

The term "stylet" as used hereinafter is defined to include both solid and hollow probes which are adapted to be passed from a catheter port through normal tissue to targeted tissues. The stylet is shaped to facilitate easy passage through tissue. It can be a solid wire, thin rod, or other solid shape or it can be a thin hollow tube or other shape having a longitudinal lumen for introducing fluids to or removing materials from a site. The stylet can also be a thin hollow tube or other hollow shape, the hollow lumen thereof containing a reinforcing or functional rod or tube such as a laser fiber optic. The stylet preferably has a sharpened end to reduce resistance and trauma when it is pushed through tissue to a target site.

The stylet can be designed to provide a variety of medically desired treatments of a selected tissue. As a radiofrequency electrode or microwave antenna, it can be used to ablate or destroy targeted tissues. As a hollow tube, it can be used to deliver a treatment fluid such as a liquid to targeted tissues. The liquid can be a simple solution or a suspension of solids, for example, colloidal particles, in a liquid. Since the stylet is very thin, it can be directed from the catheter through intervening normal tissue with a minimum of trauma to the normal tissue.

The device and method of this invention provide a more precise, controlled medical treatment which is suitable for destroying cells of medically targeted tissues throughout the body, both within and external to body organs. The device and method are particularly useful for treating benign prostate hyperplasia (BPH), and the device and its use are hereinafter

described with respect to BPH, for purposes of simplifying the description thereof. It will be readily apparent to a person skilled in the art that the device and method can be used to destroy body tissues in any body cavities or tissue locations that are accessible by percutaneous or endoscopic catheters, and is not limited to the prostate. Application of the device and method in all of these organs and tissues are intended to be included within the scope of this invention.

BPH is a condition which arises from the replication and growth of cells in the prostate and the decrease of cell death rate, forming glandular and stromal nodules which enlarge the prostate and constrict the opening of the prostatic urethra. Glandular nodules are primarily concentrated within the transition zone, and stromal nodules within the periurethral region. Traditional treatments of this condition have included surgical removal of the entire prostate gland, digital removal of the adenoma, as well as transurethral resection of the urethral canal and prostate to remove tissue and widen the passageway. One significant and serious complication associated with these procedures is iatrogenic sterility.

More recently, laser treatment has been employed to remove tissue, limiting bleeding and loss of body fluids. Balloons have also been expanded within the urethra to enlarge its diameter, with and without heat, but have been found to have significant limitations.

Microwave therapy has been utilized with some success by positioning a microwave antenna within the prostatic urethra and generating heat in the tissue surrounding the urethra with an electromagnetic field. Coolants are sometimes applied within the catheter shaft to reduce the temperature of the urethral wall. This necessitates complicated mechanisms to provide both cooling of the immediately adjacent tissues while generating heat in the more distant prostatic tissue. This technique is similar to microwave hyperthermia. Similarly, radiofrequency tissue ablation with electrodes positioned

within the urethra exposes the urethral wall to destructive temperatures. To avoid this, low temperature settings required to protect the urethra must be so low that the treatment time required to produce any useful effect is unduly extended, e.g. up to three hours or energy application.

One embodiment of the device of this invention uses the urethra to access the prostate and positions RF electrode stylets directly into the tissues to be destroyed. The portion of the stylet conductor extending from the urethra to targeted tissues is enclosed within a longitudinally adjustable sleeve shield which prevents exposure of the tissue adjacent to the sleeve to the RF current. The sleeve movement is also used to control the amount of energy per unit surface area which is delivered by controlling the amount of electrode exposed. Thus the ablative destruction is confined to the tissues targeted fro destruction, namely those causing the constriction. Other aspects of the invention will become apparent from the drawings and accompanying descriptions of the device and method of this invention. It will be readily apparent to a person skilled in the art that this procedure can be used in many areas of the body for percutaneous approaches and approaches through body orifices.

Fig. 1 is an isometric view of an RF ablation catheter embodiment of this invention with a fiber optic viewing accessory. The flexible catheter 2, attached to handle 4, has a terminal stylet guide 6 with two stylets 8. The handle has stylet electrode tabs 10 and 11 and sleeve tabs 12 and 13 as will be described in greater detail hereinafter. The handle 4 is also connected to a optical viewing assembly 14 and RF power connector 16, transponder connector 18 and thermocouple connectors 20. The portions of the catheter 2 leading from the handle 4 to the stylet guide tip 6 can optionally has a graduated stiffness. For example, the catheter can be designed to be more stiff near the handle and more flexible near the tip, or any other stiffness profiles. The catheter can be constructed of an inner slotted stainless steel tube with outer flexible sleeve such as is described in U.S. Patent No. 5,322,064, the entire contents of which are incorporated herein by reference. It can also be made of coiled or braided wire to which an outer sleeve is bonded.

Referring to Fig. 5, the space 56 between the control tube 46 and the trilumen sleeve tube 54 can be filled with an adhesive to secure them together. The trilumen includes an electrode lumen 50, a temperature sensor lumen 58 and a fluid supply lumen 60 for supply of optional fluids such as antibiotics or anaesthetics to the area of treatment.

Fig. 6 is a cross-sectional view of a trilumen stylet of this invention taken along the line 6-6 in Fig. 3. The trilumen sleeve 30 is an insulating sleeve for the electrode 32 and includes the additional temperature sensor lumen 58 and liquid supply lumen 60. The inner surface of the electrode lumen 50 can be spaced from the outer surface of the electrode by a distance "h" which can be, for example, from about 1 to 3 mm to define an additional liquid supply conduit with an approximate annular cross-section.

Fig. 7 is a cross-sectional side view of the trilumen stylet tip shown in Fig. 6 taken along the line 7-7. The terminal end of the temperature sensor lumen 58 is sealed to protect the electrical components. Thermocouple 64 is placed at the distal end of the sleeve 50 to monitor the temperature of the tissue surrounding the electrode 32 and is preferably less than about 1mm from the exposed electrode. Thermocouple 66 is placed at least about 3mm and preferably from about 3 to 6mm from the tip of sleeve 30 to monitor the temperature of the duct wall (such as the urethra) through which the stylet is extended. This is provided to ensure the duct wall temperature does not reach destructive levels when the RF treatment of tissue surrounding the extended electrode is underway.

Fig. 8 is a plane view of the annular groove element of the current density focusing electrode of this invention. In this embodiment, the electrode is ground to a single current focusing sharp tip 68 without secondary corner or other sharp edges which could also focus or crowd current. Additional current focusing can be provided along the electrode surface by the annular grooves 70 to 62. The temperature of the tissue surrounding the electrode initially increases in initial zones 74, 76 and 78. The temperature zone then extends to two intermediate zones 80 and 82, as the zones from

the grooves merge. Thereafter all of the elevated temperature zones merge to form the single oval zone lesion 84. Use of these current focusing grooves 70 and 72 produces a more symmetrical lesion.

Fig. 9 is a plane view of the spiral groove embodiment of the current density focusing electrode of this invention. In this embodiment, the electrode is also ground to a single current focusing sharp tip 86 without secondary sharp corners or edges which could also focus or crowd current. Additional current focusing can be provided along the electrode surface by at least one spiral or helical groove 88. The temperature of the tissue surrounding the electrode initially increases in the initial tip zone 90 and spiral zone 92. The elevated temperature zone extends to two intermediate zones 94 and 96, as the spiral zone 92 merges to form a single zone 96. Thereafter all of the elevated temperature zones merge to form the single oval zone lesion 98. Use of the spiral focusing groove 88 provide a more symmetrical lesion.

Fig. 10 is an exploded view of the RF ablation catheter assembly shown in Fig. 1. The upper handle plate 276 has two central slots 278 and 280 through which the electrode control slides 10 and 11 are attached to respective left electrode slide block 282 and right electrode slide block 284. Sleeve control slides 12 and 13 are attached through outer slots 286 and 288 to respective left sleeve slide block 290 and right sleeve slide block 292. Fiber optical receptor housing 30 is mounted on the proximal surface of the upper handle plate 276. The electrical receptor 294 is received in respective cavities 296 and 298 in the upper handle plate 276 and the lower handle plate 300 attached thereto. The lower handle plate 300 has a central cavity 302 which accommodates the electrode and sleeve slide blocks and associated elements.

Microswitch activator blocks 304 (only left sleeve block shown) are connected to the sleeve slide blocks 290 and 292. They are positioned to actuate the microswitches 306 when the respective sleeve block (and sleeve attached thereto) have been advanced. The microswitches 306 hold the respective RF power circuits open until the respective sleeves are advanced to a position beyond the urethra wall and into the prostate to prevent direct exposure of the urethra to the energized RF electrodes.

Extensions of the sleeve 5 mm beyond the guide is usually sufficient to protect the urethra.

The tension-torque tube assembly 308 is mounted in the distal end of the housing in the receptor 310.

Fig. 11 is an isometric view of the adjuster block and tension tube assembly 308 of the RF ablation catheter shown in Fig. 10. The torque tube 312 extends from the torque coupler 314 through the twist control knob 316 to the stylet guide 6. Bending flexure of the torque tube 312 during use lengthens the path from the handle to the guide tip 6. To prevent a resulting retraction of the stylet sleeve and electrode components when the torque tube 312 is flexed, a tension tube 318 having a fixed length and diameter smaller than the inner diameter of the torque tube 312 is provided. The distal end of the tension tube 318 is securely attached to the stylet guide 6, and the proximal end 320 is secured to the adjuster block 322, for example by an adhesive. The axial position of the adjuster block 322 can be adjusted to ensure the stylets 8 are initially positioned just inside the outlet ports in the stylet guide 6. Torque couplet 314 is mounted on the coupler block 324. Twist control knob stop in 326 extends into a grove (not shown) and limits rotation of the control knob 316.

Fig. 12 is a detailed view "A" of the distal end tension tube connections of the tension tube shown in Fig. 11. The tension tube 318 is securely connected to the proximal end 328 of the stylet guide 6, for example by a length of shrink tubing 330.

Fig. 13 is an exploded view of the sleeve and electrode slide block assembly of the embodiment shown in Fig. 10. The right sleeve slide block 292 has a projection 332 which extends inward under the right electrode slide block 284. Right sleeve connector 334 is mounted to the inner end of the projection 332, secured to the end of the proximal end of the sleeve 336. Right electrode connector 338 is attached to an inner surface of the electrode slide block 284 and is secured to the proximal end of electrode 340. The right sleeve and electrode slide blocks 292 and 284 are slidingly attached to the right friction adjustment rail 342 by screws (not shown) through slots 388 and 346, the screws being adjustable to provide sufficient friction between the

blocks and the rail 342 to provide secure control over the stylet movement. The left sleeve slide block 290 and left electrode slide block 2892 are mirror replicas of the right blocks and are similarly mounted on the left friction rail 344. The left sleeve and electrodes are not shown.

Although preferred embodiments of the subject invention have been described in some detail, it will be appreciated by those skilled in the art, that the invention can be embodied in many other forms.

The claims defining the invention are as follows:

1. A medical probe device for medical treatment of tissue at a treatment site through a natural body opening defined by a wall comprising a guide housing having proximal and distal extremities and having a passageway extending from the proximal extremity to the distal extremity, a stylet slidably mounted in said passageway and including a flexible conductive electrode with a tip and a layer of insulating material coaxially mounted on the electrode but exposing the tip, means carried by the distal extremity of the guide housing and in communication with the passageway for directing the electrode and the layer of insulating material sidewise of the guide housing, handle means coupled to the proximal extremity of the guide housing for introducing the distal extremity of the guide housing into the natural body opening to a position adjacent the treatment site, the handle means including means for advancing the stylet to cause the tip of the electrode to penetrate the wall and extend into the tissue at the treatment site with the layer of insulating material extending through the wall, means for supplying electrical energy to the electrode to cause a thermal effect in the tissue at the treatment site while the layer of insulating material protects the wall from the thermal effect caused by the electrical energy and first and second temperature sensing means carried by the layer of insulating material, the second temperature sensing means spaced proximally of the first temperature sensing means whereby when the layer of insulating material is disposed in the wall the first and second temperature sensing means are located on opposite sides of the wall.

2. A medical probe device as in Claim 1 for treatment with radio frequency energy of tissue of a prostate through a urethra defined by a urethral wall further characterized in that the layer of insulating material having a distal extremity extending through the urethral wall when the electrode is disposed in the tissue of the prostate so that the urethral wall is protected when radio frequency energy is supplied to the electrode to create lesions in the tissue of the prostate.

3. A medical probe device as in Claim 1 further characterized in that means is carried by the guide housing for providing a lumen extending from the proximal extremity to the distal extremity.

4. A device as in Claim 3 further characterized in that the lumen constitutes an annular space surrounding the stylet, means coupled to the guide housing for supplying a liquid to the lumen for delivery into the treatment site.

5. A medical probe device as in Claim 3 further characterized in that the lumen is separate from the passageway, means coupled to the guide housing for supplying a liquid to the lumen for delivery into the treatment site.

6. A medical probe device as in Claim 1 further characterized in that means is carried by the guide housing for providing the passageway and a lumen extending from the proximal extremity to the distal extremity spaced apart from the passageway, means coupled to the guide housing for supplying a saline solution to the lumen for delivery into the treatment site.

7. A medical device as in Claim 6 further characterized in that the means carried by the guide housing for providing the passageway and the lumen further provides an additional lumen extending from the proximal extremity to the distal extremity spaced apart from the passageway and the first named lumen for the return of the saline solution from the treatment site to the proximal extremity.

8. A medical probe device for medical treatment of tissue of a prostate through a urethra defined by a urethral wall comprising a guide housing having proximal and distal extremities and a passageway extending from the proximal extremity to the distal extremity, the guide housing having a length so that when the distal extremity of the guide housing is in the vicinity of the prostate the proximal extremity of the guide housing is outside the urethra, a stylet slidably mounted in the passageway, the stylet having proximal and distal extremities and a lumen extending from the proximal extremity to the distal extremity, means carried by the distal extremity of the guide housing and in communication with the passageway for directing the stylet sidewise of the guide housing, handle means coupled to the proximal extremity of the guide housing for introducing the distal

extremity of the guide housing into the urethra so that the distal extremity of the guide housing is in the vicinity of the prostate, the handle means including means for advancing the stylet from the passageway to cause the distal extremity of the stylet to penetrate the urethral wall and to extend into the tissue of the prostate, means coupled to the guide housing for supplying a liquid to the lumen for delivery into the tissue of the prostate, means for supplying radio frequency energy through the distal extremity of the stylet to cause the temperature of the tissue of the prostate adjacent the distal extremity of the stylet to be raised to cause destruction of cells in the tissue of the prostate and first and second temperature sensing means carried by the stylet, the second temperature sensing means spaced proximally of the first temperature sensing means whereby when the stylet is disposed in the urethral wall the first and second temperature sensing means are located on opposite sides of the urethral wall.

9. A medical probe device as in Claim 8 further characterized in that the stylet includes a flexible radio frequency electrode with a tip and a layer of insulating material coaxially mounted on at least a portion of the radio frequency electrode

10. A medical probe device as in Claim 9 further characterized in that the layer of insulating material is movable relative to the radio frequency electrode, the handle means including means for causing relative movement between the layer of insulating material and the radio frequency electrode.

11. A medical probe device as in Claim 9 further characterized in that the lumen constitutes an annular space surrounding the radio frequency electrode.

12. A medical probe device as in Claim 9 further characterized in that the lumen extends through the layer of insulating material.

13. A medical probe device as in Claim 9 further characterized in that the lumen extends through the radio frequency electrode.

14. A medical probe device as in Claim 9 further characterized in that the first and second temperature sensing means are carried by the layer of insulating material.

15. A medical probe device as in Claim 9 further characterized in that the radio frequency electrode has a distal length provided with at least one current focusing groove thereon and a distal tip shaped to focus current on its terminal end whereby radio frequency current passing therefrom into surrounding tissue forms a lesion extending outward from the groove and tip.

16. A medical probe device as in Claim 17 further characterized in that the distal length of the radio frequency electrode is provided with a plurality of annular focusing grooves thereon.

17. A medical probe device as in Claim 17 further characterized in that the distal length of the radio frequency electrode is provided with a spiral focusing groove thereon.

18. A medical probe device for medical treatment of tissue at a treatment site through a nature body opening, substantially as hereinbefore described with reference to the accompanying drawings.

19. A medical probe device for medical treatment of tissue of a prostate through a urethra defined by a urethral wall, substantially as hereinbefore described with reference to the accompanying drawings.

DATED this Fourth Day of December 1997
Vidamed, Inc.

Patent Attorneys for the Applicant
SPRUSON & FERGUSON

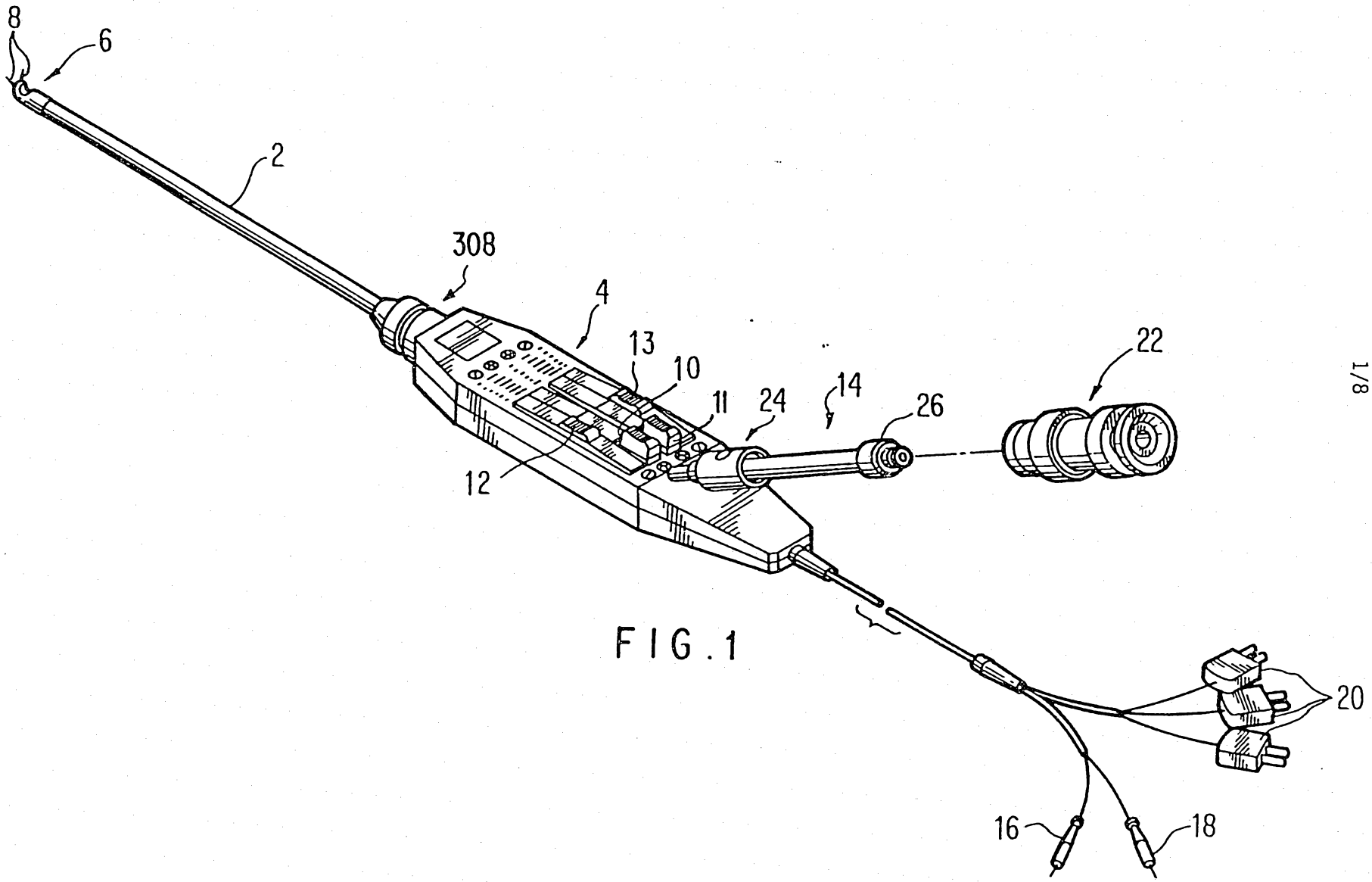

FIG. 1

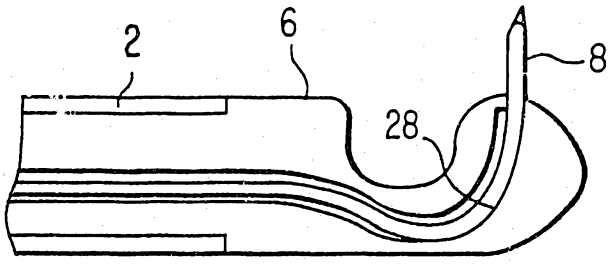

FIG. 2

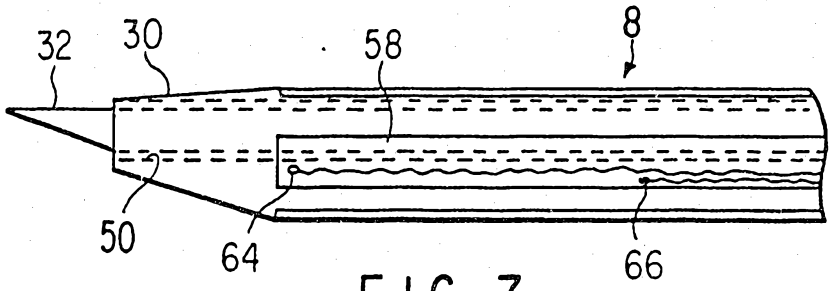

FIG. 7

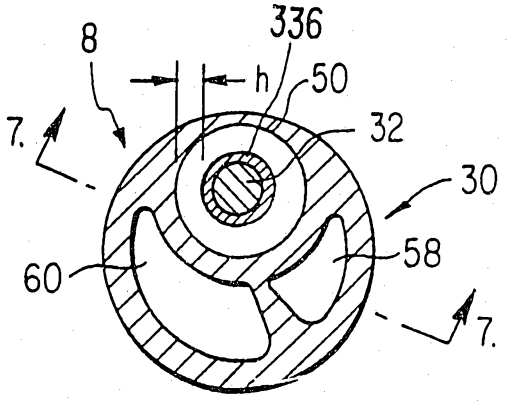

FIG. 6

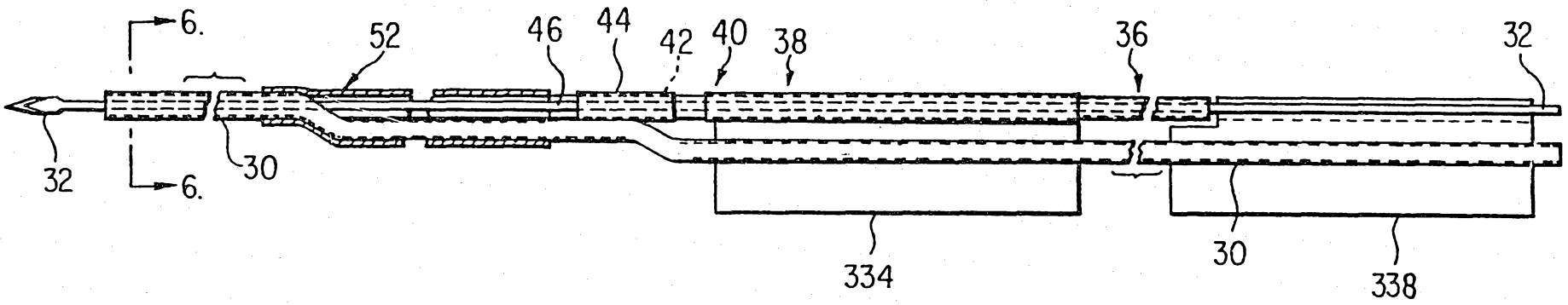

FIG. 3

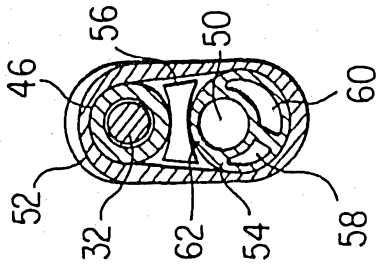

FIG. 5

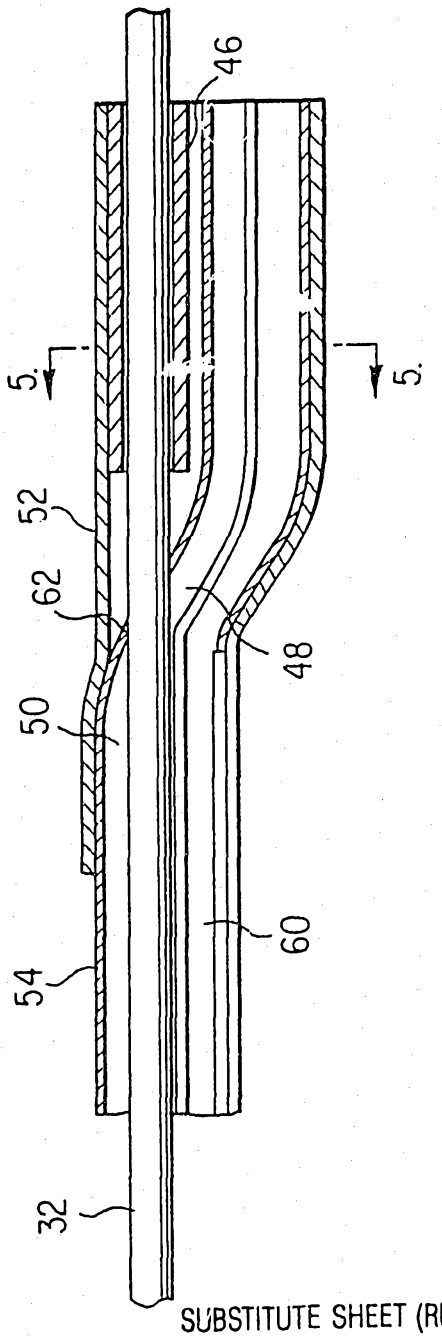

FIG. 4

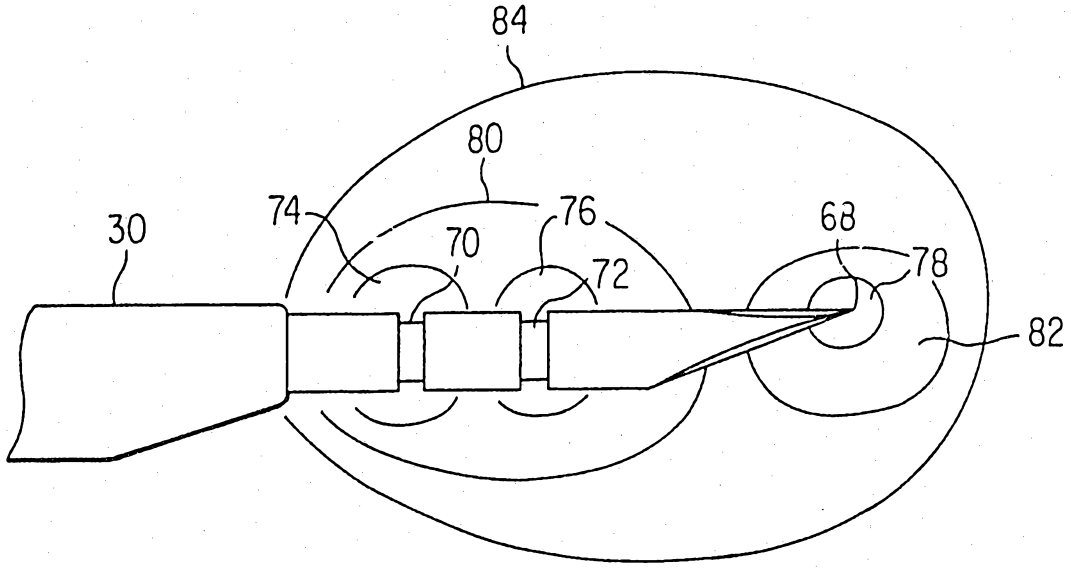

FIG. 8

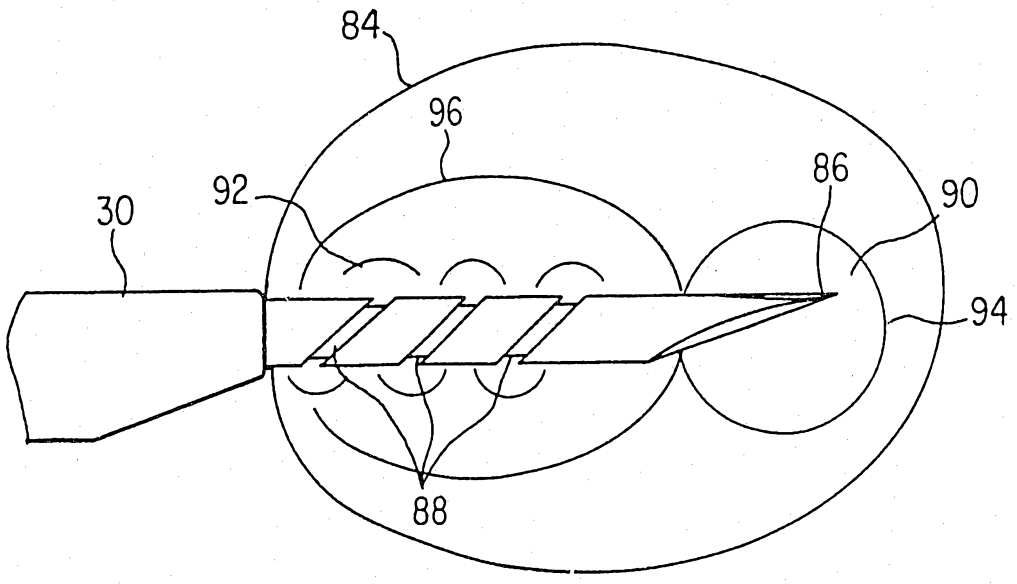

FIG. 9

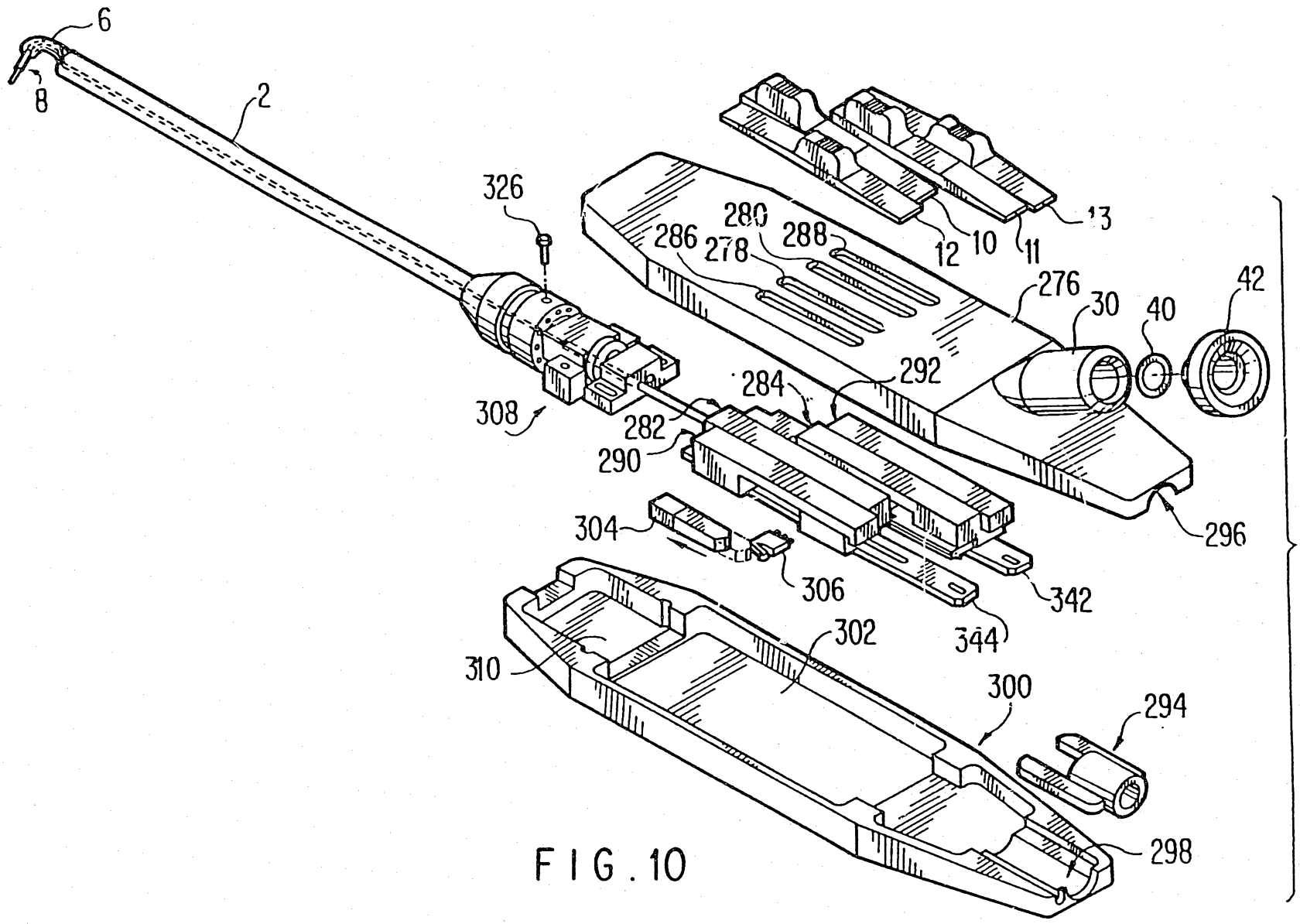
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FIG. 10

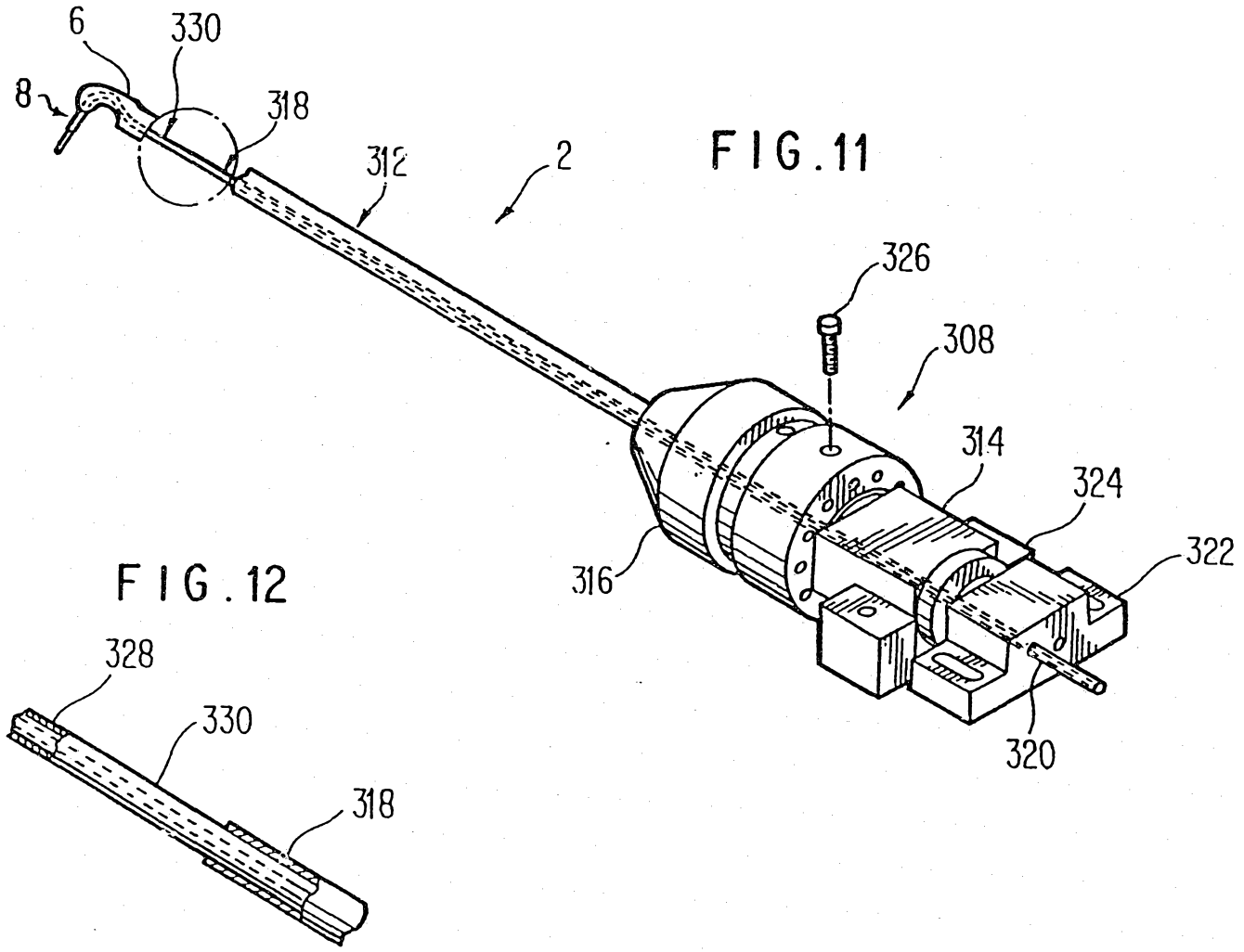
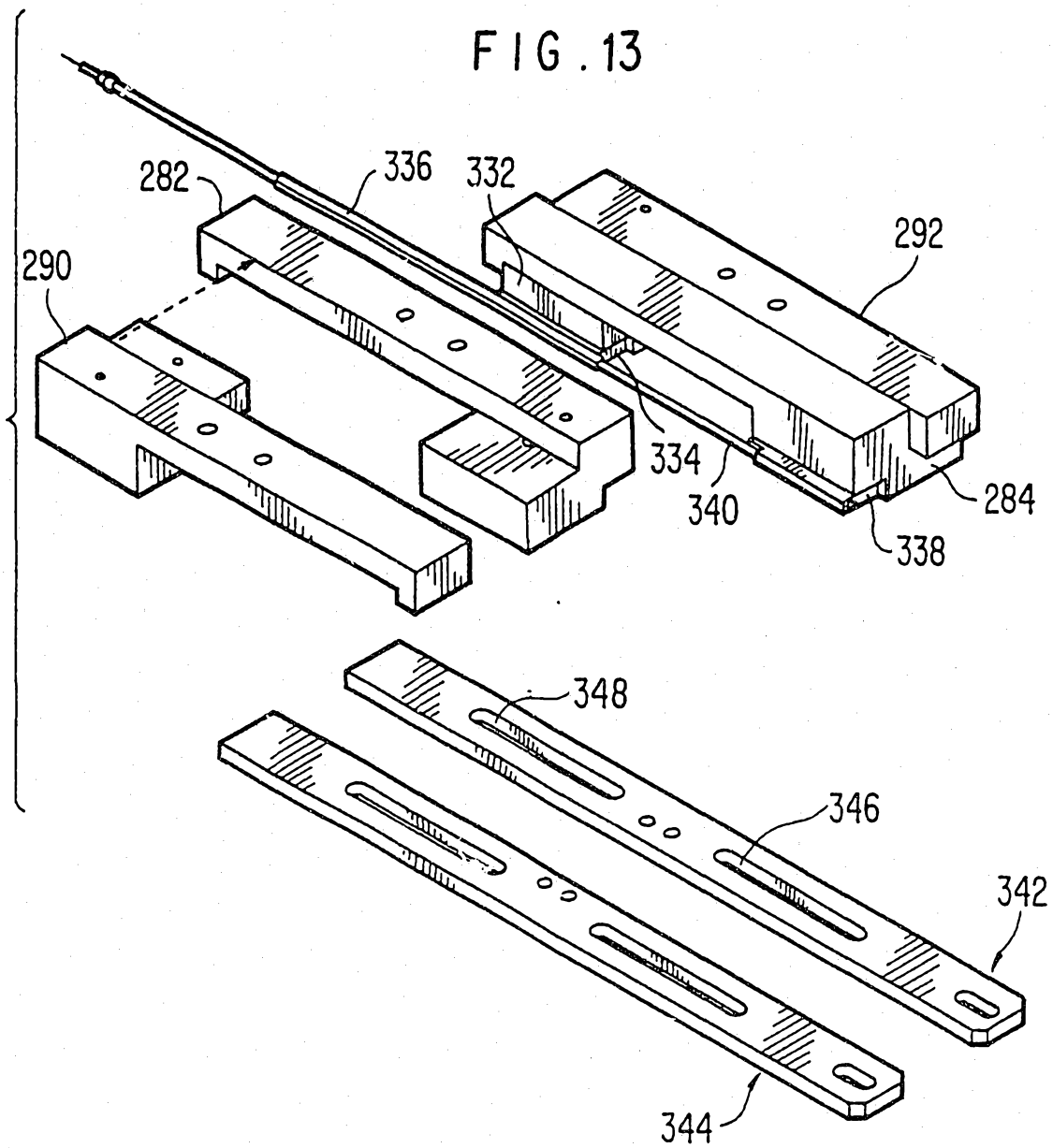


FIG. 11

FIG. 12

FIG. 13



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/04550

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61B 17/39
US CL :607/99
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. : 607/19-22; 606/39-46; 607/99-101, 111-116, 153-156

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

NONE

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

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- A	WO, A, 92/10142, (MAKOWER), 25 June 1992. See entire document.	1-13, 17 --- 14-16
Y --- A	US, A, 4,950,267, (ISHIHARA ET AL.), 21 August 1990. See entire document.	1-13, 17 --- 14-16
Y --- A	US, A, 4,907,589, (COSMAN), 13 March 1990. See column 4, lines 19-34.	1-13, 17 --- 14-16
A,P	US, A, 5,273,524, (FOX ET AL.), 28 December 1993. See Abstract, and figures.	1-17

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

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 07 JULY 1994	Date of mailing of the international search report 18 OCT 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL RAFA Telephone No. (703) 305-2214

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/04550

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,007,908, (RYDELL), 16 April 1991. See Abstract, and figures.	1-17
A	US, A, 4,565,200, (COSMAN), 21 January 1986. See entire document.	1-17
A	US, A, 4,411,266, (COSMAN), 25 October 1983. See Abstract.	1-17