United States Patent [19]

Wilson

[11] **3,890,977**

[45] **June 24, 1975**

[54] **KINETIC MEMORY ELECTRODES, CATHETERS AND CANNULAE**

[76] Inventor: **Bruce C. Wilson,** 34 Twickwood Ln., Glens Falls, N.Y. 12801

[22] Filed: **Mar. 1, 1974**

[21] Appl. No.: **447,340**

[52] **U.S. Cl.**..... **128/418;** 128/2.06 E; 128/DIG. 4; 128/348; 128/350 R; 128/404; 128/418; 128/419 P

[51] **Int. Cl.**..... **A61b 5/02;** A61m 25/00

[58] **Field of Search** ... 128/418, 419 P, 404, 2.05 R, 128/2.06 E, 2.1 E, 348, 349 R, 350 R, 351, DIG. 4; 3/1.7; 75/170, 175.5

[56] **References Cited**

UNITED STATES PATENTS

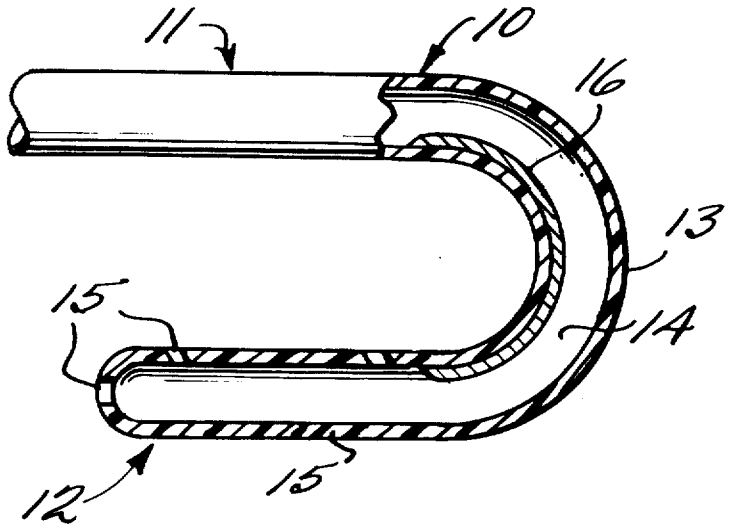
3,348,548	10/1967	Chardack	128/419 P
3,419,010	12/1968	Williamson	128/350 R
3,485,234	12/1969	Stevens	128/348
3,558,369	1/1971	Wang et al.	75/175.5
3,605,726	9/1971	Williams	128/2.05 F
3,606,592	9/1971	Madurski et al.	3/1.7
3,612,038	10/1971	Halligan	128/2.05 R
3,664,347	5/1972	Harmjanz	128/419 P
3,729,008	4/1973	Berkovits	128/4.19 P

Primary Examiner—Richard A. Gaudet
Assistant Examiner—Lee S. Cohen
Attorney, Agent, or Firm—Cushman, Darby & Cushman

[57] **ABSTRACT**

A conductive electrode-catheter, biological catheter cannula or the like which is easily inserted into the body and which is effectively anchored into a desired organ or tissue or properly located within a target cavity. The electrode, catheter, or the like incorporates a material, such as a known titanium-nickel alloy, having heat-activated mechanical memory. The device is formed and annealed at high temperature into a shape for effective anchoring or proper location in an organ or other structure of the body. Then at a temperature below its transitional temperature it is reformed into a shape for ease of insertion, and when located in the desired organ or structure is heated above its transitional temperature, thereby returning to its original annealed anchoring or proper locating shape.

15 Claims, 9 Drawing Figures



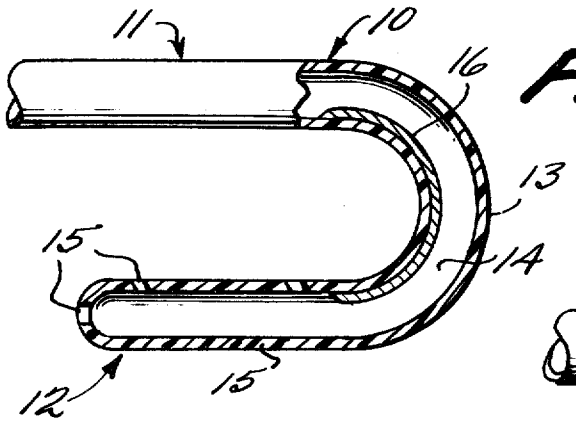


Fig. 1a.

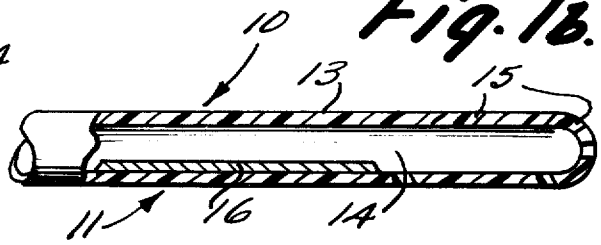


Fig. 1b.

Fig. 2a.

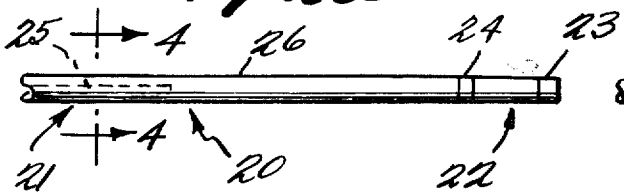


Fig. 2b.

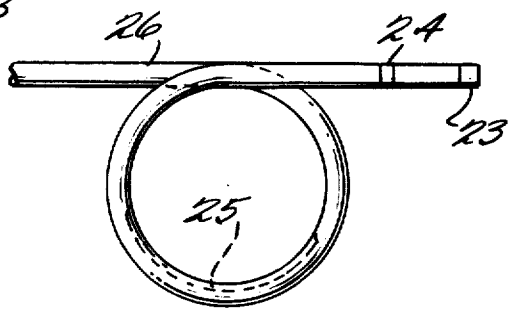
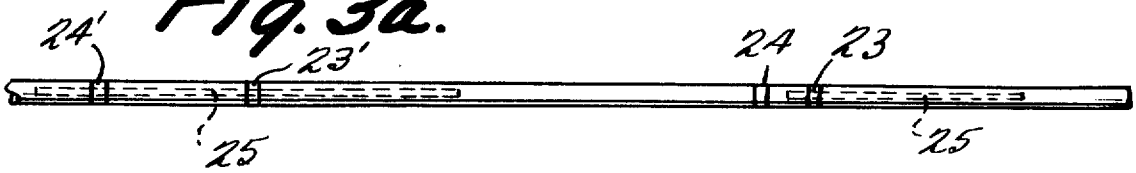


Fig. 3a.



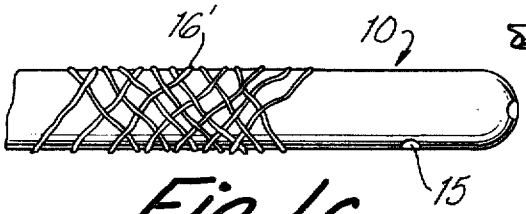


Fig. 1c

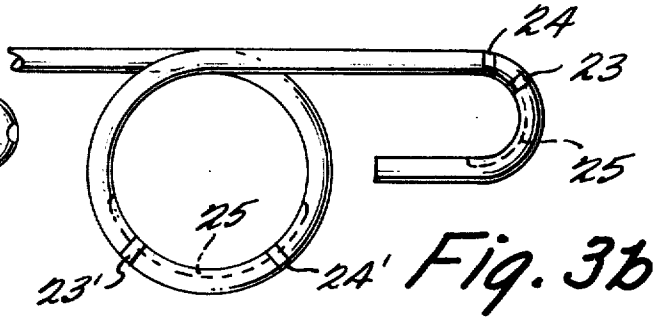


Fig. 3b

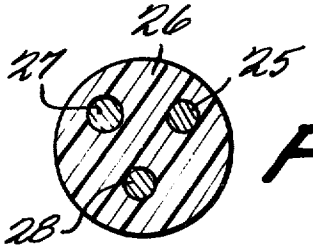


Fig. 4a.

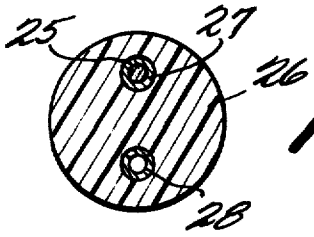


Fig. 4b.

KINETIC MEMORY ELECTRODES, CATHETERS AND CANNULAE

BACKGROUND OF THE INVENTION

This invention relates to conductive electrode-catheters, biological catheters, cannulae and the like. These devices are usually passed into and through a body orifice, incision, peripheral artery, vein, urogential or respiratory passage, etc., of an animal or human body and advanced until they reach a desired organ, structure, or cavity within the body. It has a long been a problem to provide such an electrode, cannula, or catheter that is readily insertable into the body and easily advanced, while also being effectively anchorable into a desired organ or properly locatable within a target cavity. Effective anchoring is desirable in the case of a cardiac electrode to insure positive electrode contact with the endocardium (inner wall of the heart) whether a pacemaker an EKG recorder, or the like is connected to the electrode. In the case of the biological catheter or cannula, proper location and anchoring is desirable whether the catheter is used for drainage, pressure recording, gas administration, or for injection of medication, dye, etc., into the cardiovascular, urogenital, respiratory, lymph, or digestive systems, or into other body parts.

Various attempts have been made in the past to provide electrodes or catheters which are readily insertable while being effectively anchorable or properly locatable. U.S. Pat. Nos. 3,516,412, 3,348,548, and 3,729,008 show cardiac electrodes that are mechanically held straight during insertion, and then are allowed to flex into another shape, while U.S. Pat. No. 3,419,010 shows a catheter that is mechanically held straight and then allowed to curve to properly locate it in a cavity to provide drainage. While the prior art devices have been generally acceptable, they have been cumbersome to operate and do not allow for a wide variety of design modifications depending upon particular application.

SUMMARY OF THE INVENTION

The present invention provides an electrode, catheter, or the like which is readily insertable while being effectively anchorable or properly locatable. These properties are provided by forming the device of the present invention, either wholly or in part, of a material exhibiting mechanical memory that is triggered by heat. Examples of such a material are the titanium-nickel alloy disclosed in U.S. Pat. Nos. 3,174,851 and 3,672,879, and the titanium-nickel-cobalt alloy disclosed in U.S. Pat. No. 3,558,369. This first-mentioned alloy consists essentially of from 52–56% nickel by weight and correspondingly from about 48–44% titanium by weight, said alloy having the structure of a substantially TiNi phase from about 500°C. to about −75°C. This material is originally formed with restraint and by heat annealing (typically 950°–1,100°F.) into the shape desired once it is inserted into the body (such as a curve, angle, or any other of an infinite variety of single or multiple configurations). Then the material is deformed at a temperature (typically room temperature) below its transitional temperature (from 32°–331°F depending upon relative composition, but typically from 98°–125°F) into a shape facilitating easy insertion into the body (such as a straight rod), and the material is incorporated into the electrode, catheter, or the like. After the electrode, etc., is inserted into the body and advanced into the target place, the material is heated to its transitional temperature thereby returning the material to its original shape.

The titanium-nickel-cobalt alloy disclosed in U.S. Pat. No. 3,558,369 has the formula $TiNi_xCo_{1-x}$ wherein Ti denotes titanium and constitutes approximately 50 atomic % of the composition, and the term Ni_xCo_{1-x} denotes nickel and cobalt respectively and make up the remaining approximately 50 atomic percent of the composition. x is a factor which varies from greater than 0 to less than 1 whereby the relative percentage of nickel and cobalt varies inversely from less than 100 percent to more than 0 percent. The transitional temperature of this alloy can be varied depending upon relative composition from −396° to +331°F. Otherwise, it is essentially the same as the abovementioned titanium-nickel alloy.

Once heated to its transitional temperature, the device will thereafter maintain its original shape even when cooled below its transistional temperature. The electrode, catheter, or the like of the present invention is thus easy to operate, and can be readily designed to fit a wide variety of applications.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide an improved electrode, catheter, cannula, or the like.

It is another object of this invention to provide an improved electrode, catheter, or the like that is readily insertable yet on command effectively anchorable or properly locatable.

It is a further object of this invention to fit an electrode, catheter, or the like with a transitional temperature activated mechanical memory material.

Other objects and advantages of the present invention will become clear from the ensuing detailed description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1***a* and **1***b* are side elevational views partly in section of the tip and part of the shaft portions of a catheter according to the present invention shown in its transition and reformed shapes respectively while FIG. **1***c* is a side view of the tip and part of the shaft of a modification of the catheter shown in FIGS. **1***a* and **1***b*;

FIGS. **2***a* and **2***b* are side views of a ventricular pacing electrode according to the present invention showing in phantom the location of the transitional temperature activated mechanical memory material in the shaft in both the transition and reformed shapes;

FIGS. **3***a* and **3***b* are side views of an atrialventricular pacing electrode according to the present invention showing in phantom the location of transitional temperature activated mechanical memory material in both the shaft and tip portions in both the transition and reformed shapes;

FIGS. **4***a* and **4***b* are cross-sectional views taken along lines **4**—**4** of FIG. **2***a* showing alternative embodiments of the location of the transitional temperature activated mechanical memory material within the body of the electrode.

DETAILED DESCRIPTION OF THE INVENTION

A catheter formed according to the teachings of the present invention, shown generally at **10** and having a shaft portion **11** and a tip portion **12**, is disclosed in

FIGS. 1*a* and 1*b*. The catheter has a tubular body **13**, preferably formed of plastic, silastic, rubber, or similar material, and a lumen **14**. Fluid contained in lumen **14** can be injected through holes **15** into a body part, or fluid can be drained from a body cavity or structure through holes **15** and lumen **14**. Liquid coupled pressure recordings can also be made by attaching transducers or similar diagnostic equipment to fluid filled lumen **14**.

A rod **16** of transitional temperature activated mechanical memory material is incorporated into the tip portion of the catheter. The rod **16** can either be directly incorporated into a portion of the body **13**, or it can be affixed thereto. FIG. 1*a* shows the rod in a typical shape for properly locating the catheter within a particular body part. The rod is originally annealed into this shape before incorporation into the catheter, and then assumes this shape again after cooling and subsequent heating to its transitional temperature (typically 98°–125°F). FIG. 1*b* shows the rod in a shape for easy insertion and advancement into the desired body cavity. This is the reformed shape of the rod.

In operation, the rod **16** is formed into its properly locating shape—such as shown in FIG. 1*a*—and is cooled down below its transitional temperature. The composition of the rod is preferably selected so that this transitional temperature is 98°–125°F, and the rod is cooled down to room temperature. Then the rod is reformed into a shape for ease of insertion into the body such as shown in FIG. 1*b*—and is incorporated into the catheter body **13**. Then the catheter is inserted into the body and advanced to the desired location, whereupon the rod **16** is heated above its transitional temperature. The heating can be done by any suitable means, one form of applying heat being the body heat itself. Where body heat is relied upon, it is obvious that the composition of the transitional temperature activated mechanical memory material must be selected so that it has a transitional temperature at or just below body temperature. Heating causes the rod **16** to assume its original shape—FIGS. 1*a* thereby properly locating the catheter **10**.

FIGS. **2–4** show electrodes formed according to the teachings of the present invention. In FIG. 2a a ventricular pacing electrode shown generally at **20** is disclosed. The electrode has a shaft portion **21** and a tip portion **22**. Conductive portions **23, 24** are connected to a source of current or to monitoring devices. The body portion **26** is formed of a flexible non-conductive material such as plastic, silastic, or a high medical grade durameter rubber. A rod **25** of transitional temperature activated mechanical memory material incorporated into shaft portion **21** is shown in phantom in FIGS. 2*a* and 2*b*. FIG 2*a* shows the rod in a typical shape for ease of insertion and advancement of the electrode into the proper body location, while FIG. 2*b* shows the rod in a shape for effective anchoring of the electrode into a body organ. Effective anchoring is desirable in the case of a cardiac electrode to insure positive electrode contact with the endocardium.

FIGS. 3*a* and 3*b* show an example of an atrialventricular pacing electrode having transitional temperature activated mechanical memory material rods **25** and **25'** incorporated in both the shaft portion **21** and the tip portion **22** of the electrode. The electrode has two sets of conductive portion, **23, 24** and **23', 24'**. FIG. 3*b* shows the electrode in a typical proper anchoring configuration, while FIG. 3*a* shows the rods in typical reformed shapes for ease of insertion of the electrode into a desired portion of a body.

FIGS. 4*a* and 4*b* show alternative embodiments of the location of the rod **25** in the electrode body **26**. Conductors **27, 28** are leads from electrodes **23, 24** to a source of current such as an implantable or external cardiac stimulus generator (pacemaker), or to monitoring diagnostic or sensing devices such as EKG, HIS bundle recorders, oscilliscopes, etc. In FIG. 4*a* the rod **25** is incorporated in electrode body **26** spaced from the conductors **27, 28**, while in FIG. 4b the conductors **27, 28** are hollow, and the rod (or rods) is incorporated within the hollow of one of the conductors (or both of them).

It is obvious that many modifications of the present invention are possible. For instance, the transitional temperature activated mechanical memory material may be constructed in forms other than a rod. The transitional temperature activated mechanical memory material may be formed into a braid **16'** which could overlay the catheter body, or be incorporated into the wall or solid cross-section by melting or extruding the body (see FIG. 1c) material around the braid. Similarly it could be in the form of a tube surrounding the outside diameter of the catheter, or a tube incorporated within the catheter body, or a helical wrap around the outside diameter or incorporated within the catheter body. The transitional material may also comprise a whole portion of the catheter or like device, or may extend throughout the whole length or any portion thereof. The conductors themselves, or some part thereof, could be formed from the transitional material.

The possible methods utilizable to heat the transitional temperature activated mechanical memory material to its transitional temperature after proper insertion and advancement are numerous. In addition to merely utilizing body heat, heating could be accomplished by electrical induction heating or liquid immerson or injection. For electrical induction heating, an electrical current from a specially designed current generator is fed to the transitional material. Injection into the catheter or immersion of the transitional material in a heated or cryogenically cooled liquid to either heat up the material above its transitional temperature, or to cool the material below its transitional temperature and after proper location discontinue cooling thereby allowing body heat to heat it above its transitional temperature, are also contemplated.

Other transitional temperature activated mechanical memory materials could be utilized besides the above mentioned titanium-nickel and titanium-nickel-cobalt alloys. The above-mentioned alloys are especially advantageous, however, since the anneal, reform, and revision state cycle may be repeated indefinitely as long as the original annealed temperature is not exceeded, and since in returning to its original shape it is capable of exerting considerable force (recovery stresses of 110,000 psi have been measured on an 0.020 inch diameter wire as it attempted to return to its remembered state).

Although preferred embodiments, uses, and modifications of the invention have been depicted and disclosed, such description is to be considered illustrative rather than limiting, for the invention may be variously modified, and is to be limited in scope only by construction of the following claims.

What is claimed is:

1. A catheter comprising

a. an elongated generally cylindrical body member having a proximate and a distal end, said distal end for insertion into a body,

b. a distal portion of said body member capable of assuming a shape for ready insertion into a body, and a different shape for proper location in a body, and

c. means for shifting said distal portion from said readily insertable shape to said different properly locating shape upon bringing said portion to a specified temperature, said means comprising at least a portion of transitional temperature activated mechanical memory material formed into said distal portion.

2. A catheter as recited in claim 1 wherein said body member is formed of flexible non-conductive material having at least one section of conductive material formed on the exterior of a distal portion thereof and an interior section of conductive material leading from said exterior conductive material section to the proximate end of said body member, whereby the catheter functions as an electrodecatheter.

3. A catheter as recited in claim 2 wherein said interior of conductive material is hollow, and wherein said portion of transitional temperature activated mechanical memory material comprises a rod encompassed by said section of hollow conductive material.

4. A catheter as recited in claim 2 wherein said interior section of conductive material comprises in part said transitional temperature activated mechanical memory material.

5. A catheter as recited in claim 1 wherein said body member is formed of flexible non-conductive material and has an internal cavity extending substantially throughout the length thereof, and at least one passage formed in the distal end of the body member communicating from the exterior thereof to said internal cavity.

6. A catheter as recited in claim 5 wherein said portion of transitional temperature activated mechanical memory material is in the form of a braid in engagement with the distal portion of said body member.

7. A catheter as recited in claim 5 wherein said portion of transitional temperature activated mechanical memory material is in the form of a rod.

8. A catheter as recited in claim 1 wherein said shape for ready insertion is a straight shape, and wherein said shape for proper location is a curved shape.

9. A catheter as recited in claim 1 wherein said transitional temperature activated mechanical memory material is an alloy consisting essentially of from 52-56% nickel by weight and correspondingly from about 48-44% titanium by weight.

10. A catheter as recited in claim 1 wherein said transitional temperature activated mechanical memory material is an alloy having the formula

$$TiNi_xCo_{1-x}$$

wherein

Ti denotes titanium and constitutes approximately 50 atomic percent of the composition and the term Ni_xCo_{1-x} denotes nickel and cobalt respectively and make up the remaining approximately 50 atomic percent of the composition, and x is a factor which varies from greater than 0 to less than 1 whereby the relative percentage of nickel and cobalt varies inversely from less than 100 percent to more than 0 percent with respect to each other on an atom for atom exchange basis.

11. The method of properly locating a catheter in a body structure within a body comprising the steps of

a. forming a member of transitional temperature activated mechanical memory material into a first shape,

b. incorporating said member into a portion of a catheter,

c. forming said catheter portion into a second shape for ease of insertion into the body and advancement of said catheter to the body structure,

d. inserting the catheter into the body and advancing said catheter to the body structure,

e. heating said catheter portion to a specified temperature whereby said catheter portion will revert to said first shape and will thereby assume a shape for proper location of the catheter within the body structure.

12. The method of claim 11 comprising the further step of immersing said portion of the catheter into a cooling fluid until the catheter has been inserted into the body and advanced to the body structure.

13. The method of claim 11 wherein said heating is accomplished by passing an electrical current through said transitional temperature activated mechanical memory material member of the catheter.

14. The method of claim 11 wherein said heating is accomplished by immersing said portion of the catheter into a heating fluid.

15. The method as recited in claim 11 wherein said specified temperature is body temperature or slightly less than body temperature, and wherein the body accomplishes said heating.

* * * * *