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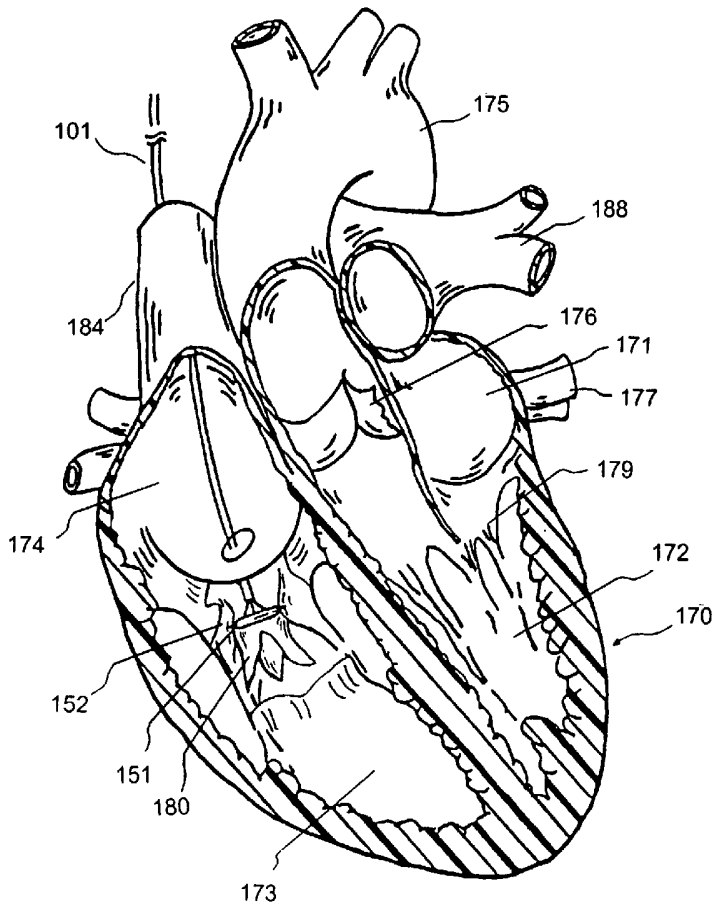
(54) **Title:** CATHETER SYSTEM AND METHODS FOR REPAIRING A VALVULAR ANNULUS



(57) **Abstract:** An ablation catheter system and methods for repairing an annular organ structure comprising high frequency ablation for the purposes of tightening and stabilizing a tissue. A catheter suitable for high frequency ablation comprises a flexible tissue contactor (105) located at the distal tip section of a catheter shaft (101) for contacting an inner wall on the annular organ structure (152), and a needle electrode (109) at or within the flexible tissue contactor means for penetrating into the tissue, wherein the needle electrode (109) is deployable out of the tissue contactor in a manner essentially perpendicular to a longitudinal axis of the catheter shaft (101).

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CATHETER SYSTEM AND METHODS FOR REPAIRING A VALVULAR ANNULUS

BACKGROUND OF THE INVENTION

The present invention generally relates to a system and methods for applying electrical energy to a patient for medical purposes such as reducing and/or shrinking a tissue mass. More particularly, the invention relates to an ablation catheter system for treating valvular annulus, atherosclerosis, or tissues in a patient by delivering therapeutic RF energy through an electrode to a specific lesion site. The circulatory system consists of a heart and blood vessels. In its path through the heart, the blood encounters four valves. The valve on the right side that separates the right atrium from the right ventricle has three cusps and is called the tricuspid valve. It closes when the ventricle contracts during a phase known as systole and it opens when the ventricle relaxes, a phase known as diastole.

The pulmonary valve separates the right ventricle from the pulmonary artery. The mitral valve, so named because of its resemblance to a bishop's mitre, is in the left ventricle and it separates the left atrium from the ventricle. The mitral valve and the tricuspid valve differ significantly in anatomy. The annulus of the mitral valve is somewhat D-shaped whereas the annulus of the tricuspid valve is more nearly circular. The fourth valve is the aortic valve. It separates the left ventricle from the aorta. In a venous circulatory system, a venous valve is to prevent the venous blood from leaking back into the upstream side so that the venous blood can return to the heart and the lungs for blood oxygenating purposes.

Clinical experience has shown that repair of a valve, either a heart valve or a venous valve, produces better long-term results than does valve replacement. Valve replacement using a tissue valve suffers long-term calcification problems. On the other hand, anticoagulation medicine, such as heparin, is required for the life of a patient when a mechanical valve is used in valve replacement. The current technology for valve repair or valve replacement requires an expensive open-heart surgery that needs a prolonged period of recovery. A less invasive catheter-based valve repair technology becomes an unmet clinical challenge.

The effects of valvular dysfunction vary. Mitral regurgitation has more severe physiological consequences to the patient than does tricuspid valve regurgitation. In patients with valvular insufficiency it is an increasingly common surgical practice to repair the natural valve, and to attempt to correct the defects. Many of the defects are associated with dilation of the valve annulus. This dilatation not only prevents competence of the valve but also results in distortion of the normal shape of the valve orifice or valve leaflets. Remodeling of the annulus is therefore central to most reconstructive procedures on the mitral valve.

As a part of the valve repair it is either necessary to diminish or constrict the involved segment of the annulus so that the leaflets may coapt correctly on closing, or to stabilize the annulus to prevent post-operative dilatation from occurring. The current open-heart approach is by implantation of a prosthetic ring, such as a Cosgrove Ring® or a Carpentier Ring®, in the supra annular position. The

purpose of the ring is to restrict and/or support the annulus to correct and/or prevent valvular insufficiency. In a tricuspid valve repair, constriction of the annulus usually takes place in the posterior leaflet segment and in a small portion of the adjacent anterior leaflet.

Various prostheses have been described for use in conjunction with mitral or tricuspid valve repair. The ring developed by Dr. Alain Carpentier (U.S. Pat. No. 3,656,185) is rigid and flat. An open ring valve prosthesis as described in U.S. Pat. No. 4,164,046 comprises a uniquely shaped open ring valve prosthesis having a special velour exterior for effecting mitral and tricuspid annuloplasty. The fully flexible annuloplasty ring could only be shortened in the posterior segment by the placement of placating sutures. John Wright et al. in U.S. Pat. No. 5,674,279 discloses a suturing ring suitable for use on heart valve prosthetic devices for securing such devices in the heart or other annular tissue. All of the above valve repair or replacement requires an open-heart operation which is costly and exposes a patient to higher risk and longer recovery than a catheter-based less invasive procedure.

Moderate heat is known to tighten and shrink the collagen tissue as illustrated in U. S. Pat. No. 5,456,662 and U. S. Pat. No. 5,546,954. It is also clinically verified that thermal energy is capable of denaturing the tissue and modulating the collagenous molecules in such a way that treated tissue becomes more resilient ("The Next Wave in Minimally Invasive Surgery" MD&DI pp. 36-44, August 1998). Therefore, it becomes imperative to treat the inner walls of an annular organ structure of a heart valve, a valve leaflet, chordae tendinae, papillary muscles, and the like by shrinking/tightening techniques.

One method of reducing the size of tissues in situ has been used in the treatment of many diseases, or as an adjunct to surgical removal procedures. This method applies appropriate heat to the tissues, and causes them to shrink and tighten. It can be performed on a minimal invasive fashion, which is often less traumatic than surgical procedures and may be the only alternative method, wherein other procedures are unsafe or ineffective. Ablative treatment devices have an advantage because of the use of a therapeutic energy that is rapidly dissipated and reduced to a non-destructive level by conduction and convection, to other natural processes.

In either case of valvuloplasty or valvular dysfunction, the annular organ structure of a heart valve, a valve leaflet, a chordae tendinae, papillary muscles, a venous valve, and the like still needs to be treated and/or tightened so that the valvular function is competent. The current technology for valve repair or valve replacement requires an expensive open-heart surgery that needs a prolonged period of recovery. A less invasive catheter-based valve repair technology having capability for simultaneously delivering radiofrequency energy and rotational sweeping massage therapy becomes an unmet clinical challenge.

Therefore, there is a clinical need to have a less invasive catheter-based approach for repairing an annular organ structure of a heart valve, a valve leaflet, chordae tendinae, papillary muscles, and the like by using high frequency energy for reducing and/or shrinking a tissue mass for tightening and stabilizing the dilated tissue adjacent a valvular annulus or an annular organ structure.

SUMMARY OF THE INVENTION

In general, it is an object of the present invention to provide a catheter system and methods for repairing an annular organ structure of a heart valve, an annular organ structure of a venous valve, a valve leaflet, chordae tendinae, papillary muscles, and the like.

It is another object of the present invention to provide a catheter system and methods by using high frequency current for tissue treatment or repairing, such as atherosclerosis, vascular vessels, intestine, colon, ureters, uterine tube and other annual organ structure.

It is still another object to provide an ablation catheter system that penetrates the tissue of a valvular annulus in order to tighten and stabilize an annular organ structure.

It is still a further object of the present invention to provide a method and an improved medical ablation device or a catheter for generating heat, to treat endometrosis, cysts, polyps, prostate, tumors, valvular annulus, or cellular tissues. It is another object of the present invention to provide a device in which rotational sweeping massage therapy is applied to the endometrosis, cysts, polyps, prostate, tumors, valvular annulus, or the target cellular tissues, for intimate contact. The "rotational sweeping massage" in this invention implies that the surface of a rotational device (e.g., a plate-like electrode or a cam-type electrode) continuously or intermittently contacts a target tissue with a normal sweeping force by the rotational device. The "target tissue" in this invention indicates the endometrosis, the cysts, the gingivae, the tumor, the prostate, the polyp, the valvular annulus, or other cellular tissues.

It is a preferred object to provide a flexible tissue-contactor means located at the distal tip section of a catheter shaft for contacting an inner wall of an annular organ structure, wherein the tissue-contactor means is deployable out of the at least one lumen by a tissue-contactor deployment mechanism at the handle and wherein the tissue-contactor means is preformed and/or preshaped to have an appropriate form and shape compatible with the inner wall of an annular organ structure.

It is another object of the invention to provide an ablation catheter shaft with a tip section having a needle electrode means for penetrating into a tissue, wherein the needle electrode means is deployable out of the catheter shaft in a manner essentially perpendicular to a longitudinal axis of the catheter shaft.

It is still another object of the present invention to provide a catheter system and methods for providing high frequency current energy to the tissue/organ at or adjacent a heart valve structure.

In one embodiment, a catheter system comprises a flexible catheter shaft having a distal tip section, a distal end, a proximal end, and at least one lumen extending between the distal end and the proximal end. A flexible tissue-contactor means is located at the distal tip section and is inside the at least one lumen of the catheter shaft for contacting an inner wall of an annular organ structure, wherein the tissue-contactor means is deployable out of the at least one lumen by a tissue-contactor deployment mechanism located at a handle. The tissue-contactor means is preformed to have an appropriate shape, form, and size compatible with and intimately fittable onto the inner wall of the annular organ structure. A needle electrode means is located at, around, or within the flexible tissue-contactor means for penetrating into a tissue, wherein the needle electrode means is deployable out of the tissue-contactor

means in a manner essentially perpendicular to a longitudinal axis of the catheter shaft. A handle is attached to the proximal end of the catheter shaft, wherein the handle comprises the tissue-contactor deployment mechanism and an electrode deployment means for advancing the needle electrode means out of the tissue-contactor means. The catheter system also comprises a high frequency current generator, wherein an electrical conductor means for transmitting high frequency current to the needle electrode means is provided. The high frequency current may be selected from the group consisting of radiofrequency current, microwave current and ultrasound current.

In a preferred embodiment, the tissue-contactor means may be selected from The group consisting of a circular ring, a round mass, a D-shaped ring, a kidney-shaped ring, an oval ring, and the like that is compatible with the shape of the to-be-treated organ. The tissue-contactor means may be made of a biocompatible material selected from the group consisting of silicone, latex, polyurethane, fabric, and a combination thereof. Alternately, the tissue-contactor means may comprise a plurality of open channels for a fluid to pass from a proximal end of said tissue-contactor means to a distal end of said tissue-contactor means. The open channels may include macropores or micropores.

In another preferred embodiment, the annular organ structure of the present invention may be a valvular annulus of a cardiovascular valve selected from the group consisting of a mitral valve, a tricuspid valve, a pulmonary valve, an aortic valve, a venous valve, or other valvular organ structure. The needle electrode means may comprise a plurality of needle electrodes that are preshaped to be essentially perpendicular to a longitudinal axis of the catheter shaft when deployed and wherein the high frequency current is delivered to each of the plurality of needle electrodes in a current delivery mode selected from the group consisting of an individual mode, a pulsed mode, a sequential mode, and a simultaneous mode. The needle electrode means may be made of a material selected from the group consisting of platinum, iridium, gold, silver, stainless steel, tungsten, and Nitinol

The catheter system of the present invention has several significant advantages over known catheters or ablation techniques for repairing an annular organ structure of a heart valve, a valve leaflet, chordae tendinae, papillary muscles, venous valve, and the like. In particular, the ablation catheter of this invention by using high frequency current energy for reducing and/or shrinking a tissue mass may tighten and stabilize the dilated tissue at or adjacent a valvular annulus.

BRIEF DESCRIPTION OF THE DRAWINGS

Additional objects and features of the present invention will become more apparent and the invention itself will be best understood from the following Detailed Description of the Exemplary Embodiments, when read with reference to the accompanying drawings.

FIG. 1 is an overall view of a catheter system having a flexible tissue-contactor means and a needle electrode means at its distal tip section constructed in accordance with the principles of the present invention.

FIG. 2 is a close-up view of the distal tip section of the catheter system comprising a retracted tissue-contactor means and a retracted needle electrode means at a non-deployed state.

FIG. 3 is a close-up view of the distal tip section of the catheter system comprising a deployed tissue-contactor means and a retracted needle electrode means.

FIG. 4 is a front cross-sectional view, section A-A of FIG. 3, of the distal tip section of a catheter system comprising a deployed tissue-contactor means.

FIG. 5 is a close-up view of the distal tip section of the catheter system comprising a deployed tissue-contactor means and a deployed needle electrode means at a fully deployed state.

FIG. 6 is a front cross-sectional view, section B-B of FIG. 5, of the distal tip section of a catheter system comprising a deployed tissue-contactor means and a deployed needle electrode means.

FIG. 7 is a simulated view of the catheter system of the present invention having a deployed tissue-contactor mans in contact with the tissue of an annular organ structure.

FIG. 8 is an overall view of the medical device having a deployable wire electrode and RF generator, constructed in accordance to the principles of the present invention.

FIG. 9 is a cross-sectional view of the distal end portion of the device, having a deployable wire electrode positioned within a lumen of the tubular shaft, at a non-deployed state.

FIG. 10 is a cross-sectional view of the distal end portion of the device, having a deployable wire electrode being deployed to its full extent, at a deployed state.

FIG. 11 is an overall view of the medical device, having an electrode with heat generating source and a rotation generating means for generating rotation of the tip portion, constructed in accordance with the principles of the present invention.

FIG. 12 is a cross-sectional view of the distal portion of the medical device in FIG. 11.

FIG. 13 is a transverse view of the electrode, including an extendible electrode of FIG. 12.

FIG. 14-A is a perspective view of the electrode of FIG. 12, which is a pre-shaped curved plate.

FIG. 14-B is a perspective view of the electrode of FIG. 12, which includes a plurality of pre-shaped curved wires.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

First Embodiment:

The following descriptions of a preferred embodiment of the invention are exemplary, rather than limiting, and many variations and modifications are within the scope of the invention. A U.S. patent application Serial Number 09/410,902 filed 2-Oct-1999 discloses a catheter system having a flexible tissue-contactor means and a needle electrode means at its distal tip section by the co-inventor of the present invention, the entire contents of which are incorporated herein by reference. FIG. 1 shows an overall view of a catheter system having a flexible tissue-contactor means and a needle electrode means at its distal tip section constructed in accordance with the principles of the present invention. A catheter system constructed in accordance with the principles of the present invention comprises a flexible catheter shaft **101** having a distal tip section **102**, a distal end **103**, a proximal end **104**, and at least one lumen **114** extending therebetween. The catheter system comprises a flexible, relatively semi-rigid tissue-contactor means **105** located at the distal tip section **102** and inside the at

least one lumen **114** of said catheter shaft **101** for contacting an inner wall **151** of an annular organ structure **152** when deployed. The tissue-contactor means **105** is deployable out of the at least one lumen **114** by a tissue-contactor deployment mechanism **115** located at a handle **107**. The tissue-contactor means **105** is preformed to have an appropriate shape compatible with the inner wall **151** of the annular organ structure **152**. The tissue-contactor means **105** may be selected from the group consisting of a circular ring, a D-shaped ring, a kidney-shaped ring, an oval ring, and other round-shaped mass.

A handle **107** is attached to the proximal end **104** of the catheter shaft **101**. The handle comprises the tissue-contactor deployment mechanism **115** and an electrode deployment means **116** for advancing a needle electrode means **109** out of the tissue-contactor means **105**.

A connector **108** secured at the proximal end of the catheter system, is part of the handle section**107**. The handle has one optional steering mechanism **110**. The steering mechanism **110** is to deflect the distal tip section **102** of the catheter shaft **101** for catheter maneuvering and positioning. By pushing forward the front plunger **111** of the handle **107**, the distal tip section **102** of the catheter shaft deflects to one direction. By pulling back the front plunger **111**, the tip section returns to its neutral position. In another embodiment, the steering mechanism **110** at the handle **107** comprises means for providing a plurality of deflectable curves on the distal tip section **102** of the catheter shaft **101**.

The catheter system also comprises a high frequency current generator **161**, wherein an electrical conductor means **162** for transmitting high frequency current to the needle electrode means **109** is provided.

FIG. 2 shows a close-up view of the distal tip section **102** of the catheter system comprising a retracted tissue-contactor means **105** and a retracted needle electrode means **109** at a non-deployed state. Both the tissue-contactor means and the needle electrode means are retractable to stay within the at least one lumen **114**. This non-deployed state is used for a catheter to enter into and to withdraw from the body of a patient. The tissue-contactor means is preformed and flexible enough so that it can easily retracted into the catheter lumen **114**. The tissue-contactor means **105** may be made of a biocompatible material selected from the group consisting of silicone, latex, polyurethane, fabric, and a combination thereof. Reinforced substrate, such as mesh, wire, fiber, and the like, may be added to the tissue-contactor means **105** to make the tissue-contactor means semi-rigid so that when it is deployed, adequate pressure is exerted to the surrounding tissue for stabilizing its placement.

The catheter system comprises a needle electrode means **109** located at or within the flexible tissue-contactor means **105** for penetrating into a tissue, such as an inner wall **151**, wherein the needle electrode means **109** is deployable out of the tissue-contactor means **105** in a manner essentially perpendicular to a longitudinal axis of the catheter shaft **101** when the needle electrode means is deployed. In another preferred embodiment, the angle of the needle electrode against a tissue may be any suitable angle from 30 degrees to 150 degrees in reference to a longitudinal axis of the catheter shaft for effective tissue penetration.

The needle electrode means **109** may comprise a plurality of needle electrodes **109A**, **109B**, **109C** that are preshaped to be essentially perpendicular to a longitudinal axis of the catheter shaft **101**

when deployed. The high frequency current may be delivered to each of the plurality of needle electrodes **109A**, **109B**, **109C** in a current delivery mode selected from the group consisting of individual delivery mode, pulsed delivery mode, sequential delivery mode, and simultaneous delivery mode.

The needle electrode means **109** may be made of a material selected from the group consisting of platinum, iridium, gold, silver, stainless steel, tungsten, Nitinol, and other conducting material. The needle electrode means **109** is connected to an electrode deployment means **116** at the handle **107** for advancing one or more needles of the needle electrode means **109** out of the tissue-contactor means **105**. This electrode deployment means may include various deployment modes of a single needle electrode deployment, a plurality of needle electrodes deployment or all needle electrodes simultaneous deployment.

The tissue-contactor means **105** in this invention is defined as a flexible semi-rigid element adapted for contacting an inner wall of an annular organ structure of a patient and is also preformed to have an appropriate shape compatible with the inner wall of the annular organ structure. The tissue-contactor means may comprise a plurality of grooves or internal channels **125** so that a needle electrode of the needle electrode means is able to deploy out of and retract into the tissue contactor means with minimal frictional resistance.

FIG. 3 shows a close-up view of the distal tip section **102** of the catheter system comprising a deployed tissue-contactor means **105** and a retracted needle electrode means **109**. The outer diameter of the deployed tissue-contactor means **105** is optionally larger than the outer diameter of the catheter shaft **101** so that the outer rim **112** of the deployed tissue-contactor means may stably stay on the inner wall of the annular organ structure. A supporting member **121** along with a plurality of auxiliary supporting members **122** on the distal end of the supporting member **121** form a connecting means for connecting the tissue-contactor means **105** to the tissue-contactor deployment mechanism **115** that is located on the handle **107**. The supporting member **121** and the auxiliary supporting members **122** are located within the at least one lumen **114** and have torque transmittable property and adequate rigidity to deploy the tissue-contactor means **105**.

The needle electrode is preferably made of conductive material, while the surfaces of the catheter shaft **101**, conducting wires **162**, the supporting member **121**, and the auxiliary supporting members **122**, are preferably covered with an insulating material or insulated.

FIG. 4 shows a front cross-sectional view, section A-A of FIG. 3, of the distal tip section of a catheter system comprising a deployed tissue-contactor means **105**. The tissue-contactor means **105** may comprise a plurality of open channels **124**, pores and the like for a fluid or blood to pass from a proximal end of the tissue-contactor means **105** to a distal end of the tissue-contactor means.

FIG. 5 shows a close-up view of the distal tip section **102** of the catheter system comprising a deployed tissue-contactor means **105** and a deployed needle electrode means **109** at a fully deployed state. The fully deployed state is used for delivery of high frequency current energy to the needle electrode means **109** and subsequently to the contact tissue for repairing the annular organ structure. The delivery of high frequency current to each of the needle electrodes may go through a splitter or

other mechanism. The needle electrode means is preformed so that when deployed, the needle electrodes are in a manner essentially perpendicular to a longitudinal axis of the catheter shaft **101** for effective thermal therapy.

FIG. 6 shows a front cross-sectional view, section B-B of FIG. 5, of the distal tip section **102** of a catheter system comprising a deployed tissue-contactor means **105** and a deployed needle electrode means **109**. The tips of the needle electrodes **109A, 109B, 109C** extend out of the rim **112** of the tissue-contactor means **105** and penetrate into a tissue for energy delivery.

FIG. 7 shows a simulated view of the catheter system of the present invention in contact with the tissue of an annular organ structure **152**. The heart **170** has a left atrium **171**, a left ventricle **172**, a right ventricle **173**, and a right atrium **174**. Aorta **175** connects with the left ventricle **172** and contains an aorta valve **176**. Pulmonary artery **177** connects with the right ventricle **173** through a pulmonary valve. Left atrium **171** communicates with the left ventricle **172** through a mitral valve **179**. The right atrium **174** communicates with the right ventricle **173** through a tricuspid valve **180**. Oxygenated blood is returned to the heat **170** via pulmonary veins **188**. In a perspective illustration, a catheter is inserted into the right atrium **174** and is positioned on the inner wall **151** of the tricuspid valve **180**. The leaflets of the tricuspid valve **180** open toward the ventricle side. Blood returned from the superior vena cava **84** and the inferior vena cava flows into the right atrium **174**. Subsequently, blood flows from the right atrium **174** to the right ventricle **173** through the tricuspid valve **180**. Therefore, the tissue-contactor means **105** of the catheter shaft **101** does not interfere with the leaflet movement during the proposed less invasive thermal therapy of the invention.

In a preferred embodiment, a method for operating a catheter system of the present invention for repairing a valvular annulus, the method comprises (a) percutaneously introducing the catheter system through a blood vessel to a valvular annulus; (b) positioning the tissue-contactor means of the catheter shaft on the inner wall of the valvular annulus; (c) advancing the needle electrode means for penetrating the needle electrode means into a tissue of the valvular annulus; and (d) applying high frequency current through the electrical conductor means to the needle electrode means for repairing a valvular annulus.

In another preferred embodiment, a method for operating a catheter system for repairing a tissue of a heart valve, the catheter system comprises a flexible catheter shaft having a distal tip section, a distal end, a proximal end, and at least one lumen extending between the distal end and the proximal end; an electrode means located at the distal tip section of the catheter shaft for contacting the tissue of the heart valve; a handle attached to the proximal end of the catheter shaft, wherein the handle has a cavity; and a high frequency current generator, wherein an electrical conductor means for transmitting high frequency current to said electrode means is provided. The method comprises (a) percutaneously introducing the catheter system through a blood vessel to the tissue of the heart valve; (b) positioning the electrode means of the catheter system at the tissue of the heart valve; and (c) applying high frequency current through the electrical conductor means to the electrode means for repairing the heart valve.

The tissue of the heart valve in the procedures may be selected from the group consisting of

valvular annulus, chordae tendinae, valve leaflet, and papillary muscles. The high frequency current in the procedures may be selected from the group consisting of radiofrequency current, microwave current, and ultrasound current.

A temperature sensor **127**, either a thermocouple type or a thermister type, is constructed at the proximity of the needle electrode **109B** (shown in FIG. 6) to measure the tissue contact temperature when high frequency energy is delivered. A temperature sensing wire **128** from the thermocouple or thermister is connected to one of the contact pins of the connector **108** and externally connected to a transducer and to a temperature controller **129**. The temperature reading is thereafter relayed to a closed-loop control mechanism to adjust the high frequency energy output. The high frequency energy delivered is thus controlled by the temperature sensor reading or by a pre-programmed control algorithm.

Second Embodiment:

Referring to FIGS. 8-10, what is shown is an embodiment of the medical device system and methods, comprising applying high frequency energy to treat the atherosclerosis, vascular vessels, or other annular cellular tissues of a patient through a wire electrode of the present invention that has been disclosed by the co-inventor as U.S. patent application Serial Number 09/414,938, filed 9-Oct-1999, the entire contents of which are incorporated herein by reference.

As shown in FIG. 8, the medical device system in the form of an elongate tubular assembly **201** comprises a flexible tubular shaft **291** having a distal section **235**, a distal end **202**, a proximal end **203**, and at least one lumen **210** or **211** extending therebetween, wherein the at least one lumen may have at least one opening at the distal end of the tubular shaft **291**. A handle **204** is attached to the proximal end **203** of the tubular shaft, wherein the handle **204** has a cavity. A hollow tubing **207** having a passageway and a locking valve **208** is attached to the handle **204**, wherein the passageway is connected to the at least one lumen **211** of the tubular shaft **291**. An elongate tubular element is located inside the at least one lumen **210** of the tubular shaft **291**, wherein the elongate tubular element comprises a distal end **213** and a proximal end, and wherein the distal end **213** comprises a preshaped spiral wire electrode **212**.

In one embodiment, the spiral wire electrode has a plurality of spirals, whereby the diameter of at least one of the next spiral **236** is larger than that of the prior spiral **237**. An electrode deployment mechanism **205** is mounted on the handle **204**, wherein the electrode deployment mechanism is attached to the proximal end of the elongate tubular element. A high frequency energy generating means **230** is part of the catheter system, wherein the high frequency energy is provided to the spiral wire electrode **212** for therapeutic purposes through the conducting wire **229** and a connector **206** secured at the proximal end of the handle **204**. The high frequency current may be selected from the group consisting of radiofrequency current, microwave current and ultrasound current.

FIG. 9 shows a cross-sectional view of the distal end portion of the device **201**, including a deployable wire electrode **212**. Under a non-deployed state, the deployable wire electrode **212** is retracted inside the lumen **210** of the distal end portion **235**. The wire end **213** is located just within the distal end **202** of the tubular shaft **291**. In one embodiment, the distal end has two lumens **210** and **211**.

One lumen **210** is used by the deployable wire electrode **212** for treating a tissue. The other lumen **211** could be used to tract a previously inserted guidewire **215** to the lesion site. The device **201** of the present invention may ride on the existing guidewire **215** to the target site **225** for ablation operations.

An insulated electrical conductor **229** or the elongate tubular element itself that may serve as a conducting means passes through the lumen **210** of the shaft **291** and is connected to the wire electrode means **212**. The other end of the electrical conductor means is connected to an external high frequency current generator **230**.

The distal portion of the deployed wire electrode and its tissue-contacting surface is made of conductive material, which is connected to the RF energy source through an insulated electrical conductor. Other portion of the tubular shaft and surface of the device is not conductive. In one embodiment, the inner, non-tissue-contacting side of the spiral wire electrode **212** is insulated or coated with an insulation material. The radially extendible spiral wire electrode **212** may be extended radially at least twice the diameter of the tubular shaft **291**.

FIG. 10 shows a cross-sectional view of the distal end portion **235** of the tubular shaft **291** at a deployed state. The deployment operation is initiated at an electrode deployment mechanism **205** that is located at the handle **204**. The deployed wire electrode **212** is extendable radially to contact the inside surface of a pre-implanted stent **221**, to contact an inner surface of an annular organ structure, or to contact a tissue. This distal portion of the deployed wire electrode and its tissue-contacting surface is made of conductive material, which is connected to the RF energy source through an insulated electrical conductor. Other portion of the tubular shaft and surface of the device is not conductive. In one embodiment, the inner, non-tissue-contacting side of the spiral wire electrode **212** is insulated or coated with an insulation material. The radially extendible spiral wire electrode **212** may be extended radially at least twice the diameter of the tubular shaft **291**.

During procedures, the ablation device is inserted into the body of a patient through natural opening or a surgical hole. For one embodiment, a method for operating a catheter system for treating a valvular annulus, the method comprises the steps of (a) percutaneously introducing the catheter system through a blood vessel to a valvular annulus, the catheter system comprising a flexible tubular shaft having a distal section, a distal end, a proximal end, and at least one lumen extending therebetween, wherein the at least one lumen has at least one opening at the distal end of the tubular shaft; a handle attached to the proximal end of the tubular shaft, wherein the handle has a cavity; a hollow tubing having a passageway and a locking valve attached to the handle, wherein the passageway is connected to the at least one lumen of the tubular shaft; an elongate tubular element located inside the at least one lumen of the tubular shaft, wherein the elongate tubular element comprises a distal end and a proximal end, and wherein the distal end comprises a preshaped wire electrode having a plurality of spirals, wherein the diameter of at least one of a next spiral is larger than that of a prior spiral; an electrode deployment mechanism mounted at the handle, wherein the electrode deployment mechanism is attached to the proximal end of the elongate tubular element; and (b) deploying the elongate tubular element to radially extend the spiral wire electrode, adapted to contact a tissue of the valvular annulus for treatment.

The method may further comprise a step of applying high frequency current to the spiral wire electrode to effect treating the valvular annulus, wherein the catheter system further comprises a high frequency current generator having an electrical conductor means for transmitting high frequency current to said spiral wire electrode. The high frequency current may be selected from the group consisting of radiofrequency current, microwave current and ultrasound current.

As an alternative illustration, a method for operating a catheter system for treating a tissue of a valvular organ structure, the method comprises the steps of (a) percutaneously introducing the catheter system through a blood vessel to the tissue of the valvular organ structure, the catheter system comprising a tubular shaft having a distal section, a distal end, a proximal end, and at least one lumen extending therebetween, wherein the at least one lumen has at least one opening at the distal end of the tubular shaft; a handle attached to the proximal end of the tubular shaft, wherein the handle has a cavity; a hollow tubing having a passageway and a locking valve attached to the handle, wherein the passageway is connected to the at least one lumen of the tubular shaft; an elongate tubular element located inside the at least one lumen of the tubular shaft, wherein the elongate tubular element comprises a distal end and a proximal end, and wherein the distal end comprises a preshaped wire electrode having a plurality of spirals, wherein the diameter of at least one of a next spiral is larger than that of a prior spiral; an electrode deployment mechanism mounted on the handle, wherein the electrode deployment mechanism is attached to the proximal end of the elongate tubular element; and a high frequency current generator having an electrical conductor means for transmitting high frequency current to said spiral wire electrode; (b) deploying the elongate tubular element to radially extend the spiral wire electrode, adapted to contact the tissue of the valvular organ structure; and (c) applying high frequency current through the electrical conductor means to the spiral wire electrode for treatment of the valvular organ structure. The tissue may be selected from the group consisting of the tissue of a valvular annulus, a chordae tendinae, a heart valve leaflet, a venous valve leaflet, and papillary muscles.

As still another alternate illustration, a method for operating an ablation catheter system for treating a tissue of a valvular organ structure of a patient, the method comprises the steps of (a) percutaneously introducing the catheter system through a blood vessel of the patient to the tissue of the valvular organ structure, the catheter system comprising a flexible tubular shaft having a distal section, a distal end, a proximal end, and at least one lumen extending therebetween; a deployable elongate tubular element located inside the at least one lumen of the tubular shaft, wherein the elongate tubular element comprises a distal end and a proximal end; an electrode means for contacting the tissue of the valvular organ structure mounted at the distal end of the deployable elongate tubular element; and a radiofrequency current generator having an electrical conductor means for transmitting radiofrequency current to said electrode means; (b) deploying the elongate tubular element out of the distal end of the flexible tubular shaft to contact the tissue of the valvular organ structure; and (c) applying radiofrequency current through the electrical conductor means to the electrode means for treating the tissue of the valvular organ structure. The tissue may be selected from the group consisting of a valvular annulus, a chordae tendinae, a heart valve leaflet, a venous valve leaflet, and papillary muscles.

In one embodiment, the external RF energy generator has the capability to supply RF energy

by controlling the time, power, and temperature through an optional separate closed-loop temperature control means. The patient is connected to the RF generator means through a DIP electrode to form a closed-loop current system. Therefore, RF energy is applied and delivered to the targeted tissue, through the electrode means of this invention. The radiofrequency energy current in this invention is preferably within the range of 50 to 2,000 kHz. The frequency of the vibration of the medical device in this invention is preferably within the range of 60 to 1000 cycles per minute. By simultaneously applying RF energy to the electrode and by applying the pressure therapy, the atherosclerosis can be treated.

Third Embodiment:

Referring to FIGS. 11 to 14, what is shown is an embodiment of a medical ablation device system, comprising simultaneously applying radiofrequency energy and applying a rotational sweeping therapeutic massage to treat the endometrosis, cysts, gingivae, tumors, prostate, polyps, valvular annulus, or cellular tissues of a patient that has been disclosed by a co-inventor as U.S. patent application Serial Number 09/456,769, filed 7-Dec-1999, the entire contents of which are incorporated herein by reference. As shown in FIG. 11, a medical ablation device system, including a flexible catheter-type device system, comprises an elongate tubular element **301** having a distal section **302**, a distal end **303**, a proximal end **304**, and at least one lumen **305** extending between the distal end and the proximal end, wherein an opening **306** is located at one side of the distal section **302**.

An inner tubing **311** is located within the lumen **305** of the elongate tubular element **301**. The inner tubing **311** has a distal section **312**, a distal end **313**, a proximal end **314**, and a lumen **315** extending between the distal end and the proximal end, wherein a deployable electrode **316** is located at the distal section **312** of the inner tubing **311**. The deployable electrode **316** comprises a pre-shaped extendible electrode **317** that stays within the lumen of the elongate tubular element **301** under a non-deployed state and extends out of the elongate tubular element **301** through the opening **306** during a deployed state.

A handle **307** is attachably secured at the proximal end **304** of the tubular element **301**. The handle **307** has a cavity **308**. An external RF energy generator (not shown) has a conducting wire **309**, wherein the RF energy is supplied to the deployable electrode **316** through the conducting wire **309**. The RF energy supply is controlled by an on-off switch button **324** located conveniently on the handle **307**.

The medical ablation device system, including a catheter-type device system, further comprises means for generating rotational motion for the distal section of the elongate tubular element **301**. The means comprises a motor **310** mounted in the cavity **308** of the handle **307**, which has a rotatable motor shaft **321** connected to an elongate connecting shaft **322** having a first end to which the proximal end **304** of the elongate tubular element **301** is coupled and connected, and a second end connected to the motor **310**, so that when the motor shaft **321** rotates, the elongate tubular element **301** also rotates. The handle **307** is also equipped with an on-off electrical controller **323** for the motor **310**, an on-off controller **324** for the RF energy delivery conducting wire **309**, a connector **326**, and an engagement controller **325**, which is used to control the extending degree of the extendible electrode **317**, either

inside the elongate tubular element **301** or out of the opening **306** of the elongate tubular element **301**.

In one embodiment, a battery means **335**, which is located at the proximal end of the cavity **308** of the handle **307**, is used to supply the energy to the motor **310**. In an alternate embodiment, the motor **310** is powered by an alternating current (AC) through a power input plug (not shown). In either case, the power supply is controlled by an on-off switch button **323** located conveniently at the proximal end of the handle **307**.

FIG. 12 shows a cross-sectional view of the distal portion of the medical device in FIG. 11. The inner tubing **311** has a deployable electrode **316** comprising a pre-shaped extendible electrode **317**, and a distal end **313**, wherein the distal end **313** is securely suspended inside a cavity **318** of an attachment member **319**. The attachment member **319** is secured to the inner side of the distal end **303** of the elongate tubular element **301**. The inner tubing **311** is rotatable relative to the elongate tubular element **301** in either direction, of which direction dictates the deployment and un-deployment states of the extendible electrode **317** from the deployable electrode **316**. After deployment of the extendible electrode, the inner tubing **311** and the elongate tubular element **301** are locked together as one unit and adapted to be rotatable by the movement of the motor shaft **321**.

In one preferred embodiment, the very distal end **303** of the elongate tubular element **301** is shaped as a needle so that the distal end can be inserted into the tissue to stabilize the medical ablation device system for ablative operations.

The window dimensions of the opening **306** of the elongate tubular element **301** are such that the extendible electrode **317** is free to deploy and retract without undue obstruction. FIG. 13 shows a transverse view of the electrode **316**, including an extendible electrode **317**. The extendible electrode **317** can be adjusted in several different deployment states, such as the non-deploy state **320**, the ready-to-deploy state **330**, and fully deployed state **340**.

FIGS. 14-A to FIG. 14-B show some of the perspective views of the deployable electrode. The extendible electrode **317** may be selected from the group consisting of a curved plate, a plurality of curved wires, a curved plate with studded surface, a plurality of coils, a meshed plate, a curved wire with a needle end, and the like. Because of its pre-shaped memory and material strength, the curved electrode **317** is advanced out of the opening **306** during the deployment phase. As shown in FIG. 13, the elongate tubular element **301** may be rotated in the same direction as the extendible electrode; in this case, the counter-clockwise direction to effect the rotational sweeping massage therapy to the target tissue. However, for the extendible electrode **317** to penetrate into a tissue for cell necrosis purposes, the elongate tubular element **301** may be rotated in the opposite direction as the extendible electrode **317**.

The extendible electrode **317** is preferably selected from the group consisting of platinum, iridium, gold, silver, stainless steel, Nitinol, tungsten, and an alloy of their mixtures. The outer surface of the medical device, except the electrode at its distal portion, is not conductive. A conducting wire **309** is used to transmit the RF energy from the external RF generator to the deployable electrode **316**. One end of the conducting wire **309** is secured and connected to the electrode **316** at the distal section **302** while the other end of the conducting wire **309** is secured to a contact pin of the connector **326**,

wherefrom the conducting wire **309** is connected to an external RF generator (not shown) or other energy source.

In one embodiment, a temperature sensor **336** is disposed close to the electrode **316**. An insulated temperature sensor wire **329** passes from the temperature sensor **336** at the distal end, through the lumen **315** of the inner tubing **311**, to an external temperature controller through the outlet connector **326**.

In another embodiment, a fluid infusion means for infusing fluid to the device is provided for the irrigation of a desired therapeutic agent, in either fluid phase or gel phase, to the endometrosis site, to the valvular annulus site, or to other target cellular tissue site. The fluid is adapted to diffuse out of the inner tubing **311** at an inner opening **342** at the proximity of the electrode **316**. The therapeutic agent is selected from the group consisting of heparin solution, saline solution, fluoroquinolene, lactic acid, glycolic acid, alpha hydroxyl organic acids, vitamins, povidone-iodine, nitrate compounds, virucidal agents, anti-inflammatory agents, antibiotics and/or their mixtures.

During procedures, the flexible catheter is inserted into the body of a patient through a natural opening or a surgical hole. For one embodiment, a method for operating a catheter system for treating a valvular annulus, the method comprises the steps of (a) percutaneously introducing the catheter system through a blood vessel to a valvular annulus, the catheter system comprising a flexible elongate tubular element having a distal section, a distal end, a proximal end, and at least one lumen extending therebetween, wherein an opening is located at one side of the distal section; an inner tubing located within the lumen of the elongate tubular element, the inner tubing having a distal section, a distal end, a proximal end, and a lumen extending therebetween, wherein a deployable electrode is located at the distal section of the inner tubing, the deployable electrode comprising a pre-shaped extendible electrode that stays within the lumen of the elongate tubular element under a non-deployed state and extends out of the elongate tubular element through the opening during a deployment state; a handle attachably secured at the proximal end of the tubular element, the handle having a cavity; and an external RF energy generator having a conducting wire, wherein the energy is supplied to the deployable electrode through the conducting wire; (b) positioning the tip of the catheter system about an entrance region of the valvular annulus; (c) deploying the extendible electrode out of the opening of the elongate tubular element of the catheter system; and (d) applying RF energy to the extendible electrode of the catheter system to effect heat treatment of the valvular annulus.

From the foregoing, it should now be appreciated that an improved catheter system having needle electrode means and high frequency current energy for penetrating the tissue of a valvular annulus in order to tighten and stabilize an annular organ structure has been disclosed for repairing an annular organ structure of a heart valve, an annular organ structure of a venous valve, a valve leaflet, chordae tendinae, papillary muscles, and the like. While the invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications and applications may occur to those skilled in the art without departing from the true spirit and scope of the invention as described by the appended claims.

What is claimed is:

1. A catheter system comprising:

a flexible catheter shaft having a distal tip section, a distal end, a proximal end, and at least one lumen extending between the distal end and the proximal end;

a flexible tissue-contactor means located at the distal tip section and inside the at least one lumen of said catheter shaft for contacting an inner wall of an annular organ structure, wherein said tissue-contactor means is deployable out of the at least one lumen by a tissue-contactor deployment mechanism and is preformed to have an appropriate shape compatible with said inner wall of the annular organ structure;

a needle electrode means located at or within the flexible tissue-contactor means for penetrating into a tissue, wherein the needle electrode means is deployable out of the tissue-contactor means in a manner essentially perpendicular to a longitudinal axis of the catheter shaft;

a handle attached to the proximal end of the catheter shaft, wherein the handle comprises the tissue-contactor deployment mechanism and an electrode deployment means for advancing the needle electrode means out of said tissue-contactor means; and

a high frequency current generator, wherein an electrical conductor means for transmitting high frequency current to said needle electrode means is provided.

2. The catheter system of claim 1, wherein the tissue-contactor means is selected from the group consisting of a circular ring, a D-shaped ring, a kidney-shaped ring, and an oval ring.

3. The catheter system of claim 1, wherein the tissue-contactor means is made of a biocompatible material selected from the group consisting of silicone, latex, polyurethane, fabric, and a combination thereof.

4. The catheter system of claim 1, wherein the tissue-contactor means comprises a plurality of open channels for a fluid to pass from a proximal end of said tissue-contactor means to a distal end of said tissue-contactor means.

5. The catheter system of claim 1, wherein the annular organ structure is a valvular annulus of a cardiovascular valve selected from the group consisting of a mitral valve, a tricuspid valve, a pulmonary valve, an aortic valve, and a venous valve.

6. The catheter system of claim 1, wherein the high frequency current is selected from the group consisting of radiofrequency current, microwave current and ultrasound current.

7. The catheter system as in claim 1 further comprising a temperature sensing means for measuring tissue temperature, wherein the temperature sensing means is located adjacent to a distal tip

of the needle electrode means.

8. A method for operating a catheter system for treating a valvular annulus, the method comprising the steps of :

(a) percutaneously introducing the catheter system through a blood vessel to a valvular annulus, the catheter system comprising a flexible tubular shaft having a distal section, a distal end, a proximal end, and at least one lumen extending therebetween, wherein the at least one lumen has at least one opening at the distal end of the tubular shaft; a handle attached to the proximal end of the tubular shaft, wherein the handle has a cavity; a hollow tubing having a passageway and a locking valve attached to the handle, wherein the passageway is connected to the at least one lumen of the tubular shaft; an elongate tubular element located inside the at least one lumen of the tubular shaft, wherein the elongate tubular element comprises a distal end and a proximal end, and wherein the distal end comprises a preshaped wire electrode having a plurality of spirals, wherein the diameter of at least one of a next spiral is larger than that of a prior spiral; an electrode deployment mechanism mounted at the handle, wherein the electrode deployment mechanism is attached to the proximal end of the elongate tubular element; and

(b) deploying the elongate tubular element to radially extend the spiral wire electrode, adapted to contact a tissue of the valvular annulus for treatment;

9. The method for operating a catheter system for treating a valvular annulus as in claim 8, the method further comprising a step of applying high frequency current to the spiral wire electrode to effect treating the valvular annulus, wherein the catheter system further comprises a high frequency current generator having an electrical conductor means for transmitting high frequency current to said spiral wire electrode.

10. The method for operating a catheter system for treating a valvular annulus of claim 8, wherein the valvular annulus is selected from the group consisting of the valvular annulus of a mitral valve, a tricuspid valve, a pulmonary valve, an aortic valve, and a venous valve.

11. The method for operating a catheter system for treating a valvular annulus of claim 9, wherein the high frequency current is selected from the group consisting of radiofrequency current, microwave current and ultrasound current.

12. A method for operating an ablation catheter system for treating a tissue of a valvular organ structure of a patient, the method comprising the steps of:

(a) percutaneously introducing the catheter system through a blood vessel of the patient to the tissue of the valvular organ structure, the catheter system comprising a flexible tubular shaft having a distal section, a distal end, a proximal end, and at least one lumen extending therebetween; a deployable elongate tubular element located inside the at least one lumen of the tubular shaft, wherein

the elongate tubular element comprises a distal end and a proximal end; an electrode means for contacting the tissue of the valvular organ structure mounted at the distal end of the deployable elongate tubular element; and a radiofrequency current generator having an electrical conductor means for transmitting radiofrequency current to said electrode means;

(b) deploying the elongate tubular element out of the distal end of the flexible tubular shaft to contact the tissue of the valvular organ structure, wherein the tissue is selected from the group consisting of a valvular annulus, a chordae tendinae, a heart valve leaflet, a venous valve leaflet, and papillary muscles; and

(c) applying radiofrequency current through the electrical conductor means to the electrode means for treating the tissue of the valvular organ structure.

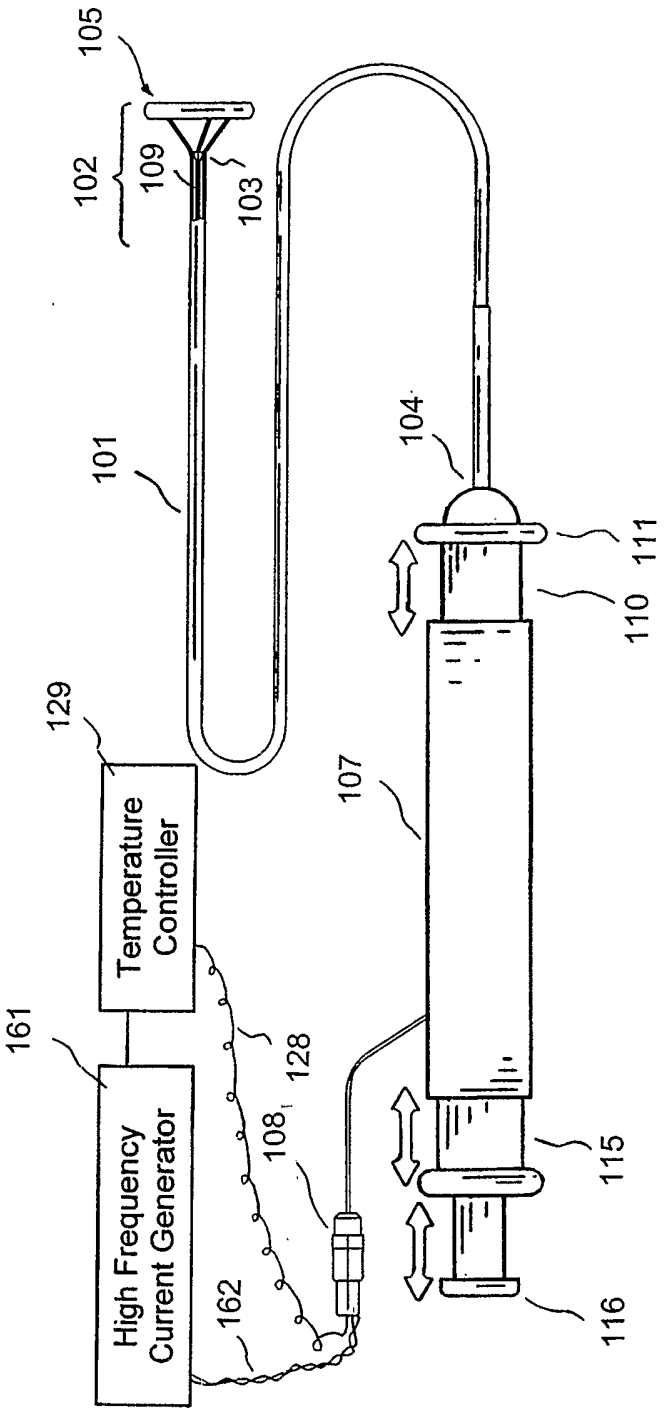
13. A method for operating a catheter system for treating a valvular annulus of a patient, the method comprising the steps of:

(a) percutaneously introducing the catheter system through a blood vessel to the valvular annulus, the catheter system comprising a flexible elongate tubular element having a distal section, a distal end, a proximal end, and at least one lumen extending therebetween, wherein an opening is located at one side of the distal section; an inner tubing located within the lumen of the elongate tubular element, the inner tubing having a distal section, a distal end, a proximal end, and a lumen extending therebetween, wherein a deployable electrode is located at the distal section of the inner tubing, the deployable electrode comprising a pre-shaped extendible electrode that stays within the lumen of the elongate tubular element under a non-deployed state and extends out of the elongate tubular element through the opening during a deployment state; a handle attachably secured at the proximal end of the tubular element, the handle having a cavity; and an external RF energy generator having a conducting wire, wherein the energy is supplied to the deployable electrode through the conducting wire;

(b) positioning the tip of the catheter system about an entrance region of the valvular annulus;

(c) deploying the extendible electrode out of the opening of the elongate tubular element of the catheter system; and

(d) applying RF energy to the extendible electrode of the catheter system to effect heat treatment of the valvular annulus.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Temperature Controller
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High Frequency Current Generator
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FIG. 1

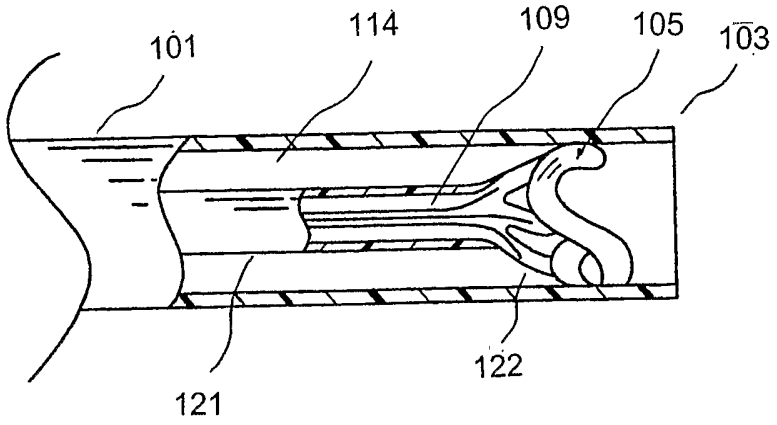
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FIG. 2

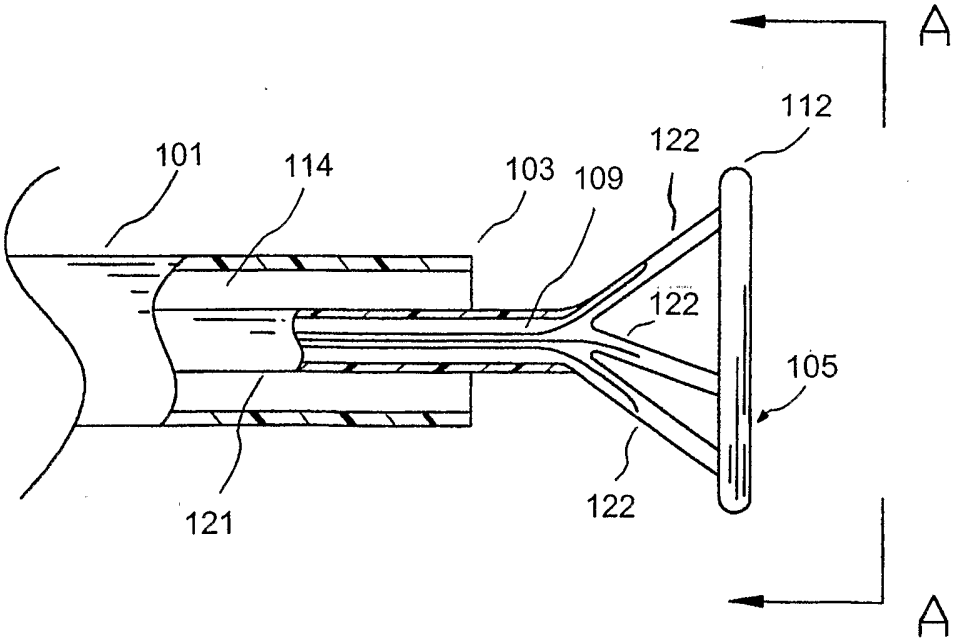
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FIG. 3

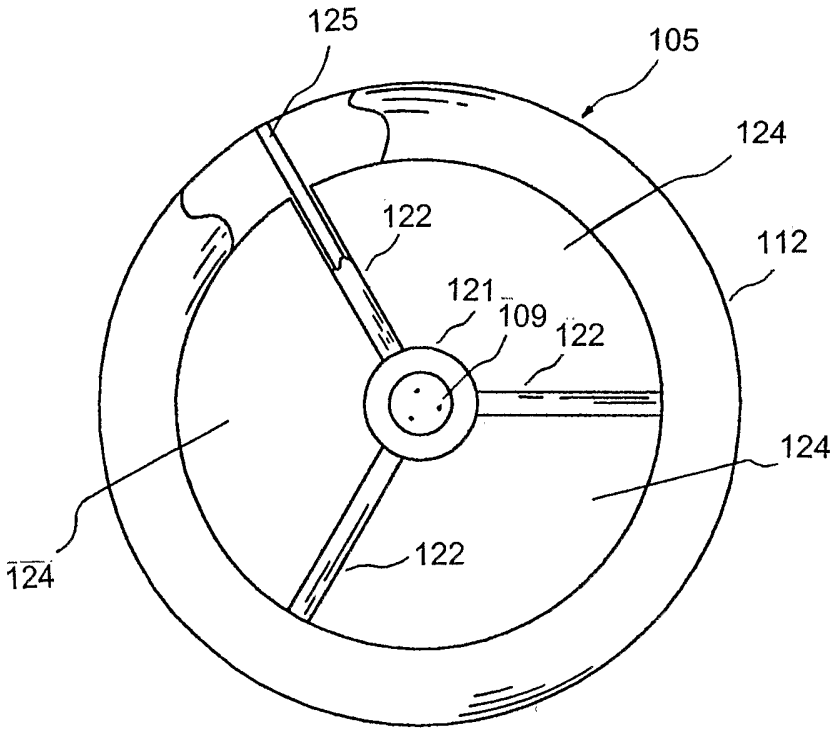


FIG. 4

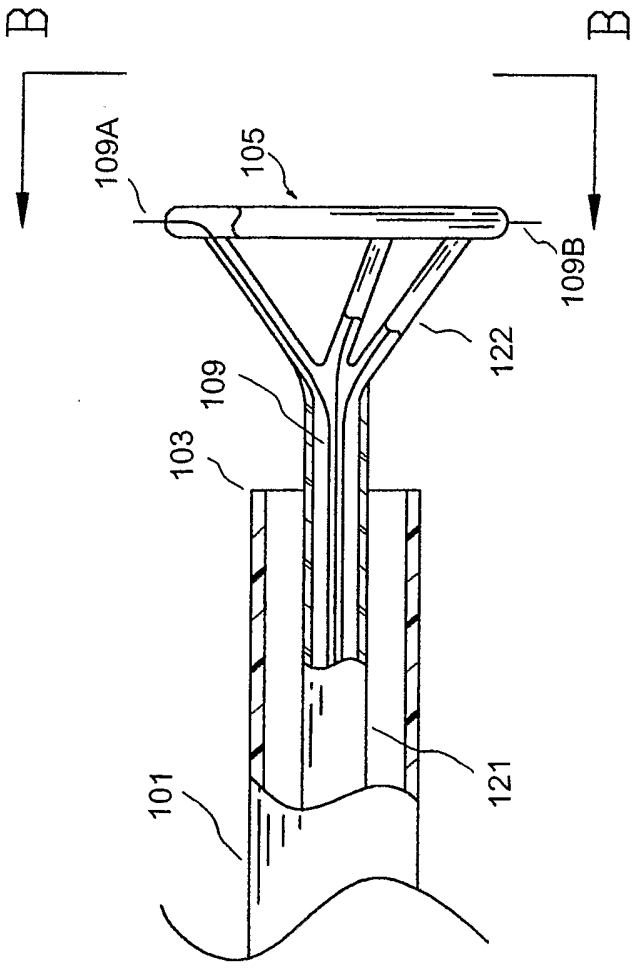


FIG. 5

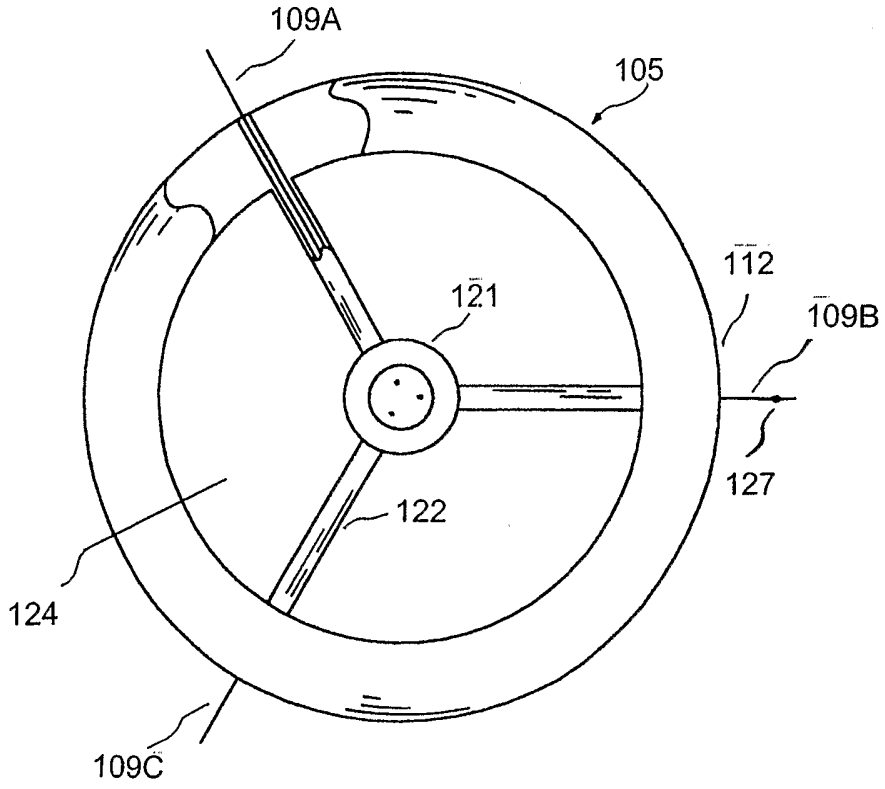


FIG. 6

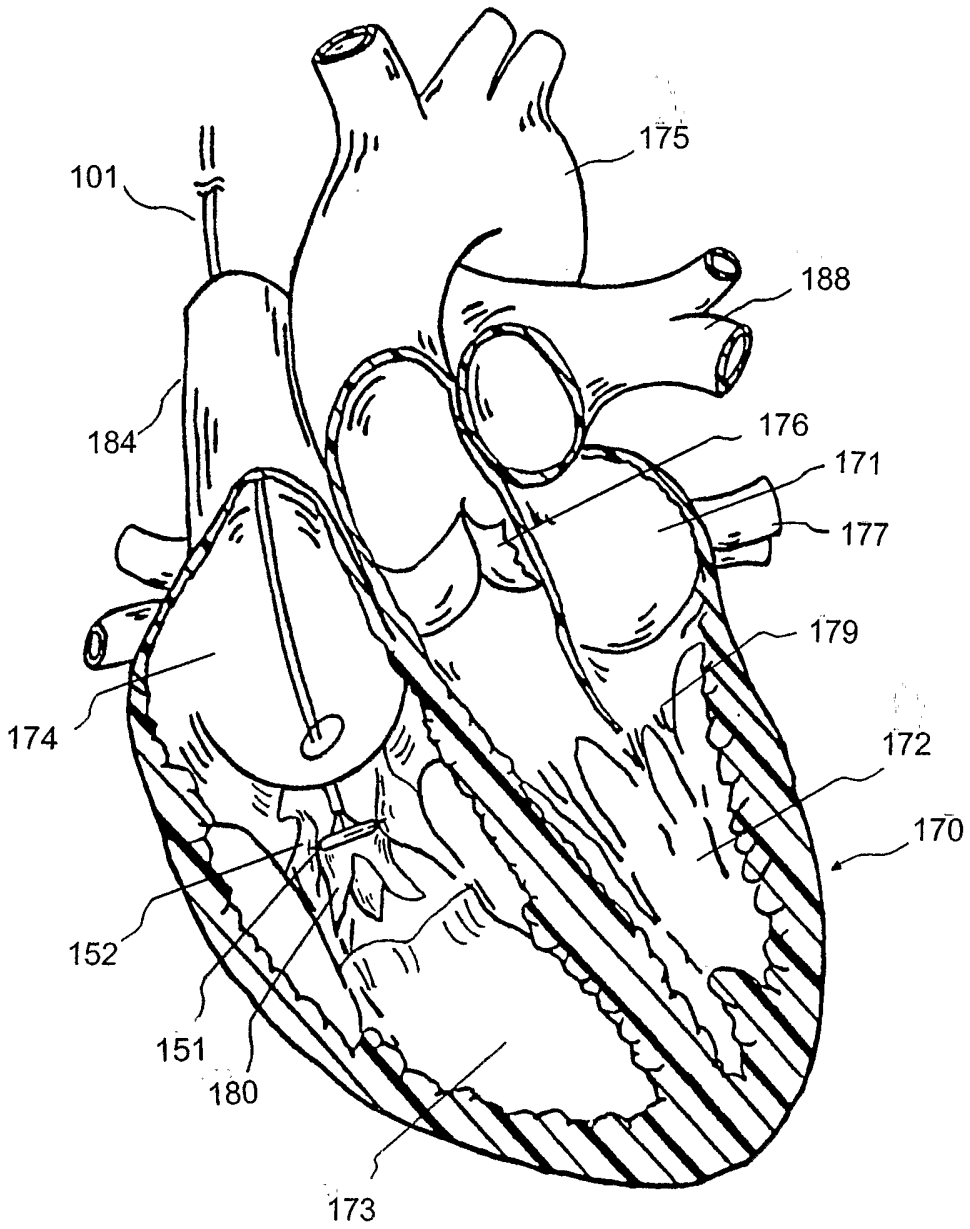
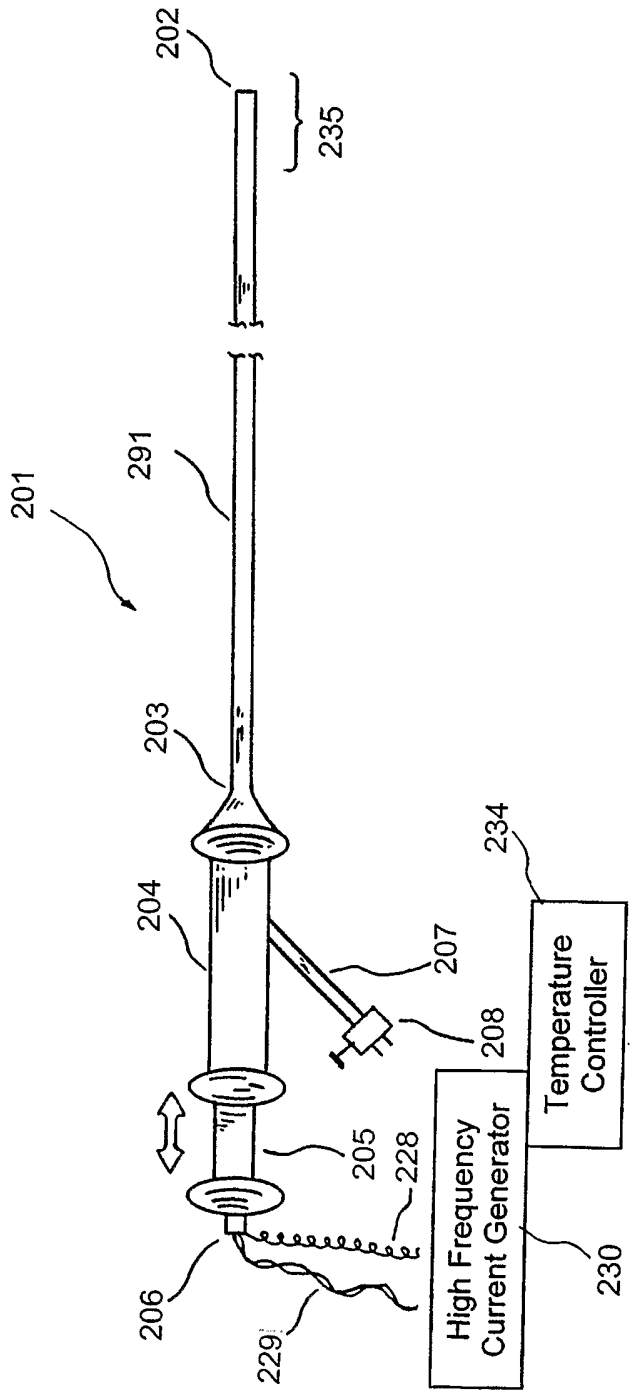


FIG. 7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Temperature Controller
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High Frequency Current Generator
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FIG. 8

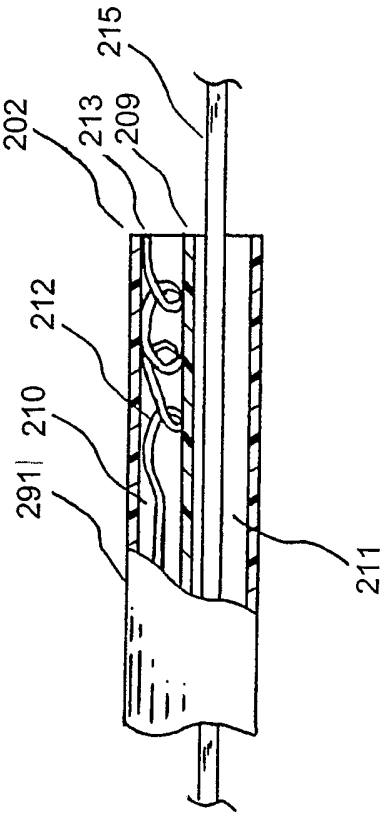

FIG. 9

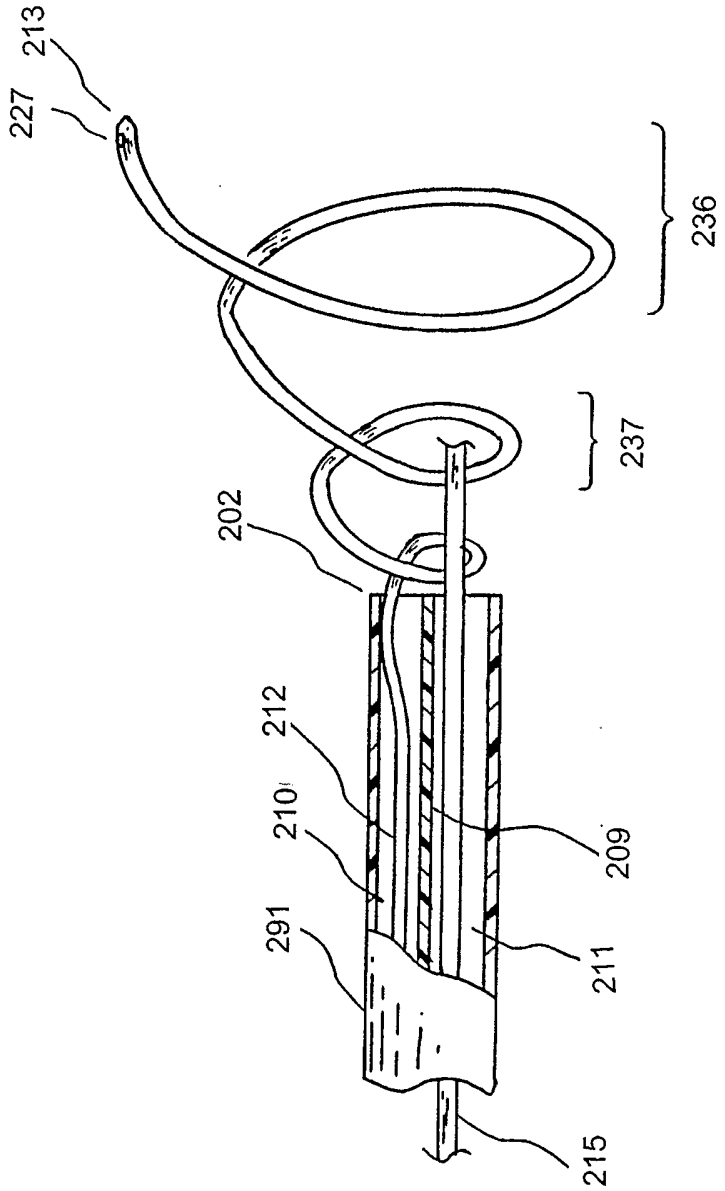

FIG. 10

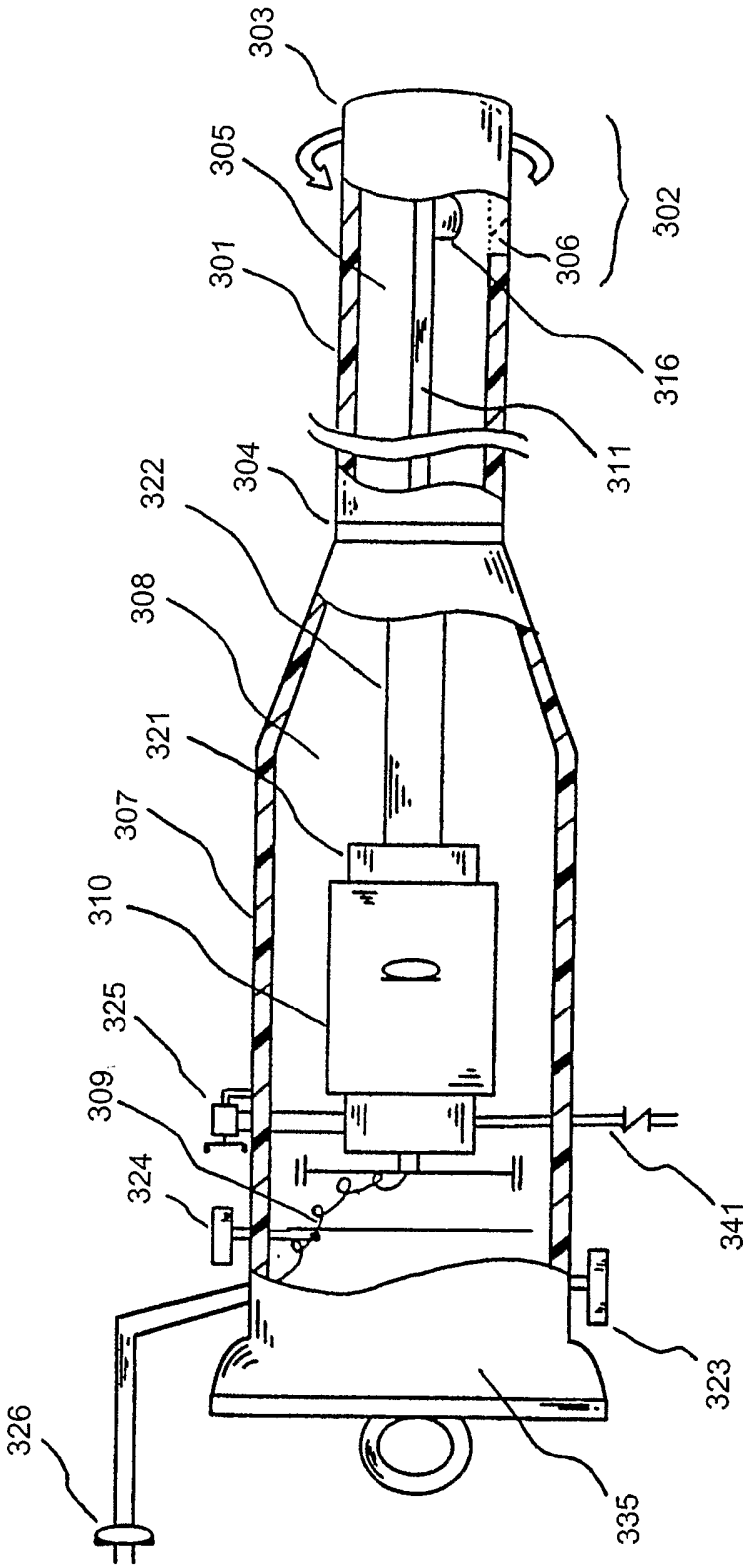
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FIG. 11

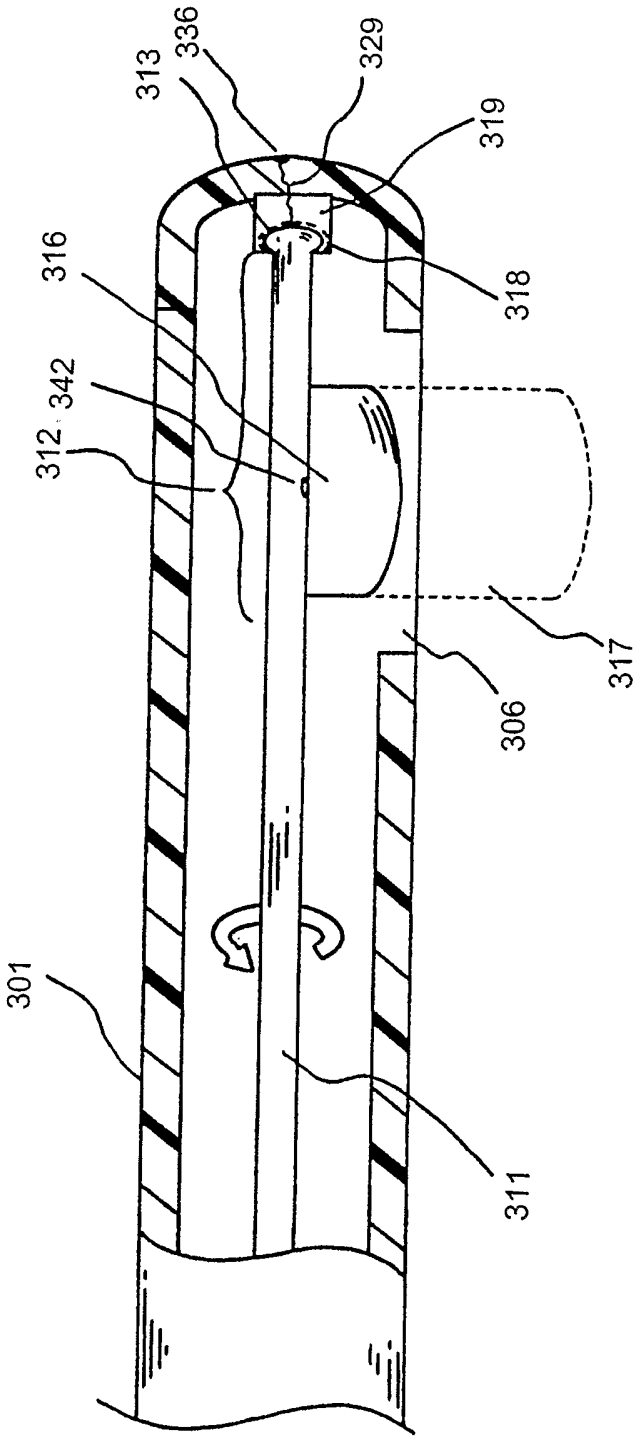

FIG. 12

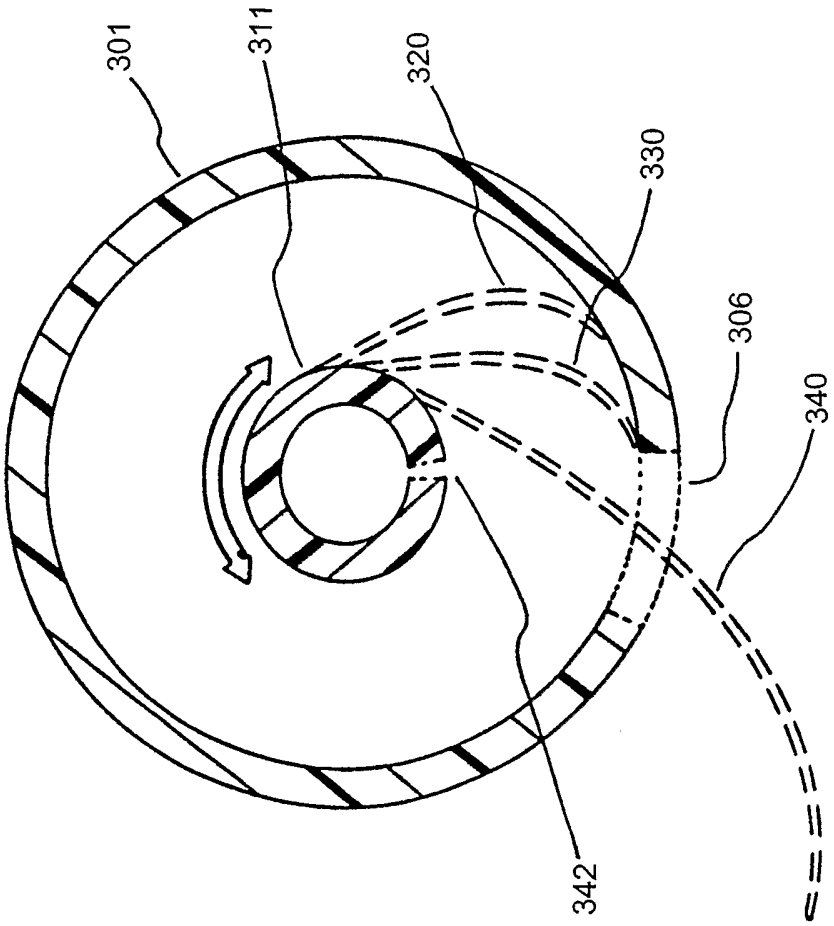

FIG. 13

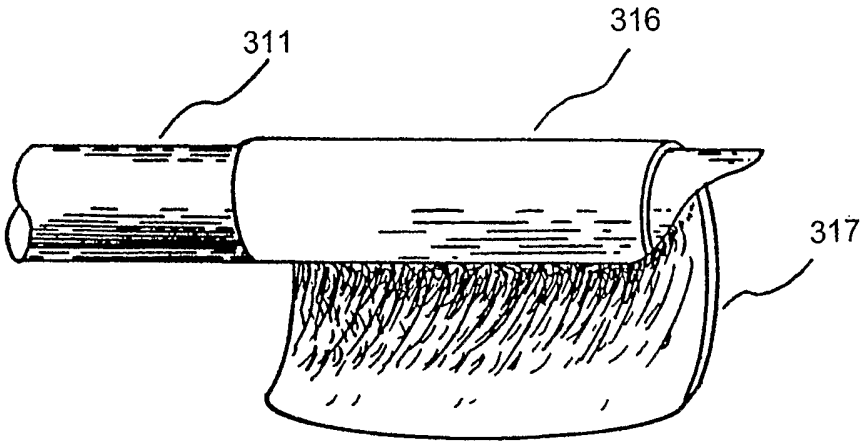

FIG. 14-A

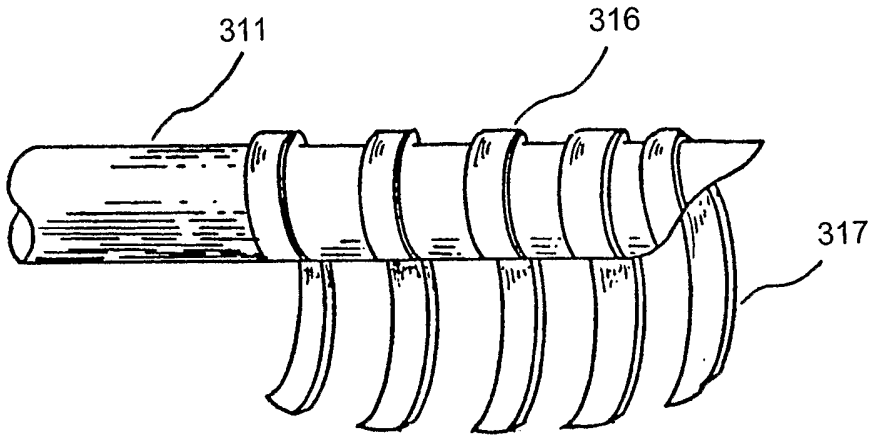

FIG. 14-B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/24025

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 18/18
US CL : 606/41

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. : 606/4141-50, 170, 171 ,180; 607/101, 102, 119, 122

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.
A	US 6,179,832 B1 (JONES et al) 30 January 2001, see entire document.	1-13
A	US 6,076,012 A (SWANSON et al) 13 June 2000, see entire document.	1-13
A	US 6,083,219 A (LAUFER) 04 July 2000, see entire document.	1-13
A	US 5,443,446 A (SHTURMAN) 22 August 1995, see entire document.	1-13

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

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"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)

"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

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