US 20050033284A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2005/0033284 A1

Hooven et al. (43) Pub. Date: Feb. 10, 2005

(54) TRANSMURAL ABLATION DEVICE WITH INTEGRAL EKG SENSOR

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(21) Appl. No.: **10/928,826**

(22) Filed: **Aug. 27, 2004**

Related U.S. Application Data

(63) Continuation of application No. 10/032,378, filed on Oct. 26, 2001, which is a continuation-in-part of application No. 09/844,225, filed on Apr. 27, 2001, now Pat. No. 6,517,536, which is a continuation-in-part of application No. 09/747,609, filed on Dec. 22, 2000, now Pat. No. 6,546,935.

(60) Provisional application No. 60/200,072, filed on Apr. 27, 2000.

Publication Classification

(51) **Int. Cl.**[7] **A61B 18/14**

(52) **U.S. Cl.** **606/41**; 606/51

(57) **ABSTRACT**

A method and apparatus for transmural ablation includes using an instrument comprising first and second jaws which each includes an ablation member. A clamping force is exerted on the two ablation members such that the tissue of the hollow organ is clamped therebetween. At least one of the first and second jaws further includes at least one EKG monitoring sensor on a tip of the associated jaw. The EKG sensor is spaced distally from its associated ablation member for contacting cardiac tissue. The EKG sensor is adapted to be connected to an EKG monitor, so that when cardiac tissue is grasped between the first and second grasping jaws, the EKG sensor contacts the cardiac tissue and transmits the signals generated by the tissue to the EKG monitor.

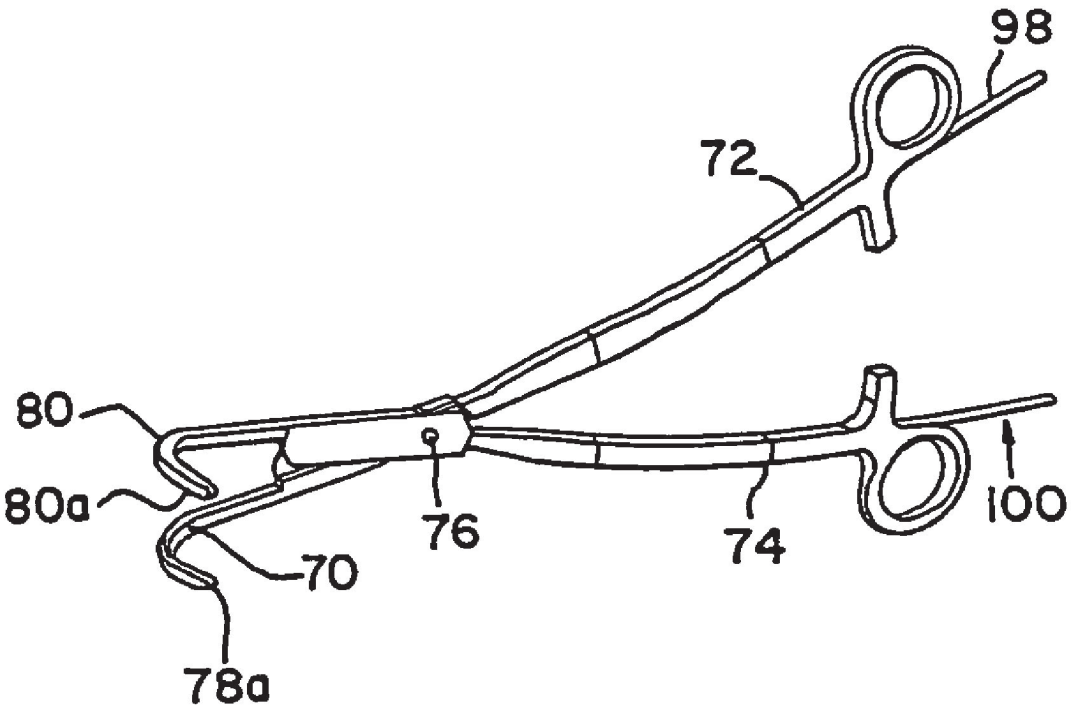


FIG. 1

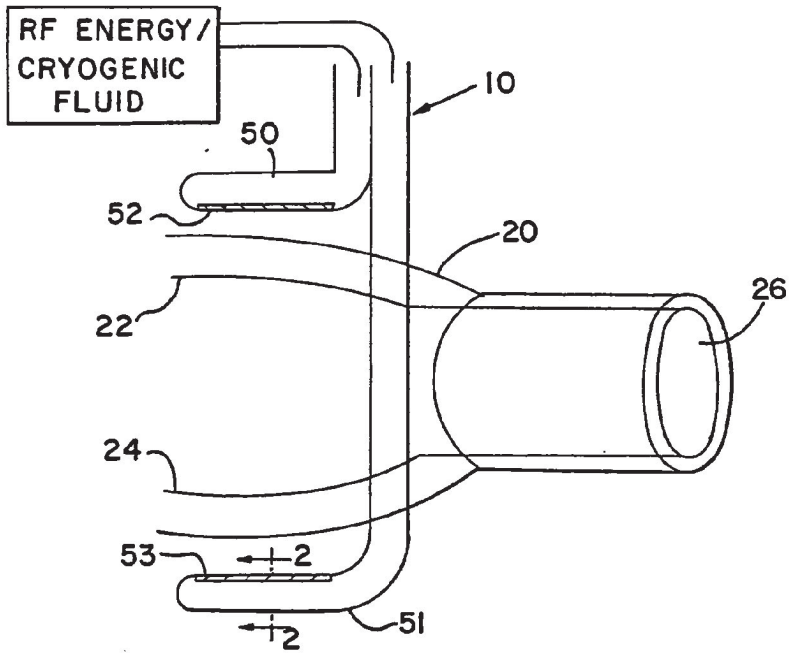


FIG. 2

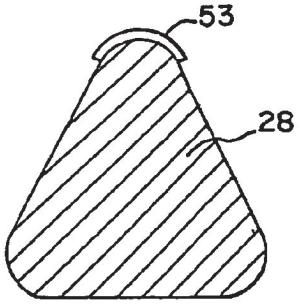


FIG. 3

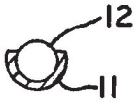


FIG. 4

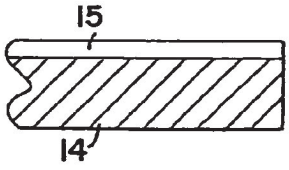


FIG. 5

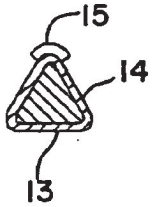


FIG. 6

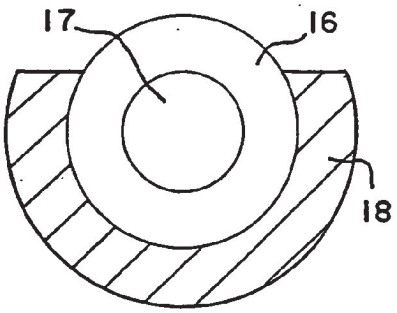


FIG.7

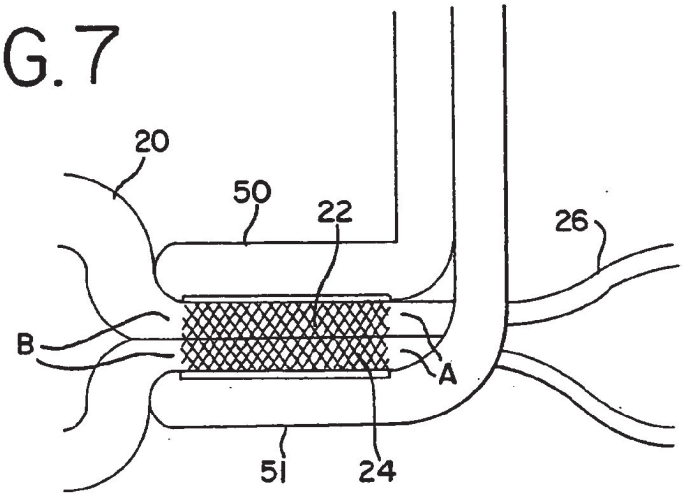


FIG.8

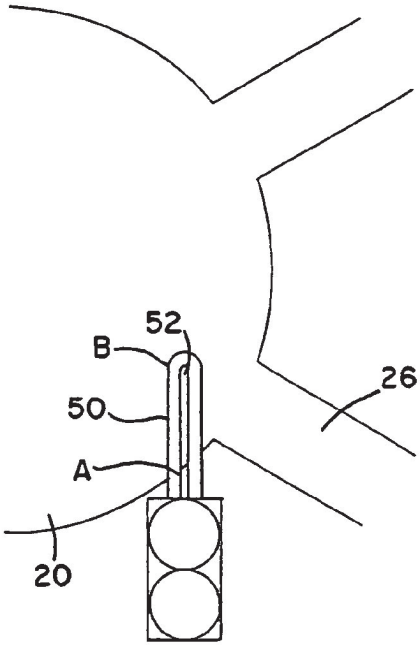


FIG.9

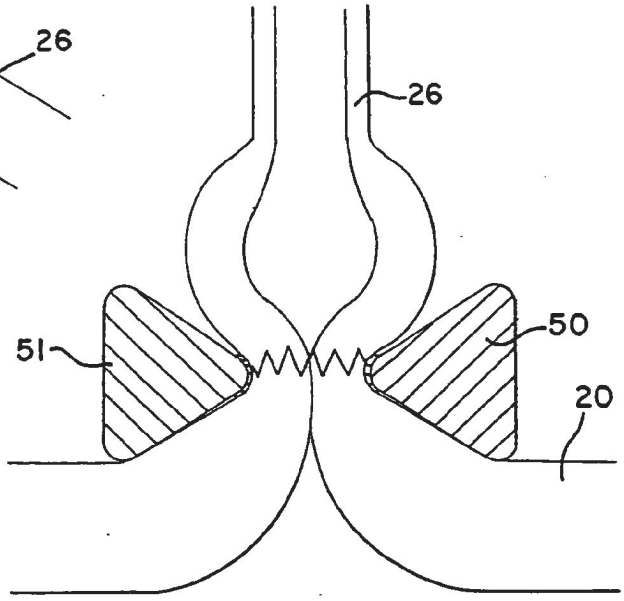


FIG. 10

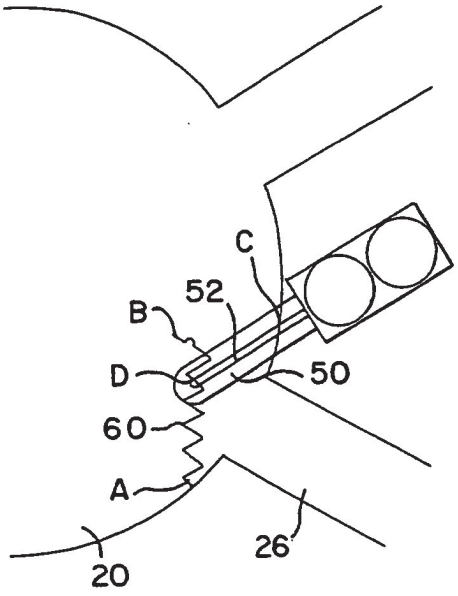


FIG. 11

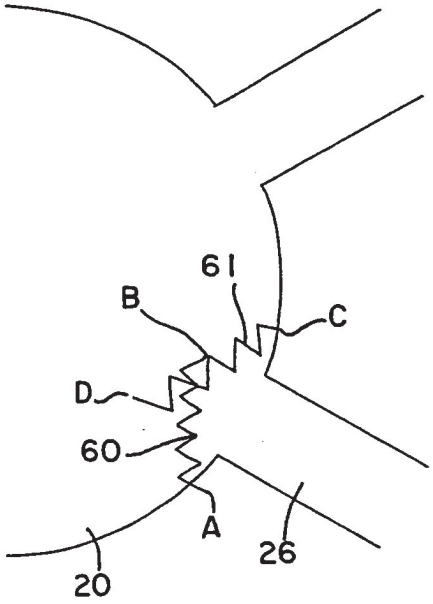


FIG. 12

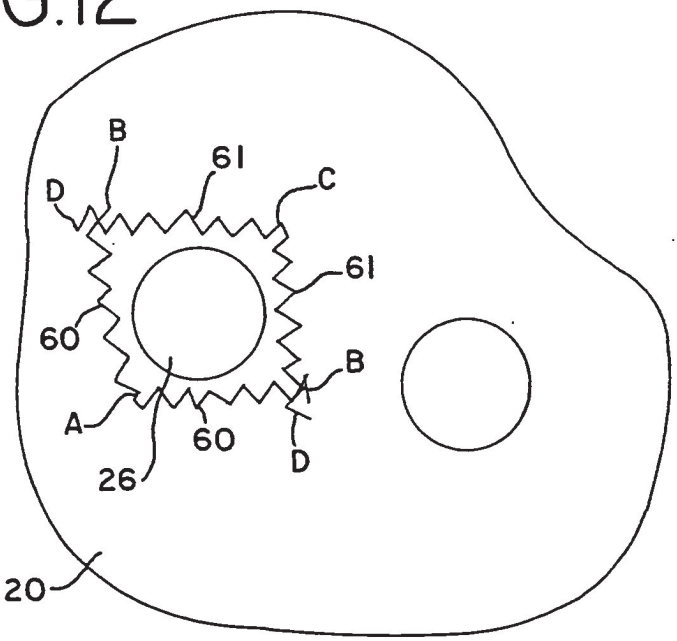


FIG. 13

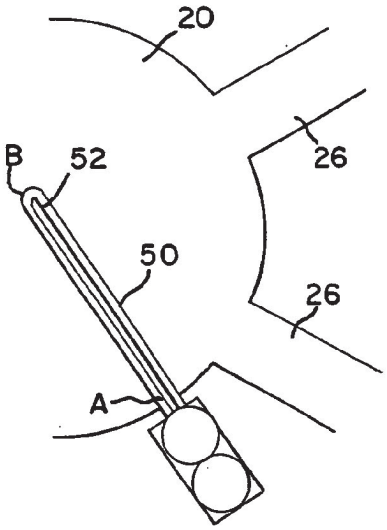


FIG. 14

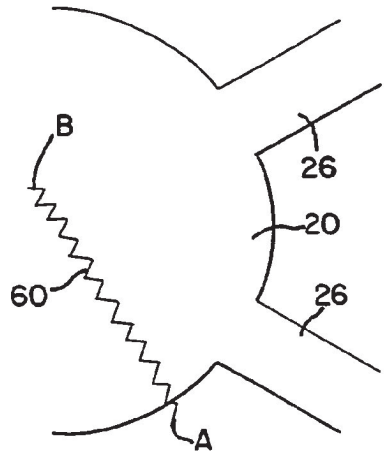


FIG. 15

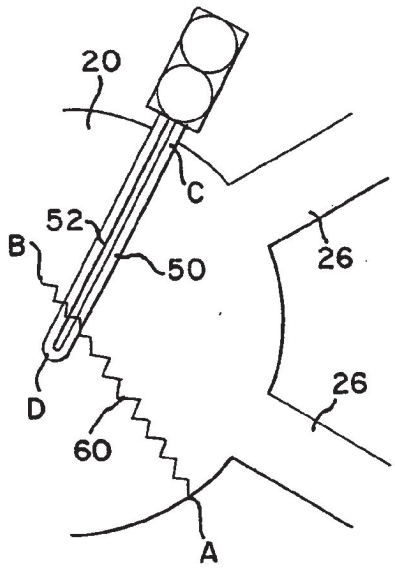


FIG. 16

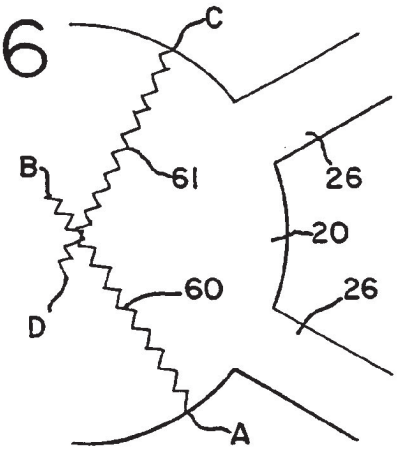


FIG. 17

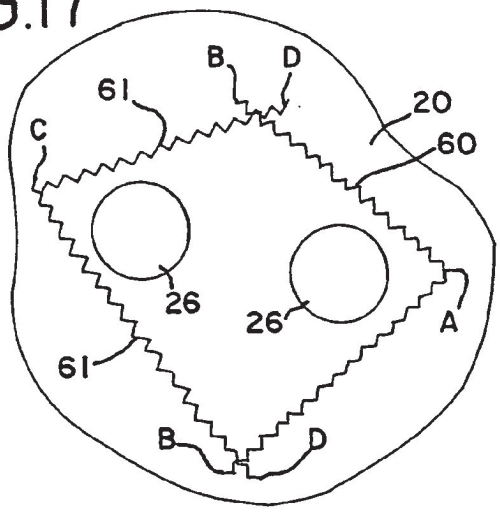


FIG. 19

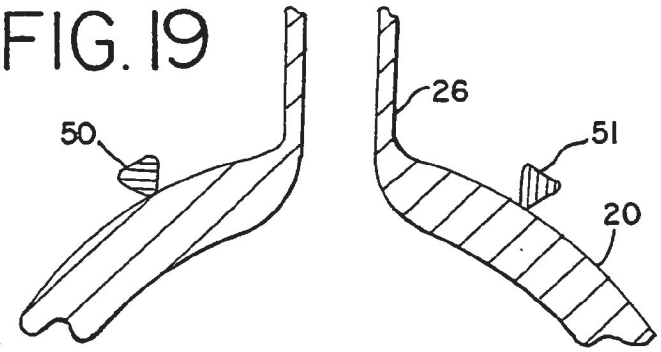


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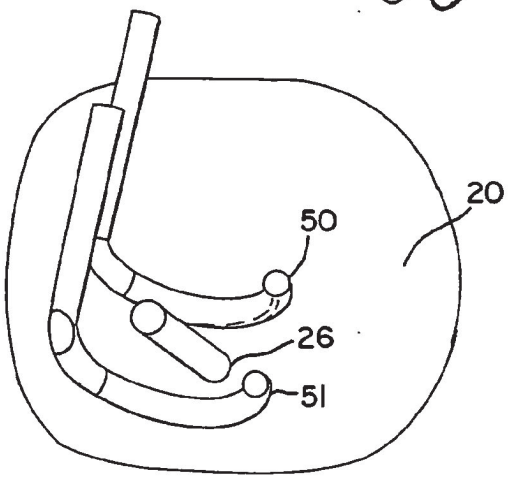


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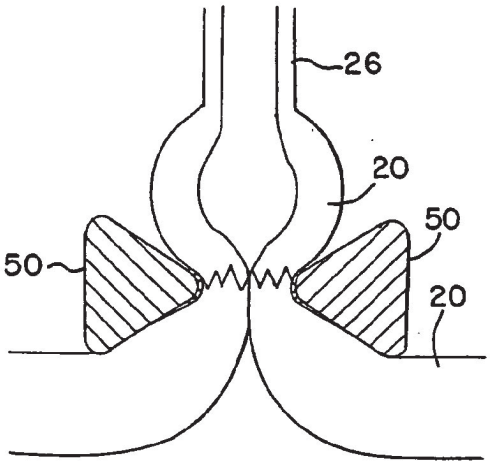


FIG. 20

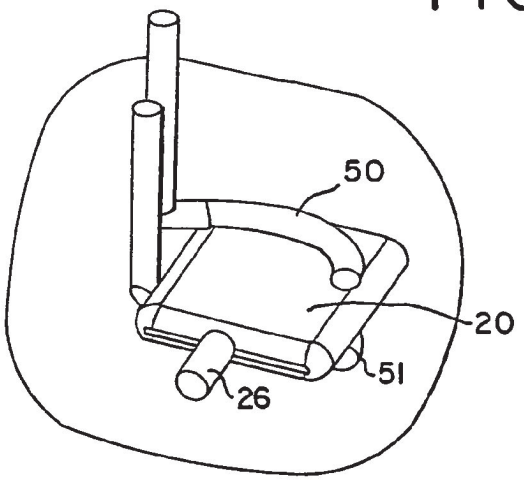


FIG. 22

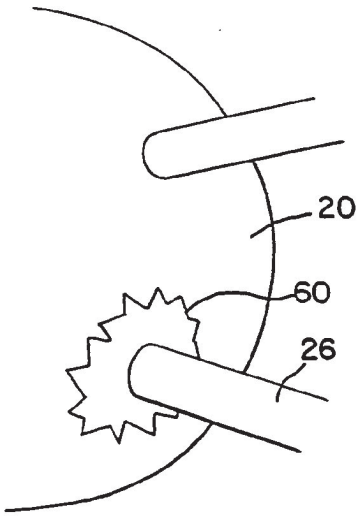


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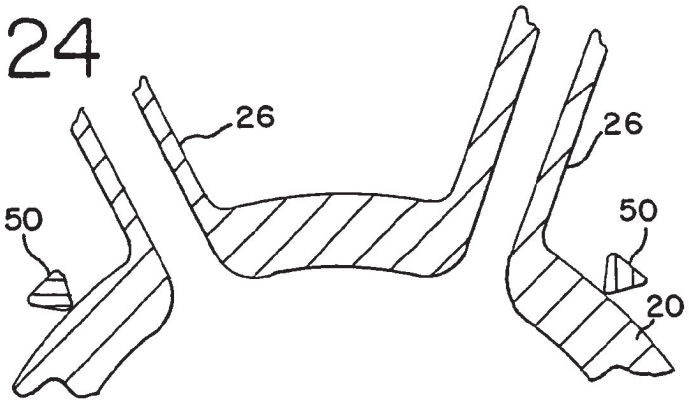


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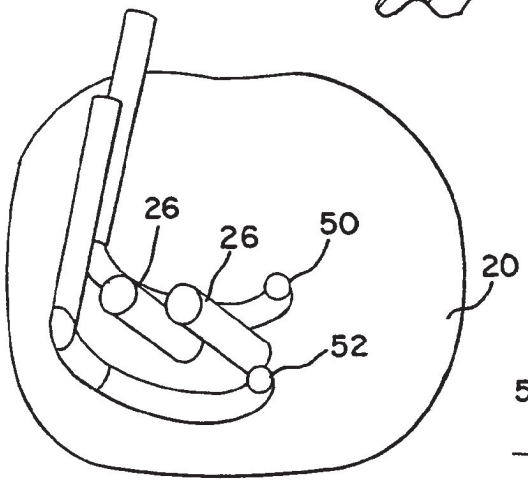


FIG.26

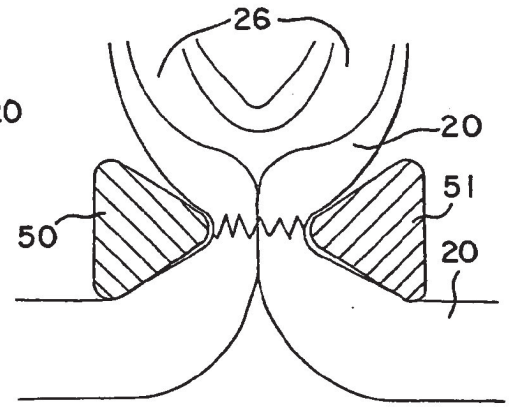


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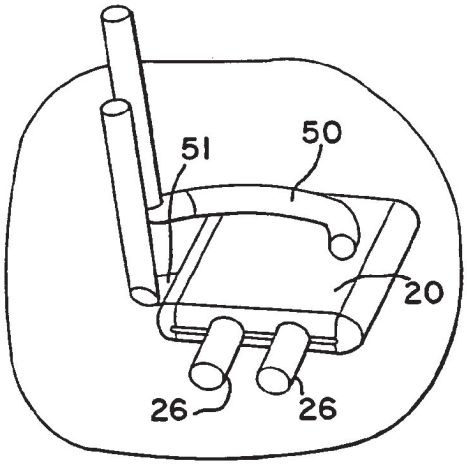


FIG.27

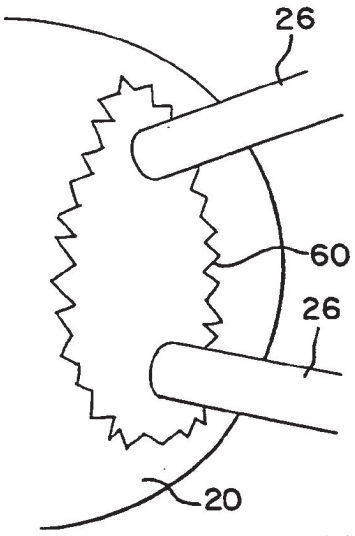


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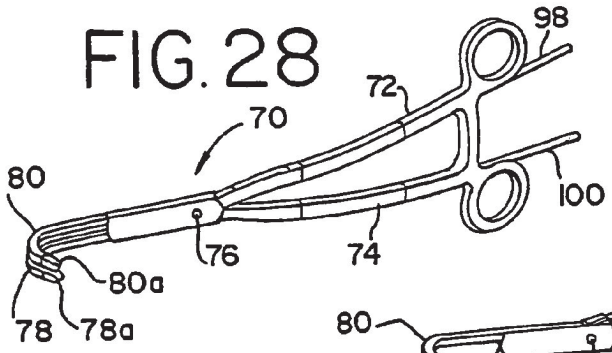


FIG. 29

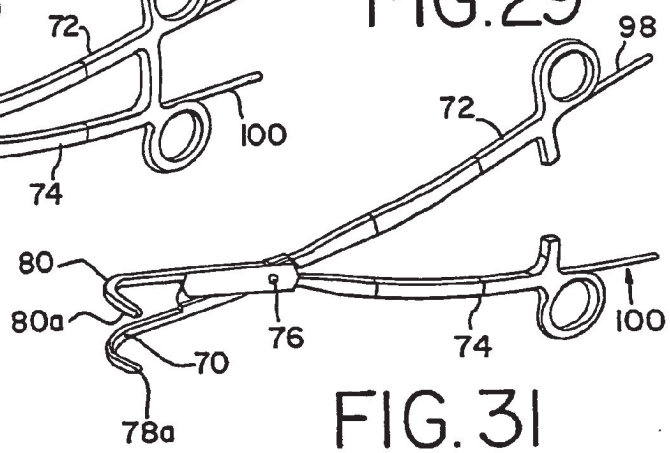


FIG. 31

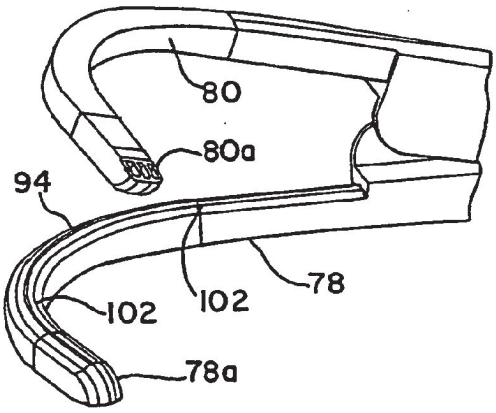


FIG. 30

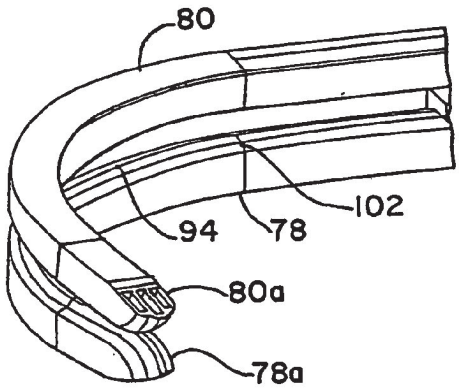
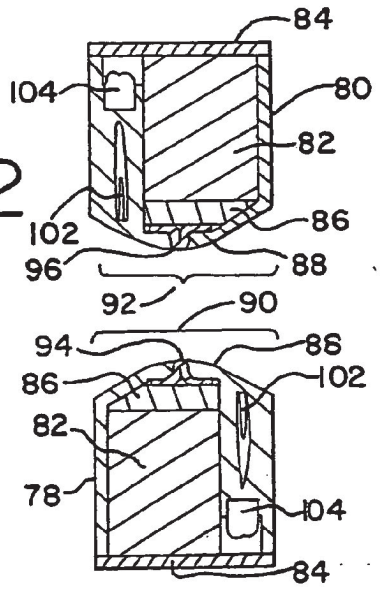


FIG. 32



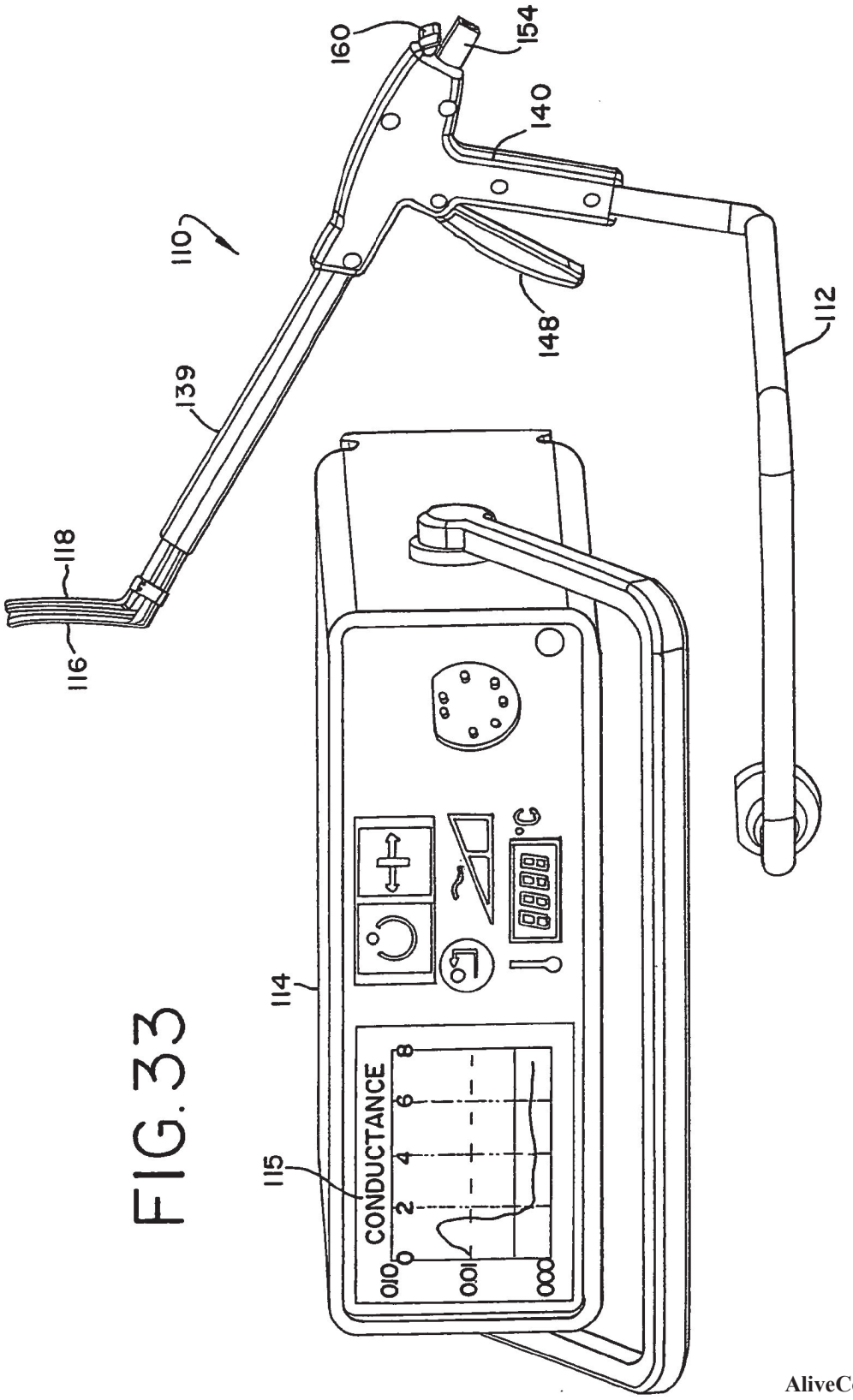

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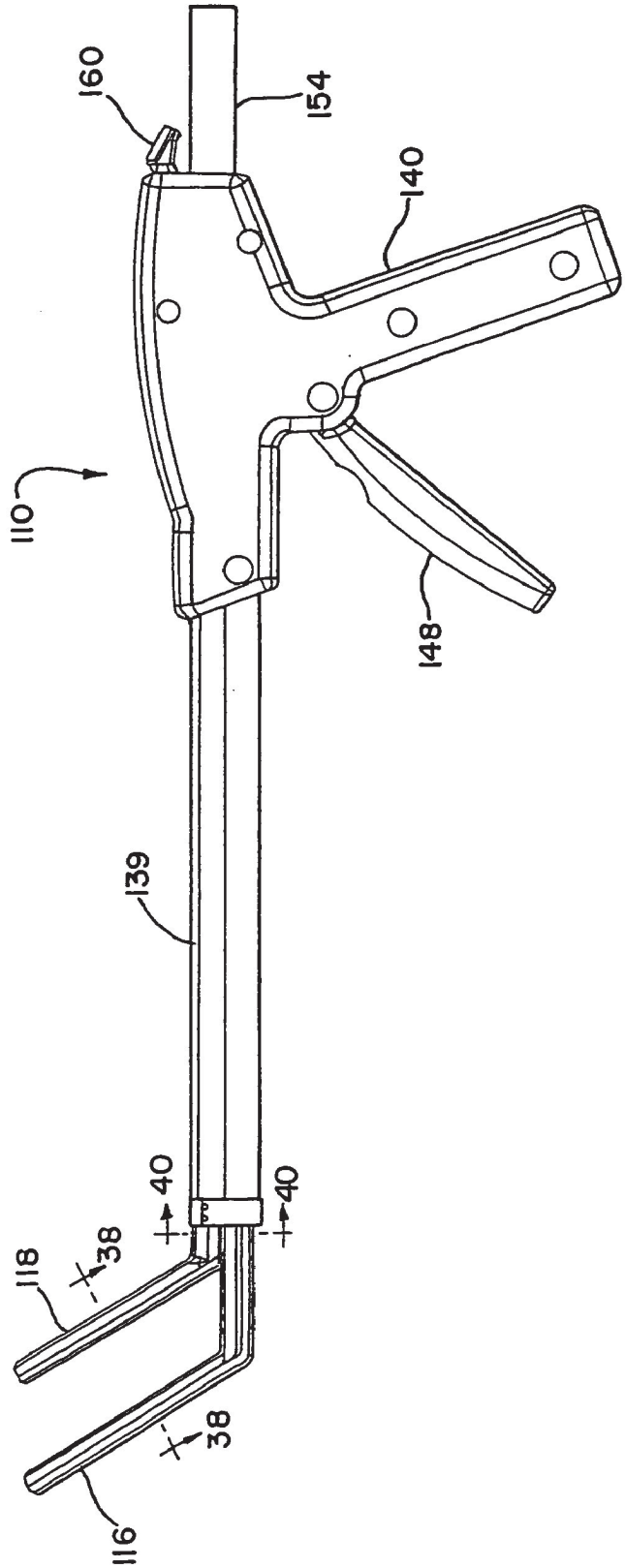


FIG. 34

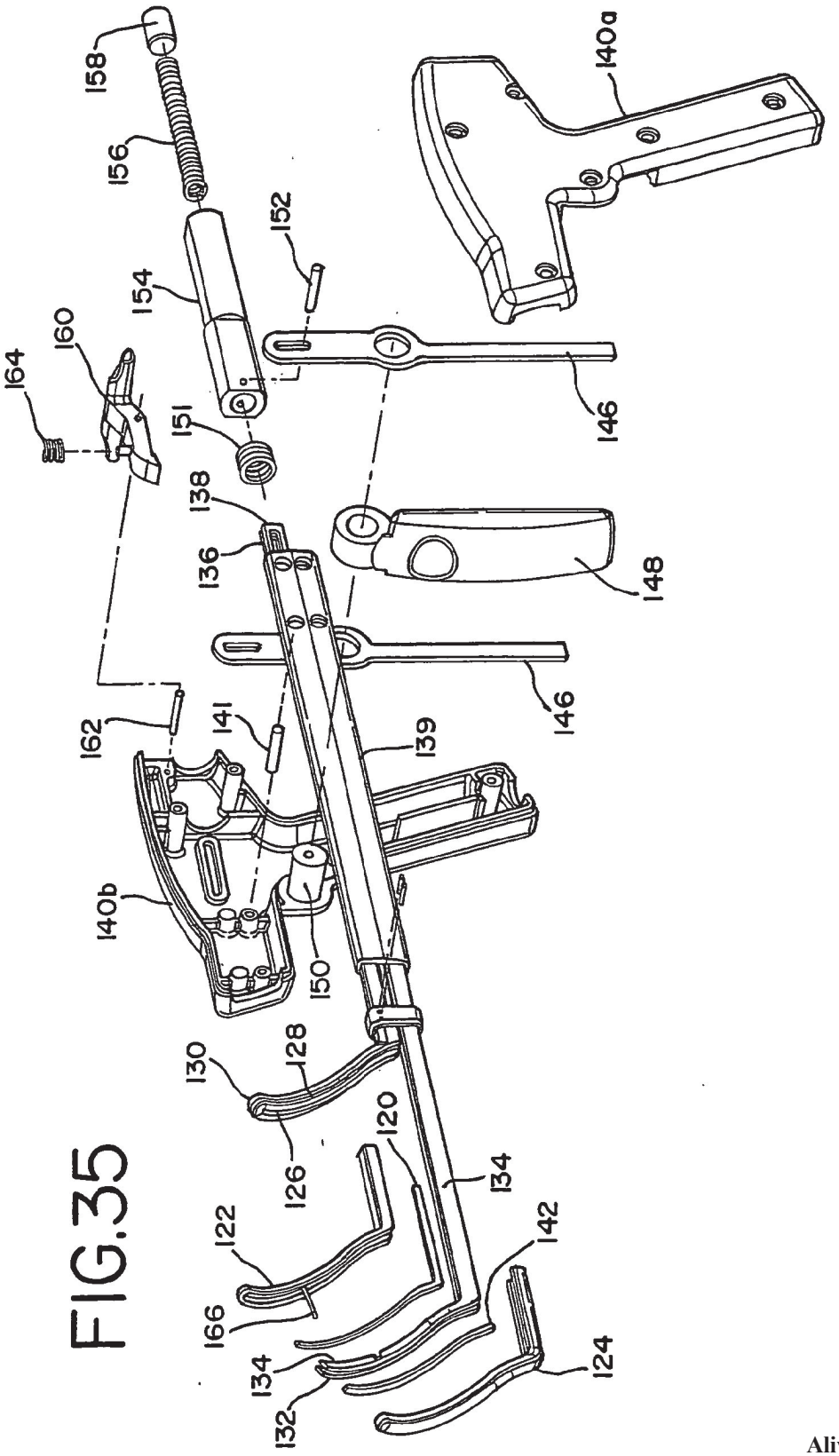

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FIG.35

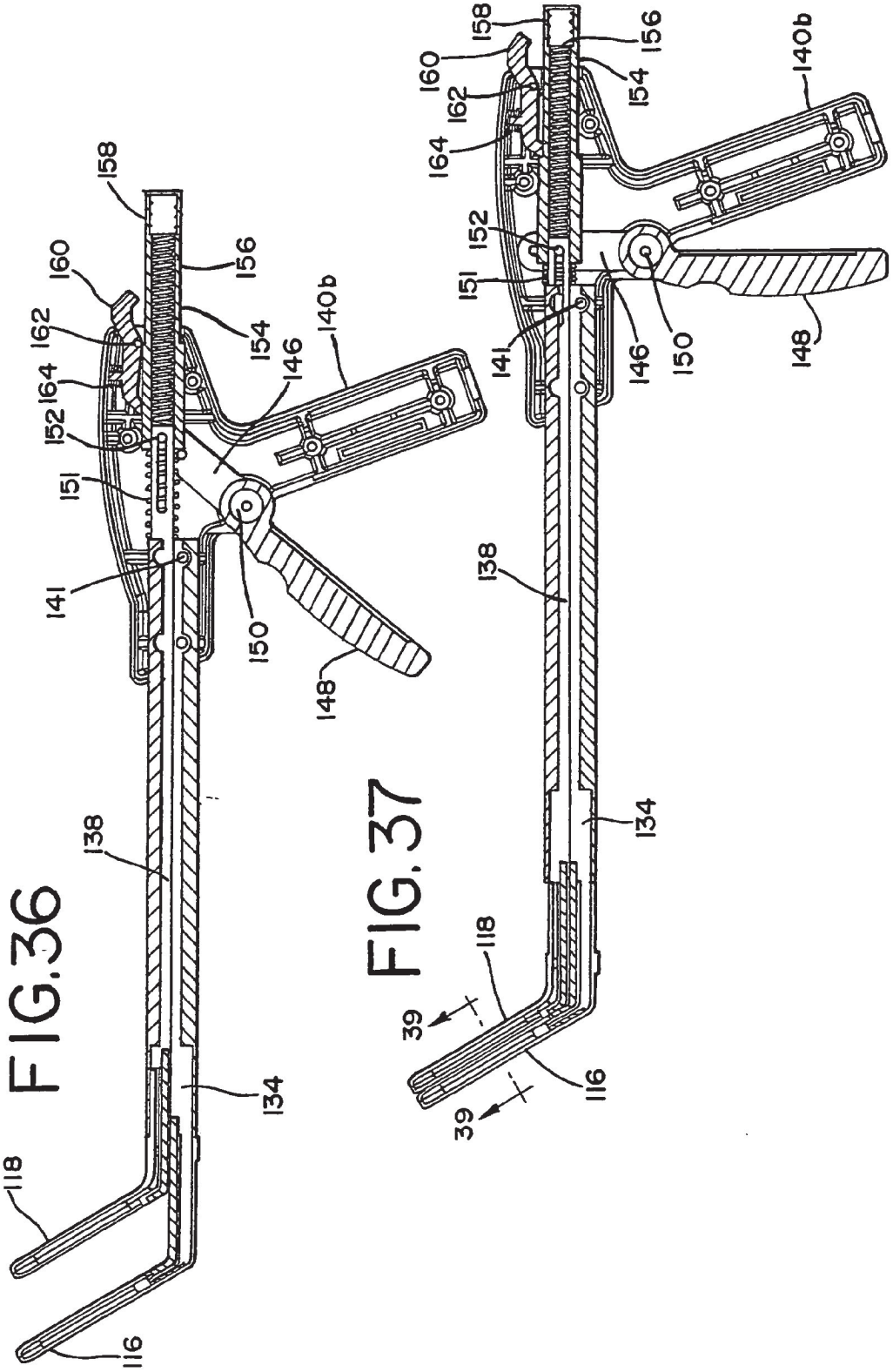

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FIG. 36

FIG. 37

FIG.38

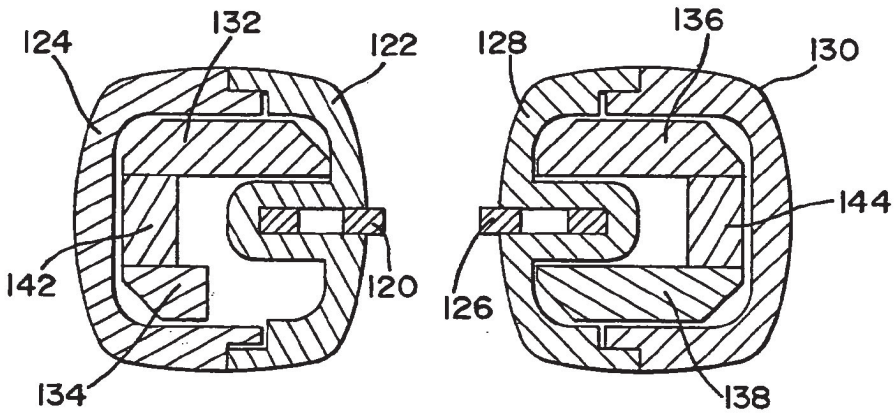


FIG.39

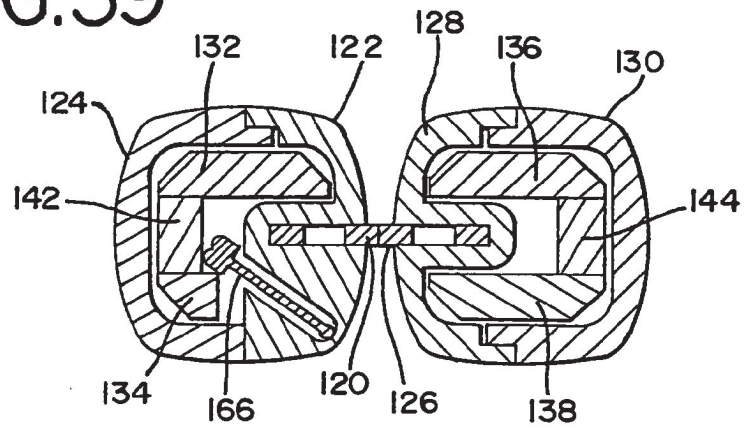


FIG.40

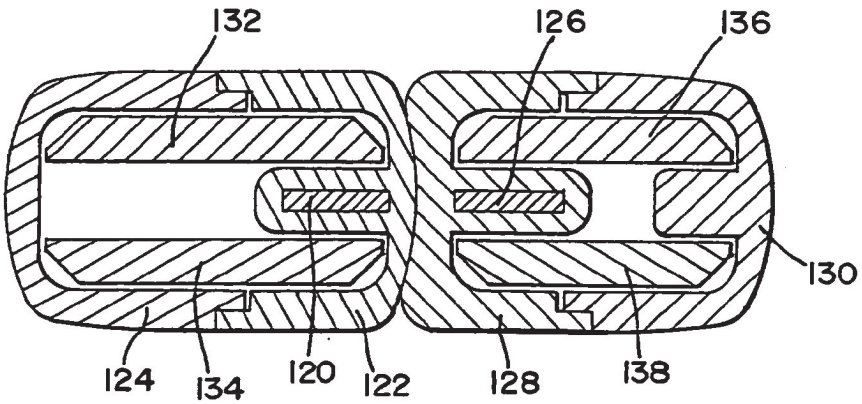


FIG.41

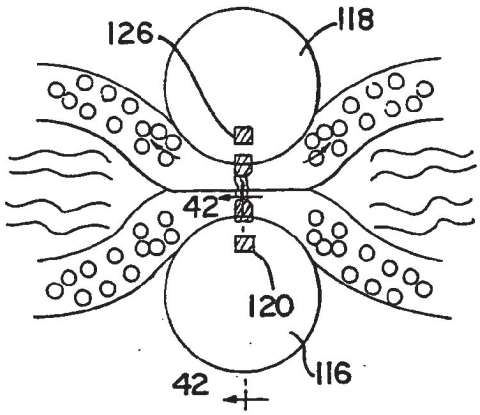


FIG.42

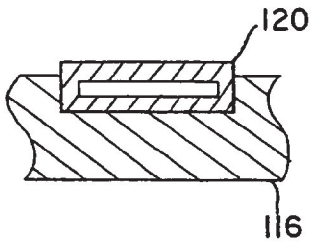


FIG.43

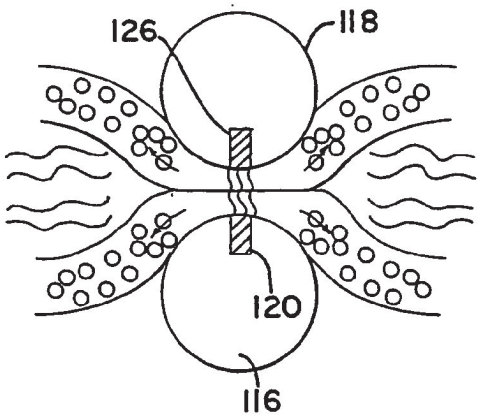


FIG.44

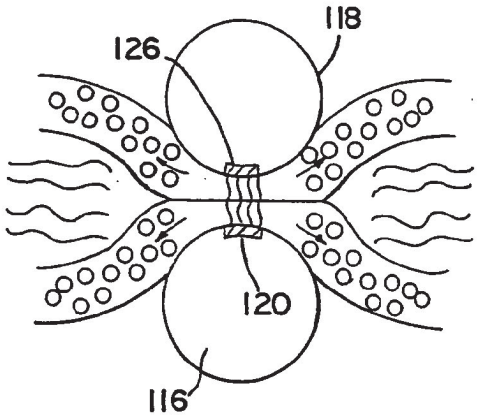


FIG.45

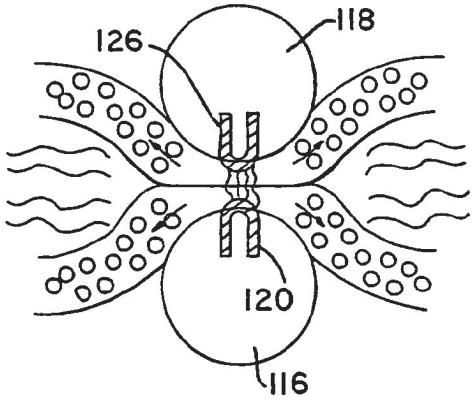


FIG.46

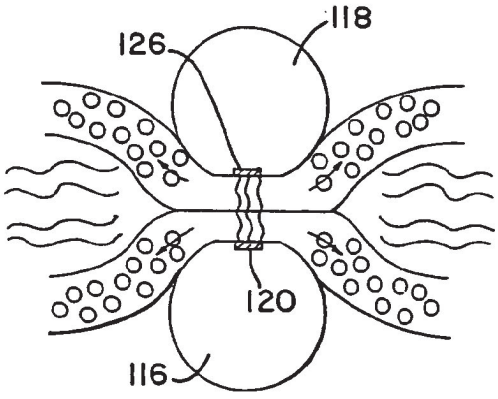


FIG.47

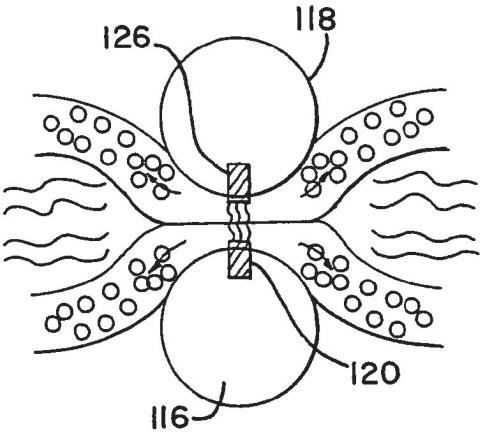


FIG.48

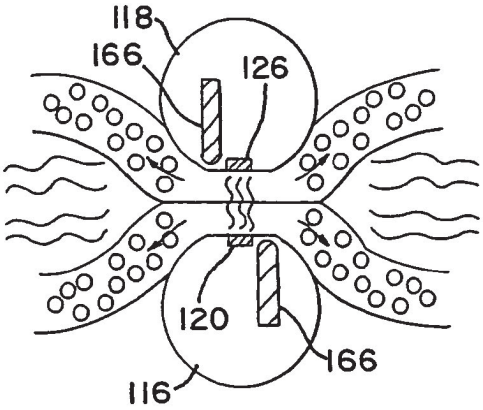


FIG.49

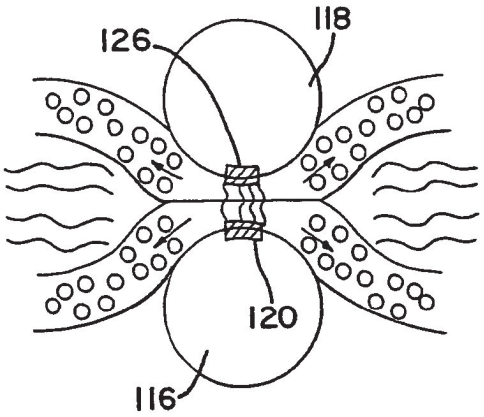


FIG.50

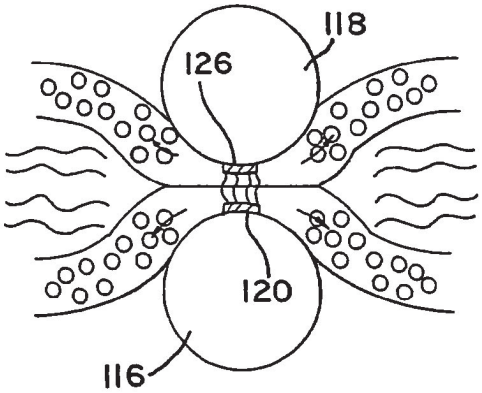


FIG.51

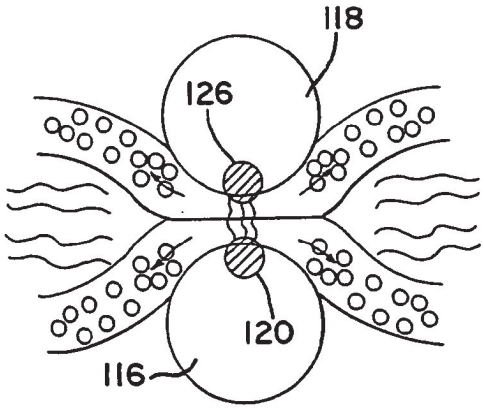


FIG.52A

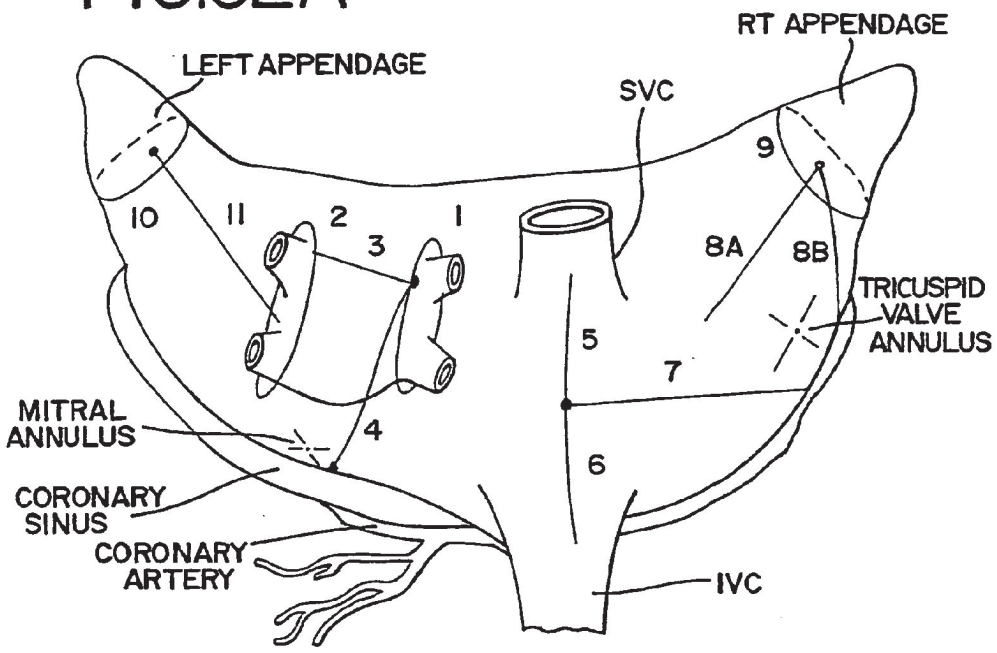


FIG.52B

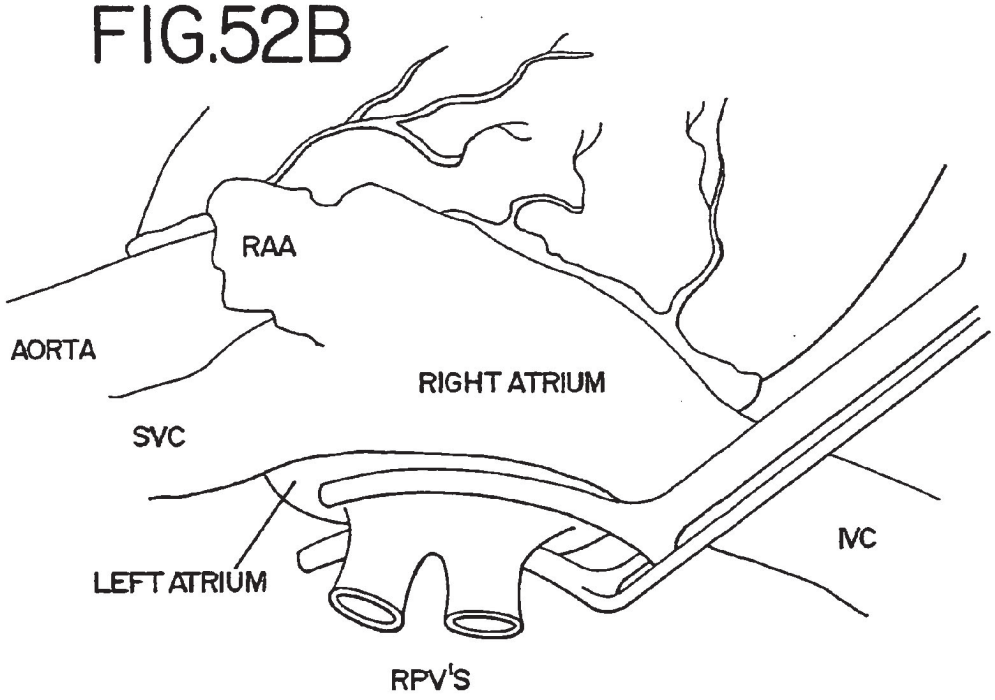


FIG.52C

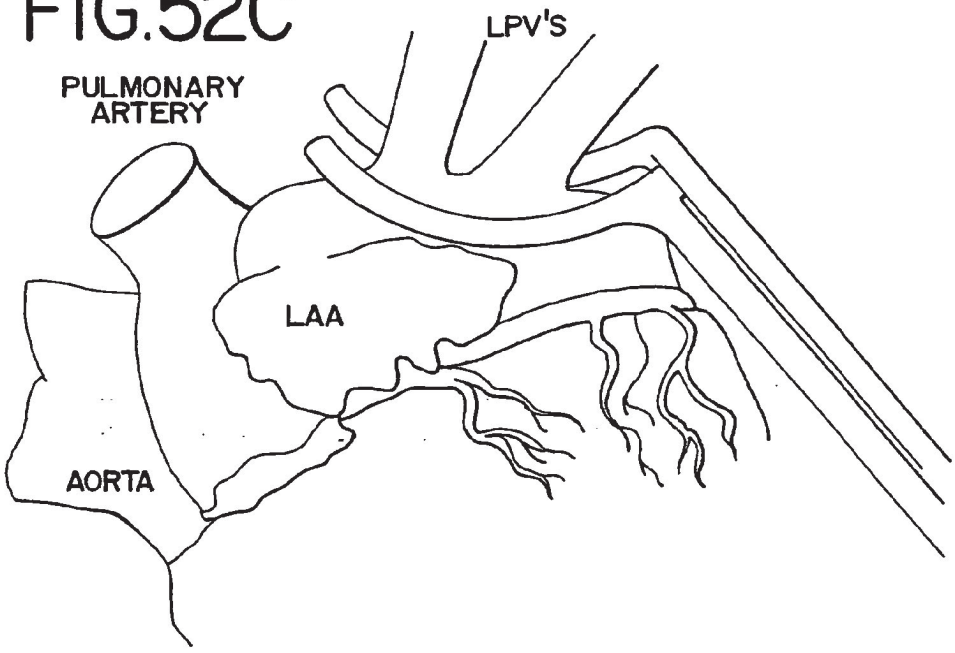


FIG.52D

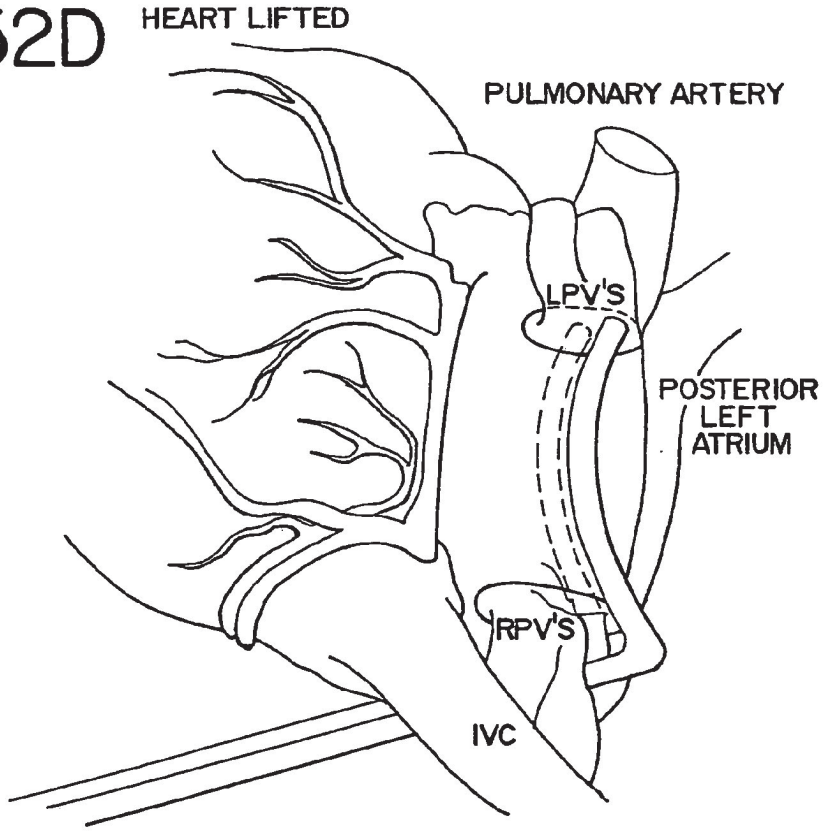


FIG.52E

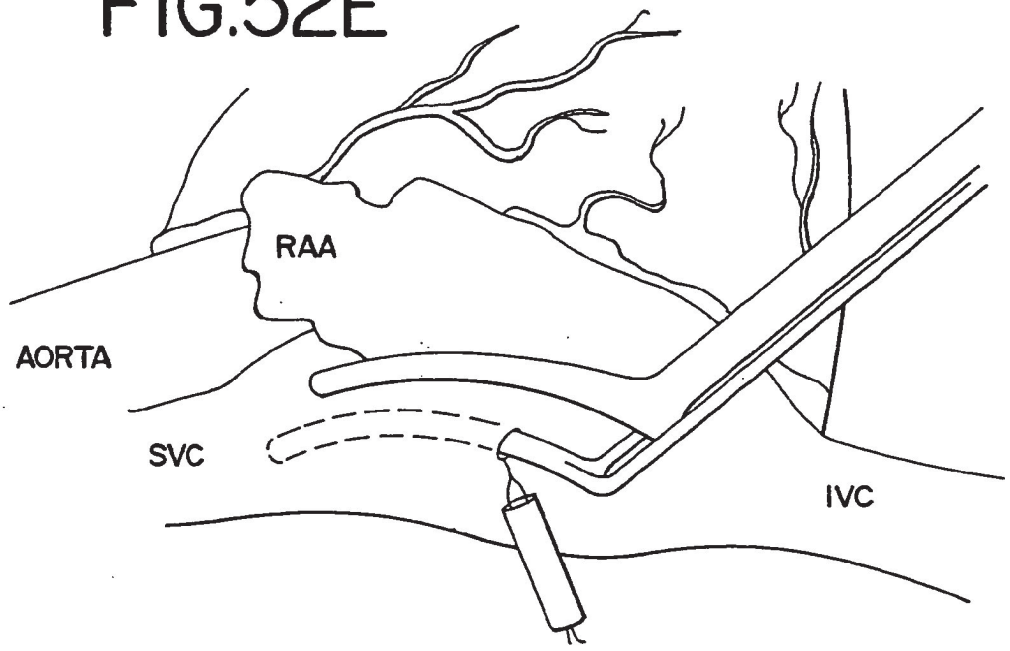


FIG.52F

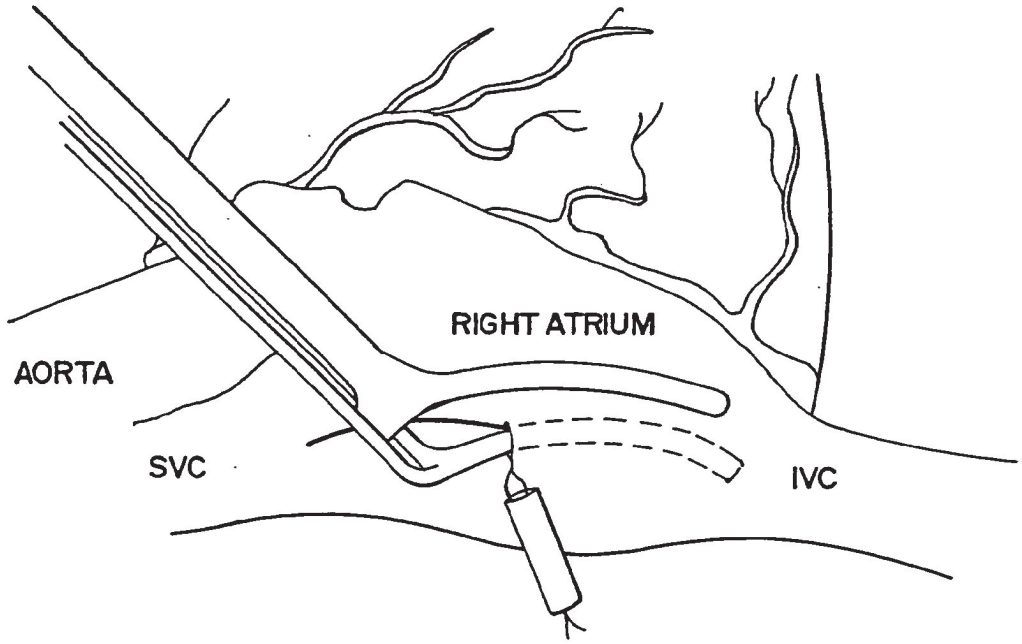


FIG.52G

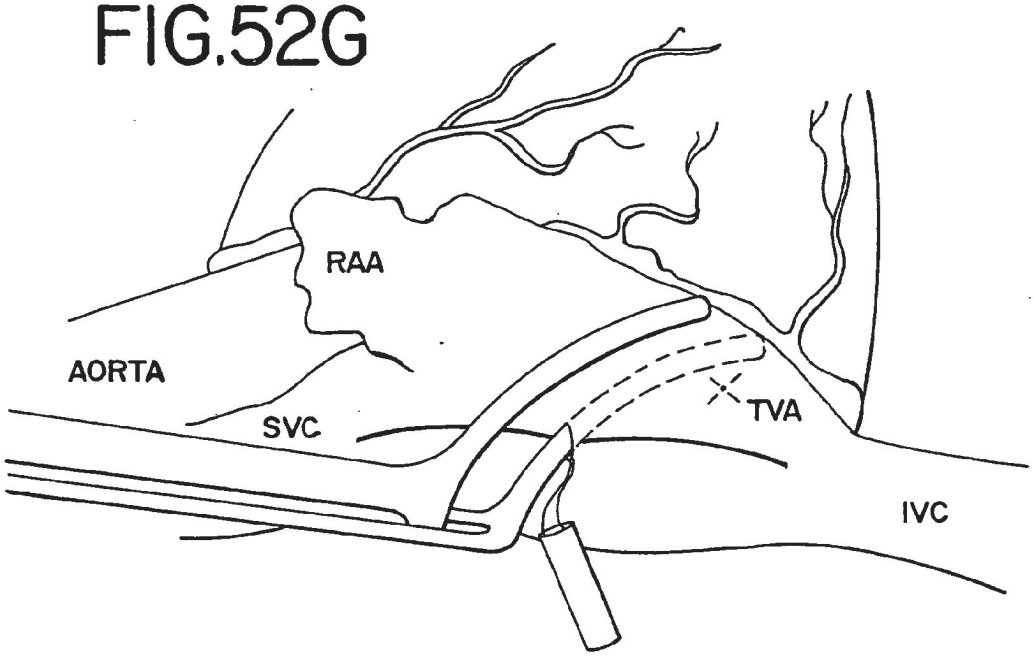


FIG.52H

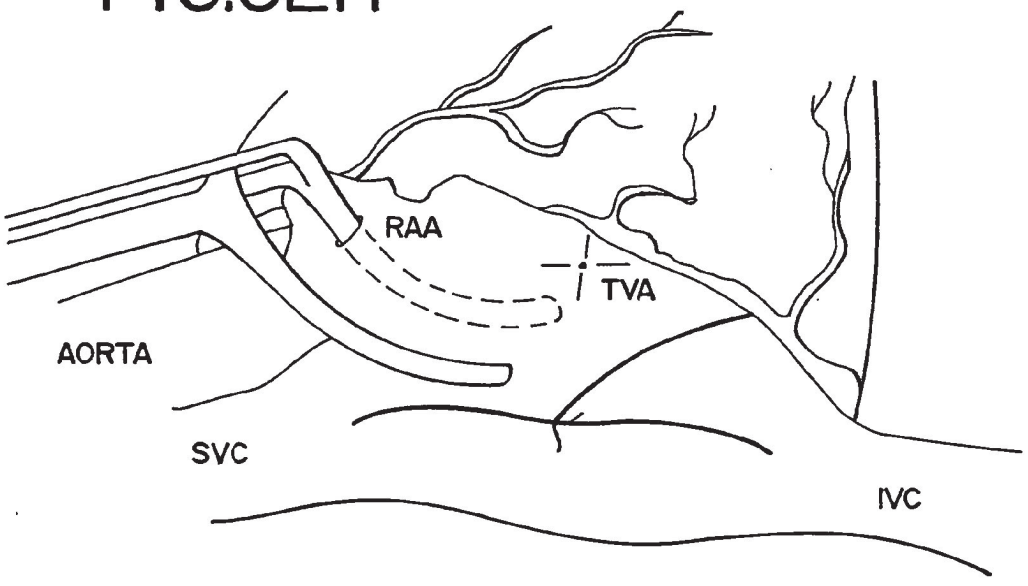


FIG. 52I

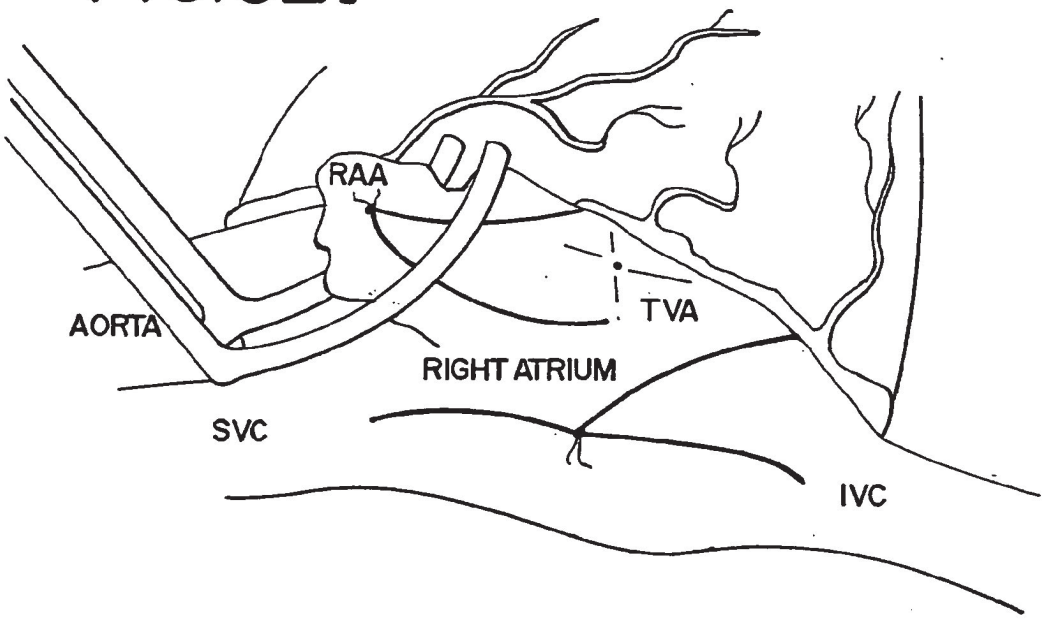


FIG. 52J

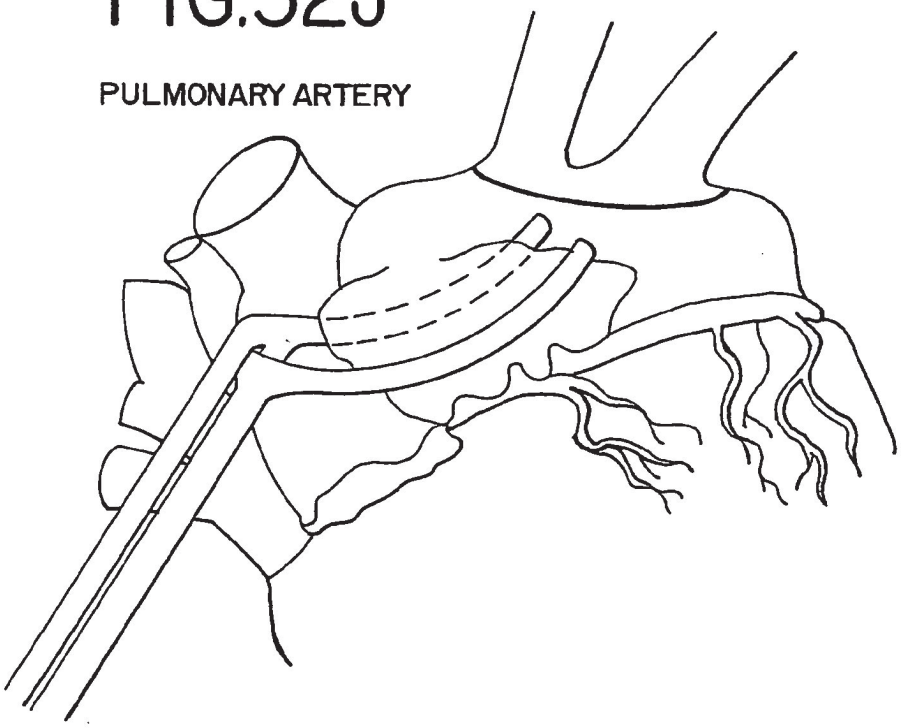
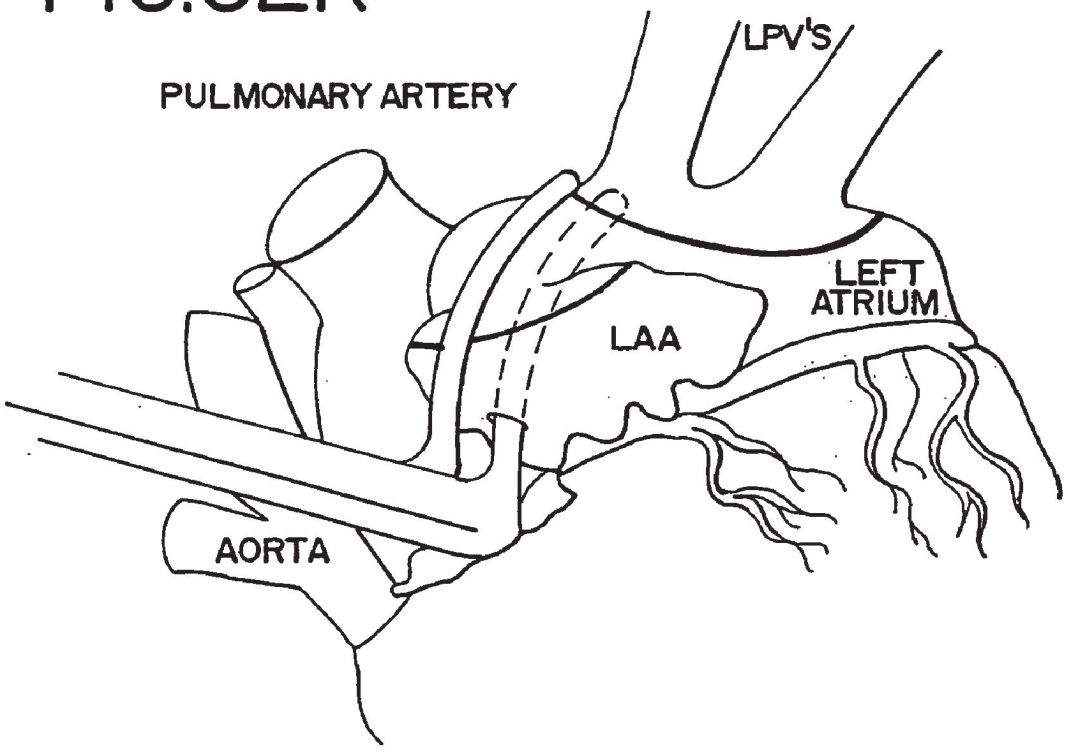


FIG.52K



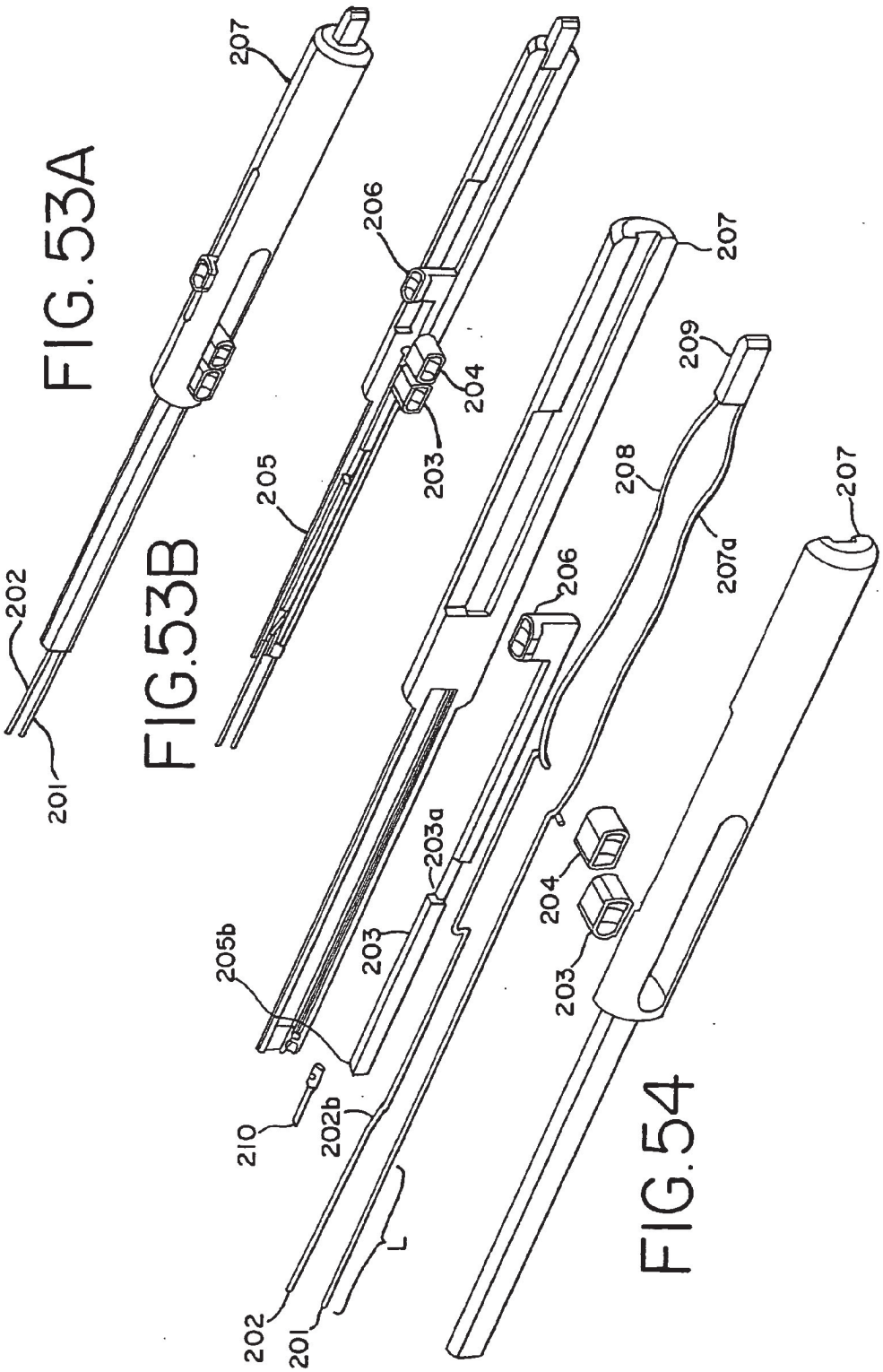

FIG. 53A
FIG. 53B
FIG. 54
201
202
203
203a
204
205
205b
206
207
208
209
207a
210
202b
L

FIG. 55

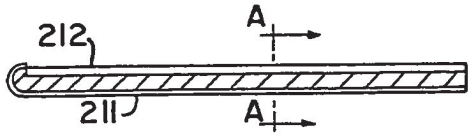


FIG. 56

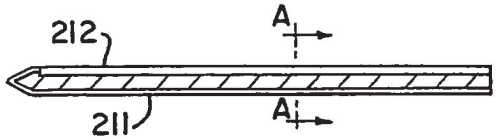


FIG. 57

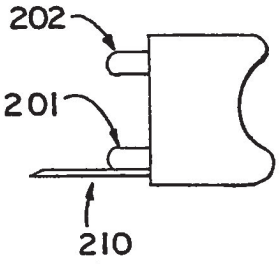


FIG. 58A

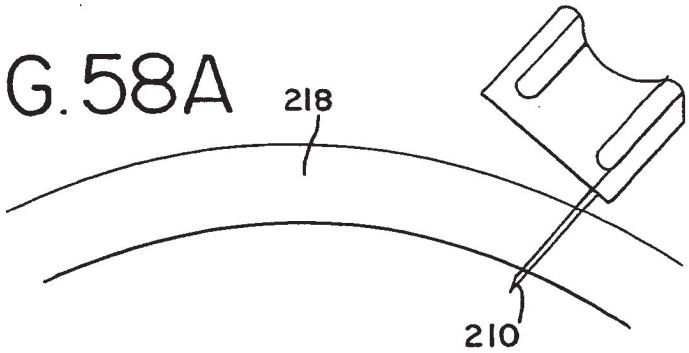


FIG. 58B

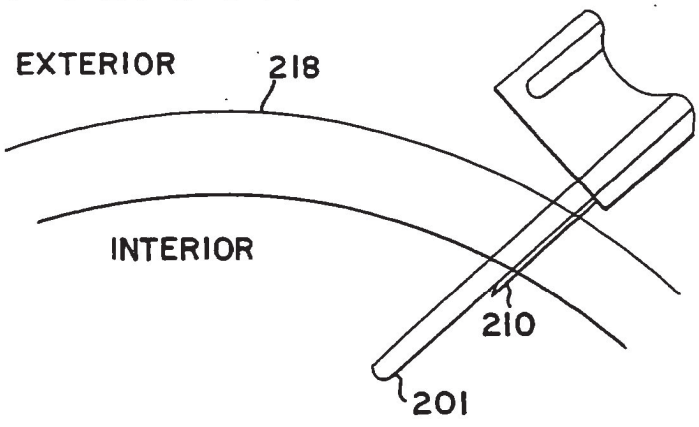


FIG. 58C

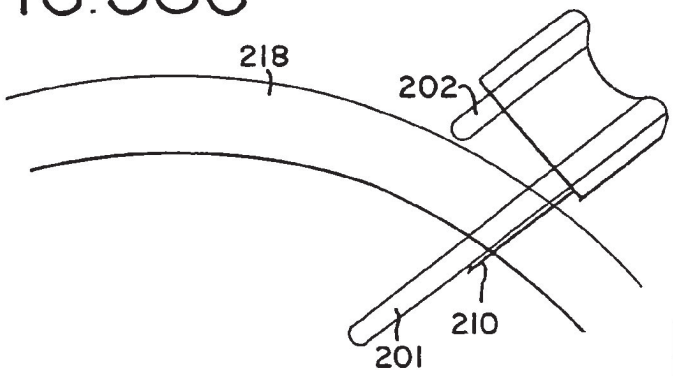


FIG. 58D

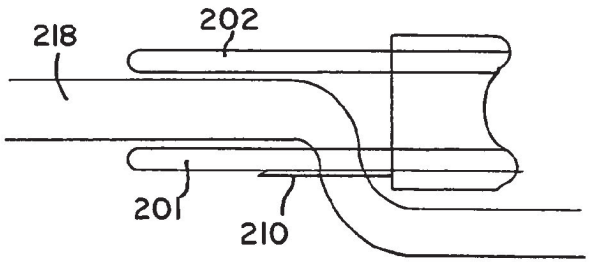


FIG. 58E

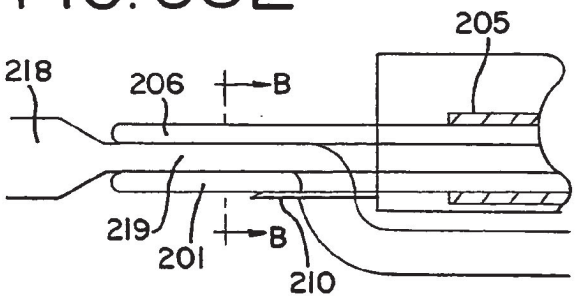


FIG. 58F

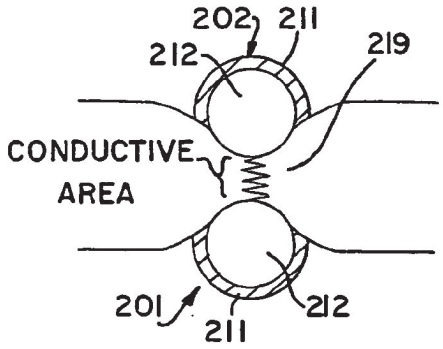


FIG. 58G

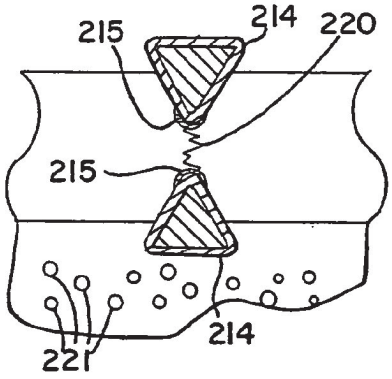


FIG. 59

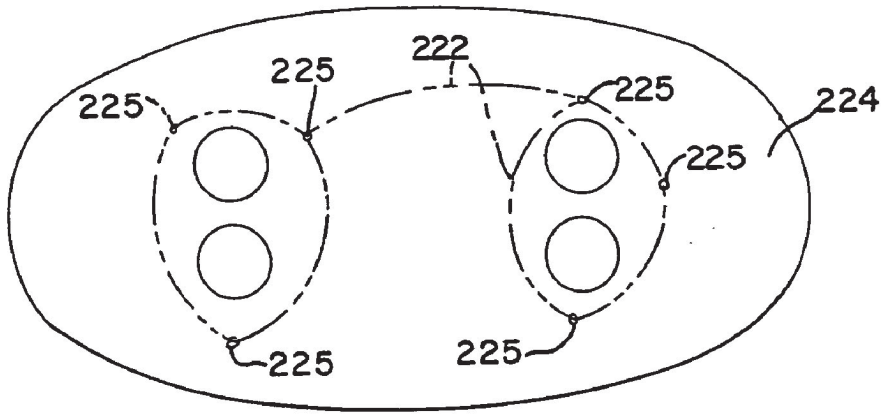


FIG. 60A

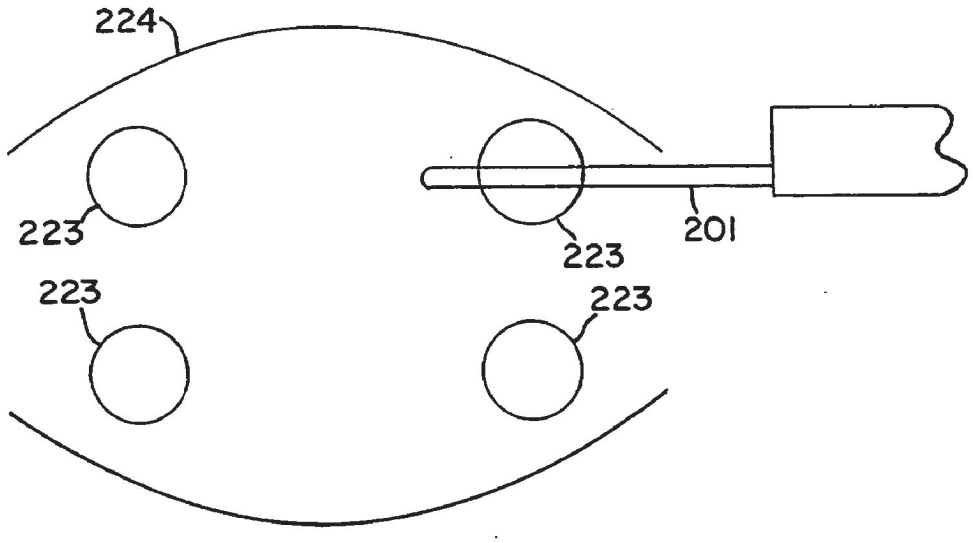


FIG. 60B

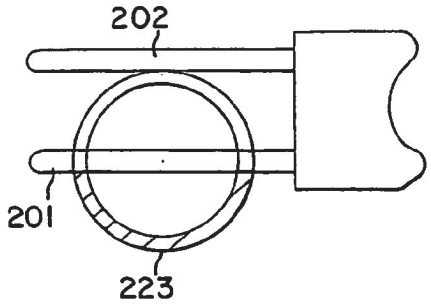


FIG. 60C

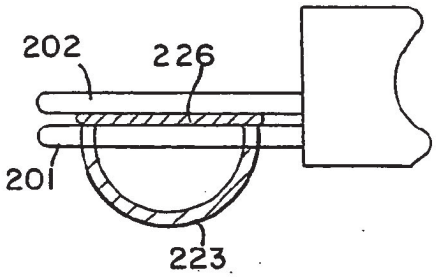


FIG. 60D

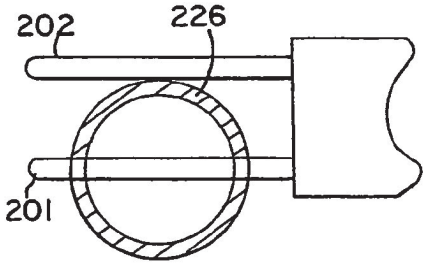


FIG. 60E

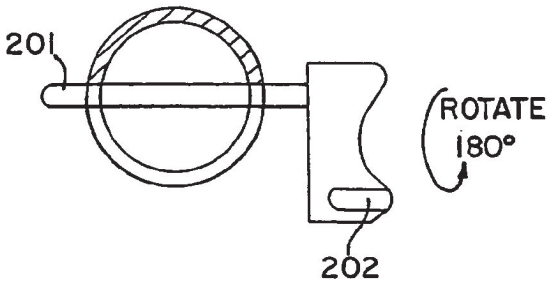


FIG. 60F

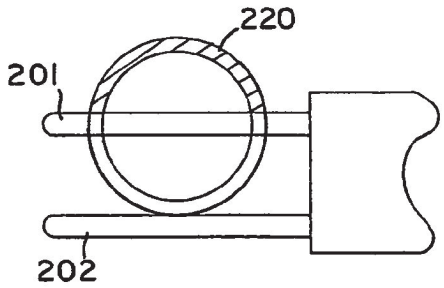


FIG. 60G

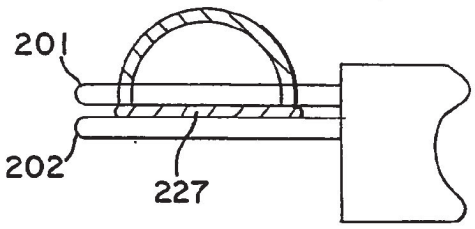


FIG. 60H

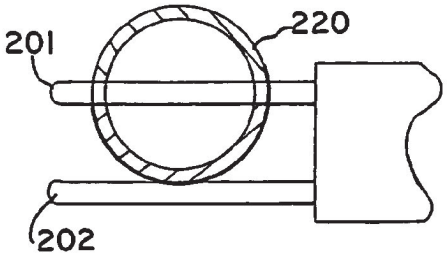
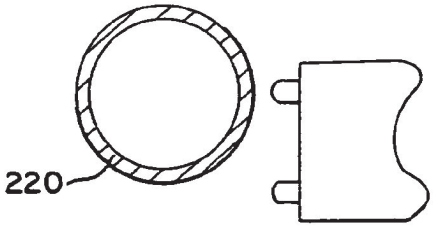


FIG. 601



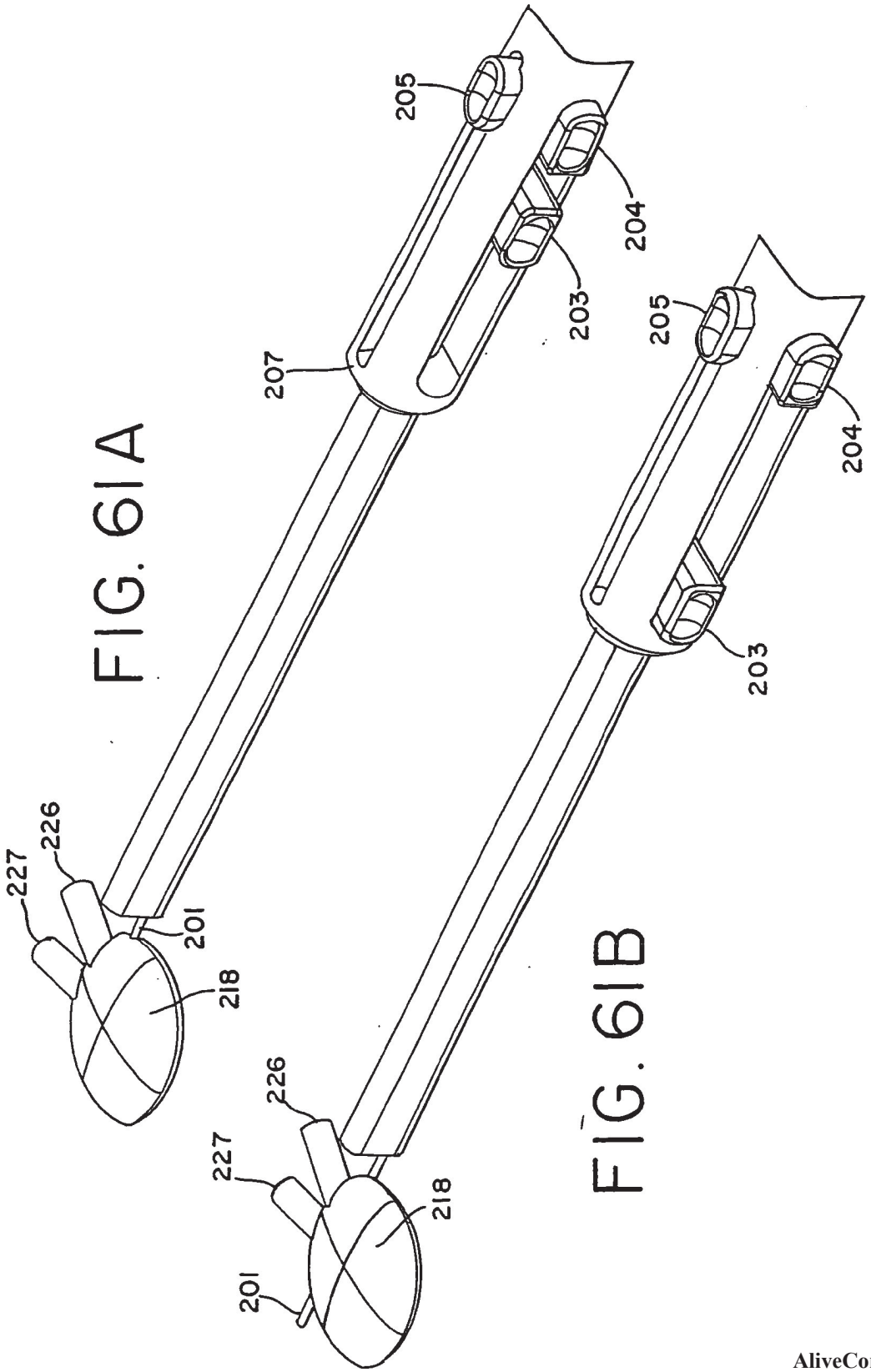


FIG. 61A

FIG. 61B

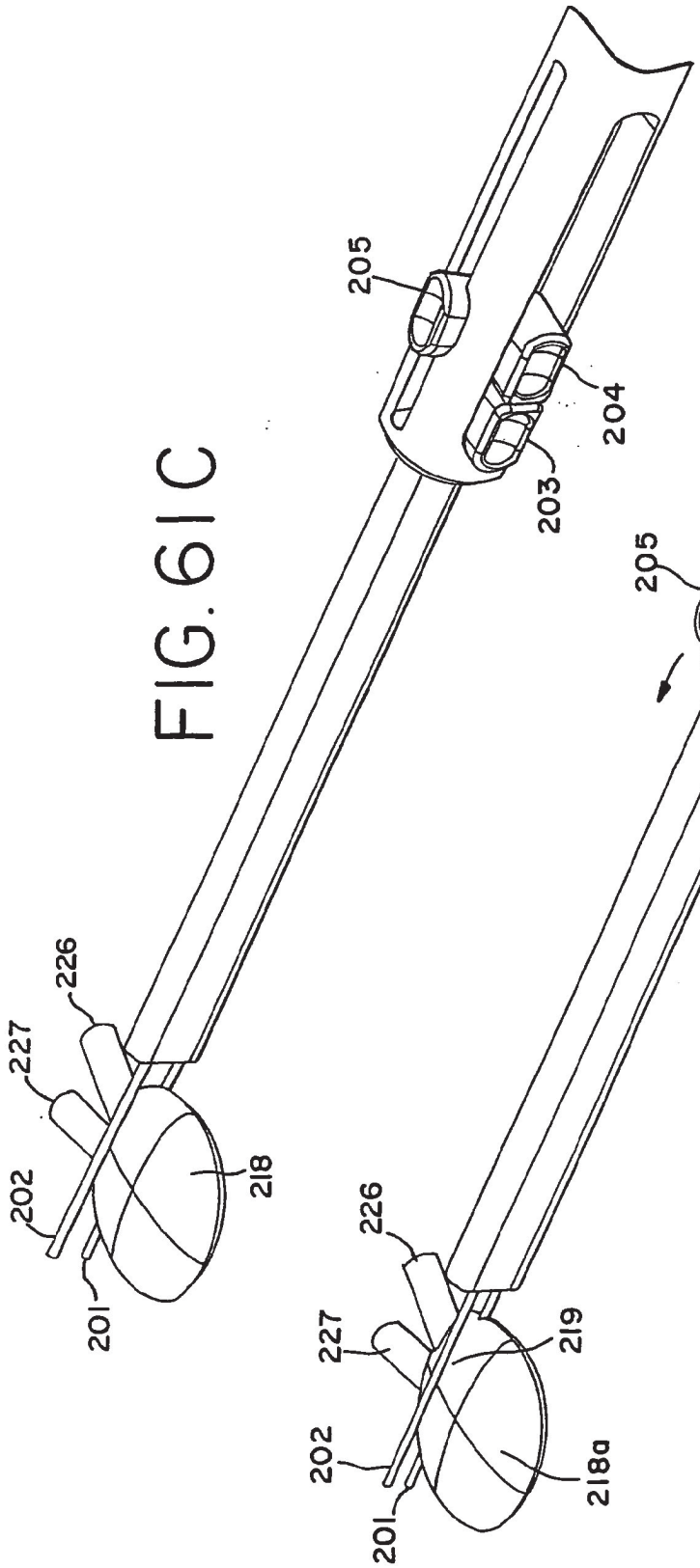


FIG. 61C

FIG. 61D

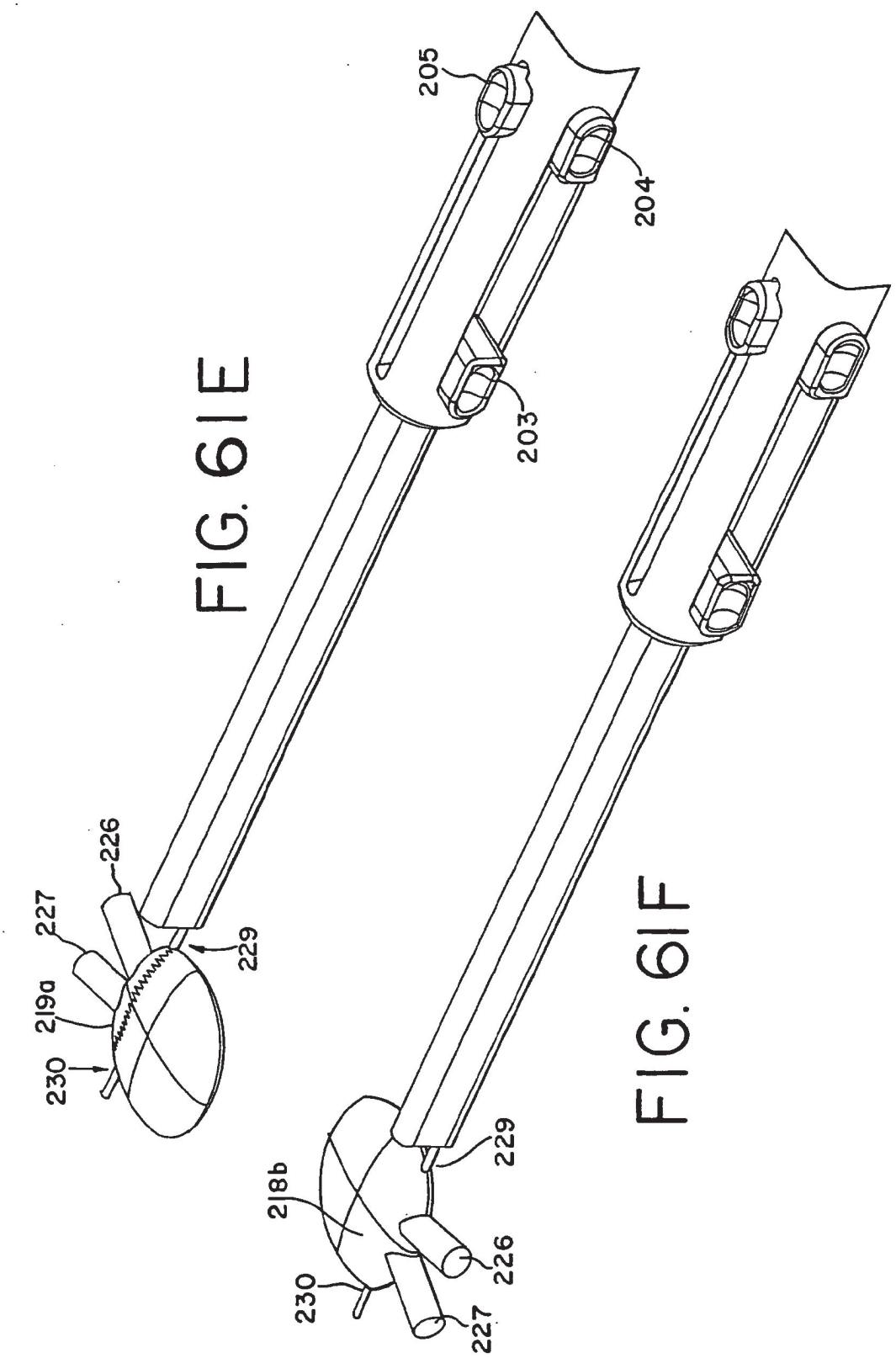


FIG. 61E

FIG. 61F

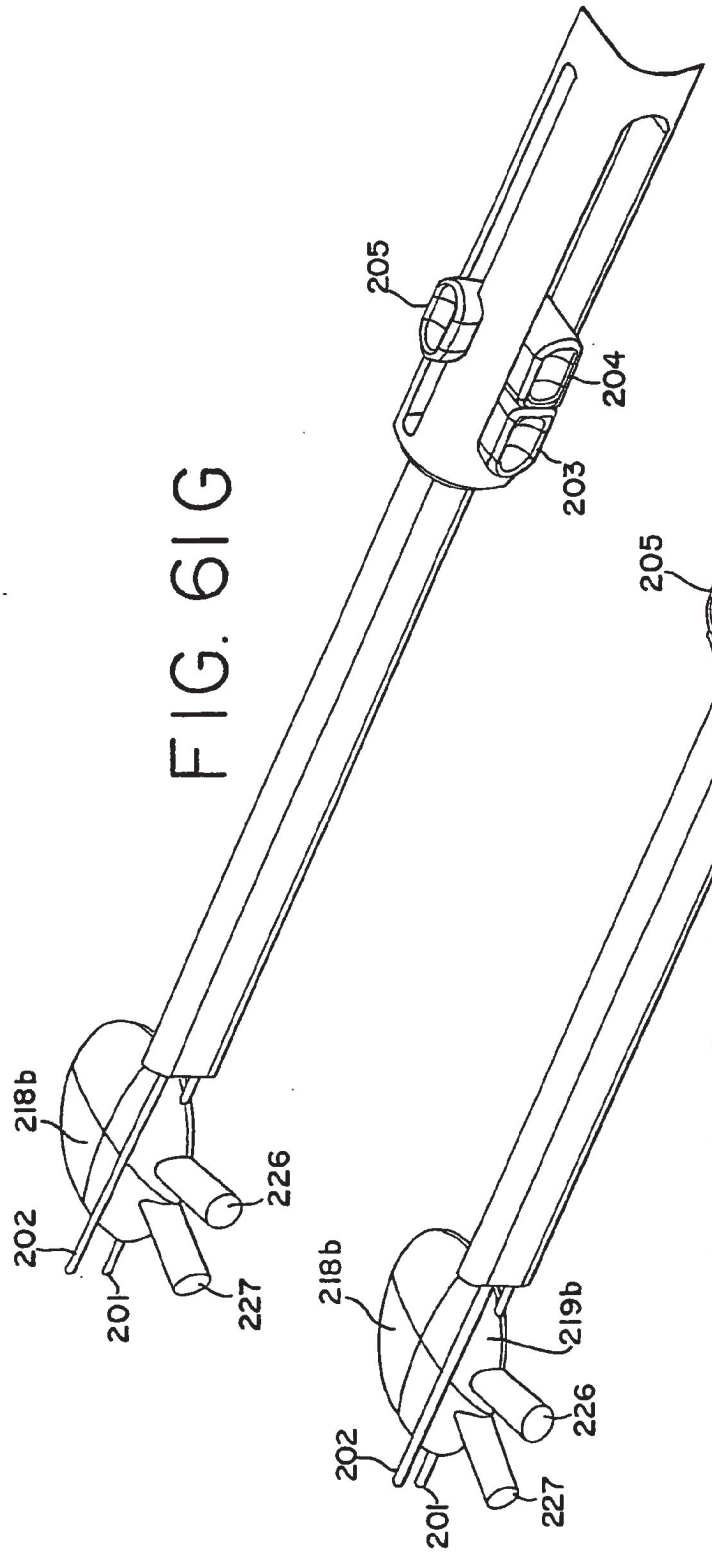


FIG. 61G

FIG. 61H

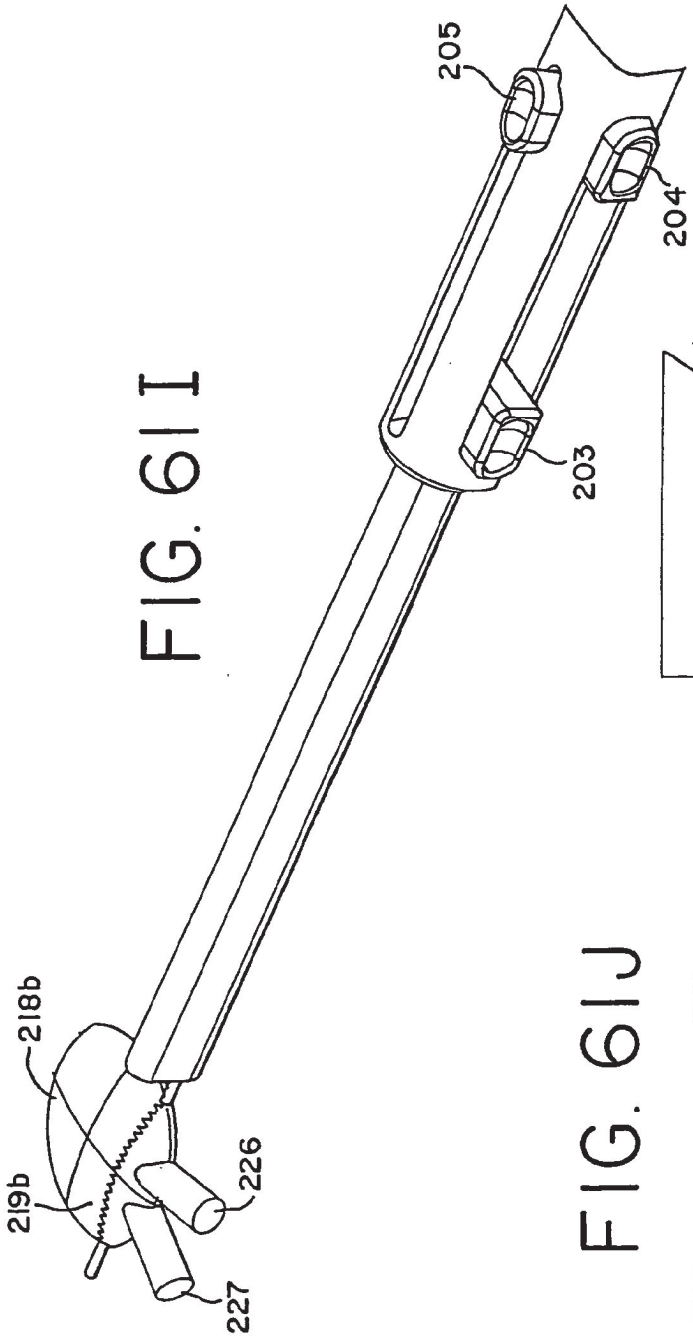


FIG. 61I

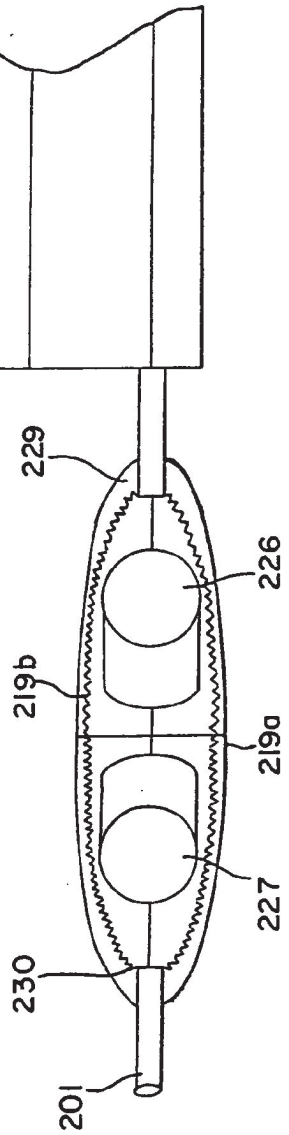


FIG. 61J

FIG.62A

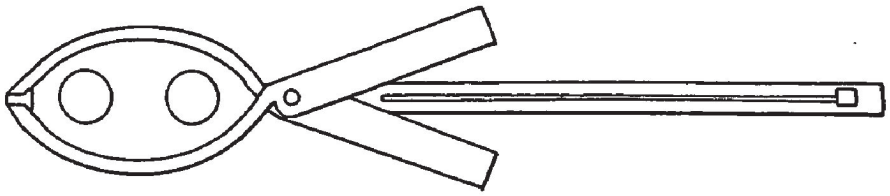


FIG.62B

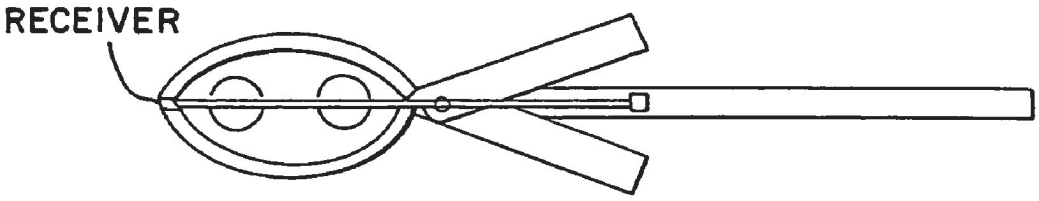


FIG.62C

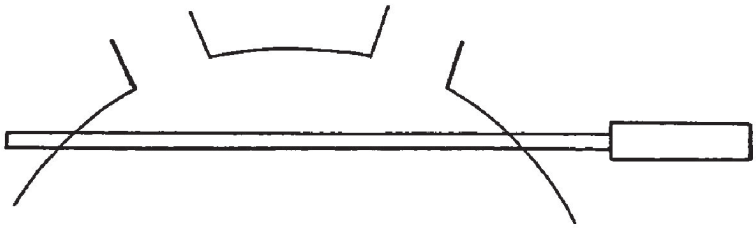


FIG. 62D

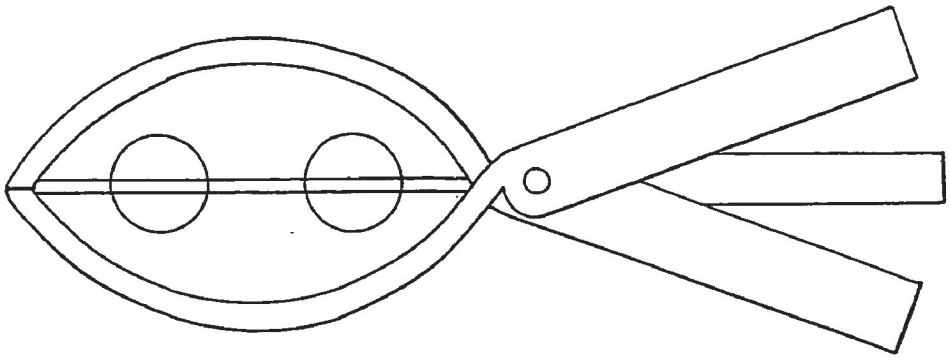


FIG. 62E

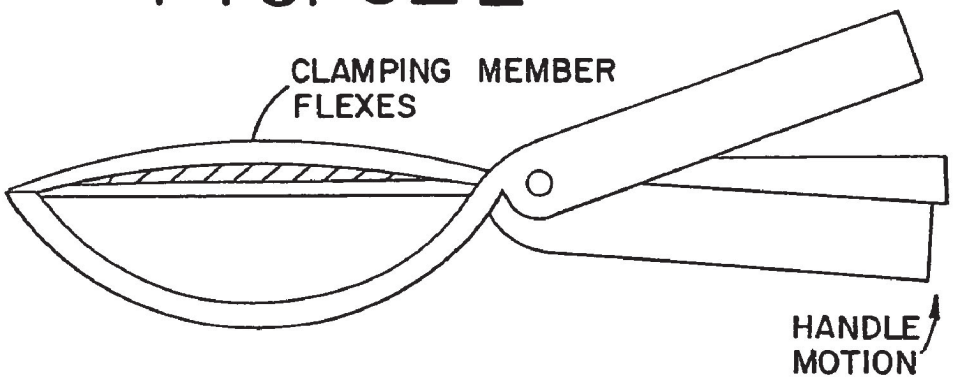


FIG. 62F

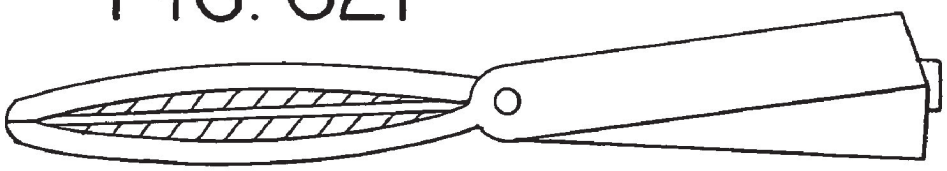


FIG. 62G

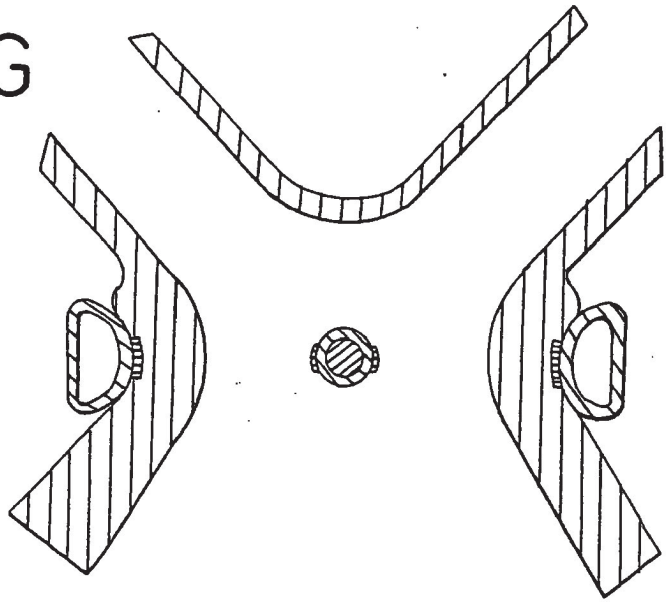


FIG. 62H

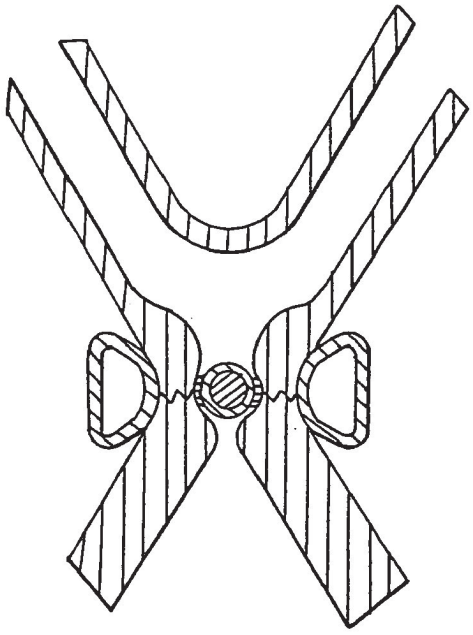


FIG. 62I

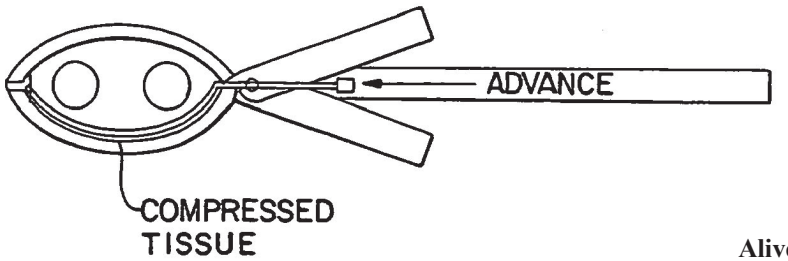


FIG. 63

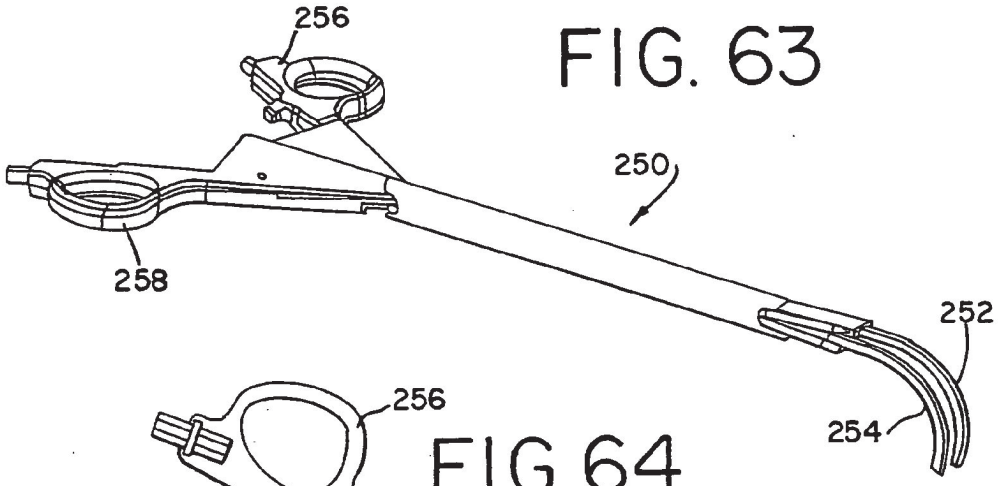


FIG. 64

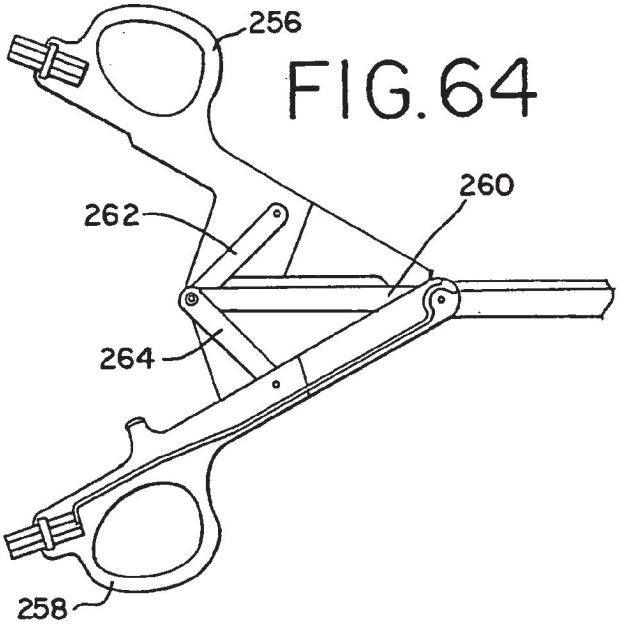


FIG. 65A

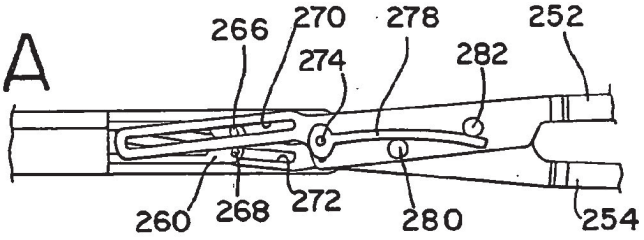


FIG. 65B

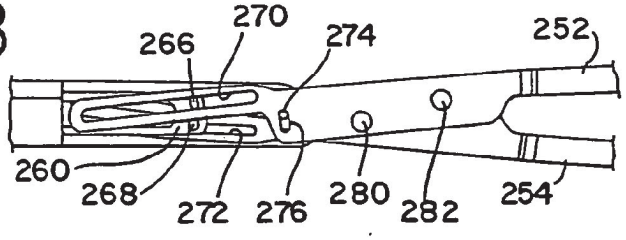


FIG. 66

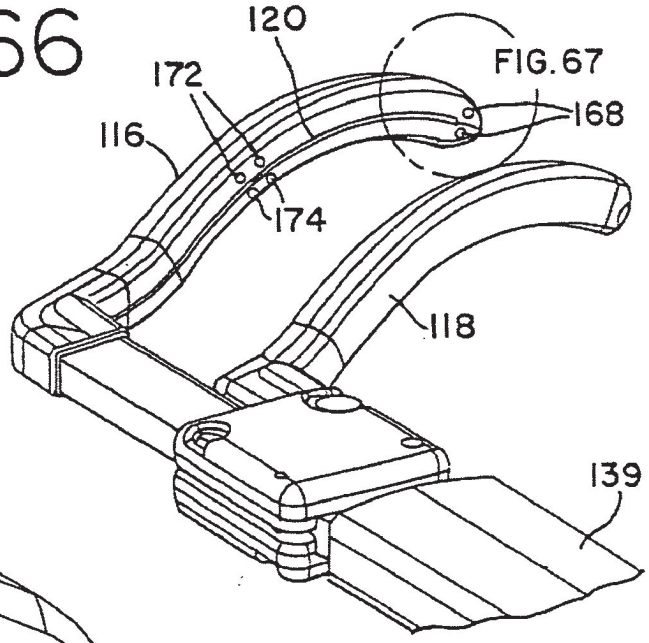
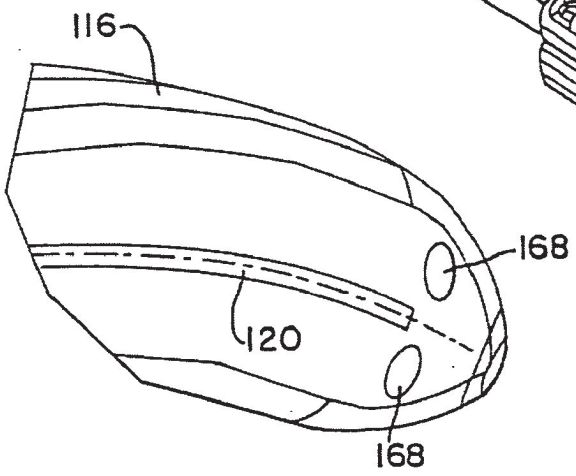


FIG. 67



TRANSMURAL ABLATION DEVICE WITH INTEGRAL EKG SENSOR

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of application Ser. No. 10/032,378, filed Oct. 26, 2001, which is a continuation-in-part of application Ser. No. 09/844,225 filed Apr. 27, 2001, now issued U.S. Pat. No. 6,517,536, which is a continuation in part of application Ser. No. 09/747,609 Dec. 22, 2000, now issued U.S. Pat. No. 6,546,935, which claims the benefit of provisional application Ser. No. 60/200,072, filed Apr. 27, 2000. Each of these applications are hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Atrial fibrillation is the most common heart arrhythmia in the world, affecting over 2.5 million people in the United States alone. Ablation of cardiac tissue, in order to create scar tissue that poses an interruption in the path of the errant electrical impulses in the heart tissue, is a commonly performed procedure to treat cardiac arrhythmias. Such ablation may range from the ablation of a small area of heart tissue to a series of ablations forming a strategic placement of incisions in both atria to stop the conduction and formation of errant impulses.

[0003] Ablation has been achieved or suggested using a variety of techniques, such as freezing via cryogenic probe, heating via RF energy, surgical cutting and other techniques. As used here, "ablation" means the removal or destruction of the function of a body part, such as cardiac tissue, regardless of the apparatus or process used to carry out the ablation. Also, as used herein, "transmural" means through the wall or thickness, such as through the wall or thickness of a hollow organ or vessel.

[0004] Ablation of cardiac tissue may be carried out in an open surgical procedure, where the breastbone is divided and the surgeon has direct access to the heart, or through a minimally invasive route, such as between the ribs or via catheter that is introduced through a vein, and into the heart.

[0005] Prior to any ablation, the heart typically is electronically mapped to locate the point or points of tissue which are causing the arrhythmia. With minimally invasive procedures such as via a catheter, the catheter is directed to the aberrant tissue, and an electrode or cryogenic probe is placed in contact with the endocardial tissue. RF energy is delivered from the electrode to the tissue to heat and ablate the tissue (or the tissue may be frozen by the cryogenic probe), thus eliminating the source of the arrhythmia.

[0006] Common problems encountered in this procedure are difficulty in precisely locating the aberrant tissue, and complications related to the ablation of the tissue. Locating the area of tissue causing the arrhythmia often involves several hours of electrically "mapping" the inner surface of the heart using a variety of mapping catheters, and once the aberrant tissue is located, it is often difficult to position the catheter and the associated electrode or probe so that it is in contact with the desired tissue.

[0007] The application of either RF energy or ultra-low temperature freezing to the inside of the heart chamber also carries several risks and difficulties. It is very difficult to determine how much of the catheter electrode or cryogenic probe surface is in contact with the tissue since catheter electrodes and probes are cylindrical and the heart tissue cannot be visualized clearly with existing fluoroscopic technology. Further, because of the cylindrical shape, some of the exposed electrode or probe area will almost always be in contact with blood circulating in the heart, giving rise to a risk of clot formation.

[0008] Clot formation is almost always associated with RF energy or cryogenic delivery inside the heart because it is difficult to prevent the blood from being exposed to the electrode or probe surface. Some of the RF current flows through the blood between the electrode and the heart tissue and this blood is coagulated, or frozen when a cryogenic probe is used, possibly resulting in clot formation. When RF energy is applied, the temperature of the electrode is typically monitored so as to not exceed a preset level, but temperatures necessary to achieve tissue ablation almost always result in blood coagulum forming on the electrode.

[0009] Overheating or overcooling of tissue is also a major complication, because the temperature monitoring only gives the temperature of the electrode or probe, which is, respectively, being cooled or warmed on the outside by blood flow. The actual temperature of the tissue being ablated by the electrode or probe is usually considerably higher or lower than the electrode or probe temperature, and this can result in overheating, or even charring, of the tissue in the case of an RF electrode, or freezing of too much tissue by a cryogenic probe. Overheated or charred tissue can act as a locus for thrombus and clot formation, and over freezing can destroy more tissue than necessary.

[0010] It is also very difficult to achieve ablation of tissue deep within the heart wall. A recent study reported that to achieve a depth of ablation of 5 mm, it was necessary to ablate an area almost 8 mm wide in the endocardium. See, "Mechanism, Localization, and Cure of Atrial Arrhythmias Occurring After a New Intraoperative Endocardial Radiofrequency Ablation Procedure for Atrial Fibrillation," Thomas, et al., *J. Am. Coll. Cardiology*, Vol. 35, No. 2, 2000. As the depth of penetration increases, the time, power, and temperature requirements increase, thus increasing the risk of thrombus formation.

[0011] In certain applications, it is desired to obtain a continuous line of ablated tissue in the endocardium. Using a discrete or point electrode or probe, the catheter must be "dragged" from point to point to create a line, and frequently the line is not continuous. Multielectrode catheters have been developed which can be left in place, but continuity can still be difficult to achieve, and the lesions created can be quite wide.

[0012] Because of the risks of char and thrombus formation, RF energy, or any form of endocardial ablation, is rarely used on the left side of the heart, where a clot could cause a serious problem (e.g., stroke). Because of the physiology of the heart, it is also difficult to access certain areas of the left atrium via an endocardial, catheter-based approach.

[0013] Recently, epicardial ablation devices have been developed which apply RF energy to the outer wall of the heart to ablate tissue. These devices do not have the same risks concerning thrombus formation, however, as

difficult to create long, continuous lesions, and it is difficult to achieve good depth of penetration without creating a large area of ablated tissue.

[0014] As noted above, other forms of energy have been used in ablation procedures, including ultrasound, cryogenic ablation, and microwave technology. When used from an endocardial approach, the limitations of all energy-based ablation technologies to date are the difficulty in achieving continuous transmural lesions, and minimizing unnecessary damage to endocardial tissue. Ultrasonic and RF energy endocardial balloon technology has been developed to create circumferential lesions around the individual pulmonary veins. See e.g., U.S. Pat. No. 6,024,740 to Lesh et al. and U.S. Pat. Nos. 5,938,660 and 5,814,028 to Swartz et al. However, this technology creates rather wide (greater than 5 mm) lesions which could lead to stenosis (narrowing) of the pulmonary veins. See, "Pulmonary Vein Stenosis after Catheter Ablation of Atrial Fibrillation," Robbins, et al., *Circulation*, Vol. 98, pages 1769-1775, 1998. The large lesion area can also act as a locus point for thrombus formation. Additionally, there is no feedback to determine when full transmural ablation has been achieved. Cryogenic ablation has been attempted both endocardially and epicardially (see e.g., U.S. Pat. No. 5,733,280 to Avitall, U.S. Pat. No. 5,147,355 to Friedman et al., and U.S. Pat. No. 5,423,807 to Milder, and WO 98/17187, the latter disclosing an angled cryogenic probe, one arm of which is inserted into the interior of the heart through an opening in the heart wall that is hemostatically sealed around the arm by means of a suture or staples), but because of the time required to freeze tissue, and the delivery systems used, it is difficult to create a continuous line, and uniform transmurality is difficult to verify.

[0015] Published PCT applications WO 99/56644 and WO 99/56648 disclose an endocardial ablation catheter with a reference plate located on the epicardium to act as an indifferent electrode or backplate that is maintained at the reference level of the generator. Current flows either between the electrodes located on the catheter, or between the electrodes and the reference plate. It is important to note that this reference plate is essentially a monopolar reference pad. Consequently, there is no energy delivered at the backplate/tissue interface intended to ablate tissue. Instead, the energy is delivered at the electrode/tissue interface within the endocardium, and travels through the heart tissue either to another endocardial electrode, or to the backplate. Tissue ablation proceeds from the electrodes in contact with the endocardium outward to the epicardium. Other references disclose epicardial multielectrode devices that deliver either monopolar or bipolar energy to the outside surface of the heart.

[0016] It is important to note that all endocardial ablation devices that attempt to ablate tissue through the full thickness of the cardiac wall have a risk associated with damaging structures within or on the outer surface of the cardiac wall. As an example, if a catheter is delivering energy from the inside of the atrium to the outside, and a coronary artery, the esophagus, or other critical structure is in contact with the atrial wall, the structure can be damaged by the transfer of energy from within the heart to the structure. The coronary arteries, esophagus, aorta, pulmonary veins, and pulmonary artery are all structures that are in contact with the outer wall of the atrium, and could be damaged by energy transmitted through the atrial wall.

[0017] Accordingly, it is the object of the present invention to provide an improved method and device for making transmural ablations to heart tissue.

[0018] It is a related object to provide a method and device for making transmural ablation in heart tissue that minimizes unnecessary damage to the heart tissue.

[0019] It is a further object to provide a method and device for making transmural ablation in heart tissue that creates continuous lesions in a single step.

[0020] It is still a further object to provide a method and device for monitoring the electrical conductivity of the tissue in the transmural lesion simultaneously with the creation of the lesion. It is also an object to provide a method and device for measuring the temperature of the tissue forming the lesion simultaneously with its creation.

SUMMARY OF THE INVENTION

[0021] These objects, and others which will become apparent upon reference to the following detailed description and attached drawings, are achieved by the use of a clamping and ablating device for use in treating cardiac arrhythmia having first and second handle members, with first and second mating parallel jaw members associated with the first and second handle members, respectively. The jaw members are preferably curved and are movable by the handle members between a first open position and a second clamped position, and the jaw members have insulated outer surfaces which may have convex, opposed mating surfaces. Each mating surface has a central region, with the central region of the first jaw being aligned with the central region of the second jaw. A first elongated electrode extends along the central region of the first jaw and a second elongated electrode extends along the central region of the second jaw. The first and second electrodes are adapted to be connected to an RF energy source so that, when activated, the electrodes are of opposite polarity. In a preferred embodiment, the electrodes are made of gold-plated copper and measure between approximately 3 to 8 cm in length and approximately 0.12 to 0.6 mm in width. By the use of such a device a clamping zone is created that is approximately at least three times wider than the contact zone of the electrodes with the tissue. This permits the ablation to be performed with a minimum of contact between the electrodes and any blood cells, thus greatly reducing the likelihood of thrombus. The design also allows for a minimum distance between the electrodes, further encouraging complete, transmural ablation that creates a continuous lesion in a single step.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] **FIG. 1** is a schematic view showing a procedure in accordance with the present invention utilizing ablation elements operatively connected to either a source of RF energy or cryogenic fluid.

[0023] **FIG. 2** is a cross-section of an ablation element for use in the present invention taken along lines 2-2 of FIG. 1.

[0024] **FIGS. 3-6** show alternate configurations for the ablation elements of the

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[0025] **FIG. 7** shows a further step in the inventive procedure in which tissue is clamped between the ablation elements.

[0026] **FIGS. 8-12** schematically illustrate the inventive procedure so as to make a transmural lesion that fully circumscribes a pulmonary vein, with **FIG. 9** showing a cross-sectional view of the clamp/ablation element in contact with the atrial tissue to express blood from the clamped area.

[0027] **FIGS. 13-17** show a further method according to the present invention in which transmural lesions are made so as to circumscribe both pulmonary veins.

[0028] **FIGS. 18-22** show a further procedure in which a transmural lesion is made so as to circumscribe a single pulmonary vein.

[0029] **FIGS. 23-27** illustrate a further procedure in which a transmural lesion is made so as to circumscribe both pulmonary veins.

[0030] **FIG. 28** is a perspective view of a further embodiment of a grasper for use in an open chest procedure in accordance with the present invention showing the grasper in its "closed" position.

[0031] **FIG. 29** is a perspective view of the grasper of **FIG. 28** with the grasper in its "open" position.

[0032] **FIG. 30** is an enlarged perspective view of the working position of the grasper of **FIG. 28** with the grasper jaws in the "closed" position.

[0033] **FIG. 31** is an enlarged perspective view of the working portion of the grasper of **FIG. 28** with the grasper jaws in the "open" position.

[0034] **FIG. 32** is an enlarged cross-sectional view of the grasper jaws for the grasper of **FIG. 28**.

[0035] **FIG. 33** is a perspective view of a further embodiment of a grasper, which may be used in either an open or a minimally invasive procedure, along with its associated electrosurgical generator.

[0036] **FIG. 34** is a side view of the grasper of **FIG. 33** showing the grasper in its "open" position.

[0037] **FIG. 35** is an exploded perspective view of the grasper of **FIG. 33**.

[0038] **FIG. 36** is a side cross-sectional view of the grasper of **FIG. 33** with the grasper jaws in the "open" position.

[0039] **FIG. 37** is a side cross-sectional view of the grasper of **FIG. 33** with the grasper jaws in the "closed" position.

[0040] **FIG. 38** is a cross-sectional view taken along line **38-38** of **FIG. 34** showing the grasper jaws in the "open" position.

[0041] **FIG. 39** is a cross-sectional view of the grasper jaws taken along the line **39-39** of **FIG. 37** showing the grasper jaws in the "closed" position.

[0042] **FIG. 40** is a cross-sectional view of the graspers taken along line **40-40** of **FIG. 34**.

[0043] **FIGS. 41-51** show alternate constructions for the electrodes suitable for use in the present invention, with **FIGS. 41 and 43-51** being cross-sectional views similar to **FIGS. 38 and 39**, and **FIG. 42** being a cross-sectional view taken along line **42-42** of **FIG. 41**.

[0044] FIGS. **52**A-K illustrate eleven different ablations to the left and right atrium (as seen from behind in **FIG. 52A**) and the methods for making the lesions (FIGS. **52**B-K).

[0045] **FIG. 53A** is a perspective view of a further embodiment of device for performing transmural ablation according to the present invention.

[0046] **FIG. 53B** is a perspective view of the transmural ablation device of **FIG. 53A** with a portion removed to show detail.

[0047] **FIG. 54** is an exploded perspective view of the transmural ablation device of **FIG. 52**.

[0048] **FIG. 55** is a longitudinal cross-sectional view of an obturator tip electrode for use in the device of **FIG. 52**.

[0049] **FIG. 56** is a piercing tip electrode for use in the device of **FIG. 52**.

[0050] **FIG. 57** is an enlarged side view of the tip of the instrument shown in **FIG. 52**.

[0051] **FIGS. 58A-58G** illustrate the use of the instrument of **FIG. 52** to form a transmural ablation.

[0052] **FIG. 59** shows a series of transmural ablations contemplated by the MAZE procedure.

[0053] **FIGS. 60A-60I** illustrate a procedure for performing a circumferential lesion in lumen such as a pulmonary vein.

[0054] **FIG. 61A-61J** show the use of the instrument of **FIG. 52** for forming a continuous transmural ablation around a pair of pulmonary veins.

[0055] **FIG. 62A**-I show a further device for performing transmural ablations and the method for making such ablations.

[0056] **FIG. 63** is a perspective view of a further embodiment of a grasper adapted for use in minimally invasive procedures.

[0057] **FIG. 64** is an enlarged plan view of the handle position of the grasper of **FIG. 63**, with portions removed to show detail.

[0058] **FIGS. 65A and 65B** are enlarged plan views of the jaw actuation mechanism for the grasper of **FIG. 63**.

[0059] FIGS. **66** is an enlarged fragmentary perspective view of the jaws of grasper of **FIGS. 33-40**.

[0060] FIGS. **67** is an enlarged perspective view of the tip of the fixed jaw shown in **FIG. 66**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0061] With reference to the present invention, the compression of the atrial tissue is important because it insures that the exposed electrode surface or cryogenic probe is not in contact with any tissue or blood except the clamped tissue to be ablated. Specifically, the clamping of the tissue

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between the electrodes or cryogenic probes insures that the conductive or cooled area is only in contact with the clamped tissue. The compressed tissue acts to isolate the electrically active or cryogenically cooled surface, and prevents inadvertent energy delivery to other parts of the heart or blood. The outside temperature of the electrode can easily be monitored to insure that the temperature of the insulation in contact with blood remains below a critical temperature (40° C., for example).

[0062] In one form of the invention, transmural ablation using RF energy is accomplished by providing an atrial ablation device having a lower "j" clamp/electrode element and placing it on the atrial tissue below the pulmonary veins.

[0063] Once the pulmonary veins have been isolated, an upper clamp/electrode element is introduced, and the clamp assembly "J" is worked back onto the epicardial atrial tissue. Once the jaws are positioned below the ostia of the pulmonary veins, the tissue is partially clamped, allowing continued flow from the pulmonary veins to the left atrium. Once the clamps are safely away from the pulmonary vein tissue, and onto atrial tissue, the clamps are closed together to compress the tissue. Once the tissue is compressed, bipolar RF energy is used to ablate the clamped atrial tissue. The clamps are then removed, the lesion having been created. Lesions may also be created by inserting one clamp/electrode element through an incision in the heart so as to permit contact with endocardial tissue. This incision may be created with a separate instrument. Alternatively, the tip of one of the jaws may have a piercing structure associated therewith for making the entry incision. Once the clamps are properly located, the tissue is compressed and RF energy is applied.

[0064] Turning now to the figures of the drawings, a method embodying the present invention is shown schematically in **FIG. 1**. A clamping type device **10** is provided to group the two walls **22**, **24** of the atrium **20**, and delivers bipolar RF energy through both walls held between the two upper and lower clamp jaws **50**, **51**. **FIG. 1** shows the upper and lower parallel clamp jaws **50**, **51** and electrodes **52**, **53** positioned above and below atrial tissue **22**, **24**, distal to the pulmonary veins. **FIG. 2**, Section **2-2** of **FIG. 1**, shows a cross-section of the clamping member including the insulator **28** and electrode **53**. Alternate configurations of the clamping members are shown in **FIGS. 3-6**. **FIG. 3** shows a cross section of the electrode consisting of an insulating layer **11**, and a conductive strip **12**. The electrode of **FIG. 3** may be constructed of a tungsten wire as the conductive material **12**, with polyamide as the insulating material **11**. The conductive strip is created by exposing a part of the tungsten wire through the polyamide. **FIGS. 4 and 5** show an alternate electrode construction consisting of a carbon fiber element **13**, and an insulating material **14**, such as ABS. The conductive strip **15** may be comprised of a copper/gold electrode plated onto the ABS. **FIG. 6** shows a cross section of yet another possible electrode design where the conductive material **16** consists of a stainless steel needle with lumen **17** and insulating material **18**.

[0065] **FIG. 7** shows the parallel jaws **50**, **51** clamping and ablating the atrial tissue **20** distal to the pulmonary veins **26**. Proximal point A is clamping and ablating the atrial tissue distal to the pulmonary veins. Proximal point A is the most proximal point of ablated tissue on both the upper and lower atrial wall. Distal point B is the most distal point of ablated tissue on both the upper and lower atrial wall.

[0066] **FIGS. 8-12** show the inventive procedure that fully circumscribes a pulmonary vein with transmural lesions. **FIG. 8** shows a top view of the instrument jaws positioned for a 2-step isolation of a single pulmonary vein. The lower jaw is directly beneath the upper jaw, and is not shown. Proximal point A and distal point B correspond to **FIG. 7**.

[0067] **FIG. 9** shows a cross-sectional view of the jaws clamping and ablating atrial tissue. Importantly, **FIG. 9** shows that the electrode/clamp configuration provides a clamped zone of tissue that is wider than the zone of ablated tissue. This is achieved by using an electrode width that is narrower than the clamped tissue width, and preferably less than one-third of the clamped tissue width. As shown in **FIG. 9** (and better illustrated in **FIG. 26**), the electrode forms the apex of the triangular clamping member. Other convex shapes are also contemplated.

[0068] The wider zone of clamped tissue serves several purposes. When the clamping members are closed onto tissue, any blood in the clamped zone is squeezed or expressed out. Further, the distance between the electrodes is minimized, so that the ablation zone remains narrow. It is important to isolate the blood from the ablation zone to avoid creating thrombus. Accordingly, a clamped zone that isolates the ablation zone from the blood minimizes the temperature at the periphery of the ablation zone and will reduce the likelihood of the formation of thrombus by the blood in contact with the clamped zone.

[0069] Once tissue has been fully ablated with the clamp in the position shown in **FIG. 8**, an ablation line of tissue on both upper and lower atrial walls is created. This is shown as ablation line **60** in **FIG. 10**. The clamp is then repositioned to the position shown in **FIG. 10**, so that the distal point D overlaps the ablation line **60**. The tissue is clamped and ablated as shown in **FIGS. 7 and 9**, and a second ablation line **61** (**FIG. 11**) is formed on both the upper and lower atrial walls. Proximal point C and distal point D correspond to points A and B respectively. The full ablation line is shown in **FIGS. 11 and 12** with points A-D as shown.

[0070] This "clamping" method and device for creating transmural lesions has a number of advantages. First, using a two step method as shown allows for clamping and ablation of atrial tissue without stopping the blood flow from the pulmonary vein. Secondly, by clamping both walls together, and delivering energy through the clamped tissue, the atrial tissue is not penetrated. Because the atrial tissue is not penetrated, a larger jaw can be used, and the clamping force can be much higher because of the increased stiffness of the jaw. Also, there is no concern of bleeding from an atrial puncture.

[0071] Another advantage of this method and device is that ablation of tissue within the pulmonary veins is avoided, as recent articles have shown that ablation of tissue within the pulmonary veins can cause pulmonary hypertension and stenosis. Specifically referring to **FIGS. 13-17**, a longer jaw could be used to create an ablation line through atrial tissue which electrically isolates both pulmonary veins using the same method. **FIGS. 18-22** show the clamping device in a curved-jaw embodiment that creates a circumferential lesion around the pulmonary vein in one step. **FIGS. 18 and 19** show the clamp jaws positioned around the pulmonary vein. **FIGS. 20 and 21** show the device clamping and ablating atrial tissue distal to the pulmonary vein. **FIG. 22** shows the

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resulting ablation line **60**. **FIGS. 23-27** show the same concept applied to a device and method for creating a lesion around both pulmonary veins. The advantage of this concept is that the entire lesion is created in one step. The disadvantage is that blood flow from the pulmonary vein(s) is cut off during ablation. Using a curved electrode also allows the user to ablate tissue more distal to the pulmonary vein than would be possible with a straight electrode. Note that this curved type electrode could be used with a two step procedure as described above, using "left" and "right" curved devices to create a lesion which was more distal to the pulmonary veins. Note also that this method and device are not limited to use around the pulmonary veins, but could be used anywhere in the atrium that the clamp could be applied.

[**0072**] Turning to **FIGS. 28-32**, there is seen a further version of a cardiac grasper **70** suitable for an open chest procedure in accordance with the present invention. The grasper **70** includes two ring handles **72**, **74** joined together for relative movement by a pivot screw or pin **76**. Each handle **72**, **74** has a jaw member **78**, **80** respectively associated therewith, each jaw being curved so that it has a major portion that is substantially perpendicular to the handles. This gives the grasper **70** an L-shaped appearance, with a working portion of the jaws being between approximately 3-8 cm in length.

[**0073**] The grasper is made of a rigid material, such as stainless steel, and is substantially encased in a durable insulating material, such as ABS plastic. With reference to **FIG. 32**, which shows the opposed jaw members in cross section, the stainless steel structural support is designated **82**. The structural support **82** is completely encased by insulating members **84**, **86** and **88**. The tips **78***a*, **80***a* of the jaws may be made of a soft, atraumatic material in order to reduce the likelihood of unintentional injury of tissue by the jaws.

[**0074**] In keeping with the invention, the grasper jaws have raised or convex, opposed tissue clamping surfaces, **90**, **92**, respectively, with each clamping surface, **90**, **92** centrally supporting an electrode **94**, **96**, respectively, of opposite polarity. RF energy of opposite polarity is supplied to the electrodes **94**, **96** through conductors **98**, **100**, which are connected to an RF generator. As with the previously-described jaw members, this electrode/clamp configuration provides a clamped zone of tissue that is significantly wider than the zone of ablated tissue created by the opposed electrodes. This causes for any blood in the clamp zone to be squeezed or expressed out of the ablation zone, thus reducing the likelihood of thrombus formation, as well as minimizing the distance between the electrodes, so that the ablation zone remains narrow. The clamping also eliminates the cooling effect of circulating blood.

[**0075**] With reference to **FIG. 32**, the electrodes **94**, **96** have a T-shaped cross section, with the cross portion of the T resting on the insulating member **88** and the upright portion of the T protruding through a narrow opening in the insulating member **84**, thus creating an exposed electrode surface that contacts the tissue grasped between the jaws. In practice, the electrodes are preferably made of gold-plated copper and extend along substantially the entire working surface of the jaw members. The exposed portions of the electrode are generally less than 1.25 mm in width, and preferably between approximately 0.12-0.6 mm in width. This insures that most of the jaw surface is insulator, and that the electrode comprises generally less than one-third of the width of the jaw.

[**0076**] In keeping with a further aspect of the invention, the graspers may provide feedback that permits the user to gauge the completeness (i.e., degree of transmurality) of the ablation. Specifically, a transmural lesion blocks electrical signals because it is non-conductive scar tissue. Because impedance is simply the inverse of conductivity, the ability of the lesion to block electrical signals is accurately indicated by its impedance, which can be measured simultaneously with the creation of the lesion. During RF energy application to the tissue to be ablated, the current and voltage applied to the tissue are measured, and the impedance calculated and stored. Based upon a function of the impedance (e.g., its value, the change in value, or the rate of change in value)) it is determined whether ablation is complete and transmural. See e.g., U.S. Pat. No. 5,403,312, which is incorporated by reference herein. Indicator lights or other types of signals (e.g., audible may be associated with the grasper to correspond to the degree of ablation determined by the impedance feedback system. For example, once the impedance reaches a certain level for a certain period of time, a red light may be activated to signal that ablation is complete.

[**0077**] In keeping with another aspect of the invention, a feedback system for determining the temperature of the ablated tissue is also provided. To this end, the jaws include a series of thermocouples **102** that are supported in the insulating member **84** remote from the associated electrode **94** near the edge of the jaw **78**. The thermocouples **102** protrude slightly through the surface of the insulating member **84** so as to engage any tissue clamped between the jaws **72**, **74**. Wires **104** are attached to the thermocouples **102** to transmit the information received to a remote location. Again, a visual or other indicator may be provided to alert the user that a certain pre-determined critical temperature (e.g., 40° C.) has been reached, thus permitting the user to avoid undesired thermal spread.

[**0078**] Turning to **FIGS. 33-37**, there is a further version of a cardiac grasper **110** suitable for both open and minimally-invasive procedures in accordance with the present invention. As seen in **FIG. 33**, the grasper **110** includes a cord **112** for housing the conductors (not shown) and for plugging into an electrosurgical generator **114** to provide current to the grasper **110**. As discussed above, the generator **114** includes a display **115** to provide a simultaneous visual indication of the degree of conductance of the tissue being ablated. The instrument **110** includes opposed parallel, curved jaw assemblies **116**, **118** with jaw assembly **116** being fixed and jaw assembly **118** being movable between an open position (as seen in **FIGS. 34 and 36**) to a closed position (shown in **FIG. 37**). The fixed jaw assembly **116** comprises a fixed electrode **120**, a fixed insulator **122** and a fixed jaw cap **124**. The fixed electrode **120** provides an electrical pathway adjacent to the tissue to be ablated and is located on the inside of the fixed jaw assembly **116** (the "inside" being defined as the side that contacts the tissue to be ablated). The fixed insulator **122** surrounds the fixed electrode **120** and forms the inside of the fixed jaw assembly **116**. The fixed jaw cap **124** forms the backside of the fixed jaw assembly **116** (the "backside" being defined as the surface opposite the [illegible] **120**).

[0079] The drive jaw assembly **118** comprises a drive electrode **126**, a drive insulator **128**, and a drive jaw cap **130**. The drive electrode **126** provides a second electrical pathway adjacent the tissue to be ablated and is located on the inside of the drive jaw assembly **118** ("inside" being defined as the side contacting the tissue to be ablated). The drive insulator **128** surrounds the drive electrode **126** and forms the inside of the drive jaw assembly **118**. The drive jaw cap **130** forms the backside of the drive jaw assembly **118** ("backside" being defined as the surface opposite the drive electrode **126**).

[0080] Each of the electrodes **120**, **126** is attached to an electrically conductive means, such as a wire, that runs the length of the extension shaft and through the conductor cord **112** for coupling to the RF generator **114**.

[0081] Each jaw assembly **116**, **118** is supported by a two piece extension shaft comprising a right fixed member **132** and left fixed member **134** (for the fixed jaw) and a right drive member **136** and left drive member **138** (for the drive jaw **118**). A shaft cap **139** covers the coextensive portions of the fixed members **132**, **134** and the drive members **136**, **138** (when the jaws are in the open position as seen in **FIG. 34**). The right fixed member **132** and left fixed member **134** combine to form a structure that extends from a handle **140**, through the shaft cap **139**, and then terminating at the distal end of the instrument **110** in the fixed jaw assembly **116** on the right and left sides, respectively, of the instrument. Similarly, the right drive member **136** and left drive member **138** extend from the handle **140**, through the shaft cap **139**, and then terminate in the drive jaw assembly **118** on the right and left sides, respectively, of the instrument. The portions of the fixed members **132**, **134** co-extensive with the fixed jaw assembly **116** are joined by a fixed bridge **142** along the length of the jaw. Similarly, the portions of the drive members **136**, **138** co-extensive with the drive jaw assembly **118** are joined together by a drive bridge **144** along the length the drive jaw **118**.

[0082] The handle **140** comprises two mating halves **140***a*, **140***b* for encapsulating the actuation and force control mechanisms for the grasper, as well as providing for grounding of the shaft components by means of a conductive shaft pin **141**. In order to move the drive jaw assembly **118** between its open and closed positions, the handle **140** includes a lever comprising a pair of lever plates **146** and a lever shroud **148**. The lever is pivotally mounted on a support member **150** extending between the two halves **140***a*, **140***b* of the handle **140**, with a lever spring **151** biasing the lever to its open position (**FIG. 34**). The lever plates **146** are coupled by a lever pin **152** to a carriage **154** that captures the proximal ends of the drive members **136**, **138**, so as to provide translational motion to these members.

[0083] The carriage **154** includes a lost motion assembly comprising a carriage spring **156** for controlling the minimum and maximum loads that can be applied to tissues that are to be captured between the jaw assemblies **116**, **118**. As can be readily appreciated, the thicker the tissue that is grasped between the jaws, the greater the compression of the spring **156**, and the greater the compression force exerted by the jaws on the tissue. (The range of tissue thickness is expected to be between about 1-15 mm.) Adjustment of the compression force is accomplished by pre-loading the carriage spring **156** with a load adjustment screw **158**. The lost motion assembly also includes a thumb latch **160** for releasing the clamping pressure and for providing a mechanical stop for the spring-loaded carriage **154**. The thumb latch **160** is pivotally mounted on a latch pin **162** to secure the thumb latch to the handle **140**. Additionally, a latch spring **164** is provided for biasing the thumb latch **160** to its locked position. A latching step on the carriage **154** interfaces with the tip of the thumb latch **160** to provide for the mechanical stop. When the lever is pivoted with respect to the handle **140**, the drive jaw assembly **118** and its drive members **136**, **138** slide along the longitudinal direction of the shaft to bring the two jaw assemblies **116**, **118** into contact with the tissue intended to be grasped.

[0084] In order to ablate a narrow, long region of biological tissue with the instrument **110**, the tissue is first placed between the open instrument jaws **116**, **118**. The user then grasps the actuation lever comprising the lever plates **146** and lever shroud **148** to apply the force required to drive the drive members **136**, **138** and drive jaw assembly **118** distally, thus compressing the tissue and automatically engaging the thumb latch **160**. The thumb latch **160** locks the position of the drive members **136**, **138** and the drive jaw assembly **118** with respect to the handle **140** and the fixed jaw assembly **116**. The amount of jaw force on the tissue is controlled by the lost motion assembly between the lever and the drive members **136**, **138**.

[0085] With the jaws closed on the tissue, the operator activates the RF generator **114**. RF energy passes through the tissue between the electrodes **120**, **126**, thus ablating the tissue between these electrodes. After completion of the ablation cycle, the operator releases the clamping of the tissue by depressing the thumb latch **160**, thus releasing the carriage **154**. With the carriage **154** released, the lever spring **151** drives the drive members **136**, **138** and the drive jaw assembly **118** proximally to their open positions. The actuation lever, since it is directly coupled to the carriage **154**, also returns to the open position.

[0086] Turning to **FIGS. 41-51** there is seen in schematic form various configurations for the electrodes **120**, **126** for use in conjunction with the grasper **110**. Each of **FIGS. 41 and 43-51** show a cross-section through the instrument jaws as clamped on the tissue to be ablated. Each electrode is formed of a piece of electrically conductive metal that may be plated with a biocompatible material.

[0087] With reference to **FIGS. 41 and 42**, the electrode geometry consists of a largely rectangular electrode with a window of material removed from the central region. The window area is filled with the insulator material **122**, **128**. At the clamping surface the electrode insulator material leads away from the electrode on a radius. The electrode material protrudes outside the clamping surface of the insulating material. However, the electrode may also be flush with the clamping surface.

[0088] With reference to **FIG. 43**, the electrode geometry is largely rectangular and the electrode insulator material leads away from the electrode on a radius. The electrode is flush with the clamping surface of the insulator material.

[0089] With reference to **FIG. 44**, the electrode is applied to fill a groove in the insulator material by way of a plating process. The electrode geometry is largely rectangular and the electrode insulator material leads away from the electrode

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trode on a radius. The electrode plating is largely flush with the clamping surface of the insulator material.

[0090] With reference to **FIG. 45**, the electrode is formed into a U-shaped element. The electrode insulator material leads away from the electrode on a radius. As shown, the electrode material extends outside the clamping surface of the insulator material. However, the electrode material may also be flush with the insulator clamping surface.

[0091] With reference to **FIG. 46**, the electrode is applied to fill a groove in the insulator material by way of a plating process, with the electrode geometry being largely rectangular. The electrode insulator material creates a small flat surface perpendicular to the closure plane that is largely flush with the surface of the plate or electrode. As shown, the electrode material is flush with the clamping surface of the insulator material. However, the electrode material may also be applied so that it extends outside the insulator clamping surface.

[0092] With reference to **FIG. 47**, the electrode geometry is largely rectangular and the electrode insulator material leads away from the electrode on a radius. The electrode material extends outside the clamping surface of the insulator material.

[0093] With reference to **FIG. 48**, the electrode configuration is again largely rectangular, with the electrode insulator material creating a small flat surface perpendicular to the closure plane that is largely flush with the surface of the plate or electrode. The electrode is flush with the clamping surface of the insulator material and a temperature sensing means, such as a thermocouple **166** (see also **FIGS. 35 and 39**), is positioned in close proximity to the electrode, but electrically isolated from the RF energy.

[0094] With reference to **FIG. 49**, the electrode is applied to fill a groove in the insulator material by way of a plating process. The electrode geometry is largely rectangular and the electrode insulator material leads away from the electrode on a radius.

[0095] With reference to **FIG. 50**, the electrode is applied to the surface of the electrode insulator material by way of a plating process. The electrode geometry is largely rectangular with the electrode insulator material leading away from the electrode on a radius. The electrode plating is largely flush with the clamping surface of the insulator material. With reference to **FIG. 51**, the electrode is round wire made from an electrically conductive metal that may be plated with a biocompatible material. The electrode insulator material leads away from the electrode on a radius. As shown, the electrode material extends outside the clamping surface of the insulator material. However, the electrode material may also be flush with the insulator clamping surface.

[0096] A further embodiment of a grasper according to the present invention is shown in **FIGS. 63-65** and is designated generally **250**. The grasper **250** has jaws **252**, **254** similar in structure to those described above in connection with the embodiments of **FIGS. 28-32** and **33-40**, but includes a different actuation mechanism. Specifically, the jaws **252**, **254** of the grasper **250** are biased so that they are normally in the closed position, the jaws being moved to the open position by moving the two handle members **256**, **258** towards each other. This action serves to withdraw a push-rod **260** (**FIG. 64**), which is pivotally connected to the handle members **256**, **258** by links **262**, **264**. With reference to **FIG. 65A** and **FIG. 65B**. The distal end of the push rod **260** includes two pins **266**, **268** which are captured in slots **270**, **272** in their respective jaw members **252**, **254**. When the pins **266**, **268** are located in the distal ends of the slots **270**, **272**, the jaws are in the closed position. The jaws **252**, **254** open as the pins **266**, **268** move proximally in the slots **270**, **272** through the withdrawal of the push rod **260** by the closing of the handle members **256**, **258**.

[0097] The jaws **252**, **254** also include a lost motion connection including a spring to bias the jaws toward the closed position. With reference again to **FIG. 65A** and **FIG. 65B**, the jaws **252** and **254** are pivotally connected to each other by means of a pin **274**. The pin **274** is secured to the jaw member **254**, but is received in an elongated slot **276** in jaw member **252**. The pin **274** is biased to the top of the slot **276**, thus biasing the jaws **252**, **254** to the closed position, by means of a leaf spring **278** having one end secured to the pin **274** and the other end captured between two studs **280**, **282** carried on the jaw member **252**.

[0098] FIGS. **52**A-K illustrate a series of 11 different lesions or ablations that may be made using either an open or a minimally invasive technique with the graspers described above. Turning first to **FIG. 52A**, there is seen a view of the heart showing the right and left atriums (as viewed from behind). The heart includes the left atrial appendage (LAA) and the right atrial appendage (RAA). The right pulmonary veins (RPVs) and left pulmonary veins (LPVs) enter into the top of the left atrium. The superior vena cava (SVC) and inferior vena cava (IVC) are also shown. The mitral valve annulus is designated as MVA, while the tricuspid valve annulus designated TVA. In **FIG. 52A**, 11 different lesions are indicated by the reference numerals **1-11**. A method for making each of these lesions is illustrated in the following FIGS. **52**B-K. It should be appreciated that, depending upon a particular patient's indications, the lesions **1-11** may be created in a variety of combinations.

[0099] With reference to **FIG. 52B**, a method for making lesion **1** to circumscribe the right pulmonary veins (RPVs) is shown. This lesion is made completely epicardially in a manner similar to that illustrated in **FIGS. 23-27**. **FIG. 52C** illustrates lesion **2**, an epicardial ablation that fully circumscribes the left pulmonary veins (LPVs). Again, this lesion may be made in a manner similar to that illustrated in **FIGS. 23-27**.

[0100] **FIG. 52D** illustrates a method for making lesion **3**, which connects lesions **1** and **2**. Lesion **3** is made with only one of the jaws of the graspers being located epicardially. The mating jaw is inserted into the interior of the heart through a small incision which is sealed using a purse-string suture. The incision as illustrated is made interior the lesion **1** encircling the right pulmonary veins (RPVs).

[0101] Lesion **4** connects the lesion **1**, which surrounds the right pulmonary veins, to the mitral valve annulus (MVA). It may be made through the same incision and purse-string suture used for making lesion **3**. With reference again to **FIG. 52D**, the jaws of the grasper are merely rotated down so that the distal end of the jaw overlies the mitral valve annulus.

[0102] When making lesion **4**, care must be exercised in locating the grasper jaws so that the lesion is complete,

energy is applied, do not damage the mitral valve leaflets. It is known that the electrical signals generated by atrial tissue differ from the electrical signals generated by ventricular tissue. Consequently, the distal tip of one of the jaw members of the grasper includes an EKG sensor so that the EKG of the tissue contacted by the tip of the grasper can be monitored.

[0103] As best seen in **FIGS. 66 and 67**, the distal tip of the fixed jaw **116** includes a pair of laterally-opposed bipolar EKG electrodes or sensors **168** spaced slightly distally from the distal-most end of the electrode **120**. The sensors **168** are connected to conductive leads **170** (**FIG. 33**) that are adapted to be connected to an EKG monitor (not shown) to provide a display of the EKG. Thus, as the jaws of the grasper are rotated downwardly after making lesion **3**, the surgeon can constantly monitor the EKG, looking for the change from an atrial EKG to a ventricular EKG, to facilitate accurate placement of the jaw tip on the mitral valve annulus, and away from the mitral valve leaflets.

[0104] It may also be desirable to make a lesion between the superior vena cava (SVC) and the inferior (IVC). This may be created in two steps, in which lesions **5** and **6** are made. With reference to **FIG. 52E**, an incision with purse-string suture is made approximately midway between the SVC and IVC, with one of the jaws of the grasper being inserted into the incision so as to have its end adjacent the base of the SVC. The lesion **5** is formed and then the instrument is rotated 180° as shown in **FIG. 52F**, to make lesion **6**. Lesion **7** may conveniently be made through the same incision and purse-string suture as lesions **5** and **6**, as shown in **FIG. 52G**. Lesion **7** extends from between the SVC and IVC out toward the right atrial appendage (RAA).

[0105] A lesion **8** is made between the right atrial appendage and the tricuspid valve annulus (TVA) utilizing an incision and purse-string suture made in the RAA, as illustrated in **FIG. 52H**. Lesion **8** is made on the opposite side of the right atrium as lesion **7**, and thus is shown in dotted line in **FIG. 52A**. A lesion **9** may also be made circumscribing the right atrial appendage so as to intersect both lesions **7** and **8**. As shown in **FIG. 52I**, lesion **9** is made epicardially. A similar epicardial ablation circumscribing the left atrial appendage is designated **10** and illustrated in **FIG. 52J**.

[0106] A final lesion **11** is illustrated that connects lesion **10** circumscribing the left atrial appendage with lesion **2** that circumscribes the left pulmonary veins. As illustrated, the lesion **11** is made utilizing an incision and purse string suture through which the grasper jaw is introduced, the incision being located in the left atrial appendage beyond the lesion **10**.

[0107] In a further embodiment, the present device consists of two long, linear, wire-type electrodes, which are in parallel relationship to each other, each approximately 1 mm in diameter, and 50 mm long. The electrodes are insulated along their entire surface with a thin layer of high dielectric material such as polyamide, except for a thin strip of electrically conductive material that runs along the length of each electrode, in face-to-face relationship with each other. The electrodes are comprised of a high modulus material, such as tungsten or carbon fiber.

[0108] One of the electrodes is designed to be introduced into the interior of a hollow organ through a small puncture wound in the wall of the organ. The second electrode is introduced on the opposite side of the hollow organ wall. The device incorporates a mechanism for advancing each electrode individually, or both simultaneously, in parallel relation with each other. The device also includes a clamping mechanism that brings the two electrodes together so that their exposed conductive surfaces are in face-to-face relation and the electrodes exert sufficient pressure to clamp the tissue. Once both electrodes have been advanced to their desired positions, the clamping mechanism is activated which brings the two wires together, and clamps the tissue between the two exposed electrode surfaces. RF energy is then applied between the two electrodes, and the tissue is ablated in a long, continuous, transmural line. A monitoring device measures the voltage, current, impedance, and/or temperature between the two electrodes, and an algorithm determines whether the tissue is fully ablated.

[0109] This device provides a way to achieve and verify a fully transmural and continuous line of tissue ablation by locating the atrial tissue between two bipolar wire electrodes, and clamping the tissue. The forceps consist of two electrode pads of opposite polarity designed to grasp and clamp tissue. A well-known method of determining the status of the tissue between the electrode pads is to monitor the current, voltage, and impedance of the tissue, as done using the Richard Wolf generator for bipolar forceps. It is well known in the art that the ablative status of tissue clamped between two bipolar electrodes can easily be determined by monitoring the increase in tissue impedance as the tissue dessicates.

[0110] This device is to be used with an RF generator that monitors current, voltage, and impedance to determine the state of tissue ablation of the tissue compressed between the inner and outer electrodes. The RF generator will be equipped with an indicator which informs the user of the status of the clamped tissue, and when ablation is complete (i.e., transmural along the entire length of the electrodes).

[0111] This device provides the capability of creating long, transmural lesions through atrial wall tissue of varying thickness because it employs an active bipolar electrode on each side of the atrial wall, and the ablation proceeds from both the inside and outside of the atrial wall. The device is also unique in that the electrodes are used to compress the tissue to be ablated. This compression is critical because the inside and outside surfaces of the atrium can have irregularities, and a high clamping pressure insures that both electrodes are making good contact with tissue along the full length of each electrode. Clamping the tissue also reduces the distance between the electrodes, and makes the ablation more efficient because the electrical energy is more concentrated. Because of this higher concentration of energy, lower powers and temperatures can be used to achieve complete ablation, and the process is considerably faster.

[0112] As an example, to fully ablate a 5 mm deep lesion, 30 cm long can take several minutes with an endocardial catheter electrode array, and the temperatures can be as high as 80 to 90 degrees centigrade at the tissue surface with the generator power as high as 40 to 50 watts. In benchtop testing of the present invention in animal hearts, a fully transmural 30 mm line through 5 mm of tissue was achieved in 5 seconds at 20 watts.

[0113] With reference to **FIGS. 53-54**, a further embodiment of the device is shown and consists of an inner

wire electrode wire electrode **201**, an outer wire electrode **202**, an inner slider button **203**, an outer slider button **204**, and a clamping slider tube **205** and button **206**. The device body **207** houses the wire electrodes, slider tube and buttons, connector wires **207***a* and **208**, and bipolar connector **209**. The device may also include slit needle introducer tip **210**.

[0114] The operation of the device begins by advancing the inner electrode wire **201** by advancing the slider button **203**. Once the inner electrode **201** is advanced to the desired length, the outer electrode **202** is advanced by advancing slider button **204**. Note that further advancement of slider button **204** also advances slider button **203**, so that both electrodes **201** and **202** advance simultaneously. Because of the bend **202***a* in the electrode wire **202**, and the notch **205***a* in the slider tube assembly **205**, the slider tube advances along with the outer electrode **202**. Once both electrodes are advanced to the desired length, the slider tube **205** is advanced so that the end **205***b* of the slider tube **205** contacts the arcuate wire segment **202***b* of electrode wire **202**. Further advancement of slider tube **205** acts to compress the electrode wires **201** and **202** together along the entire effective length L.

[0115] **FIGS. 55 and 56** show two types of electrode wires, a piercing tip (**FIG. 56**), and an obturator, or blunt tip (**FIG. 55**). The electrodes may be similar in construction to those shown in **FIGS. 2-6**, which are described above. **FIG. 57** shows a side view of the instrument tip.

[0116] **FIG. 58A** shows the instrument used to penetrate the wall of a hollow organ, such as the heart. The slit needle **210** penetrates tissue through the wall of the atrium **218**. In **FIG. 58B**, the inner wire electrode **201** is advanced through the puncture wound into the interior of the atrium. In **FIG. 58C**, the outer needle **202** is initially advanced onto the external surface of the atrial wall **218**. **FIG. 58D** shows the inner **201** and outer **202** needles as they are simultaneously advanced along the inner and outer surfaces of the atrial wall **218**. **FIG. 58E** shows the pusher tube **205** advanced to compress the tissue of the atrial wall **218** at location **219**. RF energy is then applied between the conductive strips **212** on each electrode to ablate the compressed tissue **219**. **FIG. 58F** shows section B-B of **FIG. 58E**, with the inner **201** and outer **202** electrodes compressing the tissue **219**. The area of ablated tissue is shown as **220**. The alternate electrode configuration of **FIG. 5** is shown in **FIG. 58G**. Blood cells are represented as **221**.

[0117] The compression of the tissue is important because it insures that the exposed electrode surface is not in contact with any tissue or blood except the clamped tissue to be ablated. Referring to **FIGS. 58F and 58G** one can see that the clamping of the tissue between the electrodes insures that only the conductive area is in contact with the clamped tissue. Especially important is avoiding any contact between the conductive area of the electrode and blood in the atrium. Contact between an active electrode and blood in the atrium is major cause of thrombus formation in ablation procedures. The compressed tissue acts to isolate the electrically active surface, and prevents inadvertent energy delivery to other parts of the heart or blood. The outside temperature of the electrode can easily be monitored to insure that the temperature of the insulation in contact with blood remains below a critical temperature (40° C., for example).

[0118] **FIG. 59** shows a potential series of continuous transmural ablation lines **222** located around the pulmonary veins **223** in the left atrium **224**. A series of puncture wounds **225** are shown as one means to achieve the pattern of ablation lines (shown in dot-dash lines).

[0119] **FIG. 60A** shows a method for achieving a circumferential lesion in a pulmonary vein **223**. The inner needle **201** is a piercing tip as shown in **FIG. 56**. The needle is advanced completely through the wall of the pulmonary vein until it exits the vein. In **FIG. 60B**, the outer electrode **2** is advanced parallel to the inner electrode **201**. In **FIG. 60C**, the electrodes are compressed, and the compressed vein wall tissue **226** is ablated by applying RF energy between the two electrodes. In **FIG. 60D**, the electrodes are released, and the vein wall tissue **226** returns to its original shape. **FIG. 60E** shows the outer electrode **202** retracted back into the instrument body, and the instrument is rotated **180** degrees about the axis of electrode **201**.

[0120] **FIG. 60F** shows the outer electrode **202** advanced along the opposite side of the pulmonary vein from the ablated tissue **220**. In **FIG. 60G**, the electrodes are compressed, and the compressed vein wall tissue **227** is ablated by applying RF energy between the electrodes. **FIG. 60H** shows the position of the electrodes with the pusher tube retracted, and the fully circumferential lesion **220**. **FIG. 60I** shows the instrument retracted from the vein, and the circumferential lesion of ablated tissue **220**.

[0121] **FIGS. 61A-61J** show the instrument used in a method to create a circumferential lesion around a pair of pulmonary veins **226** and **227**. In **FIG. 61A** the inner electrode **201** is advanced into the side of the atrial wall **218**, just below the ostium of the pulmonary vein **226** by advancing slider button **203**. **FIG. 61B** shows electrode **201** and slider **203** fully advanced, and exiting the atrial tissue **218** just below the ostium of pulmonary vein **227**. **FIG. 61C** shows outer electrode **202** advanced fully in parallel and to the same length as inner electrode **201** by advancing slider **204**. Note that slider tube button **205** has advanced to its intermediate position.

[0122] **FIG. 61D** shows slider button **205** fully advanced, which clamps electrodes **201** and **202** together just below the ostia of the pulmonary veins on the side of the veins indicated by tissue surface **218***a*, and compresses the atrial wall tissue. RF energy is then applied between the two electrodes, and the clamped tissue **219** is ablated. In **FIG. 61E**, electrode **202** is retracted by retracting slider button **4**. The line of ablated tissue is shown as **219***a*. This line of ablated tissue **219***a* will be completely continuous and transmural, and connect inner needle entry point **229** with inner needle exit point **230** and extend along the side of the atrial wall.

[0123] **FIG. 61F** shows the device body **207** rotated 180 degrees about the axis of the inner electrode **201** so that the atrial surface **218***b* on the opposite side of the pulmonary veins is exposed. **FIG. 61G** shows slider button **204** and outer electrode **202** advanced over the opposite surface of the atrium **218***b*. **FIG. 61H** shows slider button **205** advanced, and the electrodes **201** and **202** clamping the tissue **219***b* just below the ostia of the pulmonary veins **226** and **227** along atrial wall **218***b*. RF energy is then applied between the electrodes **201** and **202** to ablate the compressed tissue **219***b*. In **FIG. 61I** the slider button **205** is retracted, and the electrodes release the tissue **219***b*. The outer electrode is then retracted, exposing the ablated tissue **219***b*.

fully ablated as indicated by the line **219***b*. **FIG. 16J** shows a top view of **FIG. 61I** showing the continuous line of ablated tissue surrounding pulmonary veins **226** and **227**, connected by entry point **229** and exit point **230** of internal electrode **201**. The electrode is then retracted, leaving a continuous transmural lesion that electrically isolates the pulmonary veins from the rest of the atrial tissue.

[**0124**] In another embodiment of the invention, a penetrating compressive/tensile electrode is used. Once the jaws are positioned below the ostia of the pulmonary veins, the tissue is partially clamped, allowing continued flow from the pulmonary veins to the left atrium. An electrode needle is introduced which enters the left side of the atrial tissue and exits on the right side into a tip securing point on the lower jaw. This point will prevent the tip from moving axially when a needle is pushed. The lower atrial tissue can be compressed by "pushing" on the needle with a force that compresses tissue between the needle electrode and the lower jaw electrode. Bipolar RF energy is then applied between the needle and lower jaw electrodes to ablate a line of tissue from the needle entry to exit point. Once the lower atrial tissue has been ablated, the upper jaw is moved down to contact the tip of the lower jaw. Note that this still provides an open lumen for blood flow from the pulmonary veins to the left atrium. The needle is rotated 180 degrees on its axis so that the electrode surface faces up. The needle is then "pulled" to create tension, and exert a compressive force that compresses tissue between the needle electrode and the upper jaw. Bipolar RF energy is then applied between the needle electrode and upper jaw to ablate the tissue. Note that the partial closing of the upper jaw to contact the tip of the lower jaw could be done prior to compressing the lower atrial tissue.

[**0125**] With reference to **FIGS. 62A-62I** the clamping apparatus as generally described above is shown. As illustrated, the device is a "pliers type" apparatus. The device is shown clamped around the atrial tissue below the ostia of the pulmonary veins. In **FIGS. 62B-62D**, an electrode needle is advanced through the atrial tissue to contact a receiver at the tip of the device. **FIG. 62E** shows one method of clamping the tissue to a rigid needle electrode, using a non-rigid outer clamping member that flexes either by further motion of the handle as shown or by further extension of the electrode member. **FIG. 62F** shows both sides of the clamping member flexed, and the tissue compressed between. **FIG. 62G** shows the position of the clamping members and electrode prior to tissue clamping. **FIG. 62H** shows these positions during tissue clamping. Bipolar RF energy is applied between the clamping members, and the inner electrode to ablate the atrial tissue, creating a lesion, as shown in **FIG. 62H**. Note also, that if the inner electrode had only one exposed electrode surface, the tissue ablation could be carried out first on one side, then the other, without occluding the lumen between the pulmonary veins and the atrium.

[**0126**] **FIG. 62I** shows another way to achieve tissue compression by advancing a relatively flexible needle electrode which bends as shown to compress the tissue between the electrode and one of the device jaws.

[**0127**] Thus, it can be seen that a transmural ablation device and method have been provided that overcome the limitations of the prior art. First, current technology involves ablation devices deliver ablation energy to either the inside (endocardium) or outside (epicardium) of the heart. Using these techniques, the tissue ablation proceeds from one wall of the heart through the tissue to the opposite wall. To date, there has been no reliable way to consistently achieve lesions that penetrate the full thickness of the atrial wall (transmural lesions), and there has been no way to determine either continuity or transmurality of these lesions. If the lesion does not penetrate through enough of the atrial wall, conduction can still occur, and the lesion does not fully block the electrical signals that are causing the arrhythmia. Using an endocardial approach, if the lesion penetrates too far through the wall, critical structures such as coronary arteries, veins, or the esophagus can be damaged on the outside of the heart. Using an epicardial approach, if the lesion penetrates too far, blood can be coagulated, or critical structures such as valves, nodes, or connective tissue can be damaged on the inside of the heart.

[**0128**] There has also been no reliable and consistent way to safely achieve fully continuous, long (greater than 1 cm) lesions in the atrial wall without a high risk of thrombus, damage to critical structures, or extensive damage to the atrial tissue.

[**0129**] The present invention overcomes these shortcomings because the conductive area of each electrode is very narrow compared to the width of the clamped area. As a result, the thermal damage to the tissue is minimal. In contrast, current technology uses catheter electrodes which are typically 1 or 2 mm diameter requiring a lesion width of almost 8 mm to achieve a depth of 5 mm. Using the present invention, a lesion depth of 5 mm with a width of less than 2 mm can be achieved. This aspect of the invention allows for longer linear lesions with less power delivery because less tissue is being heated. There is, therefore, considerably less damage to healthy atrial tissue for a lesion of a given depth and length. Recent efforts in creating linear lesions using endocardial electrodes resulted in ablation of over 20% of the atrial endocardium, and a commensurate decrease in atrial contractility.

[**0130**] Another advantage of this device is that ablation can be done on a beating heart. Using a high modulus material such as tungsten or carbon fiber would allow a minimum diameter, and a maximum clamping pressure for a given clamping length. Once the device is clamped onto the atrial wall, the position of the electrodes can be verified by visually inspecting the position of the outer electrode before delivery of RF energy. If the clamping pressure is higher than the atrial pressure, then clamping over a coronary artery would cut off blood flow, and the resulting change in the EKG would act as a warning to the user prior to applying RF energy. The clamping will prevent any movement of the electrodes relative to the heart wall, and RF energy can be applied with confidence that the ablated tissue will be contained completely between the two electrodes.

[**0131**] Another important feature of this device is that the energy transfer is limited to the tissue clamped between the two electrodes. The insulated electrodes protect structures on the outside of the heart from being exposed to RF energy. Because of this limitation of current flow, damage to critical structures can be avoided.

[**0132**] Another advantage of this device is that it can easily be adapted to a minimally invasive thoracoscopic approach. The device [illegible] reduced [illegible]

diameter device, and can probably be reduced to 3 mm or less. Using video thoracoscopy, the device could be introduced through a small intracostal incision, and used to create fully transmural linear lesions on a beating heart, possibly under local anesthesia on an anesthetized patient.

[0133] Accordingly, a device for performing transmural ablation has been provided that meets all the objects of the present invention. While the invention has been described in terms of certain preferred embodiments, there is no intent to limit the invention to the same. Instead it is to be defined by the scope of the appended claims.

1. A device for clamping and ablating cardiac tissue comprising:

a handle member;

first and second mating jaw members, at least one of the jaw members being associated with the handle member and being movable by the handle member between a first open position and a second clamped position, the jaw members having an opposed clamping surfaces;

a first elongated ablation member carried by the first jaw member;

a second elongated ablation member carried by the second jaw member;

the first and second ablation members being adapted to be connected to an ablation energy source; and

at least one of said first and second jaw members including at least one EKG monitoring sensor spaced distally from its associated ablation member for contacting cardiac tissue and being adapted to be connected to an EKG monitor, so that when cardiac tissue is grasped between the first and second jaws, the at least one EKG sensor contacts the cardiac tissue and transmits the signals generated by the tissue to the EKG monitor.

2. The device of claim 1 wherein the ablation members are between approximately 3 to 8 cm in length and approximately 0.12 to 0.6 mm in width.

3. The device of claim 1 wherein the ablation members comprise gold-plated copper.

4. The device of claim 1 wherein one of the jaw members is fixed and the at least one EKG monitoring sensor is associated with the fixed jaw.

5. The device of claim 1 wherein at least one of the jaw members includes a pair of EKG monitoring sensors.

6. A cardiac tissue grasping apparatus comprising:

first and second grasping jaws, the grasping jaws being relatively moveable between open and closed positions; each jaw including an ablation member and a clamping surface in face-to-face relation with the ablation member and clamping surface of the other jaw; the clamping surfaces of the jaws comprising an insulating material and the face-to-face ablation members being connectible to an ablation power source;

whereby when tissue is grasped between said clamping surfaces, the ablation members are substantially entirely contacted by the tissue; and

at least one of said first and second grasping jaws including at least one EKG monitoring sensor spaced distally from its associated ablation member for contacting cardiac tissue and being adapted to be connected to an EKG monitor, so that when cardiac tissue is grasped between the first and second grasping jaws, the EKG sensors contact the cardiac tissue and transmit the signals generated by the tissue to the EKG monitor.

7. The apparatus of claim 6 wherein the ablation members are between approximately 3 to 8 cm in length and approximately 0.12 to 0.6 mm in width.

8. The apparatus of claim 6 wherein the ablation members comprise gold-plated copper.

9. The device of claim 6 wherein one of the jaw members comprises a piercing tip adapted to puncture myocardial tissue.

10. The device of claim 6 wherein one of the jaw members is fixed and the at least one EKG monitoring sensor is associated with the fixed jaw.

11. The device of claim 6 wherein at least one of the jaw members includes a pair of EKG monitoring sensors.

12. A device for clamping and ablating cardiac tissue comprising:

a handle member;

first and second jaw members, at least one of the jaw members being associated with the handle member and being movable by the handle member between a first open position and a second clamped position;

a first elongated ablation member carried by the first jaw member;

a second elongated ablation member carried by the second jaw member;

the first and second ablation members being adapted to be connected to an ablation energy source; and

at least one of said first and second jaw members including a pair of EKG monitoring sensors spaced distally from its associated ablation member for contacting cardiac tissue and being adapted to be connected to an EKG monitor, so that when cardiac tissue is grasped between the first and second jaws, the EKG sensors contact the cardiac tissue and transmit the signals generated by the tissue to the EKG monitor.

13. The device of claim 12 wherein the ablation members are between approximately 3 to 8 cm in length and approximately 0.12 to 0.6 mm in width.

14. The device of claim 12 wherein the ablation members comprise gold-plated copper.

15. The device of claim 12 wherein one of the jaws is fixed and the EKG monitoring sensors are associated with the fixed jaw.

16. A cardiac tissue grasping apparatus comprising:

first and second grasping jaws, the grasping jaws being relatively moveable between open and closed positions; each jaw including an elongated ablation member and a clamping surface in face-to-face relation with the ablation member and clamping surface of the other jaw; the clamping surfaces of the jaws comprising an insulating material and the face-to-face ablation members being connectible to an ablation power source; and

at least one of said first and second grasping jaws including a pair of EKG monitoring sensors spaced distally from its associated ablation member for contacting cardiac tissue and being adapted to be connected to an EKG monitor, so that when cardiac tissue is grasped

between the first and second grasping jaws, the EKG sensors contact the cardiac tissue and transmit the signals generated by the tissue to the EKG monitor.

17. The apparatus of claim 16 wherein the ablation members are between approximately 3 to 8 cm in length and approximately 0.12 to 0.6 mm in width.

18. The apparatus of claim 16 wherein the ablation members comprise gold-plated copper.

19. The device of claim 16 wherein one of the jaw members comprises a piercing tip adapted to puncture myocardial tissue.

20. The device of claim 16 wherein one of the jaws is fixed and the EKG monitoring sensors are associated with the fixed jaw.

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