Dec. 17, 1968 D. C. FISHER ET AL 3,416,533

CONDUCTIVE CATHETER

Filed May 20, 1966

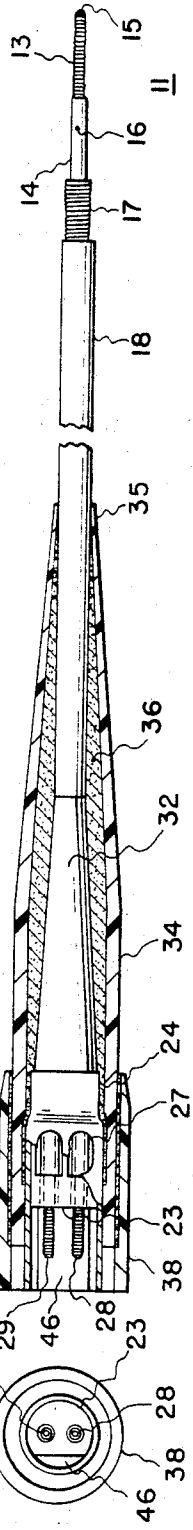

FIG. 1

FIG. 2

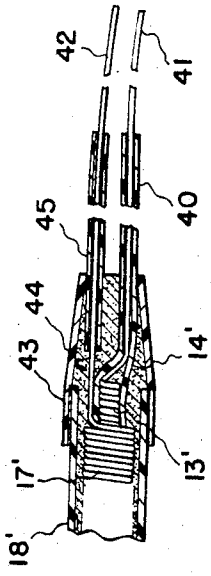

FIG. 4

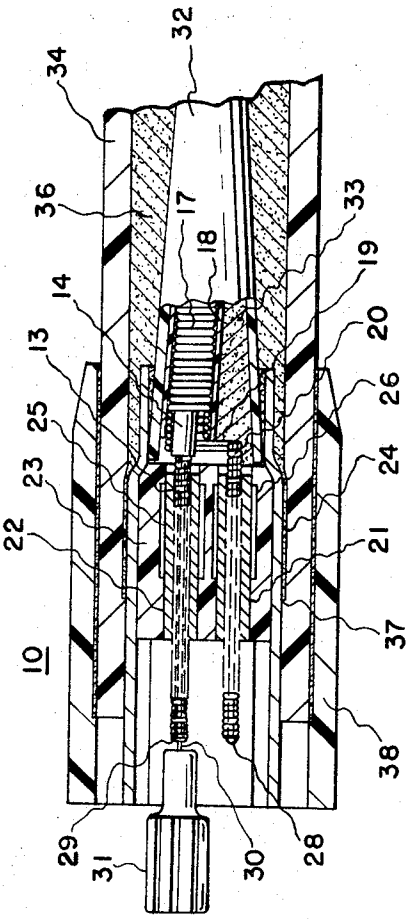

FIG. 3

INVENTORS
DAVID C. FISHER
HENRY J. CZECH
BY Ralph G. Hohenfeldt
ATTORNEY

United States Patent Office 3,416,533
Patented Dec. 17, 1968

3,416,533

CONDUCTIVE CATHETER

David C. Fisher, Brookfield, and Henry J. Czech, Milwaukee, Wis., assignors to General Electric Company, a corporation of New York

Filed May 20, 1966, Ser. No. 551,686
5 Claims. (Cl. 128—404)

ABSTRACT OF THE DISCLOSURE

A flexible wire helix is insulated and inserted coaxially in another helix. Corresponding uninsulated distal ends of the helices serve as spaced electrodes for passing current to the heart. The opposite proximal end of the helices are stiffened and serve as pins in a connector that may join a mating connector on an electric heart stimulator. A removable stylet may be inserted in the small helix through its hollow connector pin for stiffening the conductor as it is being directed to its destination.

This invention pertains to a conductive catheter or electrode assembly for connecting an electric stimulator to an internal organ of a body. A typical use of the catheter is to connect an implanted electronic cardiac stimulator to the heart of a patient.

One version of the new catheter is adapted for being advanced transvenously, such as through the jugular vein, until its distal end, which comprises electrodes, reaches the interior of the right ventricle of the patient's heart. The proximal end of the catheter that extends outside the vein terminates in an electric connector which may be joined with a stimulator power supply. The latter is often implanted subcutaneously in the axillary region and, of course, concealed by tissue as is the catheter itself.

The foregoing procedure has been practiced with available types of conductive catheters to eliminate open-chest surgery which is required when the stimulator leads are attached to the myocardium by way of the exterior of the heart. However, prior art catheters have not been completely satisfactory for several reasons. Among them is that, after repeated flexures, they undergo electrical discontinuities too frequently. Their cross-section is unduly large as a result of the conductors and insulation running side-by-side. Their electrode tips are stiff at the distal end and are inclined to perforate the interior of the heart. Besides, the tips are vulnerable to falling off the patient's heart.

Accordingly, objects of the present invention are to provide a conductive catheter: that is reliable and durable; that has coaxial conductors and insulation for reducing the size; that has continuous current paths from end to end without junctions that may open or tips that may separate; that is unusually flexible over its length including the unitary tip that constitutes its distal electrodes or terminals; and, that is adapted to be stiffened with a removable stylet for facilitating passing it along a devious route to its destination in the heart. Another object of the invention is to provide a new type of conductive catheter, the basic features of which can be used for electrodes that are adapted to connect to the exterior of an organ.

In general terms, the new conductive catheter comprises a small diameter, but relatively long, helical wire spring that is in an insulating tube and surrounded by an outer helical wire spring which is also insulated with a flexible outside tube, although the latter may be omitted in some cases. At the proximal end, the center helix continues directly through an insulating part of an electrical connector to form one prong of a two prong connector plug. An extension of the larger outside helical spring is wound on a mandrel of such size that its outside diameter is essentially that of the inside coil. This extension portion

is off-set and projects through the insulator as the other prong of the connector. Both prongs are suitably stiffened. At the distal end, the inside helical spring extends from its tubular insulating cover to form a soft and flexible electrode tip. The outside helcal spring has near the distal end, a short uninsulated portion exposed to act as the other electrode. The two electrodes are spaced axially to form a gap across which electric current may be conducted by blood or contacting tissue to stimulate the heart. The inside helix is stiffened with a small internal tube over the region forming the prong at the connector end. The tube permits passing a stylet wire into the catheter through the prong end to stiffen it and thereby facilitate passing it through the veins.

In an alternative embodiment, the distal end comprises two insulated wires that may be provided with surgical needles for suturing them directly into the exterior surface of the myocardium or other tissue. In either case, the conductive paths through the helices each constitute one continuous wire conductor from the point of contact with the organ at the distal end to the tips of the connector prongs at the proximal end.

Embodiments of the invention will now be described in more detail in reference to the drawing in which:

FIGURE 1 is a plan view of the new conductive catheter assembly with some parts in cross-section;

FIGURE 2 is a view taken from the left end of the catheter connector shown in FIGURE 1;

FIGURE 3 is an enlarged cross-section of the proximal or connector end of the catheter; and,

FIGURE 4 shows in cross-section the distal end of a conductor as modified for making a relatively permanent attachment to the exterior of an organ.

Referring to FIGURE 1, the proximal end is designated by the reference numeral **10** and the distal end is generally designated by the reference numeral **11**. At the distal end **11**, one may see that the catheter comprises an inside helical coil spring **13** which may be wound on a small mandrel and covered with a pliable insulating tube **14** which is preferably body-compatible silicone rubber. Some silicone rubber adhesive may be introduced in the end **15** of the catheter tip to seal and round it off. The adhesive may be allowed to flow inwardly to approximately the point **16**.

An outside helical spring **17** is wound independently and covered with a silicone rubber tube **18** and then the smaller helix is slid axially through the larger to form the coaxial catheter assembly. The uninsulated or bare regions of the helical wire springs **13** and **17** as seen in FIGURE 1 are about three-eighths of an inch long and constitute the electrodes or terminals through which current is conducted to the organ. Of course, silicone rubber, or other body-compatible, insulating coatings may be applied to the helices in place of silicone rubber tubes **14** and **18** to serve as an insulating layer.

Termination of the helical springs at the proximal end **10** of the catheter may be seen best in FIGURE 3 to which attention is invited. This figure shows the outside insulating tube **18** ending near the end of outside helix **17**. The outside helix **17** may be wound of two wires in parallel as can be seen by the continuation of helix **17** that extends radially and is identified by the reference numeral **19**. These parallel wires are wound on a smaller mandrel and are offset as shown to form the helical connector prong **20**. Winding of the outer helical spring **17** with two or more wires results in parallel paths of lower resistivity and provides some redundancy and, therefore, insurance against open-circuiting if one of the wires breaks in the region of continuation **19**. Of course, the inside helix may also be wound with two or more wires to secure the same advantages of parallel circuits.

The inside helical spring **13** is not off-set but continues straight along the axis of the outside spring to form the

other prong of the connector plug. Spring **13** and the extension **20** of spring **17**, constituting the connector prongs, have equal outside diameters.

The prong **20** extending from spring **17** and the prong formed by helical spring **13** each pass through metal tubes **21** and **22**, respectively, which are molded in an insulator **23**. A tubular metal shell **24**, which is preferably gold-plated, surrounds the insulator **23**. The latter has some through-holes **25** and **26** to enable the jaws of a staking tool, not shown, to enter for crimping tubes **21** and **22** and thereby secure the prongs. Tubes **21** and **22** are also preferably gold-plated. Metal shell **24** has pairs of diametrically opposite holes **27** for admitting the jaws of the staking tool as can be seen in FIGURE 1. Insulator **23** has an integral extension **46** which is flat on one side and curved on the other, as may be seen in FIG. 2. This extension registers with a cavity in the mating part of the connector, not shown, to assure that the polarity of the catheter conductors is always the same.

Prior to crimping tube **21** on prong **20**, the latter has inserted from its end a headed pin or nail **28**. This pin **28** becomes a permanent part of prong **20** for stiffening it. The pin **28** should be substantially equal to the length of the prong **20**. Before inserting headed pin **28** in the helcal wire prong **20**, a small ring of gold, not shown, may be slid over the shank of the pin to abut the head. The prong may then be heated in a suitable furnace to flow the gold and effect a braze between the helical wire and the pin to smooth the prong, coat it with gold for corrosion resistance, and preclude unwinding of the helical wire.

Before crimping metal tube **25** on the other prong formed by inside helix **13**, a flanged tube **29** is inserted endwise of helix **13**. The flanged tube may also have a gold ring applied and treated in the manner just described and for the same purposes. Then an oversized wire, not shown, is passed into flanged tube **29** so as to maintain its internal diameter when tube **25** is crimped on helix **13**. After crimping, the wire is withdrawn. This leaves an internal diameter large enough for a stylet wire **30** to pass through freely. The stylet wire **30** is made of stiff spring steel and is long enough to extend through the catheter to approximately the point **16** at the distal end, see FIGURE 1. The stylet wire **30** is provided with a knob **31** to facilitate admission and withdrawal after the catheter distal end **11** is guided to its destination. When the stylet is in, the catheter may be bent slightly near its distal end and the bend will stay because the stylet takes a permanent set. Thus, turning the stylet when passing the catheter in results in the distal end swinging around so that it may be steered through sharp bends in the blood vessel.

The insulated coaxial springs are re-inforced and stiffened somewhat by a conical sleeve **32** which may be polyethylene or some other material that is more stiff than silicone rubber. This cone extends into metal connector shell **24** and butts against connector insulator **23**, as can be seen clearly in FIGURE 3. The cavity inside of cone **32** is filled with silicone rubber adhesive **33** to impart desired electrical and mechanical properties.

A silicone rubber re-inforcing sleeve **34** is slipped over the assembly after which its tapered end **35** is spread away from outside insulating tube **18** to admit the tip of a hypodermic needle for introducing some self-curing silicone rubber **36**, see FIGURE 1. The silicone rubber adhesive **36** flows into all the cavities as may be seen by inspection of FIGURE 3.

Adhesive is applied over most of the interface between the inside of sleeve **34** and the outside of metal connector shell **24**, except that in a region from the left end of metal shell **24** as seen in FIGURE 3 to a point approximately at **37**, there is no adhesive, so that cone **34** may expand radially to form a seal when the connector is introduced into its mating part, not shown. Further radial sealing pressure is developed by an external silicone rubber re-inforcing tube **38** which preferably has medical grade silicone adhesive between it and cone **34** which it surrounds.

Either or both helical wire springs **13** and **17** may be wound with a single wire, or preferably, a number of wires to provide parallel paths for lower electrical resistance and an alternative conductive path in the event that one of the wires should break after extended service. The wire used in a commercial embodiment is a composite of wires known as drawn, brazed strand. This wire comprises a central pure silver filament surrounded by six stainless filaments which are silver coated and brazed to the central filament. The composite is then drawn to the desired size which is preferably five to nine thousandth's of an inch inside wire diameter. In one practical case, the outside diameter of inside helical spring **13** is about 0.040 inch and the outside diameter of outside helical spring **17** is about 0.070 inch. The silicone rubber tubes **14** and **18** have a wall thickness of 0.010 inch. Thus, the outside diameter of the conductive catheter may be under one-tenth of an inch or even smaller if the outside insulating tube **18** is omitted.

An alternative form of distal end for attaching the conductor assembly to the exterior of an organ is shown in FIGURE 4. The inside helix **13'** is wound on a mandrel and covered with an insulating tube **14'**. The end of the tube **14'** has a reduced diameter portion **40** which surrounds the end of the wire from the helix **13'** which is brought straight out as shown. The wire may be sealed into reduced diameter portion **40** with self-curing silicone adhesive. A surgical needle, not shown, may be attached to the end of the wire beyond the point marked **41** for facilitating suturing the conductor to the organ. The other conductor **42** is an extension of outside helical spring **17'** which is wound in the manner described in connection with the FIGURE 1 embodiment, and insulated with a concentric silicone rubber tube **18'**. A flexible reinforcing cone **43** is provided and self-curing silicone rubber adhesive **44** may be admitted to its interior to seal off the end of the assembly, provide electrical insulation, and secure the insulating extensions **40** and **45** which surround the conductors **41** and **42**. The conductor **42** may also be provided with a surgical needle, not shown. The proximal end of the conductive leads whose distal end is shown in FIGURE 4 may be the same as proximal end **10** in FIGURE 1.

In the FIGURE 4 example, the helices may be wound out of a cable instead of a single one of the silver coated, drawn and brazed wires described earlier. In other words, several small wires of this kind may be twisted into strands and the strands twisted into a cable which is wound as a helix. The individual wires are preferably 0.005 inch in diameter or smaller when they are to be formed into cable. Thus, the electrode wires **41** and **42** will be more flexible when they are cables and they will be less likely to break or impose any restraint on the heart when they are sutured into the myocardium. Of course, the helices may be wound from cable in the FIGURE 1 embodiment too. In any case, however, the ends of the cable has to be brazed or soldered to prevent fraying. In this specification, for convenience, the conductor out of which the helices are wound has been called wire, but that term is to be interpreted broadly to cover wire in its usual sense and cable as well.

In summary, there has been described a coaxial conductor catheter that has a tip at its distal end made of a spring section that is very flexible, easy to pass through bends and unlikely to perforate the wall of an organ from the interior. The distal tip is joined by a continuous helically wound wire to the connector prong at the proximal end of the catheter. There are no electrical or mechanical discontinuities. The other electrode near the distal end, is similarly without discontinuities all the way to the end of the other prong at the proximal end. Desired stiffness may be imparted to the catheter by the stylet which is admitted through one of the prongs and passes down the center of the internal helical spring. The assembly is internally sealed so that it will not pass

fluid from end to end. The overall outside diameter is minimal because of the coaxial arrangement of the conductor.

Although embodiments of the invention have been described in considerable detail, such description is to be considered illustrative rather than limiting, for the invention may be variously embodied and is to be limited in scope only by construction of the claims which follow.

It is claimed:

1. A conductive catheter comprising:
(a) a first wire helix that has proximal and distal ends,
(b) a second wire helix that has proximal and distal ends and that surrounds the first helix substantially coextensive with its length,
(c) a flexible insulating layer disposed between the helices with the distal end of the first helix extending from the layer, whereby an interelectrode gap is formed between the distal ends of the helices,
(d) an insulator,
(e) the proximal end of the first wire helix projecting through the insulator in line with the first helix to form a first electrical connector prong,
(f) the wire of the second helix being offset and formed in a continuous helix extension that projects through the insulator as a second electrical connector prong which is substantially parallel to the first prong.

2. The invention set forth in claim 1 including:
(a) a tube means extending into said first connector prong, said tube means defining a passageway for admitting a stylet to the inside of the first wire helix.

3. The invention set forth in claim 1 including:
(a) a pin extending into said second connector prong to stiffen said prong.

4. A body organ electrode assembly comprising:
(a) a first wire helix and a first tubular insulating layer surrounding the same,
(b) a second wire helix and a second tubular insulating layer surrounding the same,
(c) the first helix and first insulating layer being inside of and coaxial with the second helix,
(d) a distal end portion of the wire of each helix being nonhelical and extending away from the helices in the general direction of their common axis to form individual organ attaching means,
(e) insulation on a section of each wire distal end portion,
(f) a seal between the insulation on the sections and said insulation layers.
(g) an insulator,
(h) the proximal end of the first wire helix projecting through said insulator to form a first electrical connector prong,

(i) the wire of the second helix being offset at its proximal end and formed in a continuous helix extension that projects through the insulator as a second electrical connector prong which is substantially parallel to the first prong.

5. A conductive catheter comprising:
(a) a first wire helix that has proximal and distal ends,
(b) a first silicone rubber insulating tube surrounding said first helix over most of its length except for a short bare region at its distal tip and another short region at its proximal end,
(c) a second wire helix that has proximal and distal ends and that surrounds said first insulating tube coaxially,
(d) a second silicone rubber insulating tube that surrounds said second helix from its proximal end to near its distal end, whereby an uncovered part of the second helix may serve as an electrode that is spaced from the bare region at the distal end of the first wire helix,
(e) an insulator at the proximal ends of said helices,
(f) a metal shell around said insulator,
(g) a pair of metal tubes extending through said insulator,
(h) the proximal end of the first wire helix extending directly through one tube to serve as a connector prong,
(i) the proximal end of the second wire helic terminating in a helical portion of smaller diameter than the second helix, which portion is formed continuously with the wire of the second helix,
(j) the smaller helical portion being offset in parallelism with the second helix and extended through the other tube to form another connector prong.
(k) a silicone rubber sleeve extending over part of the metal shell and part of the second silicone rubber insulating tube, and
(l) silicone rubber adhesive inside the sleeve for sealing the interior thereof.

References Cited

UNITED STATES PATENTS

301,417	7/1884	Wilkinson	174—47 X
2,949,910	8/1960	Brown et al.	128—2.5
3,333,045	7/1967	Fisher et al.	128—416 X
3,348,548	10/1967	Chardack	128—418

WILLIAM E. KAMM, *Primary Examiner.*

U.S. Cl. X.R.

174—28