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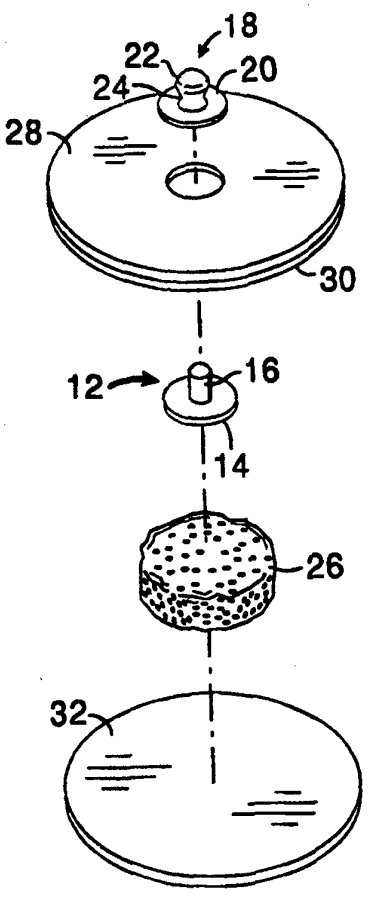
(54) **Title:** MEDICAL ELECTRODE

(57) **Abstract**

A medical electrode having a resilient terminal press fit onto an eyelet (12). The eyelet (12) is plastic and has a conductive coating thereon. The terminal (18) is made of a resilient nonmetallic composition, such as a polypropylene blend loaded with carbon fiber. An electrolyte composition (26) is spread upon the bottom of the eyelet (12) for making electrical contact with the skin of a patient. The eyelet (12), the terminal (18) and the electrolyte composition (26) are preferably all at least translucent to x-rays.



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MEDICAL ELECTRODE

BACKGROUND OF THE INVENTION

The present invention is directed to a medical electrode for temporary adhesive placement on a patient. More particularly, this invention relates to a two piece conductor adapted for interconnection between an electrolyte and suitable signal processing or monitoring equipment.

U.S. Patent No. 3,964,469 describes a disposable electrode having a two piece conductor in contact with a gel pad. The part of the conductor in contact with the gel pad is a silver plated plastic snap fastener eyelet. The second part of the conductor is a conventional metal snap fastener stud.

U.S. Patent No. 3,976,055 discloses an electrode with a conductor that can be molded in one piece. The conductor formed in one piece is made of a plastic rendered conductive by including carbon and a modest percentage of metal particles. The patent further discloses an alternate embodiment in which a second part of the conductor includes a conventional metal snap fastener that is press fit onto the first conductor. The two piece conductor disclosed in both patents recited herein will interfere with an x-ray.

SUMMARY OF THE INVENTION

In accordance with the present invention, a new electrode terminal replaces the metal snap of the prior art. The electrode terminal of the invention is a conductor made from a conductive resilient nonmetallic composition. The composition may be a resilient plastic composition loaded with carbon fiber. The other conductive part into which the terminal is press fit is a metallic coated plastic eyelet. The resilient terminal is advantageously less likely to shear off portions of the metallic coating on the eyelet

when press fit thereon as compared with a rigid terminal such as one made of metal or ABS.

The metallic coating on the eyelet is made from either silver or silver salt. The thickness of the coating is sufficient to provide the necessary conductivity, but is thin enough to substantially avoid interfering with x-rays. The entire electrode of the present invention is translucent to x-rays. The design of a two-piece x-ray translucent electrode is able to take advantage of the abundant manufacturing capacity of existing two-piece electrode assembly machines.

Other objects and advantages of the invention will become apparent during the following description of the presently preferred embodiment of the invention taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded view of a medical electrode of the present invention.

Fig. 2 is a side cross section view of the medical electrode of Fig. 1.

Fig. 3 is a bottom plan view of the medical electrode of Fig. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, the present invention shall be described in the context of a conventional electrode arrangement as shown in Figs. 1, 2 and 3. The electrode arrangement discussed herein has been selected for illustration purposes only and is not meant to limit the scope of the invention to use therein. Rather, the terminal and two part conductor of the invention may be used in any of a wide variety of electrode arrangements. Machinery for producing medical electrodes with two part conductors is commonly available in the industry.

A first conductor is formed by an eyelet 12. The eyelet 12 is formed of a disc 14 and a post 16 sticking up from the disc 14. The bottom surface of the disc 14 provides a surface area for mounting proximate to the skin of a patient. The eyelet 12 is generally made from plastic. The plastic may be mixed with a conductive material. The eyelet is formed in a mold. In the presently preferred embodiment, the eyelet is made from acrylic butylstyrene (ABS) loaded with glass of about 20% by weight. A conductive layer is coated about the plastic eyelet 12. Preferably, the conductive coating is made from silver or a silver salt such as silver chloride. The conductivity of the eyelet must satisfy AAMI standards in order to prevent loss of ECG readings from the patient during and after defibrillation. In accordance with the present invention, the thickness of the conductive coating is preferably thin enough to be at least x-ray translucent (if not transparent) and yet thick enough to provide sufficient conductivity to meet the safety requirement for defibrillation. The thickness of the metallic coating should be within the range of from .02 to .10 mils depending largely upon the conductivity of the eyelet material. In accordance with the presently preferred embodiment, the conductive coating is .065 mils in thickness. The presently preferred method for coating the plastic eyelet with the silver or silver chloride is through the use of electroless plating. Conventional electroplating may be used instead of or in addition to electroless plating to get the desired coating thickness. Another alternative coating method is to spray a silver-silver chloride ink on the plastic eyelet.

A second conductor is used as the terminal 18 of the electrode. The terminal 18 is shaped as a hollow stud that can be press fit onto the post 16 of the plastic eyelet 12. The hollow stud of terminal 18 sits atop an annular disc 20 having a hole therein. The hollow stud is preferably formed integral with the annular disc in a mold. The hollow stud includes a top crown portion 22 and a bottom waist portion

24. The bottom waist portion 24 extends up from the annular disc 20 and encircles the hole in the disc. The top crown portion 22 is preferably wider in circumference than the base waist portion 24 of the stud. The top crown 22 portion may thus be grabbed onto by an electrical apparatus for making a sufficiently secure electrical connection. The hollow cavity within the stud has a sufficiently small inner diameter to snugly fit about the post 16 of the plastic eyelet 12.

The terminal 18 of the present invention is made from a conductive resilient composition. The terminal 18 is resilient so that when it is press fit, i.e., snapped onto, the plastic eyelet, the metallic coating on the plastic eyelet remains substantially intact. Another advantage of using a resilient material is so that when it is press fit over the post 16, the terminal does not crack.

In addition, the terminal 18 of the invention is nonmetallic so that it is at least translucent to x-rays. The presently preferred composition for the terminal 18 is a plastic composition loaded with a conductive material, such as carbon fiber. In particular, the presently preferred plastic is a polypropylene and carbon 50-50 blend loaded with carbon fibers to about 20% by weight. It has been found that the polypropylene blend loaded with carbon fibers provides sufficient conductivity and is sufficiently resilient to form a tight fit over the post 16 without cracking when it is press fit thereover.

In order to provide a conductive path to the skin of a patient, an electrolyte composition 26 is applied about the bottom surface of the eyelet 12. The electrolyte composition 26 is generally a gel or jelly, either by itself or soaked throughout a pad of cellular material. Suitable conductive gels for this purpose are well known in the art. Commonly used gel materials for providing the conductive path from the bottom surface of the eyelet to the skin include hydrogel, adhesive gel and liquid gel. Any of these commonly used gels or equivalents may be combined with the

two part conductor of the present invention to form an electrode.

The terminal 18 should fit tightly over the post 16 on the eyelet. Metallic terminals in conventional two-part electrodes have been known to fail to meet the defribillation recovery standards when gel seeps between the terminal and the eyelet. This is due to a batterY effect. The resilient nonmetallic terminal is less apt to fail due TO such gel seepage.

In order to keep the electrolyte 26 beneath the electrode, a nonporous separator sheet 28 is mounted between the disc of the terminal 18 and the disc of the eyelet. The nonporous sheet 28 may also serve to provide a location on which a manufacturer can indicate its name for the product.

The composition of the electrode of the invention can also be defined electrically. The metallic coating on the eyelet 12 and the conductive material in the terminal 18 provides sufficient conductivity so that the completed electrode has an AC impedance at 10 Hz of less than 200 ohms before and after performing a defribillation. The conductivity can be adjusted by changing the thickness of the metallic coating on the eyelet 12 and/or the quantity of conductive material in the terminal 18.

In order to keep the electrode on the skin of a patient, an adhesive is generally included on the electrode. The electrolyte 26 may itself be an adhesive gel. While this may be sufficient, typically, an adhesive layer 30 is a part of the electrode. A common arrangement is to provide an adhesive layer 30 on the underside of the nonporous sheet 28. Before the electrode is put into use, a removable backing sheet 32 covers the adhesive layer 30. In the simple electrode arrangement shown in the drawings, the backing sheet 32 is made of a nonporous transparent plastic so as to prevent the electrolyte composition from leaking through.

Alternative electrode arrangements may include a plastic foam ring. In this case, the adhesive layer may be

provided on the bottom side of the foam ring. The top side of the foam ring is firmly adhered to the nonporous separator sheet. The foam makes a ring around the electrolyte composition.

To use the electrode of the present invention, the removable backing sheet 32 is peeled off the bottom of the electrode revealing the electrolyte composition. The electrolyte composition 20 remains stuck to the bottom surface of the disc on the eyelet 12. The electrode can then be pressed against the skin. The adhesive in the electrolyte composition or the adhesive layer 30 serves to hold the electrode to the skin. The electrolyte 20 provides electrical conductivity between the skin and the two part conductor. All pieces of the electrode of the present invention are advantageously at least translucent to x-rays so that x-ray photos of the patient can be made without the removal of the electrodes. The electrode of the present invention is advantageously made with a two part conductor so that the assembly machines commonly available in the industry may be used in the assembly of the x-ray translucent electrode.

Of course, it should be understood that various changes and modifications to the preferred embodiment described above will be apparent to those skilled in the art. For example, there are many ways to arrange an electrode with a two part conductor mounted therein. The electrode may include a foam ring, a plastic reservoir cover for the electrolyte and paper backing sheets. These and other changes can be made without departing from the spirit and scope of the invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the following claims.

WHAT IS CLAIMED IS:

1. A terminal for use on a medical electrode comprising:

an annular disc having a hole therein;

a hollow stud having a crown portion and a base portion, the crown portion being larger in circumference than the base portion and the base portion extending up from said disc and encircling the hole; and

said disc and said hollow stud being integrally formed of a resilient conductive composition.

2. The terminal of claim 1 wherein the resilient conductive composition comprises a resilient plastic composition loaded with a conductive material.

3. The terminal of claim 2 wherein the conductive material comprises carbon fiber.

4. The terminal of claim 3 wherein the resilient plastic composition is loaded with at least about 20% by weight of carbon fiber.

5. The terminal of claim 2 wherein the resilient plastic composition comprises polypropylene.

6. The terminal of claim 1 wherein the resilient conductive composition is at least translucent to x-rays.

7. An electrode, mountable on skin, comprising:

a first conductor for being mounted proximate to the skin;

a second conductor, in electrical communication with said first conductor, and mechanically mounted thereto, for providing a terminal, said second conductor being made of a conductive resilient composition; and

means for adhering said first conductor proximate to the skin.

8. The electrode of claim 7 wherein the conductive resilient composition of the second conductor is a resilient plastic composition loaded with a conductive material.

9. The electrode of claim 8 wherein the conductive material is carbon fiber.

10. The electrode of claim 8 wherein the plastic composition comprises polypropylene.

11. The electrode of claim 8 wherein the second conductor includes sufficient conductive material such that said electrode has an AC impedance at 10 Hz of less that 200 ohms before and after a defibrillation.

12. The electrode of claim 7 wherein said first conductor comprises a metallic coated plastic eyelet.

13. The electrode of claim 12 wherein the metallic coating on the plastic eyelet comprises at least one component selected from the group consisting of silver and a silver salt.

14. The electrode of claim 12 wherein the metallic coating has a thickness between .02 and .1 mils.

15. The electrode of claim 12 wherein said second conductor comprises a stud press fit onto said eyelet.

16. The electrode of claim 7 wherein said means for adhering comprises an electrolyte composition spread over a bottom surface of said first conductor.

17. The electrode of claim 7 further comprising a nonporous layer mounted between said first conductor and said second conductor.

18. The electrode of claim 17 wherein said means for adhering comprises an adhesive layer on said nonporous layer.

19. The electrode of claim 18 further comprising a removable backing sheet covering the adhesive layer.

20. The electrode of claim 7 wherein said first and second conductors are at least translucent to x-rays.

21. An electrode, mountable on skin, comprising:

a first conductor, at least translucent to x-rays, for being mounted proximate the skin;

a terminal, in electrical connection with said first conductor and mechanically mounted thereto, said terminal being made of a second conductor that is at least translucent to x-rays; and

adhering means for adhering said first conductor proximate to the skin.

22. The electrode of claim 21 wherein said second conductor is made of a conductive resilient non-metallic composition.

23. The electrode of claim 22 wherein the conductive resilient non-metallic composition is a plastic composition loaded with carbon fiber.

24. The electrode of claim 23 wherein the plastic composition is loaded with at least about 20% by weight of carbon fiber.

25. The electrode of claim 23 wherein the plastic composition comprises polypropylene.

26. The electrode of claim 22 wherein the conductive resilient non-metallic composition includes sufficient

conductive material such that said electrode has an AC impedance at 10 Hz of less than 200 ohms before and after a defibrillation.

27. The electrode of claim 21 wherein said first conductor comprises a metallic coated plastic eyelet.

28. The electrode of claim 27 wherein the metallic coating on the plastic eyelet comprises at least one component selected from the group consisting of silver and a silver salt.

29. The electrode of claim 28 wherein the metallic coating has a thickness between .02 and .1 mils.

30. The electrode of claim 27 wherein said terminal comprises a stud press fit onto said eyelet.

31. The electrode of claim 27 wherein said adhering means comprises an electrolyte composition spread over a bottom surface of said first conductor.

32. The electrode of claim 21 further comprising a nonporous layer mounted between said first conductor and said terminal.

33. The electrode of claim 32 wherein said adhering means comprises an adhesive layer spread on said nonporous layer.

34. The electrode of claim 33 further comprising an electrolyte composition spread over a bottom surface of said first conductor.

35. The electrode of claim 33 further comprising a removable backing sheet covering the adhesive layer.

36. An electrode mountable on skin comprising:

a plastic eyelet including a disc with a bottom surface and a post sticking up from the disc;

a conductive layer coating said plastic eyelet;

a terminal shaped as a hollow stud press fit onto the post of said plastic eyelet, made of a conductive resilient non-metallic composition; and

an electrolyte composition spread upon the bottom surface of said plastic eyelet.

37. The electrode of claim 32 wherein the conductive resilient non-metallic composition is a plastic composition loaded with carbon fiber.

38. The electrode of claim 37 wherein the plastic composition is loaded with at least about 20% by weight of carbon fiber.

39. The electrode of claim 37 wherein the plastic composition comprises polypropylene.

40. The electrode of claim 37 wherein said conductive layer has a thickness of between .02 and .1 mils.

41. The electrode of claim 40 wherein the conductive resilient non-metallic composition includes sufficient conductive material such that said electrode has an AC impedance at 10 Hz of less than 200 ohms before and after a defibrillation.

42. The electrode of claim 36 wherein said conductive layer on said plastic eyelet comprises at least one component selected from the group consisting of silver and a silver salt.

43. The electrode of claim 36 further comprising a nonporous sheet mounted between the disc of said plastic eyelet and said terminal.

44. The electrode of claim 36 wherein said conductive layer, said electrolyte composition and said terminal are at least translucent to x-rays.

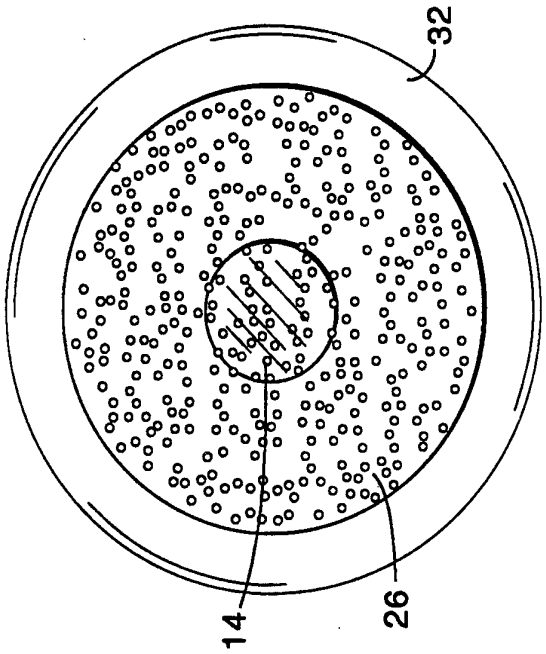


FIG. 3

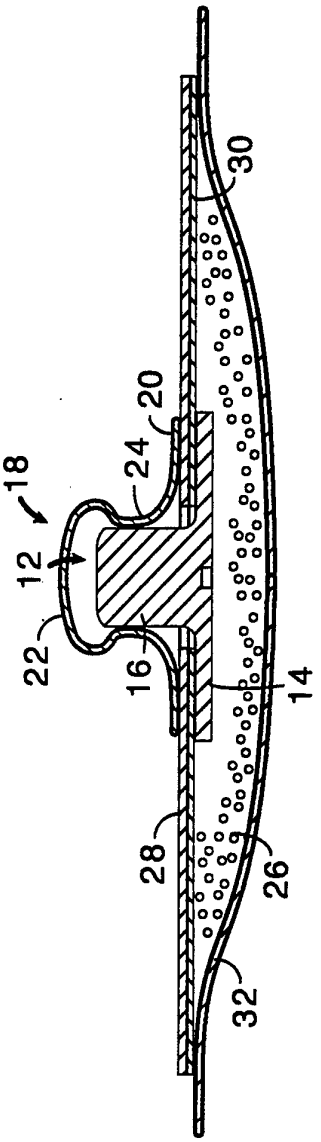
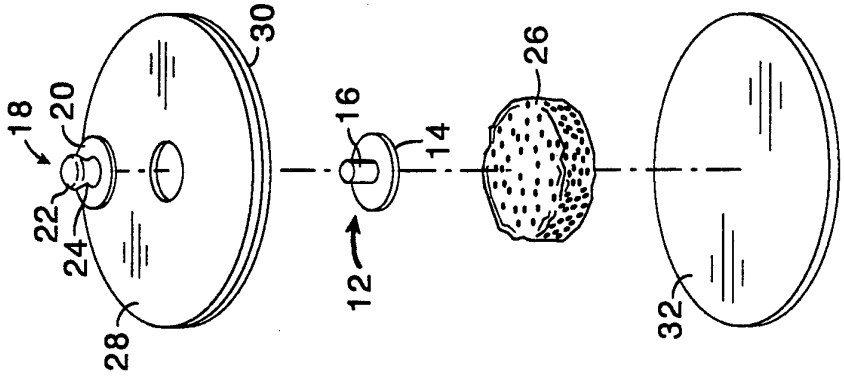


FIG. 2

FIG. 1



INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 94/09674

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/0408 A61B5/0416

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	CA,A,1 144 606 (R. BRABANT) 12 April 1983 see page 6, line 28 - page 7, line 30	1,7,12, 13,15-19 21-23, 27-29, 31-36, 42,43
A	see page 8, line 16 - line 31; figures --- -/--	30,43

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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A	see page 1, line 1 - line 17 see page 4, line 3 - line 24 see page 6, line 24 - page 8, line 18 see page 9, line 9 - line 10 see page 10, line 20 - line 24 see page 14, line 9 - page 15, line 21; claims; figures	2-4,6-9, 11-14, 16-20, 26,37, 38,40, 41,44
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