United States Patent [19]

Citron et al.

[11] **3,902,501**

[45] **Sept. 2, 1975**

[54] **ENDOCARDIAL ELECTRODE**

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[22] Filed: **June 21, 1973**

[21] Appl. No.: **372,269**

[52] **U.S. Cl.** ..... **128/418;** 128/404; 128/419 P

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

[58] **Field of Search**.... 128/418, 419 P, 404, 2.05 F, 128/407–409, 242–244, 325, 344, 345, 348–350, DIG. 16, 2.06 E

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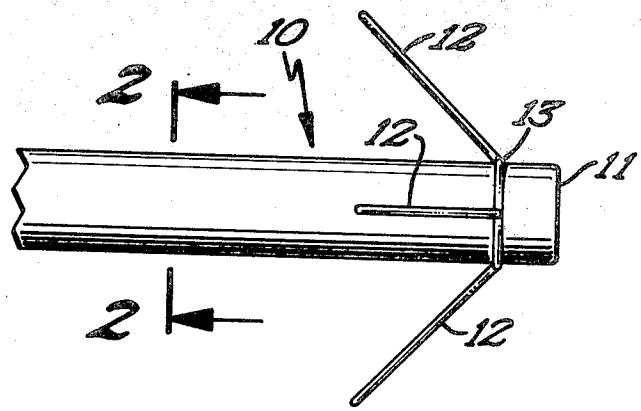
Attorney, Agent, or Firm—Lew Schwartz; Wayne A. Sivertson

[57] **ABSTRACT**

A medical electrode uniquely adapted for use as an endocardial electrode. An electrical conductor is encased in a material which is generally inert to body fluids and terminates at an exposed electrically conductive tip. A plurality of pliant tines extend from the electrode adjacent the tip and form an acute angle with the electrode body. Provision is made for holding the tines against the electrode body during insertion while allowing their release when the tip is in position. The released tines cooperate with the heart tissue, particularly the trabeculae found in the ventricles and the right atrial appendage, to maintain the electrode tip in position.

17 Claims, 13 Drawing Figures



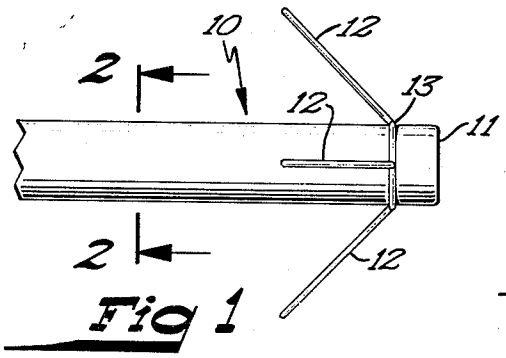


Fig 1

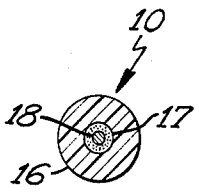


Fig 3

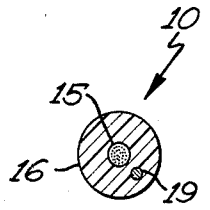


Fig 2

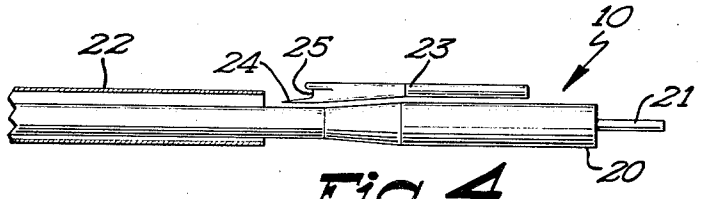


Fig 4

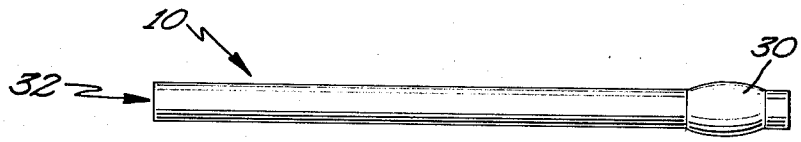


Fig 5

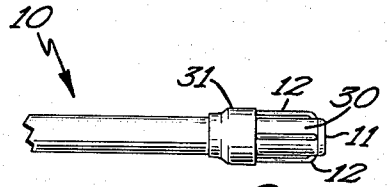


Fig 6

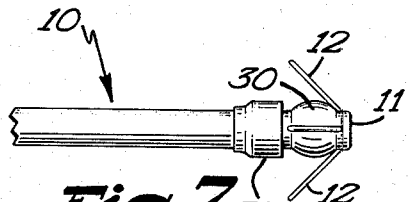


Fig 7

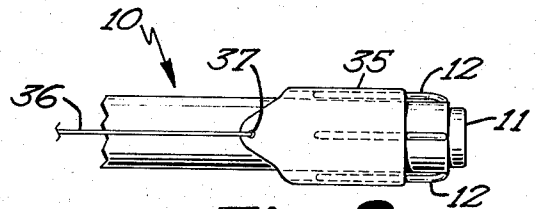


Fig 8

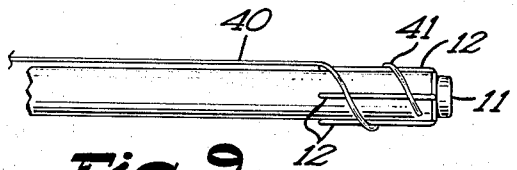


Fig 9

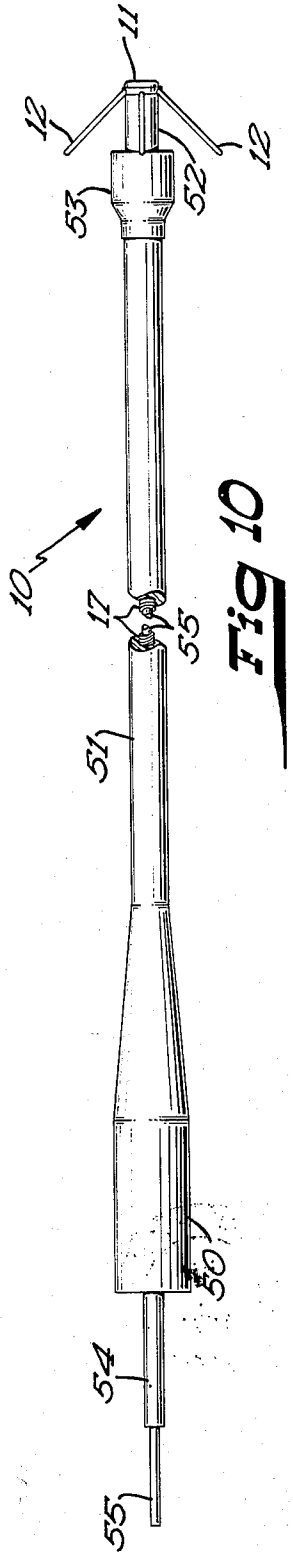


Fig 10

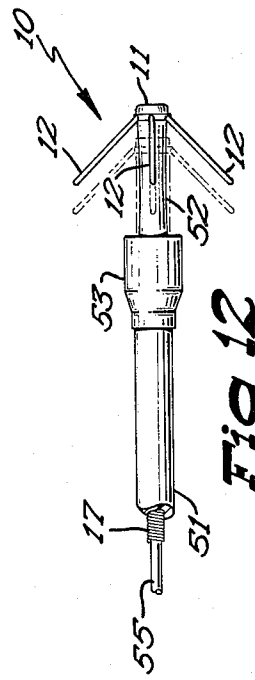


Fig 12

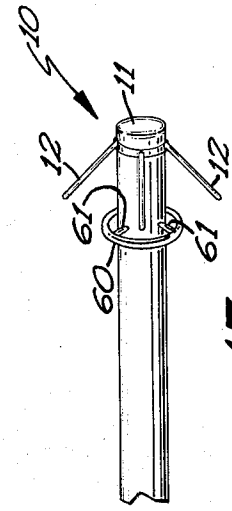


Fig 13

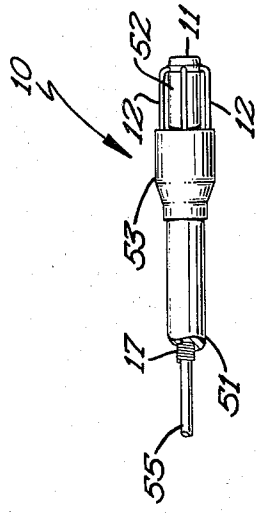


Fig 11

ENDOCARDIAL ELECTRODE

BACKGROUND OF THE INVENTION

Electrical stimulation of heart action is well-known and has been employed to counter a variety of heart dysfunctions. Dependent upon the particular dysfunction, optimal placement of the electrical contact point or points may vary. However, optimal electrode placement has often been sacrificed to other considerations such as minimization of the surgical risk and reliability of the electrode securement. To date, the greatest number of electrodes have been ventricular electrodes with the transvenous-endocardial approach coming into the fore in recent years.

The advantages of a reliable electrical contact with the atrium are well-known. Such a contact would allow atrial pacing or atrial synchronized pacing thereby preserving the contribution of the atrial contraction in the overall cardiac output. Additionally, an atrial contact would be advantageously employed for arrhythmia management and other purposes which may not be accomplished through ventricular electrical stimulation. For reasons well-known to those skilled in the art, the greatest advantages can be obtained through an electrical contact with the right atrium, the right atrial appendage providing a suitable site.

An attempt to accomplish transvenous or endocardial atrial pacing is described in Smyth et. al. "Permanent Transvenous Atrial Pacing, An Experimental and Clinical Study", The Annals of Thoracic Surgery, Volume 11, No. 4, Apr. 19, 1971, pages 360–70. Here, a J-shaped catheter with a flange near the tip was inserted into the right atrial appendage through a transvenous approach. The catheter was straightened by the insertion of a stylet. When the stylet was withdrawn, the catheter assumed its preformed J shape for placement of the electrode tip in the atrial appendage. There was no attempt to artificially secure the electrode tip in position, the atrial trabeculae and shape of the catheter being relied upon to maintain it in location until the heart tissue itself enveloped and fixed the tip. The metal parts of the catheter may be radiopaque to facilitate placement by viewing through fluoroscopy.

A sensing atrial endocardial electrode is described in Portsmann et. al., "P Wave Synchronous Pacing Using Anchored Atrial Electrode Implanted Without Thoractomy", The American Journal of Cardiology, Volume 30, July 11, 1972, pages 74–76. A J-shaped applicator catheter was used to direct the electrode tip into the right atrial appendage. The electrode however, had two fine wire hooks positioned at its tip each ending in a relieving loop. The hooks were held back by the applicator catheter to spring out and anchor the electrode in the trabeculae of the right atrial appendage when the electrode tip left the end of the applicator catheter.

In the applicator catheter technique described above, the applicator catheter was radiopaque so that it could be viewed as it was inserted into the right atrial appendage. It is imperative with the double hook tip that the electrode be properly placed before the hooks are released. The placement was checked not only through fluoroscopy but also by extending the tip slightly beyond the end of the applicator catheter to take a threshold measurement. The tip had to be extended sufficiently to take an accurate measurement while still retaining the hooks within the applicator catheter. Because of its size, it is extremely difficult to accomplish this test measurement without also releasing the hooks. Additionally, the metallic nature of the hooks, their sharp points and spring action creates the possibility that the hooks may perforate the wall of the appendage if the catheter tip is not precisely positioned. Also, the configuration and rigidity of the hooks make it extremely difficult to remove the electrode without damage to the heart tissue while its metallic properties severely limit its utility as a pacing electrode.

SUMMARY OF THE PRESENT INVENTION

The present invention provides an electrode uniquely adapted for use as an atrial endocardial electrode. The electrode may be positioned in the right atrial appendage through the use of a J-shaped catheter known to the prior art. Alternatively, a J-shaped stylet may be employed which is held in a straightened position by the walls of the vein used to approach the heart, the stylet assuming its J-shape upon entry into the right atrium. A plurality of pliant non-conductive tines are provided at the tip of the electrode to cooperate with the heart tissue, particularly the trabeculae found in the right atrial appendage, to maintain the electrode tip in electrical contact with the heart tissue while allowing a removal of the electrode should that prove necessary. Provision is also made for holding the tines against the electrode body during insertion while allowing their release when the tip is in position and after a test threshold measurement. Although the electrode is discussed in the context of the right atrial appendage, it is suitable for use in any portion of the heart having the requisite cooperating tissue and may be employed as either a sensing or pacing electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a preferred embodiment of the present invention.

FIG. 2 shows a cross section of the preferred embodiment of FIG. 1 taken along the line 2—2 in FIG. 1.

FIG. 3 shows a cross section of another preferred embodiment taken along the line 2—2 in FIG. 1.

FIG. 4 illustrates apparatus which may be used with the preferred embodiment of FIG. 1.

FIG. 5 shows a component of another preferred embodiment of the present invention.

FIG. 6 shows a preferred embodiment of the present invention which utilizes the component of FIG. 5, the tines being in a restrained position.

FIG. 7 shows the embodiment of FIG. 6 with the tines unrestrained.

FIG. 8 shows another preferred embodiment of the present invention.

FIG. 9 shows still another preferred embodiment of the present invention.

FIG. 10 shows a further preferred embodiment of the present invention.

FIG. 11 shows a portion of the preferred embodiment of FIG. 10.

FIG. 12 shows a portion of the preferred embodiment of FIG. 10.

FIG. 13 shows an additional preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring now to FIG. 1, there is shown a body member 10 terminating at an exposed electrically conduc-

tive tip 11 and a plurality of tines 12 extending at an acute angle from the body member 10 from a position adjacent the tip 11. The electrically conductive tip 11 may be of any material suitable for the environment; platinum-iridium, for example. The tines 12 are of a pliant material which is generally inert to body fluids; silicone rubber or polyurethane, for example. The tines 12 may be attached to the body member 10 in any convenient manner. For example, the tines may extend from, and be unitary with, a disc 13 which disc is held in position between the body member 10 and tip 11. Alternatively, the member 13 may be in the form of a ring which lies over either the body member 10 or tip 11 and is adhered thereto in any convenient manner. The tines 12 may take any angle with the body member 10, their purpose being to cooperate with the body tissue, particularly the trabeculae of the right atrial appendage, to maintain the tip 11 in electrical contact with the body tissue. It can be seen that an acute angle formed by the tines 12 and the body member 10 will have the greatest tendency to push against and become involved with the cooperating trabeculae and maintain the tip 11 in electrical contact. It has been found, that an angle of approximately 45° maintains the necessary electrical contact is a very efficient manner. Further, any number of tines may be used, three having proven to be adequate in most situations.

Referring now to FIG. 2 wherein there is shown a cross section of a preferred embodiment of the body member 10 of FIG. 1 taken along the line 2—2. In this embodiment, an elongated electrical conductor 15 runs substantially the length of the body member 10 and makes electrical contact with the tip 11. The conductor 15 is encased within a catheter 16 of a material which is generally inert to body fluids.

It is desirable that the catheter — conductor combination be made as flexible as possible. To accomplish this purpose while providing the necessary rigidity for insertion of the electrode, a stylet lumen 19 is provided, the stylet being within the lumen 19 during insertion of the electrode and being withdrawn after placement is accomplished. In a preferred embodiment, the stylet which is placed into the lumen 19 has a J configuration similar to that of the prior art applicator catheters. During insertion, the stylet is maintained in a "straightened" configuration by the walls of the vessel through which insertion is accomplished. When the electrode tip reaches the atrium, the stylet assumes its J configuration thereby allowing an easy insertion into the appendage. When the placement of the electrode tip is accomplished, the stylet is withdrawn. In this embodiment, the electrical conductor can be of any known type, one preferred form being a multistrand wire of platinum, for example, commonly referred to as "tinsel wire."

A second preferred form for the body member 10 is illustrated in FIG. 3. Here, the electrical conductor is a coiled member 17 which again runs substantially the length of the body member 10. The coil 17 is encased in a catheter 16 substantially identical to that shown in FIG. 2. The central portion of the coil 17 is left at least partially void to form a lumen 18 for the insertion of a stylet, the stylet serving essentially the same function in this embodiment as in the embodiment of FIG. 2. Further, in both the embodiments of FIG. 2 and FIG. 3, the lumens 19 and 18 may be lined with Teflon or any other appropriate material to facilitate the insertion and removal of the stylet.

Referring now to FIG. 4, there is again shown an electrode body portion 10 this time at the end farthest from the tip 11. In some applications, a pin type connection to an external stimulator or sensing device is desired. For this purpose, the body portion 10 commonly has an enlarged segment 20 from which extends the connecting pin 21. If it is desired to insert the electrode through the use of the J-shaped applicator catheter known to the prior art, the catheter must be made sufficiently large to slide back over the enlarged portion 20 or, alternatively, some other system for removal of the catheter must be provided. Here, the applicator catheter is shown at 22 of a size not sufficiently large to be withdrawn over the enlarged portion 20. A cutting tool 23 is shown adjacent the enlarged portion 20 and extending forward of the enlarged portion with a wedge 24 and a knife blade 25. The cutting tool 23 may be separate from the electrode body 10 or may be attached thereto in any convenient manner. In operation, the wedge portion 24 slips under the edge of the applicator catheter 22 and, as the applicator catheter 22 is drawn toward the cutting tool 23, the wedge will direct the catheter 22 into contact with the knife blade which will then cut and separate it thus allowing the removal of the applicator catheter over the enlarged portion 20.

The electrode shown in the embodiment of FIG. 1 may be successfully inserted into the right atrial appendage through a transvenous approach using the stylet technique of either FIGS. 2 or 3 or the J-shaped applicator catheter technique. In the applicator catheter technique, the tines 12 are not exposed during insertion. In the stylet technique of either FIGS. 2 or 3, however, the tines are non-restrained or extended during the entire operation. Although the electrode may be successfully positioned in this condition, it is found that the blood flow tends to draw the electrode tip into the ventrical. For this reason, some means of restraining the tines during insertion is desirable.

Referring now to FIG. 5, there is shown a balloon catheter similar to the balloon catheters used for other applications. Specifically, the catheter body 10 has a portion 30 which is inflatable from an end 32. The inflation is accomplished through a lumen similar to the stylet lumen 19 and 18 of FIGS. 2 and 3 respectively. Indeed, the inflation can be accomplished through the stylet lumens 19 and 18, the lumens being made sufficiently large to accomodate the stylet while allowing a passage for air to inflate the balloon. The ballooning feature of the electrode body 10 may be accomplished in any known manner. Referring now to FIG. 6, there is shown an electrode having a body 10 and a tip 11 as described with reference to the embodiment of FIG. 1. The body 10 is composed of a balloon catheter as illustrated in FIG. 5 with the ballooning or inflatable part lying adjacent the tip 11. A hold down shroud 31 is positioned near the tip 11 and is adapted to receive at least the ends of the tines 12 to restrain them in a position wherein they overlie the inflatable portion 30 of the electrode body 10. With the tines in this restrained position, a stylet may be inserted into a lumen such as that illustrated in FIGS. 2 or 3 and the electrode inserted through a transvenous approach without any interference from the extended tines. When the electrode tip is believed to be in an acceptable position as viewed by fluoroscopy, a test measurement can be made. If the

site of the electrode tip proves satisfactory, the balloon **30** can be inflated from the end of the electrode still outside the body causing the tines to withdraw from the shroud **31** and extend into their normal unrestrained position as illustrated in FIG. **7.** With the tines freed from the shroud **31** the inflating pressure can be released and the balloon **30** will deflate to a normal configuration. The shroud **31** may take any shape which can accept at least the end portions of the tines **12.** A ring which is attached to the body by spaced tethers is an example of an obvious modification of the shroud **31.**

An alternative shroud to the shroud **31** of FIG. **7** is illustrated at **35** in FIG. **8.** This shroud **35** again is adapted to accept at least the end portion of the tines **12** to restrain them in a position wherein they overlie the body of the electrode **10.** A line **36** is attached to the shroud **35** at **37,** and when the tip is properly positioned, a force on the line **36** will cause the shroud **35** to withdraw thus freeing the tines **12** to assume their extended unrestrained position. A similar approach is illustrated in FIG. **9** wherein a stylet **40** is shown having a coiled portion **41** which coiled portion is wrapped around the tines causing them to lie flat against the body member **10.** Again, when the tip **11** is properly positioned, the stylet will be withdrawn thereby freeing the tines for interaction with the trabeculae of the right atrial appendage, for example.

Referring now to FIG. **10,** there is shown another preferred embodiment of the present invention. Specifically, there is shown an electrode body **10** composed of a connecting portion **50,** a central portion **51** and an end portion **52** which lies between the tip **11** and the shroud **53.** The cross section of the central portion **51** may be as illustrated in FIG. **3.** That is, the electrical conductor is a coiled member **17** having a void lumen forming central portion **18,** the conductor extending from the tip **11** back to the connecting portion **50.** The connecting portion **50** is similar to that illustrated in FIG. **4** with the connecting pin **54** making an electrical contact with the electrical conductor **17** and having a lumen coincident with the lumen **18** of the conductor **17.** With this configuration, it is possible to insert a stylet **55** through the end of the connecting pin **54** to abut the tip **11.** Inasmuch as the electrical conductor is a coiled member it can be stretched or elongated by applying a pressure against the tip **11** with the stylet **55.** Since the electrical conductor is typically uniform throughout its length, the location at which the electrode body will give or elongate can be controlled to the durometer or diameter of the electrode body, or both. For reasons to be explained more fully below, it is desired that the portion **52** of the electrode body **10** "give" before the central portion **51** or the connecting portion **50.** Therefore, the portion **52** is illustrated as having a smaller diameter than either the central portion **51** or the connecting portion **50.** Alternatively, the material comprising the portion **52** may have a lower durometer than either of the other portions of the electrode body **10** or it may have a lower durometer and diameter, as desired.

FIG. **11** illustrates the embodiment of FIG. **10** with the tines **12** having at least their ends restrained by the shroud **53** in a manner substantially identical to that illustrated in FIG. **6.** With the tines in their restrained position, the electrode can be inserted and positioned and, when a proper positioning is obtained as described above, the stylet is forced against the tip **11** causing the portion **52** to stretch as illustrated in FIG. **12** thereby releasing the tines **12** from the shroud **53.** With the tines released, the stylet is removed thereby allowing the portion **52** to assume its normal shape as illustrated in phantom at FIG. **12.**

As stated with regard to the shroud **31** of FIGS. **6** and **7,** the shroud **53** of FIGS. **10–12** may take the form of a ring connected to the electrode body by means of a plurality of tethers. Such a ring shroud is illustrated at **60** in FIG. **13.** As can be seen, the shroud **60** has a ring or a "doughnut" configuration and is held in place by means of tethers **61** which perform essentially as the spokes of a wheel, the tethers **61** being positioned so as not to interfere with the restraining and release of the tines **12.**

From the above, it can be seen that the present invention provides a new medical electrode uniquely adapted for use as an endocardial electrode. The electrode provides means for cooperating with the heart tissue, particularly the trabeculae of the ventricles and right atrial appendage, to provide an artificial fixation until such time as a natural fixation has occurred. The tines are of a pliant material which is sufficiently rigid to accomplish their purpose without having the snapping action and sharp points attendant in the prior art devices. Further, the present invention provides a system for positioning the electrode and making any necessary test measurements prior to its being finally positioned, the position of the tip with regard to the inserting devices being much less critical in the present invention than in the prior art devices because the tines may be selectively released independently of the insertion device.

Obviously, many modifications and variations of the present invention are possible in light of the above teaching. An example of such a modification would be to make the body member **10** or the tines **12,** or both, radiopaque to facilitate the positioning by observation of the electrode through X-ray, fluoroscopy, etc. We have found that this can be accomplished through impregnation with carbon, barium sulfate or Tantalum. Of course, any suitable substance and method will be acceptable for this purpose. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

What is claimed is:

1. In an endocardial lead of the type having an electrical conductor encased in a material which is generally inert to body fluids, the conductor terminating at an exposed electrically conductive electrode tip, the improvement which comprises:

nonconducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

2. The lead of claim **1** wherein the improvement further comprises means external to said encasing mate-

rial for releasably restraining said tine means in a position overlying said encasing material.

3. The lead of claim 2 wherein said restraining means comprises shroud means for accepting at least the end portion of said tine means.

4. The lead of claim 3 wherein said restraining means further comprise means cooperating with said shroud means for effecting the release of said tine means at a point spaced from said shroud means.

5. The lead of claim 3 wherein the improvement further comprises:

inflatable means underlying said tine means when said tine means are in said restrained position; and

means spaced from said inflatable means for selectively inflating said inflatable means.

6. The lead of claim 4 wherein said tine means are non-metallic.

7. An endocardial lead which comprises:

elongated electrically conductive means;

flexible catheter means surrounding said electrically conductive means and having a lumen substantially parallel to and coextensive with said electrically conductive means;

electrically conductive tip means at one end of said catheter means and electrically connected to said electrically conductive means; and

nonconducting tine means extending from said catheter means and away from said tip from a point adjacent said tip means for cooperation with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said catheter means and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.

8. The lead of claim 7 further comprising means for releasable restraining said tines in a position wherein they overlie said catheter means.

9. The lead of claim 8 wherein said restraining means comprises shroud means for accepting at least the end portion of said tine means.

10. The lead of claim 9 wherein said restraining means further comprises means cooperating with said shroud means for effecting the release of said tine means at a point spaced from said shroud means.

11. The lead of claim 9 wherein said catheter means comprises a balloon catheter, the balloon underlying the tines when the tines are in the restrained position.

12. The lead of claim 11 wherein said elongated electrically conductive means comprises a coiled electrical conductor having a void central portion, said lumen coinciding with said void central portion.

13. The lead of claim 11 wherein said elongated electrically conductive means is positioned substantially at the center of the cross section of said catheter means and said lumen lies off the center of said cross section.

14. In a medical lead of the type in which an electrical conductor is positioned within a catheter and terminates at an exposed electrically conductive electrode tip, the improvement which comprises:

nonconducting tine means including a plurality of tines each extending from said catheter and away from said tip from a point adjacent said tip and forming an acute angle with said catheter for cooperating with heart tissue to hold the tip in position, said tine means being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue;

means for releasably restraining said tine means in a position wherein said tine means overlie said catheter; and

means underlying said tine means when said tine means are in said restrained position and inflatable from a point spaced from said restraining means for releasing said tine means from said restraining means upon inflation.

15. The medical lead of claim 14 wherein the angle formed by said tine means and said catheter is approximately 45°.

16. The medical lead of claim 14 wherein said pliant tine means material comprises a material which is relatively inert to body fluids, at least a portion of said material being radiopaque.

17. The medical lead of claim 16 wherein the radiopaque material portion is a material treated with a material selected from the group consisting of carbon, barium sulfate or Tantalum.

* * * * *