Nov. 9, 1965 W. M. CHARDACK 3,216,424

ELECTRODE AND LEAD

Filed Feb. 5, 1962

Fig.1.

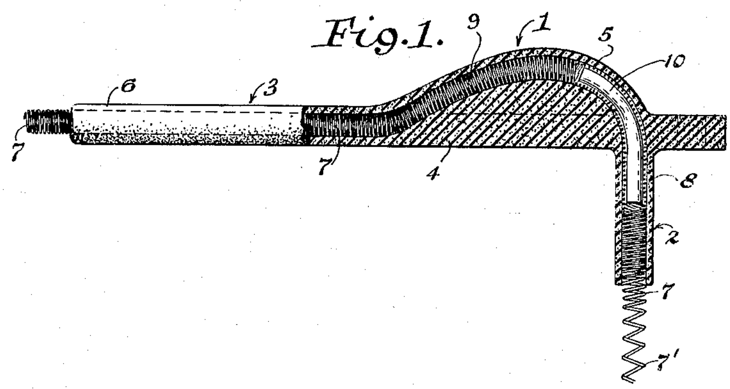


Fig.2.

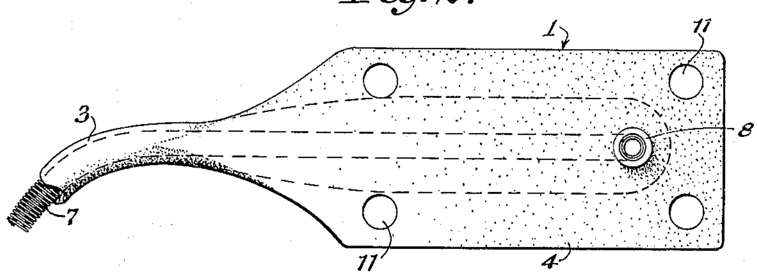
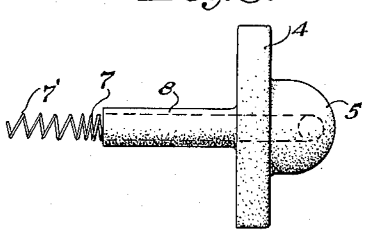


Fig.3.



INVENTOR.
WILLIAM M. CHARDACK

United States Patent Office

3,216,424
Patented Nov. 9, 1965

1

3,216,424
ELECTRODE AND LEAD
William M. Chardack, 144 Ivyhurst Road, Buffalo, N.Y.
Filed Feb. 5, 1962, Ser. No. 171,189
5 Claims. (Cl. 128—418)

This invention relates generally to the electrical arts, and more specifically to a new and useful electrode and lead. The electrode and lead of this invention were originally developed for implantation within the human body, but they are not by any means limited to such use.

In certain cases of heart disease the impulses which normally elicit contraction of the cardiac ventricle are blocked. This leads to an abnormally low heart rate severely restricting the patient's activities. Episodes of complete arrest occur in this condition leading to loss of consciousness which may terminate fatally. In some patients, the condition cannot be controlled short of electrical stimulation of the heart. A number of devices, known as "pacemakers" have been developed for this purpose. They provide a suitable stimulating current pulse. Some of these devices are external, some are suitable for complete implantation within the body, and some are partly external and operate by induction through the intact skin through a subcutaneously buried coil. In all cases, however, the impulse ultimately travels to the heart muscle by an electrode and its leads, either from an external pacemaker through the skin and deeper tissue to the heart muscle or from a subcutaneously implanted pacemaker or an induction coil to the heart. In all these arrangements, a high incidence of electrode failure has occurred and has been the principal obstacle to long-term electrical stimulation of the heart.

The provision of an electrode suitable for implanting in the heart muscle presents a severe problem, because of the varied motions which must be accommodated. The primary requirement of such an electrode, and connecting lead, are that they be flex-resistant to a high degree. That is to say, they must be capable of withstanding constantly, rapidly repeated flexing over a long period of time. For example, if the heart is stimulated once each second, there will be 60 flexing actions each minute, or more than 30 million flexing actions each year. The conductor and its insulation must be capable of withstanding repeated lateral and axial flexing on this order, without failure-producing fatigue. In addition, they must be able to withstand momentary elongation, such as produced by movement of the chest cavity during respiration, and by body motion as when bending, stretching, and the like, as well as by motion of the heart. Also, when implanted in a youth whose body size will increase, the electrode and lead must be capable of accommodating such growth.

Accordingly, the primary object of my invention is to provide an electrode and lead capable of withstanding the above-designated forces over a period of years.

In one aspect thereof, a flex-resistant lead of my invention is characterized by the provision of a coil of electrically conductive material wound along an axis, and a body of electrically insulating material enclosing the coil, the insulating body precluding entry between adjacent convolutions of the coil, and the coil being extensible along its axis.

In another aspect thereof, a flex-resistant lead of my invention is characterized by the provision of a sleeve of electrically insulating material, and a coiled wire of electrically conductive material wound along the axis of the sleeve, the wire being encased within the sleeve and movable relative thereto along its axis.

In still another aspect thereof, a flex-resistant lead and electrode of my invention is characterized by the

2

provision of a coiled wire of electrically conductive material wound along an axis, and a sleeve of electrically insulating material surrounding the coiled wire, the wire being extensible along its axis, independently of the sleeve, and extending beyond the sleeve at one end thereof, the extension of the coiled wire beyond the sleeve forming an electrode.

In yet another aspect thereof, an electrode constructed in accordance with my invention is characterized by the provision of a body of electrically insulating material, a sleeve of electrically insulating material projecting from the body, and a coiled conductor encased within the body and including a spike portion extending through the sleeve and projecting therebeyond.

The foregoing and other objects, advantages and characterizing features of the electrode and lead of my invention will become clearly apparent from the ensuing detailed description of an illustrative, presently preferred embodiment thereof, taken in conjunction with the accompanying drawing illustrating the same wherein like reference numerals denote like parts throughout the various views and wherein:

FIG. 1 is a longitudinal, sectional view through an electrode of my invention, the electrode lead being broken away for convenience in illustration and part of the conductor coil being shown in section to show the internal stabilizing core;

FIG. 2 is a bottom plan view thereof; and

FIG. 3 is an end elevational view thereof.

Referring now in detail to the illustrative embodiment of my invention depicted in the accompanying drawing, there is shown an electrode, generally designated **1**, carrying a spike **2** adapted to penetrate the heart muscle, and having a lead **3** adapted for connection to an impulse generator, not shown. The body of electrode **1** comprises a normally, generally flat base plate **4**, and a raised, dome-shaped housing **5** on one face of base **4**. Lead **3** comprises a tubular sleeve **6** of cylindrical wall form, enclosing a wire conductor **7** in the form of a coiled spring spirally wound about and along the axis of sleeve **6**. Spike **2** includes a sleeve **8** which projects from the opposite face of the base plate **4** adjacent one end thereof, at generally a right angle thereto.

Lead **3** projects from the end of base **4** opposite the spike end, substantially in the plane of base plate **4**. Coiled conductor **7** extends through both spike **2** and lead **3**, and therefore must turn 90° in the body of electrode **1**. To accomplish this with minimum strain, the conductor **7** is curved upwardly from lead **3** and then downwardly to spike **2**, following the contour of housing **5**, thereby providing an upwardly bowed, smoothly curved conductor portion **9** interconnecting the lead portion of conductor **7** and the spike portion thereof.

Conductor **7** passes through the body of electrode **1**, and is rigidly embedded therein whereby it can be anchored at that point to the heart wall. Conductor **7** continues downwardly, through spike sleeve **8** and therebeyond, and the terminal portion **7'** of conductor **7** is distinguished by a relatively open coil construction.

Conductor **7** is formed of an electrically conductive material offering low electrical resistance, such as for example a platinum-iridium alloy. Such alloy can comprise 90 percent platinum and 10 percent iridium, with the iridium being included for added springiness. This material meets the added requirement, for use in the human body, that it be resistant to corrosion by body fluids. Base **4** and housing **5** of the electrode body, along with sleeves **6** and **8**, are formed of an electrically insulating material, such as a silicone rubber. This material also meets the added requirement, for use within the human body, that it be a material to which body tissue does not adhere. While there is a degree of friction, or stiction between the silastic rubber material and body tissue, there is no true adherence and it is possible to draw the silicone rubber freely through body tissue without tearing the tissue, with only a very slight amount of resistance being felt.

Of particular significance in this construction is the coiled spring form of conductor **7**. The coils are wound relatively tightly to provide a maximum number of turns per unit length and thereby provide optimum strain distribution. However, there can be a slight space between the turns, as illustrated. This spirally coiled spring construction is essential, because it also permits a substantial degree of elongation within the elastic limits of the material as well as distribution along the conductor of flexing stresses which otherwise might be concentrated at a particular point. This strain distributing action is enhanced by another highly significant characteristic of my invention, comprising the freedom of movement of the coiled conductor **7** within the insulating sleeves **6** and **8**. While the conductor **7** is fixed within the body **4, 5** of electrode **1**, it is free to move slightly within the spike sleeve **8**, and very freely within the lead sleeve **3**, whereby neither conductor nor sleeve is limited, in its flex accommodation, by the properties of the other. Both sleeves **6** and **8** are elastic, as is conductor **7**, and this together with the fredom of movement therebetween assures maximum distribution of flexing strains. Sleeve **6** also serves to prevent growth of tissue between convolutions of conductor **7**, which would anchor the conductor and inhibit its intended freedom of movement.

If spike sleeve **8** and the enclosed conductor **7** were permitted to flex at their juncture with base **4**, there would be a tendency toward stress concentration at the juncture. This danger is eliminated, with my invention, by the inclusion of a stabilizing core **10** within the coil and conductor **7**. Core **10** is rigid, comprising a solid wire of the same material as conductor **7**, to avoid any electrolytic action therebetween. It fits tightly in conductor **7**, and extends from a point midway between the ends of spike sleeve **8** through base **4** and into housing **5**, thereby stabilizing conductor **7** at the juncture between sleeve **8**, and base **4**.

This rigid stabilizing core causes flexing of spike **2** to be distributed from an intermediate point along sleeve **8** outwardly to the end of conductor terminal **7'**. This flex-distributing action is enhanced by the extension of the closely wound conductor coil **7** beyond the end of the sleeve **8**, terminating in the more open coiled construction **7'**. Thus, commencing from the rigid stabilizing core, there is provided a spike of progressively increasing flexibility, proceeding outwardly, with at least three zones of successively greater flexibility comprising the closed coil conductor **7** within sleeve **8**, the closed coil conductor **7** beyond sleeve **8**, and the open coil conductor **7'**, respectively.

The open coiled construction of terminals **7'** permits the muscle and tissue of the heart to grow around these coils, thereby firmly embedding tip **7'** in the heart wall. Spike sleeve **8** can be used to confine the current path to terminal **7'**, as well as functioning as a strain reliever. Base **4** can be sutured in place, through openings **11**.

Accordingly, it is seen that my invention fully accomplishes its intended objects, and provides a flex-resistant electrode and lead which can be implanted within the human body and depended upon to function without failure for periods of time measured in years, instead of months or even weeks as before. The coiled spring conductor, movable within the straight tubing, provides a high degree of flex resistance, and the spike construction and stabilizing core distribute stress in a manner further reducing the likelihood of fatigue.

The non-adhering nature of the insulating material relative to body tissue contributes to the desired result, by permitting movement of the insulating material in the

body. Durability is further enhanced by the complete absence of any man-made joints, the conductor **7, 7'** being a continuous, single piece of conductor wire.

The particular materials used may be varied, although those named have been found to be particularly suitable. When intended for use within the body, the materials used must be non-toxic, in addition to the properties previously enumerated. However, the electrode and lead of my invention are not limited to use in the body, nor need the electrode take the particular form illustrated, although the electrode shown is conveniently manipulated, with the housing **5** providing a ready means for grasping the electrode. The lead **3** will have utility in other applications, and if conductor **7** is extended beyond the end of sleeve **6**, just as conductor **7'** extends beyond the end of sleeve **8**, it will comprise a simple electrode suitable for many purposes.

Other variations and modifications will occur to those skilled in the art, and are intended to be included within the scope of the appended claims.

Having fully disclosed and completely described my invention, together with its mode of operation, what I claim as new is:

1. A flex-resistant electrode adapted for implantation in an animal body comprising a body member having a normally relatively flat base plate portion, a spike including a sleeve projecting from one face of said base plate portion at generally a right angle thereto, a lead including a sleeve projecting from one of said plate base portion in generally the plane thereof, said body and said sleeves being made of electrically insulating material resistant to the adhesion of body tissue, and a closely coiled wire of electrically conductive material resistant to corrosion by body fluids extending through said lead sleeve into said body and through said body to and through said spike sleeve, the portion of said coiled wire within said sleeves being elastically extensible relative thereto, the portion of said coiled wire extending through said body being fixed relative thereto, a generally rigid core filling said wire from a point between the ends of said spike sleeve through the juncture of said spike sleeve and said base plate portion and therebeyond, said wire extending beyond said spike sleeve in tightly wound condition and terminating in a series of relatively widely spaced coils.

2. A flex-resistant electrode comprising an elastic sleeve of electrically insulating material, and a closely coiled electrical conductor wound along the axis of said sleeve, said sleeve surrounding said conductor and said conductor being elastically extensible along said axis relative to said sleeve, said conductor extending beyond one end of said sleeve and terminating in a series of relatively widely spaced convolutions.

3. A flex-resistant electrode comprising a body of electrically insulating material adapted to be supported against a member to be penetrated by the electrode, a sleeve of electrically insulating material projecting from said body, and a coiled electrical conductor encased within said body and including a spike portion extending through said sleeve and projecting therebeyond, said spike portion being relatively tightly wound within said sleeve and adjacent the outer end thereof, the remaining exposed end of said spike portion being loosely wound to provide spaced-apart convolutions for embedding in the member to be penetrated.

4. A flex-resistant electrode adapted for implantation in an animal body comprising a body having a base portion, a spike sleeve projecting from said base portion at generally a right angle thereto, a lead sleeve projecting from said base portion in generally the plane thereof, said body and said sleeves being made of electrically insulating material resistant to the adhesion of body tissue, and a closely coiled wire of electrically conductive material resistant to corrosion by body fluids extending through said lead sleeve, said body and said spike sleeve, said wire extending beyond said spike sleeve and terminating in a series of relatively widely spaced coils for ingrowth of tissue.

5. A flex-resistant lead adapted for implantation in an animal body comprising an elastic sleeve of electrically insulating material resistant to adhesion of body tissue, and an elastic coil of electrically conductive material resistant to corrosion by body fluids closely wound along the axis of said sleeve, said coil being encased within said sleeve and being extensible along said axis relative to said sleeve, wherein one end of said coil extends beyond one end of said sleeve to comprise an electrode, said one coil end being relatively tightly wound adjacent said one sleeve end and terminating in relatively widely spaced convolutions.

References Cited by the Examiner

UNITED STATES PATENTS

433,384	7/90	Woodward	128—408 X
789,161	5/05	Linn	128—409 X
1,499,341	7/24	Cameron	128—409 X
2,100,116	11/37	Webb	128—409 X
3,035,583	5/62	Hirsch et al.	128—218 X

FOREIGN PATENTS

787,477	7/35	France.

RICHARD A. GAUDET, *Primary Examiner.*