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Muench

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[54] **PACING CATHETER WITH FRICTIONAL FIT LEAD ATTACHMENT**

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[52] **U.S. Cl.** ..... **128/404**, 128/419 P

[51] **Int. Cl.** **A61n 1/04**

[58] **Field of Search** ..... 128/404, 418, 419 P, 128/2.7 S

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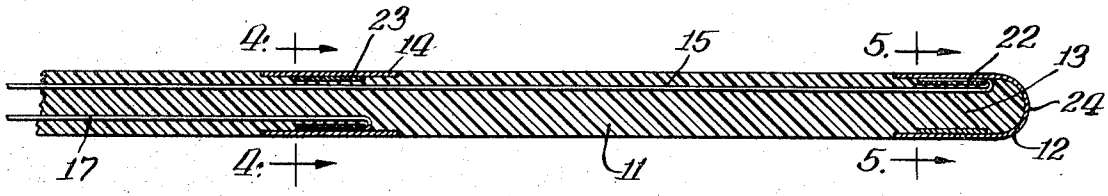
[57] **ABSTRACT**

A device for transvenous insertion such as for use in connection with transmitting electrical pulses in a heart pacer. The device comprises a catheter having highly flexible electrical conductors spaced apart therein connected to a pair of spaced electrodes at the distal end for delivering a pacing signal. The conductors are formed of stranded tantalum filaments of extremely small cross-section. The catheter may include an axial lumen through which blood pressure measurements may be taken as well as permitting extension of guide wires therethrough for guiding the catheter as during venous insertion. The device may comprise an extruded plastic element with the conductor wires being coextruded therein for facilitated manufacture.

6 Claims, 7 Drawing Figures



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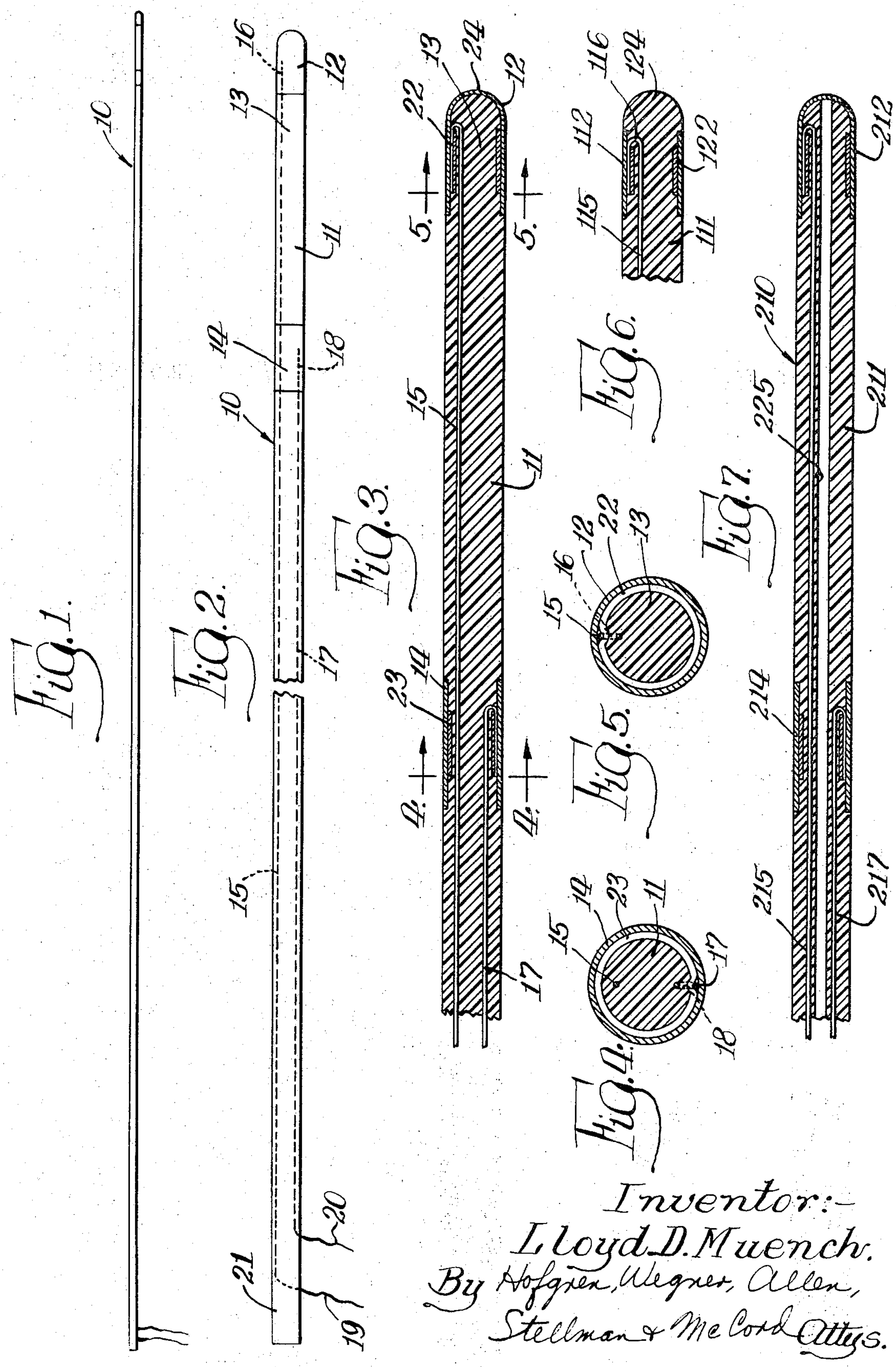

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PACING CATHETER WITH FRICTIONAL FIT LEAD ATTACHMENT

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to transvenous insertion devices and in particular to insertion devices suitable for use in connection with transmitting electrical pulses in heart pacers.

2. Description of the Prior Art

In the conventional heart pacer means, a pulse conducting element is provided in the form of an elongated flexible device which may be guided through a vein of the patient to dispose the distal end thereof in electrical connection association with the heart muscle. The proximal end of the device is connected to a voltage source, such as a battery, which may also be implanted in the patient's body. The voltage source includes means delivering time-spaced pulses to the heart muscle for suitably regulating, or pacing, the heart pumping action.

It is extremely important that the electrical conductors of the device remain unbroken notwithstanding the flexing thereof occurring in the use of the device. The device must be extremely small and flexible for transvenous insertion into the heart and for limited interference with the normal body functions. Further, the device must be resistant to effect by body fluids, and reversely, must be physiologically inert so as to not adversely affect the patient when implanted therein.

SUMMARY OF THE INVENTION

The present invention comprehends an improved electrical conductor device suitable for use as a pervenous heart pacing electrode, particularly for use in acute or emergency situations. The device comprises an elongated plastic catheter having a pair of electrical conductors extending from suitable leads at the proximal end to suitable spaced electrodes at the distal end. The conductors may comprise wires formed of stranded tantalum filaments having extremely small cross-section providing high flexibility. The catheter may be formed as a plastic extrusion with the wires being coextruded therein.

Since the catheter of this invention is intended for use primarily as an acute transvenous pacing catheter, as in an emergency wherein the catheter is fed to the heart through a vein and is used for only a relatively short period of time (e.g., 1 day to 3 weeks), extreme flexibility is essential so that the catheter may be fed into the vein and "floated" by the normal blood flow in the vein to the right vertical or atrium of the heart. It should also be noted, however, that this extreme flexibility also permits prolonged implantation in other than emergency situations providing a highly durable and break-resistant structure.

The catheter may be provided with an axial lumen for providing functioning in addition to the pacing function, as desired.

The distal electrode may comprise a cup-shaped element defining the leading tip of the catheter. Alternatively, the distal electrode may comprise a cylindrical electrode spaced rearwardly of a rounded tip of the plastic element.

The catheter may have a circular cross-section for facilitated transvenous insertion.

BRIEF DESCRIPTION OF THE DRAWING

Other features and advantages of the invention will be apparent from the following description taken in connection with the accompanying drawing wherein:

FIG. 1 is a side elevation of a pacing catheter embodying the invention;

FIG. 2 is a fragmentary enlarged side elevation thereof illustrating more clearly the electrical connections therein;

FIG. 3 is a fragmentary further enlarged diametric section of the distal end thereof;

FIG. 4 is a further enlarged transverse cross-section taken substantially along the line 4—4 of FIG. 3;

FIG. 5 is a further enlarged transverse cross-section taken substantially along the line 5—5 of FIG. 3;

FIG. 6 is a fragmentary diametric section of the distal end of a modified form of pacing catheter embodying the invention; and

FIG. 7 is a fragmentary diametric section of still another form of pacing catheter embodying the invention provided with an axial lumen.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the exemplary embodiment of the invention as disclosed in FIGS. 1–5 of the drawing, a bipolar transvenous pacing catheter generally designated **10** is shown to comprise an elongated element **11** formed of a flexible, electrically insulating material suitable for transvenous insertion. A first electrode **12** is provided at the distal end **13** of the elongated element, and a second electrode **14** is provided spaced rearwardly from electrode **12.** A first electrical conductor **15** is extended longitudinally through elongated element **11** to have the distal end **16** thereof electrically connected to electrode **12.** A second electrical conductor **17** is extended longitudinally through elongated element **11** to have the distal end **18** thereof electrically connected to electrode **14.** Conductor **15** includes an input lead portion **19** and conductor **17** includes an input lead portion **20** brought out from the element **11** at the proximal end **21** thereof. Suitable electrical connecting means may be provided at leads **19** and **20** and may be suitably color-coded for identification of the respective conductors **15** and **17.** Any suitable method of effecting the electrical connection may be employed as will be obvious to those skilled in the art.

Catheter **10** may have a suitable length for use in conducting electrical pulses from an external or implanted battery power source to the heart muscle of the patient. Thus, illustratively, the catheter may have a length of approximately 100 centimeters. Element **11** is preferably circular in outer cross-section and may have a diameter of approximately 0.05 inch for facilitated transvenous insertion. Element **11** is preferably formed of a physiologically inert material, such as silicone rubber. Other suitable flexible plastic materials, such as polyvinyl chloride, may be used, as will be obvious to those skilled in the art. Element **11** may be formed by extrusion and conductors **15** and **17** may be coextruded therewith for facilitated manufacture. Electrodes **12** and **14** may have axial lengths of approximately 3 mm. and may be spaced apart approximately 1 cm. at distal end **13** of element **11.**

Electrical conductors **15** and **17** comprise stranded wires of highly flexible, small diameter metal filaments.

The invention comprehends the provision of such wires formed of filaments having a diameter of under approximately 50 microns. Preferably, the filaments are twisted such as with a conventional twist of approximately 5 turns per inch. Illustratively, the electrical conductors may comprise 270 strands each of 12 micron filaments. An excellent filamentary material for such use comprises tantalum, although metals such as platinum, silver or stainless steel may also be used. The tantalum wires may be anodized such as with a 20 to 25 volt film.

As best seen in FIG. 3, the conductors 15 and 17 comprise stranded filament bundles, or wires, electrically connected to the respective electrodes 12 and 14 by means of crimp rings 22 and 23, respectively. The crimp rings are preferably similarly formed of tantalum and have a length approximately one-half the axial length of the electrodes. In effecting the connection of the wires to the electrodes, the ends 16 and 18 of the conductors are brought out from the element 11 at a point adjacent the distal end of the crimp ring. The conductor is then folded back toward the proximal end of the device. The electrode is then slipped over the lead and crimp ring to clamp the end of the conductor therebetween. For facilitated installation of the crimp ring on the element 11, the element may be axially stretched to reduce its cross-section permitting the crimp ring to be moved thereover to the desired position. Upon release of the element 11, the expansion thereof provides a snug arrangement of the crimp ring at the desired location. The electrode elements may be crimped about the crimp rings to provide maintained association thereof. Upon installation of the electrodes, the assembly may be dipped in a suitable adhesive material to fill the bores from which the conductors may be removed in bringing the ends 16 and 18 outwardly from element 11. As will be obvious to those skilled in the art, other suitable methods of connecting the electrodes to the conductors may be employed, such as welding, soldering, etc.

As best seen in FIG. 3, electrode 14 may comprise a tubular electrode. Electrode 12 may comprise a cup-shaped electrode defining a rounded distal tip 24.

As shown in FIG. 6, a modified form of distal electrode generally designated 112 is shown to comprise a tubular electrode similar to electrode 14 with the distal tip 124 of element 111 extending forwardly beyond the electrode 112 to define the leading end of the device. Thus, in the arrangement of FIG. 6, connection of conductor 115 to electrode 112 may be similar to the connection described above relative to electrode 14.

As indicated briefly above, the invention comprehends the provision of a tubular element in lieu of the solid cross-section element 11 when desired. Thus, as shown in FIG. 7, a pacing cathode generally designated 210 is shown to comprise a tubular elongated element 211 having embedded in the wall thereof electrical conductors 215 and 217 connected to electrodes 212 and 214 similarly as the connection of conductors 15 and 17 to electrodes 12 and 14 in catheter 10. Catheter 210 differs from catheter 10 solely in the provision of the axial lumen 225. In illustrating catheter 210, a cup-shaped distal electrode 212 is shown which effectively closes lumen 225, with a suitable opening or port being provided as desired along the length of the catheter. If desired, however, a cylindrical electrode, such as electrode 112 of FIG. 6, may be provided, permitting the lumen to be used for additional functions such as for use in making blood pressure measurements. Further, the lumen is adapted to accept guide wires and the like for guiding the catheter during the insertion process. Illustratively, where the lumen has a diameter of approximately 0.016 inch a 0.015 inch stainless steel stylet may be used therewith.

Thus, the disclosed catheters are extremely simple and economical of construction while yet providing a highly reliable pervenous or transvenous structure such as for use in electrically pacing a heart muscle. The catheters utilize extremely small diamater stranded filament tantalum wires permitting "floating" insertion into the heart and long trouble-free life notwithstanding the substantial flexing thereof occurring in such heart pacer use.

It should be understood that the present invention may also be used in those heart pacing procedures wherein a single electrode or unipolar device is inserted into the heart with the patient's body serving as a common electrical ground return between the heart and the power source. For use in applications such as this, only a single conductor would be extruded in the catheter and only a single distal electrode would be provided.

The foregoing disclosure of specific embodiments is illustrative of the broad inventive concepts comprehended by the invention.

I claim:

1. A transvenous pacing catheter comprising an elongate element formed of a flexible, electrically insulating material suitable for transvenous insertion, a tubular metal member surrounding a distal end portion of said element in tight frictional engagement, a tubular electrode surrounding said metal member in generally concentric relation therewith, and a stranded bundle of metal filaments each having a diameter under approximately 50 microns and defining an electrical conductor embedded in said element and extending from a proximal end portion toward the distal end portion thereof, said conductor having a distal end portion emerging from said element and extending between said metal member and said electrode in tight frictional engagement therebetween to provide a current conductive connection between said electrode and the proximal end portion of said conductor.

2. The transvenous pacing catheter of claim 1 wherein said metal member has a radially inwardly deformed portion receiving the distal end portion of said conductor.

3. The transvenous pacing catheter according to claim 1 wherein the distal end portion of said conductor emerges from said element at a location distally of said metal member and extends toward the proximal end portion of said element.

4. The transvenous pacing catheter of claim 1 further including a second tubular metal member surrounding the distal end portion of said element in tight frictional engagement and in axially spaced relation from said electrode, a second electrode having a tubular portion surrounding said second metal member in generally concentric relation therewith, and a second stranded bundle of metal filaments each having a diameter under approximately 50 microns and defining a second electrical conductor embedded in said element and extending from the proximal end portion toward the distal end portion thereof, said second conductor emerging from said element and extending between said second metal

member and said tubular portion of said second electrode in tight frictional engagement therebetween to provide a current conductive connection between said second electrode and the proximal end portion of said second conductor.

5. The transvenous pacing catheter of claim 4 wherein the distal end portion of said second conductor emerges from said element at a location distally of said second metal member and extends toward the proximal end of said element.

6. The transvenous pacing catheter of claim 5 wherein said second electrode is generally cup-shaped with an outer substantially rounded distal end defining the distal tip of the catheter.

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