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(54) UNITARY SUBCUTANEOUS ONLY IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR AND OPTIONAL PACER

EINHEITLICHER, NUR SUBKUTAN IMPLANTIERBARER KARDIOVERTIERER-DEFIBRILLATOR UND WAHLWEISER HERZSCHRITTMACHER

SYSTEME MONOBLOC DE DEFIBRILLATION-CARDIOVERSION ET STIMULATION CARDIAQUE EVENTUELLE POUVANT ETRE IMPLANTE UNIQUEMENT DE MANIERE SOUS-CUTANEE

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Description

CROSS-REFERENCE TO RELATED APPLICATION (S)

[0001] This application is related to a PCT patent application entitled Unitary Subcutaneous Only Implantable Cardioverter-Defibrillator and Optional Pacer with the same inventors herein and filed on the same day as this application.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates to an apparatus for performing electrical cardioversion/defibrillation and optional pacing of the heart via a totally subcutaneous non-transvenous system.

2. Background of the Invention

[0003] Defibrillation/cardioversion is a technique employed to counter arrhythmic heart conditions including some tachycardias in the atria and/or ventricles. Typically, electrodes are employed to stimulate the heart with electrical impulses or shocks, of a magnitude substantially greater than pulses used in cardiac pacing.

[0004] Defibrillation/cardioversion systems include body implantable electrodes and are referred to as implantable cardioverter/defibrillators (ICDs). Such electrodes can be in the form of patches applied directly to epicardial tissue, or at the distal end regions of intravascular catheters, inserted into a selected cardiac chamber. U.S. Pat. Nos. 4,603,705, 4,693,253, 4,944,300, 5,105,810 disclose intravascular or transvenous electrodes, employed either alone or in combination with an epicardial patch electrode. Compliant epicardial defibrillator electrodes are disclosed in U.S. Pat. Nos. 4,567,900 and 5,618,287. A sensing epicardial electrode configuration is disclosed in U.S. Pat. No. 5,476,503.

[0005] In addition to epicardial and transvenous electrodes, subcutaneous electrode systems have also been developed. For example, U.S. Patent Nos. 5,342,407 and 5,603,732 teach the use of a pulse monitor/generator surgically implanted into the abdomen and subcutaneous electrodes implanted in the thorax. This system is far more complicated to use than current ICD systems using transvenous lead systems together with an active can electrode and therefore it has no practical use. It has in fact never been used because of the surgical difficulty of applying such a device (3 incisions), the impractical abdominal location of the generator and the electrically poor sensing and defibrillation aspects of such a system.

[0006] Recent efforts to improve the efficiency of ICDs have led manufacturers to produce ICDs which are small enough to be implanted in the pectoral region. In addition, advances in circuit design have enabled the housing of the ICD to form a subcutaneous electrode. Some examples of ICDs in which the housing of the ICD serves as an optional additional electrode are described in U.S. Pat. Nos. 5,133,353, 5,261,400, 5,620,477, and 5,658,321.

[0007] ICDs are now an established therapy for the management of life threatening cardiac rhythm disorders, primarily ventricular fibrillation (V-Fib). ICDs are very effective at treating V-Fib, but are therapies that still require significant surgery.

[0008] As ICD therapy becomes more prophylactic in nature and used in progressively less ill individuals, the requirement of ICD therapy to use intravenous catheters and transvenous leads is an impediment to very long term management as most individuals will begin to develop complications related to lead system malfunction sometime in the 5-10 year time frame, often earlier. In addition, chronic transvenous lead systems, their reimplantation and removals, can damage major cardiovascular venous systems and the tricuspid valve, as well as result in life threatening perforations of the great vessels and heart. Consequently, use of transvenous lead systems, despite their many advantages, are not without their chronic patient management limitations in those with life expectancies of >5 years. Moreover, transvenous ICD systems also increase cost and require specialized interventional rooms and equipment as well as special skill for insertion. These systems are typically implanted by cardiac electrophysiologists who have had a great deal of extra training.

[0009] In addition to the background related to ICD therapy, the present invention requires a brief understanding of automatic external defibrillator (AED) therapy. AEDs employ the use of cutaneous patch electrodes to effect defibrillation under the direction of a bystander user who treats the patient suffering from V-Fib. AEDs can be as effective as an ICD if applied to the victim promptly within 2 to 3 minutes.

[0010] AED therapy has great appeal as a tool for diminishing the risk of death in public venues such as in air flight. However, an AED must be used by another individual, not the person suffering from the potential fatal rhythm. It is more of a public health tool than a patient-specific tool like an ICD. Because >75% of cardiac arrests occur in the home, and over half occur in the bedroom, patients at risk of cardiac arrest are often alone or asleep and can not be helped in time with an AED. Moreover, its success depends to a reasonable degree on an acceptable level of skill and calm by the bystander user.

[0011] What is needed therefore, is a combination of the two forms of therapy which would provide prompt and near-certain defibrillation, like an ICD, but without the long-term adverse sequelae of a transvenous lead system while simultaneously using most of the simpler and lower cost technology of an AED. What is also need-

ed is a cardioverter/defibrillator that is of simple design and can be comfortably implanted in a patient for many years. We call such a device a unitary sub-cutaneous only ICD (US-ICD) and is described in detail below.

SUMMARY OF THE INVENTION

[0012] The preferred embodiment for the unitary subcutaneous only ICD (US-ICD) with optional pacing consists of five basic components: 1) a curved housing which houses a battery supply, capacitor, and operational circuitry; 2) two cardioversion/defibrillating electrodes are attached to the outer surface of the housing; 3) one or more sensing electrodes located on the housing; and 4) sense circuitry suitable to an ICD or AED V-FIB detection algorithm. Additionally, an application system is provided for simple insertion of the US-ICD. No transvenous lead system is used, eliminating a significant impediment to broader scale prophylactic use.

[0013] The housing will provide energy and voltage intermediate to that available with ICD and AEDs. The typical maximum voltage necessary for ICDs using most biphasic waveforms is approximately 750 V and associated maximum energy of approximately 40 J. The typical maximum voltage necessary for AEDs is approximately 2000-5000 V with an associated maximum energy of approximately 150-360 J. The US-ICD of the present invention will use voltages in the range of 800 to 2000 V and associated with energies of approximately 40-150 J.

[0014] The cardioversion/defibrillation electrodes are electrically insulated from each other and are about 5-10 cm length. In the preferred embodiment, the sense electrodes are located between the cardioversion/defibrillation electrodes and are spaced about 4 cm from each other to provide a reasonable QRS signal from a subcutaneous extracardic sampling location but may be of variable length to allow for sense optimization.

[0015] The sense circuitry in the preferred embodiment is designed to be highly sensitive and specific to the presence or absence of life threatening ventricular arrhythmias only. Features of the detection algorithm are programmable but the algorithm is focused on the detection of V-Fib and high rate ventricular tachycardia (V-Tach) of greater than 240 bpm. This type of cardioverter-defibrillator is not necessarily designated to replace ICD therapy for those with pre-identified problems of V-Tach/V-Fib or even atrial fibrillation, but is particularly geared to use as a prophylactic, long-term device, used for the life of the patient at risk of his/her first V-Fib/V-Tach event. The device of the present invention may infrequently be used for an actual life threatening event but can be employed in large populations of individuals at modest risk and with modest cost by physicians of limited experience. Consequently, the preferred embodiment of the present invention focuses only on the detection and therapy of the most malignant rhythm disorders. As part of the detection algorithm's applicability to children, the upper rate range is programmable upward for use in children, who are known to have more rapid supraventricular tachycardias as well as more rapid ventricular tachycardias compared to adults.

[0016] The incision to apply the device of the present invention can be anywhere on the thorax although in the preferred embodiment, the device of the present invention will be applied in the anterior mid-clavicular line approximately at the level of the mammary crease beneath the left areolus. A subcutaneous path will then be made and will extend to the posterior thoracic region ideally at the level of the inferior scapula tip. Such a lead position will allow for a good transthoracic current delivery vector as well as positioning of the proximally positioned sense bipole in a good location for identification of the QRS ECG signal. A specially designed curved introducer set, through which local anesthetic can be delivered, is provided to assist in the placement of the US-ICD.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] For a better understanding of the invention, reference is now made to the drawings where like numerals represent similar objects throughout the figures where:

FIG. 1 is a schematic view of a Unitary Subcutaneous ICD (US-ICD) of the present invention;
FIG. 2 is a schematic view of the US-ICD subcutaneously implanted in the thorax of a patient;
FIG. 3 is a schematic view of the method of making a subcutaneous path from the preferred incision for implanting the US-ICD;
FIG. 4 is a schematic view of an introducer for performing the method of US-ICD implantation; and
FIG. 5 is an exploded schematic view of an alternate embodiment of the present invention with a plug-in portion that contains operational circuitry and means for generating cardioversion/defibrillation shock waves.

DETAILED DESCRIPTION

[0018] Turning now to Fig. 1, the US-ICD of the present invention is illustrated. The US-ICD consists of a curved housing 11 with a first and second end. The first end 13 is thicker than the second end 15. This thicker area houses a battery supply, capacitor and operational circuitry for the US-ICD. The circuitry will be able to monitor cardiac rhythms for tachycardia and fibrillation, and if detected, will initiate charging the capacitor and then delivering cardioversion/defibrillation energy through the two cardioversion/defibrillating electrodes 17 and 19 located on the outer surface of the two ends of the housing. Examples of such circuitry are described in U.S. Patent Nos. 4,693,253 and 5,105,810. The circuitry can provide cardioversion/defibrillation energy in different types of wave forms. In the preferred embodi-

ment, a 100 uF biphasic wave form is used of approximately 10-20 ms total duration and with the initial phase containing approximately 2/3 of the energy, however, any type of wave form can be utilized such as monophasic, biphasic, multiphasic or alternative waveforms as is known in the art.

[0019] In addition to providing cardioversion/ defibrillation energy, the circuitry can also provide transthoracic cardiac pacing energy. The optional circuitry will be able to monitor the heart for bradycardia and/or tachycardia rhythms. Once a bradycardia or tachycardia rhythm is detected, the circuitry can then deliver appropriate pacing energy at appropriate intervals through the electrodes. Pacing stimuli will be biphasic in the preferred embodiment and similar in pulse amplitude to that used for conventional transthoracic pacing.

[0020] This same circuitry can also be used to deliver low amplitude shocks on the T-wave for induction of ventricular fibrillation for testing S-ICD performance in treating V-Fib as is described in U.S. Patent No. 5,129,392. Also the circuitry can be provided with rapid induction of ventricular fibrillation or ventricular tachycardia using rapid ventricular pacing. Another optional way for inducing ventricular fibrillation would be to provide a continuous low voltage, i.e., about 3 volts, across the heart during the entire cardiac cycle.

[0021] Another optional aspect of the present invention is that the operational circuitry can detect the presence of atrial fibrillation as described in Olson, W. et al. "Onset And Stability for Ventricular Tachyarrhythmia Detection in an Implantable Cardioverter and Defibrillator," Computers in Cardiology (1986) pp. 167-170. Detection can be provided via R-R Cycle length instability detection algorithms. Once atrial fibrillation has been detected, the operational circuitry will then provide QRS synchronized atrial defibrillation/cardioversion using the same shock energy and waveshape characteristics used for ventricular defibrillation/cardioversion.

[0022] The sensing circuitry will utilize the electronic signals generated from the heart and will primarily detect QRS waves. In one embodiment, the circuitry will be programmed to detect only ventricular tachycardias or fibrillations. The detection circuitry will utilize in its most direct form, a rate detection algorithm that triggers charging of the capacitor once the ventricular rate exceeds some predetermined level for a fixed period of time: for example, if the ventricular rate exceeds 240 bpm on average for more than 4 seconds. Once the capacitor is charged, a confirmatory rhythm check would ensure that the rate persists for at least another 1 second before discharge. Similarly, termination algorithms could be instituted that ensure that a rhythm less than 240 bpm persisting for at least 4 seconds before the capacitor charge is drained to an internal resistor. Detection, confirmation and termination algorithms as are described above and in the art can be modulated to increase sensitivity and specificity by examining electrocardiographic QRS beat-to-beat uniformity, QRS signal frequency content, R-R interval stability data, and signal amplitude characteristics all or part of which can be used to increase or decrease both sensitivity and specificity of US-ICD arrhythmia detection function.

[0023] In addition to use of the sense circuitry for detection of V-Fib or V-Tach by examining the QRS waves, the sense circuitry can check for the presence or the absence of respiration. The respiration rate can be detected by monitoring the impedance across the thorax using subthreshold currents delivered across the active can and the high voltage subcutaneous lead electrode and monitoring the frequency in undulation in the waveform that results from the undulations of transthoracic impedance during the respiratory cycle. If there is no undulation, then the patient is not respiring and this lack of respiration can be used to confirm the QRS findings of cardiac arrest. The same technique can be used to provide information about the respiratory rate or estimate cardiac output as described in U.S. Patent Nos. 6,095,987, 5,423,326, 4,450,527.

[0024] The housing of the present invention can be made out of titanium alloy or other presently preferred ICD designs. It is contemplated that the housing is also made out of biocompatible plastic materials that electronically insulate the electrodes from each other. However, it is contemplated that a malleable canister that can conform to the curvature of the patient's chest will be preferred. In this way the patient can have a comfortable canister that conforms to the unique shape of the patient's rib cage. Examples of conforming ICD housings are provided in U.S. Patent No. 5,645,586. In the preferred embodiment, the housing is curved in the shape of a 5th rib of a person. Because there are many different sizes of people, the housing will come in different incremental sizes to allow a good match between the size of the rib cage and the side of the US-ICD. The length of the US-ICD will range from about 15 to about 50 cm. Because of the primary preventative role of the therapy and the need to reach energies over 40 Joules, a feature of the preferred embodiment is that the charge time for the therapy, intentionally be relatively long to allow capacitor charging within the limitations of device size.

[0025] The thick end of the housing is currently needed to allow for the placement of the battery supply, operational circuitry, and capacitors. It is contemplated that the thick end will be about 0.5 cm to about 2 cm wide with about 1 cm being presently preferred. As microtechnology advances, the thickness of the housing will become smaller. Examples of small ICD housings are disclosed in U.S. Patents Nos. 5,957,956 and 5,405,363.

[0026] The two cardioversion/defibrillation electrodes on the housing are used for delivering the high voltage cardioversion/defibrillation energy across the heart. In the preferred embodiment, the cardioversion/defibrillation electrodes are coil electrodes, however, other cardioversion/defibrillation electrodes could be used such

as having electrically isolated active surfaces or platinum alloy electrodes. The coil cardioversion/defibrillation electrodes are about 5-10 cm in length. Located on the housing between the two cardioversion/defibrillation electrodes are two sense electrodes 25 and 27. The sense electrodes are spaced far enough apart to be able to have good QRS detection. This spacing can range from 1 to 10 cm with 4 cm being presently preferred. The electrodes may or may not be circumferential with the preferred embodiment. Having the electrodes non-circumferential and positioned outward, toward the skin surface, is a means to minimize muscle artifact and enhance QRS signal quality. The sensing electrodes are electrically isolated from the cardioversion/defibrillation electrode via insulating areas 23. Analogous types of cardioversion/ defibrillation electrodes are currently commercially available in a transvenous configuration. For example, U.S. Patent No. 5,534,022 discloses a composite electrode with a coil cardioversion/ defibrillation electrode and sense electrodes. Modifications to this arrangement is contemplated within the scope of the invention. One such modification is to have the sense electrodes at the two ends of the housing and have the cardioversion/defibrillation electrodes located in between the sense electrodes. Another modification is to have three or more sense electrodes spaced throughout the housing and allow for the selection of the two best sensing electrodes. If three or more sensing electrodes are used, then the ability to change which electrodes are used for sensing would be a programmable feature of the US-ICD to adapt to changes in the patient physiology and size over time. The programming could be done via the use of physical switches on the canister, or as presently preferred, via the use of a programming want or via a wireless connection to program the circuitry within the canister.

[0027] The housing will provide energy and voltage intermediate to that available with ICDs and most AEDs. The typical maximum voltage necessary for ICDs using most biphasic waveforms is approximately 750 Volts with an associated maximum energy of approximately 40 Joules. The typical maximum voltage necessary for AEDs is approximately 2000-5000 Volts with an associated maximum energy of approximately 200-360 Joules depending upon the model and waveform used. The US-ICD of the present invention uses maximum voltages in the range of about 800 to about 2000 Volts and is associated with energies of about 40 to about 150 Joules. The capacitance of the S-ICD could range from about 50 to about 200 micro farads.

[0028] The sense circuitry contained within the housing is highly sensitive and specific for the presence or absence of life threatening ventricular arrhythmias. Features of the detection algorithm are programmable and the algorithm is focused on the detection of V-FIB and high rate V-TACH (>240 bpm). Although the US-ICD of the present invention may rarely be used for an actual life threatening event, the simplicity of design and implementation allows it to be employed in large populations of patients at modest risk with modest cost by non-cardiac electrophysiologists. Consequently, the US-ICD of the present invention focuses mostly on the detection and therapy of the most malignant rhythm disorders. As part of the detection algorithm's applicability to varying patient populations, the detection rate range is programmable upward or downward to meet the needs of the particular patient based on their cardiac condition and age.

[0029] Turning now to FIG. 2, the optimal subcutaneous placement of the US-ICD of the present invention is illustrated. As would be evidence to a person skilled in the art, the actual location of the US-ICD is in a subcutaneous space that is developed during the implantation process. The heart is not exposed during this process and the heart is schematically illustrated in the figures only for help in understanding where the device and its various electrodes are three dimensionally located in the thorax of the patient. The US-ICD is located between the left mid-clavicular line approximately at the level of the inframammary crease at approximately the 5th rib and the posterior axillary line, ideally just lateral to the left scapula. This way the US-ICD provides a reasonably good pathway for current delivery to the majority of the ventricular myocardium.

[0030] FIG. 3 schematically illustrates the method for implanting the US-ICD. An incision 31 is made in the left anterior axillary line approximately at the level of the cardiac apex. A subcutaneous pathway 33 is then created that extends posteriorly to allow placement of the US-ICD. The incision can be anywhere on the thorax deemed reasonably by the implanting physician although in the preferred embodiment, the US-ICD of the present invention will be applied in this region. The subcutaneous pathway 33 is created medially to the inframammary crease and extends posteriorly to the left posterior axillary line. The pathway is developed with a specially designed curved introducer 40 (see FIG. 4). The trocar has a proximal handle 41 and a curved shaft 43. The distal end 45 of the trocar is tapered to allow for dissection of the subcutaneous pathway 33 in the patient. Preferably, the trocar is cannulated having a central lumen 46 and terminating in an opening 48 at the distal end. Local anesthetic such as lidocaine can be delivered, if necessary, through the lumen or through a curved and elongated needle designed to anesthetize the path to be used for trocar insertion should general anesthesia not be employed. Once the subcutaneous pathway is developed, the US-ICD is implanted in the subcutaneous space, the skin incision is closed using standard techniques.

[0031] As described previously, the US-ICDs of the present invention vary in length and curvature. The US-ICDs are provided in incremental sizes for subcutaneous implantation in different sized patients. Turning now to FIG. 5, a different embodiment is schematically illustrated in exploded view which provides different

sized US-ICDs that are easier to manufacture. The different sized US-ICDs will all have the same sized and shaped thick end 13. The thick end is hollow inside allowing for the insertion of a core operational member 53. The core member comprises a housing 57 which contains the battery supply, capacitor and operational circuitry for the US-ICD. The proximal end of the core member has a plurality of electronic plug connectors. Plug connectors 61 and 63 are electronically connected to the sense electrodes via pressure fit connectors (not illustrated)inside the thick end which are standard in the art. Plug connectors 65 and 67 are also electronically connected to the cardioverter/defibrillator electrodes via pressure fit connectors inside the thick end. The distal end of the core member comprises an end cap 55, and a ribbed fitting 59 which creates a water-tight seal when the core member is inserted into opening 51 of the thick end of the US-ICD.

[0032] The core member of the different sized and shaped US-ICD will all be the same size and shape. That way, during an implantation procedure, multiple sized US-ICDs can be available for implantation, each one without a core member. Once the implantation procedure is being performed, then the correct sized US-ICD can be selected and the core member can be inserted into the US-ICD and them programmed as described above. Another advantage of this configuration is when the battery within the core member needs replacing it can be done without removing the entire US-ICD.

[0033] The US-ICD device of the present invention may be embodied in other specific forms without departing from the scope of the claims defining the invention. The described embodiments are therefore to be considered in all respects as illustrative and not restrictive, the invention being defined by the appended claims rather than by the foregoing description, and all changes which come within the wording the claims are therefore to be embraced therein.

Claims

1. A unitary subcutaneous implantable cardioverter-defibrillator comprising:

a long thin housing with a first and second ends that is curved in a shape of a patient's rib wherein the housing contains a source of electrical energy, a capacitor, and operational circuitry that senses the presence of potentially fatal heart rhythms;

cardioversion/defibrillation electrodes located at the ends of the housing;

means for delivering electrical cardioversion-defibrillation energy when the operational circuitry senses a potentially fatal heart rhythm; and

the absence of a transvenous, intracardic, epicardial, or subcutaneous electrode.

2. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy is equal to or greater than 800 Volts.

3. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy ranges from about 40 Joules to about 150 Joules.

4. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 further comprising at least two sensing electrodes located on the housing.

5. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 4 wherein the sensing electrodes are spaced apart by about 1 to about 10 cm.

6. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 5 wherein the first and second sensing electrodes are spaced apart by about 4 cm.

7. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 where in the operational circuitry can also sense the presence of bradycardia rhythm.

8. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 7 further comprising means for delivering cardiac pacing energy when the operational circuitry senses a bradycardia rhythm.

9. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry is programmable.

10. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can detect tachycardia.

11. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 10 further comprising means for delivering antitachycardia pacing when the operational circuitry senses a tachycardia rhythm.

12. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 10 wherein the ventricular tachycardia detected is greater than 240 beats per minute.

13. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can detect atrial tachycardia and atrial fi-

brillation.

14. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can induce ventricular tachycardia or ventricular fibrillation.

15. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 14 wherein the ventricular tachycardia or ventricular fibrillation is induced by shocks on the T wave.

16. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 14 wherein the ventricular tachycardia or ventricular fibrillation is induced by low direct current voltage applied during the entire cardiac cycle.

17. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 2 wherein the electrical cardioversion-defibrillating energy ranges from about 800 volts to about 2000 volts.

18. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy is delivered in a biphasic wave form.

19. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the capacitance is about 50 to about 200 micro farads.

20. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 where in the canister is malleable.

21. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is provided with at least one sensing electrode.

22. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is provided with one or more sensing electrodes, the subcutaneous electrode is provided with one or more sensing electrodes, and means for selecting two sensing electrodes from the sensing electrodes located on the canister and the sensing electrode located on the subcutaneous electrode that provide adequate QRS wave detection.

23. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy is delivered for about 10 to about 20 milliseconds total duration and with the initial positive phase containing approximately 2/3 of the energy delivered.

24. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry comprises an impedance detection for measuring the undulations in transthoracic impedance created during respiration.

25. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 24 wherein the operational circuitry can also measure the cardiac output using transthoracic impedance.

26. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 13 wherein the operational circuitry can deliver defibrillation energy to treat the detected atrial fibrillation.

27. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the housing ranges in length from about 15 to about 20 cm.

28. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the unitary subcutaneous implantable cardioverter-defibrillator is provided in different incremental sizes.

29. The unitary subcutaneous implantable cardioverter-defibrillator of Claim 1 further comprising a plug-in core member inside the housing of the unitary subcutaneous implantable cardioverter-defibrillator wherein the plug-in core member contains the source of electrical energy, the capacitor, and the operational circuitry.

Patentansprüche

1. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator, aufweisend: ein langes dünnes Gehäuse mit einem ersten und einem zweiten Ende, welches in Form einer Rippe eines Patienten gekrümmt ist, wobei das Gehäuse eine Quelle für elektrische Energie, einen Kondensator und einen Operationsschaltkreis aufweist, der die Anwesenheit von potentiell tödlichen Herzrhythmen erfasst, Elektroschock/Defibrillationselektroden, welche an den Enden des Gehäuses angeordnet sind, Mittel zum Liefern von elektrischer Elektroschock/Defibrillationsenergie, wenn der Operationsschaltkreis einen potenziell tödlichen Herzrhythmus erfasst, und die Abwesenheit von transvenösen, intrakardialen, epikardialen oder subkutanen Elektroden.

2. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei die elektrische Elektroschock/Defibrillationsenergie gleich oder größer als 800V ist.

3. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei die

elektrische Elektroschock/Defibrillationsenergie von etwa 40J bis etwa 150J reicht.

4. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, der ferner zumindest zwei Erfassungselektroden aufweist, die an dem Gehäuse angeordnet sind.

5. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 4, wobei die Erfassungselektroden etwa 1 bis etwa 10cm voneinander entfernt angeordnet sind.

6. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 5, wobei die erste und zweite Erfassungselektrode etwa 4cm voneinander entfernt liegen.

7. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Operationsschaltkreis auch die Anwesenheit von bradykardischen Rhythmen erfassen kann.

8. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 7, der ferner Mittel zum Liefern von herzschrittmacherstimulierender Energie aufweist, wenn der Operationsschaltkreis einen bradykardischen Rhythmus erfasst.

9. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Operationsschaltkreis programmierbar ist.

10. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Operationsschaltkreis Tachykardien erfassen kann.

11. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 10, der ferner Mittel zum Liefern von antitachykardischen Schrittmacherstimulierungen aufweist, wenn der Operationsschaltkreis einen tachykardischen Rhythmus erfasst.

12. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 10, wobei die erfasste ventrikuläre Tachykardie größer als 240 Schläge pro Minute ist.

13. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Operationsschaltkreis atrielle Tachykardie und atrielle Fibrillation erfassen kann.

14. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Operationsschaltkreis eine ventrikuläre Tachykardie oder ein ventrikuläres Flimmern induzieren kann.

15. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 14, wobei die ventrikuläre Tachykardie oder die ventrikuläre Fibrillation durch Schocks auf der T-Welle induziert werden.

16. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 14, wobei die ventrikuläre Tachykardie oder die ventrikuläre Fibrillation durch niedrige direkte Stromspannung induziert wird, die während des gesamten Herzzyklus angelegt wird.

17. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 2, wobei die elektrische Elektroschock/Defibrillationsenergie von etwa 800V bis etwa 2000V reicht.

18. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei die elektrische Elektroschock/Defibrillatinsenergie in einer zweiphasigen Wellenform abgegeben wird.

19. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei die Kapazität etwa 50 bis etwa 200mF ist.

20. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Behälter verformbar ist.

21. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Behälter mit zumindest einer Erfassungselektrode ausgestattet ist.

22. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Behälter ausgestattet ist mit einer oder mehreren Erfassungselektroden, wobei die subkutane Elektrode mit einer oder mehrerer Erfassungselektroden ausgestattet ist, und Mitteln zum Auswählen von zwei Erfassungselektroden von den Erfassungselektroden, die an dem Behälter angeordnet sind, und der Erfassungselektrode, die an der subkutanen Elektrode angeordnet ist, die eine angemessenen QRS Wellendetektion schaffen.

23. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei die elektrische Elektroschock/Defibrillationsenergie mit einer Gesamtdauer von etwa 10 bis etwa 20ms und einer initialen positiven Phase abgegeben wird, die annähernd 2/3 der gelieferten Energie enthält.

24. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der Operationsschaltkreis eine Impedanzdetektion zum Messen der Welligkeit in der transthorakalen Impedanz aufweist, die während der Atmung erzeugt wird.

25. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 24, wobei der Operationsschaltkreis auch die Herzleistung unter Verwendung der transthorakalen Impedanz messen kann.

26. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 13, wobei der Operationsschaltkreis Defibrillationsenergie liefern kann, um das detektierte Vorhofflimmern zu behandeln.

27. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei die Länge des Gehäuses in einem Bereich von etwa 15 bis etwa 20cm liegt.

28. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, wobei der kombinierte subkutane implantierbare Elektroschock/Defibrillator in unterschiedlich abgestuften Größen bereitgestellt ist.

29. Kombinierter subkutaner implantierbarer Elektroschock/Defibrillator nach Anspruch 1, der ferner ein Einsteck-Kernelement in dem Gehäuse des kombinierten subkutanen implantierbaren Elektroschock/Defibrillators aufweist, wobei das Einsteck-Kernelement die Quelle der elektrischen Energie, den Kondensator und den Operationsschaltkreis enthält.

Revendications

1. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée comprenant :

une gaine fine longue avec une première et une seconde extrémités qui est incurvée dans une forme de côte d'un patient dans lequel la gaine contient une source d'énergie électrique, un condensateur, et un circuit opérationnel qui détecte la présence de rythmes cardiaques qui peuvent être mortels ;
des électrodes de défibrillation/cardioversion placées aux extrémités de la gaine ;
un moyen pour distribuer de l'énergie électrique de défibrillation/cardioversion lorsque le circuit opérationnel détecte un rythme cardiaque qui peut être mortel ; et
l'absence d'une électrode transveineuse, intracardiaque, épicardique, ou sous-cutanée.

2. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée selon la revendication 1, dans lequel l'énergie électrique de défibrillation/cardioversion est égale ou supérieure à 800 Volts.

3. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel l'énergie électrique de défibrillation/cardioversion s'échelonne d'environ 40 Joules à environ 150 Joules.

4. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, comprenant en outre au moins deux électrodes de détection placées sur la gaine.

5. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 4, dans lequel les électrodes de détection sont espacées d'environ 1 à environ 10 cm.

6. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 5, dans lequel la première et la seconde électrode de détection sont espacées d'environ 4 cm.

7. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel le circuit opérationnel peut également détecter la présence de rythme bradycardique.

8. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 7, comprenant en outre un moyen pour distribuer une énergie de stimulation cardiaque lorsque le circuit opérationnel détecte un rythme bradycardique.

9. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel le circuit opérationnel est programmable.

10. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel le circuit opérationnel peut détecter une tachycardie.

11. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 10, comprenant en outre des

moyens pour délivrer une stimulation anti-tachycardique lorsque le circuit opérationnel détecte un rythme tachycardique.

12. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 10, dans lequel la tachycardie ventriculaire détectée est supérieure à 240 battements par minute.

13. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel le circuit opérationnel peut détecter une tachycardie auriculaire et une fibrillation auriculaire.

14. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel le circuit opérationnel peut déclencher une tachycardie ventriculaire ou une fibrillation ventriculaire.

15. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 14, dans lequel la tachycardie ventriculaire ou la fibrillation ventriculaire est déclenchée par des chocs sur l'onde T.

16. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 14, dans lequel la tachycardie ventriculaire ou la fibrillation ventriculaire est déclenchée par une tension à courant continu faible appliquée pendant le cycle cardiaque entier.

17. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 2, dans lequel l'énergie électrique de défibrillation/cardioversion s'échelonne d'environ 800 volts à environ 2000 volts.

18. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel l'énergie électrique de défibrillation/cardioversion est distribuée dans une forme d'onde biphasée.

19. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel la capacité est d'environ 50 à environ 200 microfarads.

20. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel l'absorbeur est malléable.

21. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel l'absorbeur est muni d'au moins une électrode de détection.

22. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel l'absorbeur est muni d'une ou de plusieurs électrode(s) de détection, l'électrode sous-cutanée est munie d'une ou de plusieurs électrode(s) de détection, et des moyens permettent de sélectionner deux électrodes de détection parmi les électrodes de détection placées sur l'absorbeur et l'électrode de détection placée sur l'électrode sous-cutanée qui fournissent une détection d'onde QRS appropriée.

23. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel l'énergie électrique de défibrillation/cardioversion est distribuée pendant une durée totale d'environ 10 à environ 20 millisecondes, la phase positive initiale contenant approximativement 2/3 de l'énergie distribuée.

24. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel le circuit opérationnel comprend une détection d'impédance pour mesurer les ondulations dans l'impédance transthoracique créée pendant la respiration.

25. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 24, dans lequel le circuit opérationnel peut également mesurer le débit cardiaque en utilisant l'impédance transthoracique.

26. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 13, dans lequel le circuit opérationnel peut distribuer une énergie de défibrillation pour traiter la fibrillation auriculaire détectée.

27. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel la gaine s'échelonne en longueur d'environ 15 à environ 20 cm.

28. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, dans lequel le système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée est fourni dans différentes tailles incrémentielles.

29. Système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée de la revendication 1, comprenant en outre un élément

principal enfichable à l'intérieur de la gaine du système monobloc de défibrillation-cardioversion pouvant être implanté de manière sous-cutanée dans lequel l'élément principal enfichable contient la source d'énergie électrique, le condensateur, et le circuit opérationnel.

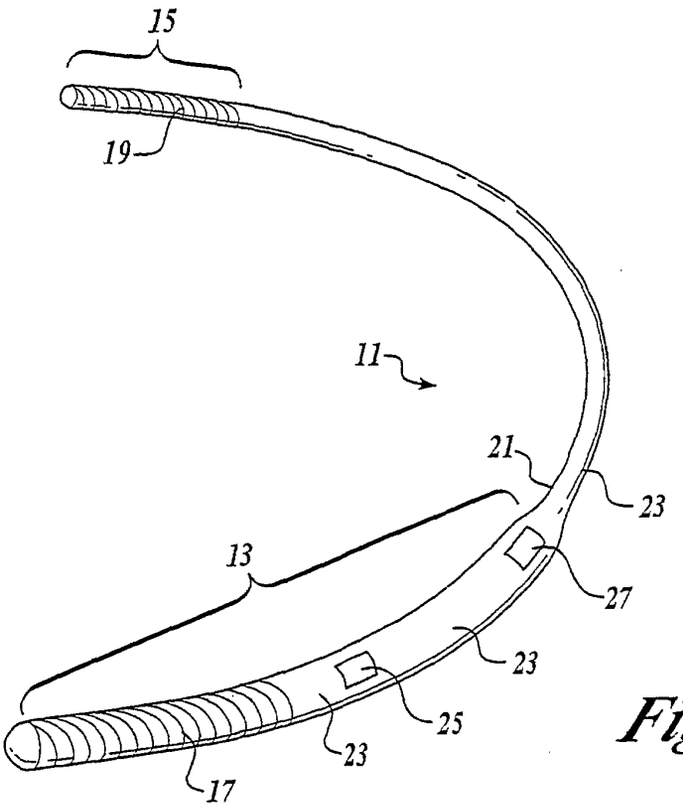

Fig.1

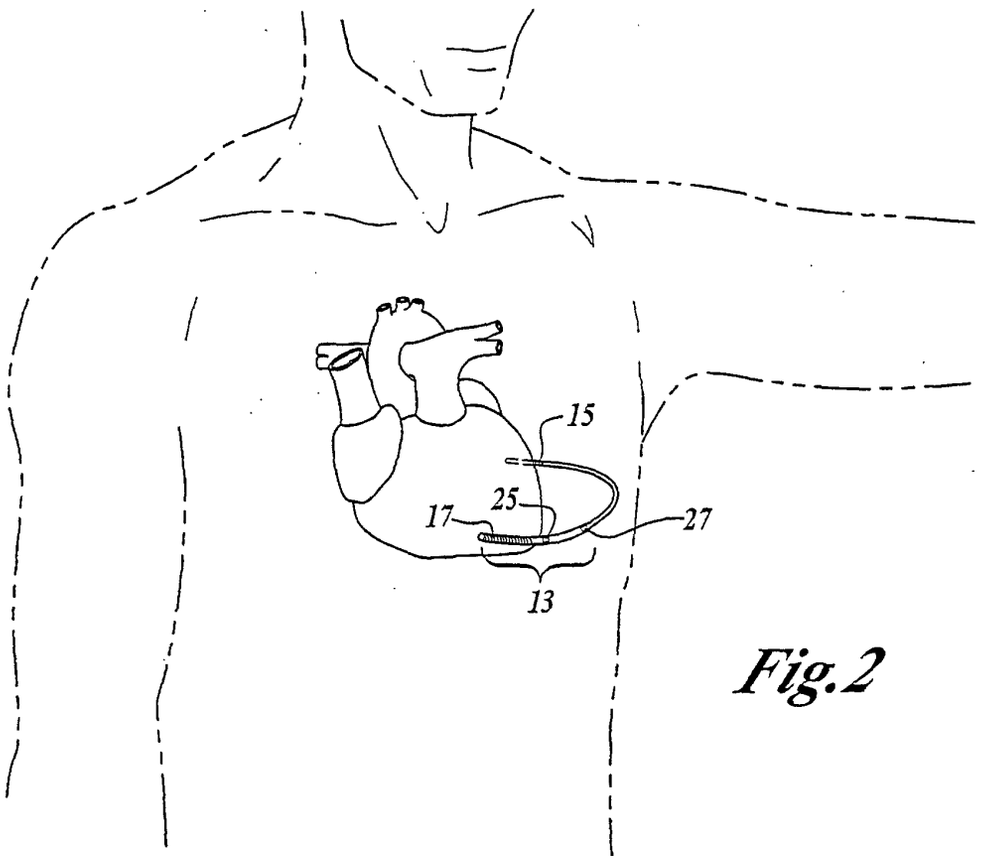

Fig.2

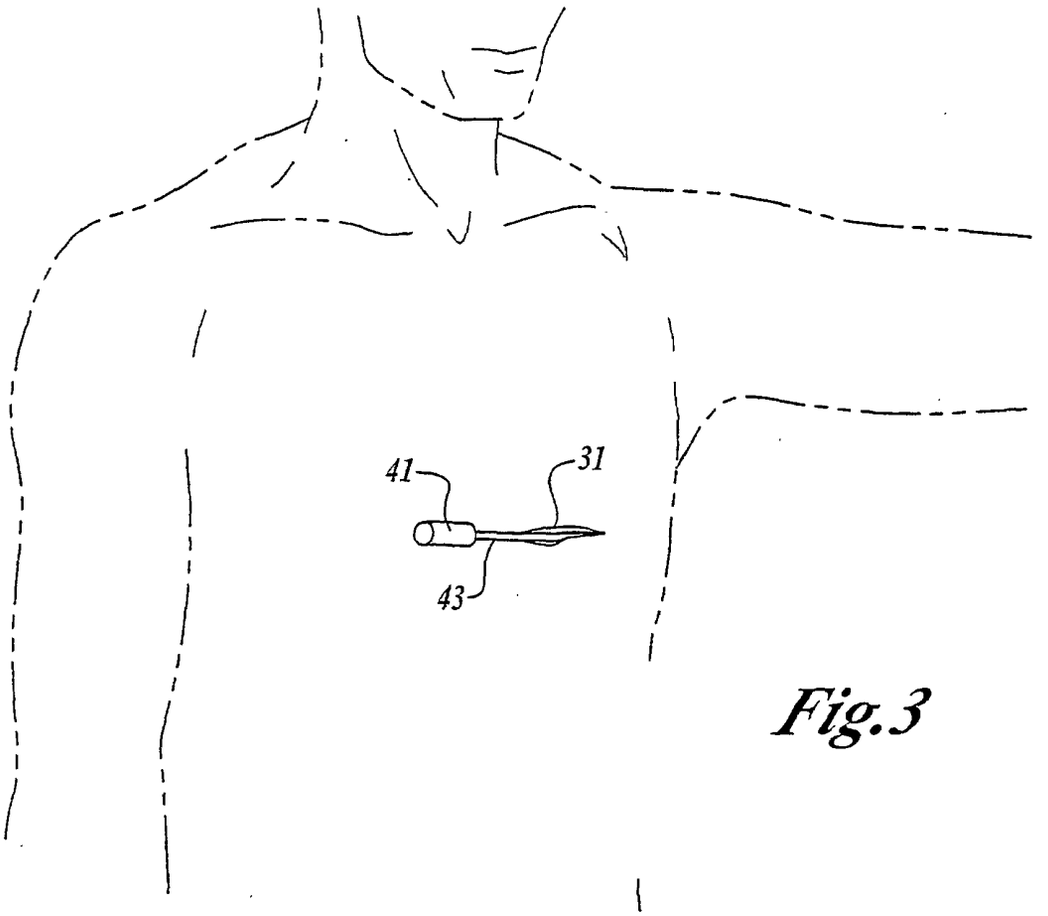

Fig.3

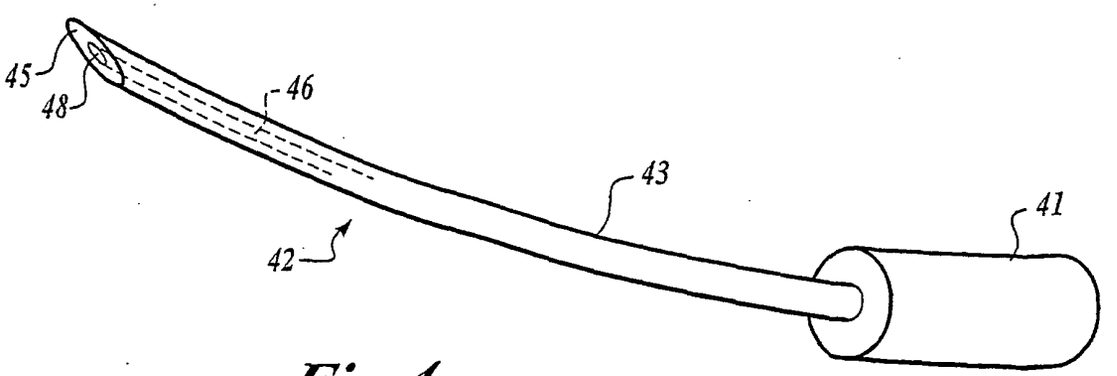

Fig.4

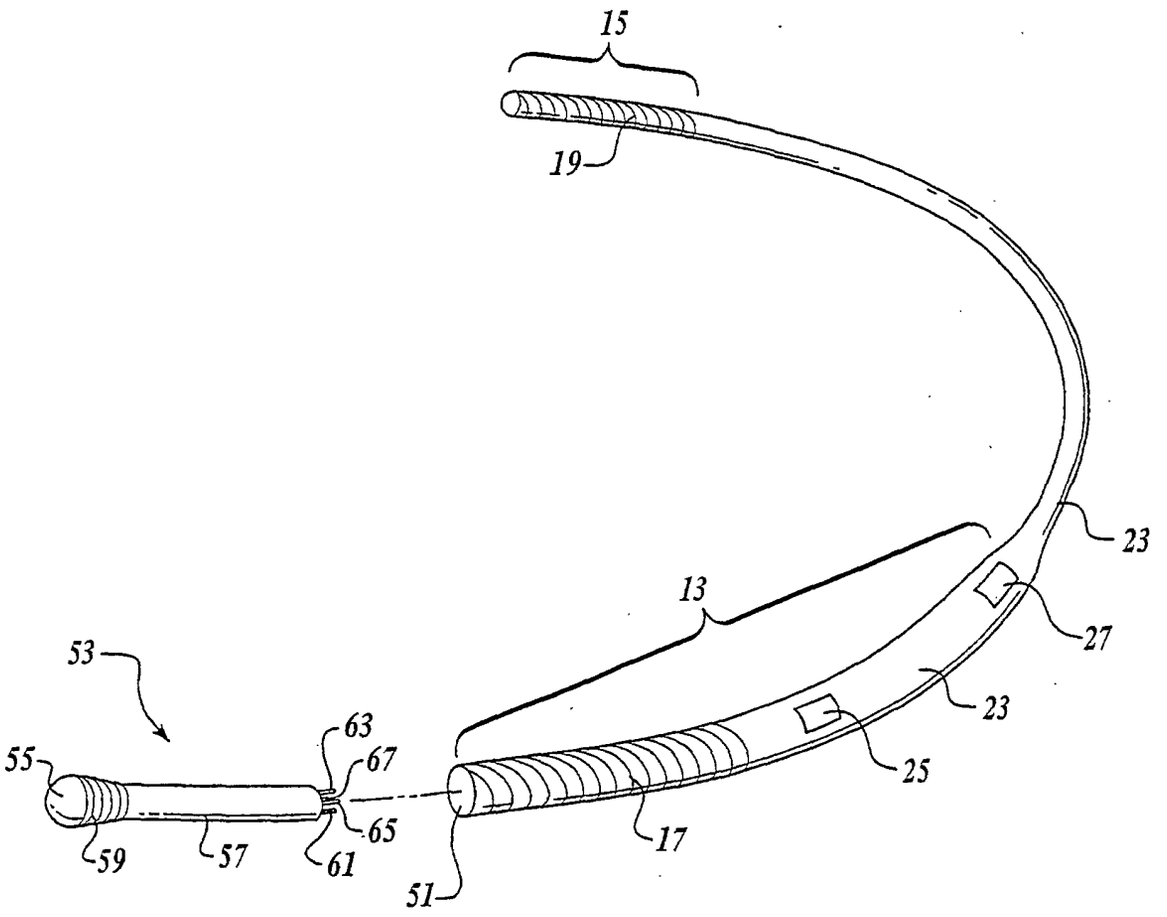

Fig. 5