DESCRIPTION

The present invention relates to electrodes or pacing leads that are implantable in the body and is more particularly concerned with a stylet for use with such pacing leads with a view to stiffening them during implantation.

Implantable electrodes are nowadays widely known and used in medicine for making diagnoses, for treating patients and particularly for patients who have a cardiac disease, which is tried to be solved by implanting a pacemaker.

These electrodes comprise a hollow elongated electric conductor that is highly flexible and which is sheathed with insulating material over its entire length. The conductor as such usually consists of a helical winding of several strands of wire, the strands being also helicoidally wound. Such a construction provides the conductor with the required flexibility for it continuously to adapt to the changes in shape of the blood vessels through which it extends, in particular in the region of the heart. For implantation, however, the conductor should be sufficiently rigid for the electrode to follow the curves in the blood vessels and it is one of the functions of a stylet temporarily to provide the conductor with the required stiffness. Such a stylet may comprise a stiffish filament of elastic metal that is inserted into the electrode and that is somewhat longer than the latter.

Therefore, once the assembly of the pacing lead and the stylet is implanted by a surgeon, he immediately withdraws the latter and connects the electrode to a pacemaker or similar device.

As is known, an electrode, particularly a pacing lead used to pace the heart, must become fastened to the tissue having to be stimulated and this is generally achieved by providing the electrode with a suitably shaped head (a particular configuration of the surface of the head, barbs inclined to the axis, etc.). Despite these precautions, the electrode still frequently comes loose, particularly during the first few weeks after implantation as the tissue has not yet been able to grow sufficiently to latch on to the electrode. Surgeons thus regularly check whether the electrode has

fastened properly some time after implanting it. This checking operation may be performed with a stylet similar to that used for the implantation.

An implanted electrode normally closely follows the path of the blood vessel in which it is inserted. At times, however, it may become quite convoluted after the stylet is withdrawn, particularly where the blood vessel branches off. The electrode may then, for instance, form single or even double, e.g. S-shaped, tight twists or bends. Now, if the stylet filament is fitted with a simple blunting tip such as a ball point (such as disclosed for example in patent GB-A-2 064 963) or even more simply is formed with a rounded nose (such as disclosed in US-A-2 118 631), the stylet can then only be inserted with difficulty into the electrode as, in the curves, the tip tends to catch in the grooves between the contiguous turns of the conductor. In so doing, the tip will tend to move them apart and even to be pushed through the conductor and the insulating sheath surrounding it. If this happens, the stylet is then very likely to perforate the blood vessel. This has induced practitioners to discard this method of checking the implantation with a stylet and to resort to X-rays instead.

An object of the invention is to provide a stylet with which an implantation can be checked without danger of piercing the conductor of the electrode or the blood vessel.

The invention thus provides a stylet for the implantation and for the checking on an implantable electrode of the kind having a hollow elongated conductor of coiled wire forming contiguous turns, said stylet comprising an elastic filament which, during implantation of the electrode, is maintained in it in order to stiffen it over its entire length and which is provided at its front end with a blunting tip having an axially symmetrical shape coaxially secured to the front end of the filament, and having a diameter slightly smaller than the internal diameter of the conductor of the electrode, characterized in that the blunting tip has a bullet shape.

With such a design, the blunting tip cannot catch in the grooves between the contiguous turns of the conductor, even if the latter forms tight bends because when the elastic filament is being pushed

inwardly, the filament is caused to flex as the tip encounters resistance from the contiguous turns in the bends of the conductor, thereby causing the tip to tilt and its front end to move away from the turns of the conductor. Thus, the tip is caused to slip over the contiguous turns in the bends of the conductor, hence considerably facilitating insertion of the stylet.

The tilting action on the tip can be enhanced and the insertion of the stylet facilitated still further if, according to another feature of the invention, the tip is formed at its rear end with an axial, cylindrical recess into which extends the distal end portion of the filament, the latter being secured to the tip at a region proximate to the bottom of the recess, the latter having a diameter greater than that of the filament.

The forces involved in the tilting action can thus be made to act at points that are as far apart as possible from each other. With such a construction, even tighter bends can be negotiated without danger of piercing the insulating sheath of the conductor or, all the more so, a blood vessel.

The invention will be better understood with the following description of an embodiment of the invention.

In the accompanying drawings, given by way of example :

- Figure 1 illustrates on an enlarged scale an axial section of the front end of a stylet according to the invention;
- Figure 2 shows a modified, at this time preferred, embodiment of the invention;
- Figure 3 diagrammatically illustrates the progress of the tip of the stylet inside an electrode which is already implanted and follows a sinuous path;
- Figure 4 shows, in section and on an enlarged scale, the tip of the stylet visible in Figure 3.

There is shown in Figure 1 a stylet according to a first embodiment of the invention. It comprises a stiffish elastic filament 1, the rear end of which being provided with a manipulation knob 2 for an easy use by the surgeon.

A blunting member or tip 3 is secured to the filament. It has a generally bullet shape with a rounded nose, 4, a frusto-conical

surface 5 which smoothly merges with nose 4, and a rear cylindrical surface 6 which smoothly merges with surface 5.

The mounting of the tip on the corresponding end of filament 1 is preferably made by brazing or by setting this end in the body of the tip.

The entire stylet may for instance be made of stainless steel.

As a matter of example only, the diameter of the tip is of at most 0,60 mm when the internal diameter of the conductor (not shown) of an implantable electrode associated with the stylet is of 0,80 mm. The length of the tip is of about 1,20 mm, while the cylindrical part of the filament should have a diameter of about 0,20 mm.

In the embodiment of Figure 1, tip 3 is solid and filament 1 is only free from the rear end face 7 of the tip.

On the contrary, in the embodiment of Figure 2, which is at present preferred, tip 3 is formed with an axial, generally cylindrical recess 8 at its rear end 7. It may be noted that the diameter of the recess is significantly higher than the diameter of filament 1; for example, if the diameter of the latter is of 0,20 mm, the recess should have a diameter of about 0,35 mm.

The front end portion of the filament, i.e. its frusto-conical portion 9, extends through recess 8 and is threaded into an axial aperture 10 which extends from recess 8. In order to secure the filament in this aperture 10, a solder 11 is provided on end face 4, this solder being shaped so that this face erges smoothly with frusto-conical surface 5. Alternately, the filament may be secured to tip 3 by projecting its end slightly beyond aperture 10 and spreading it to rivet it.

One can see that, thanks to the light conical shape of front end 8, the filament can be easily arranged to position itself automatically axially in relation to tip 3 and the filament can be cut off to the required length at the front end of aperture 10, before it is secured by soldering or riveting operation.

It has been found that the slant of frusto-conical surface 5 with respect to the axis of the stylet must be carefully chosen. According to the expected curvature of the electrode when it is

implanted, the slant angle can be chosen between 15° and 50°. However it has been found that an angle of 26° as best suited to the usual curvature conditions encountered in practice.

Advantageously, a rounded surface portion 12 is formed between the side wall of tip 3 and the rear face of the same to facilitate withdrawal of the stylet from the pacing lead either after implantation or after checking of the latter.

Figure 3 shows the operation of a stylet according to the embodiment of Figure 2. It shows a blood vessel V provided with an electrode E consisting of a hollow helicoidal winding C of several strands of thin electrically conductive wires also helicoidally wound. A secondary blood vessel VS is shown branching off main vessel V and it is assumed that a few days after implantation, electrode E has formed in the region of the branching off point a first sharp bend CD to the right followed by a sharp bend CB to the left as viewed from the rear end of the electrode (at the lower part of the Figure).

When the stylet according to the invention is not being acted upon in any way, it is normally quite straight as shown in Figure 1 and it will tend to return to this configuration when released after having been moved away therefrom. However, it is sufficiently flexible to follow the bends which are created by the configuration of the electrode during a first or a subsequent insertion operation.

Therefore when tip 3 enters the right bend, as shown in Figure 3, it comes into contact with the inner surface of electrode E.

The blocking effect is all the more important as the inner surface is formed by contiguous turns between which depressions are created. This is why the progress of prior art stylets involving a blunting tip consisting merely of a small ball point was inhibited.

However, thanks to the particular shape of the tip according to the invention, as soon as the filament becomes subjected to slight axial strain due rot the resistance exerted on the tip and due to the force applied by the surgeon, the filament flexes slightly causing the tip to tilt out of alignment with the front portion 9 of the filament 1. This causes frusto-conical surface 5 of the tip, instead of nose 4, to come into contact with the inner surface

of the electrode. Because of the slant of surface 5, the latter provides a sliding contact which promotes the progress of the stylet. This tilting action will occur whenever the tip abuts on the inner surface of the electrode.

A simplified analysis shows that tip 3 is subjected to a tilting couple FF, which tends to move it away from the surface or at least to apply thereagainst a generatrix of frusto-conical portion 5 of tip 3.

Because of the tip's axially symmetrical shape, the above couple may occur whatever the curve direction (i.e. in the plane of Figure 3 or any other plane).

The tilting action described above will occur both with the tip described with reference to Figure 1 and with the tip illustrated in Figures 2 and 4. The latter construction will, however, produce a couple having a much greater moment since the force is made to act as closely as possible to the fron end of tip 3. Furthermore, if filament 1 flexes sufficiently to contact the inner surface of the recess at 13 (Figure 4), the tilting action is enhanced still further.



CLAIMS

1. A stylet for the implantation and for the checking of an implantable electrode (E) of the kind having a hollow elongated conductor (F) of coiled wire forming contiguous turns, said stylet comprising an elastic filament (1) which, during implantation of electrode (E), is maintained in it in order to stiffen it over its entire length and which is provided at its front end with a blunting tip (3) having an axially symmetrical shape coaxially secured to the front end (9) of filament (1), and having a diameter slightly smaller than the internal diameter of conductor (F) of electrode (E), characterized in that the blunting tip (3) has a bullet shape.

2. A stylet according to claim 1, characterized in that the outer shape of said tip (3) is defined by a rear cylindrical surface (6), a rounded front face (4) and a frusto-conical transition surface (5) which tapers to the front end and which smoothly merges with the front face (4) and the cylindrical surface (6).

3. A stylet according to claim 2, characterized in that said frusto-conical surface (5) is inclined to the axis of the tip by an angle ranging from 15 to 50°.

4. A stylet according to claim 3, characterized in that said angle is equal to 26°.

5. A stylet according to any one of claims 1 to 4, characterized in that said tip (3) is formed at its rear end with an axial recess (8) into which extends the front end portion of the filament, the latter being secured to the tip in a region proximate to the bottom of said recess, and in that the diameter of this recess (8) is substantially greater than that of the filament (1).

6. A stylet according to claim 5 having a filament the front end portion (9) of which has a frusto-conical shape, characterized in that said tip (3) is formed with an axial, cylindrical aperture (10) extending from said recess (8) from the front end and in that the diameter of said aperture corresponds to a diameter of the frusto-conical front portion of the filament.