

- [54] METHOD OF MAKING A BIPOLAR ELECTRODE STRUCTURE

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Related U.S. Application Data

- [62] Division of Ser. No. 366,701, June 4, 1973, abandoned.

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24/255 AS; 174/168; 339/101

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- [58] **Field of Search** 128/2.06 E, 2.1 E, 404,
128/418, DIG. 14, 348; 174/163 R, 168, 174,
175; 339/101, 108 R, 108 CP, 110 C, 110 R,
124, 228, 252 R, 252 S, 260, 261; 24/20 S,
110, 115 G, 237, 243 LC, 243 H, 243 AC,
255 AS, 255 BC, 255 C

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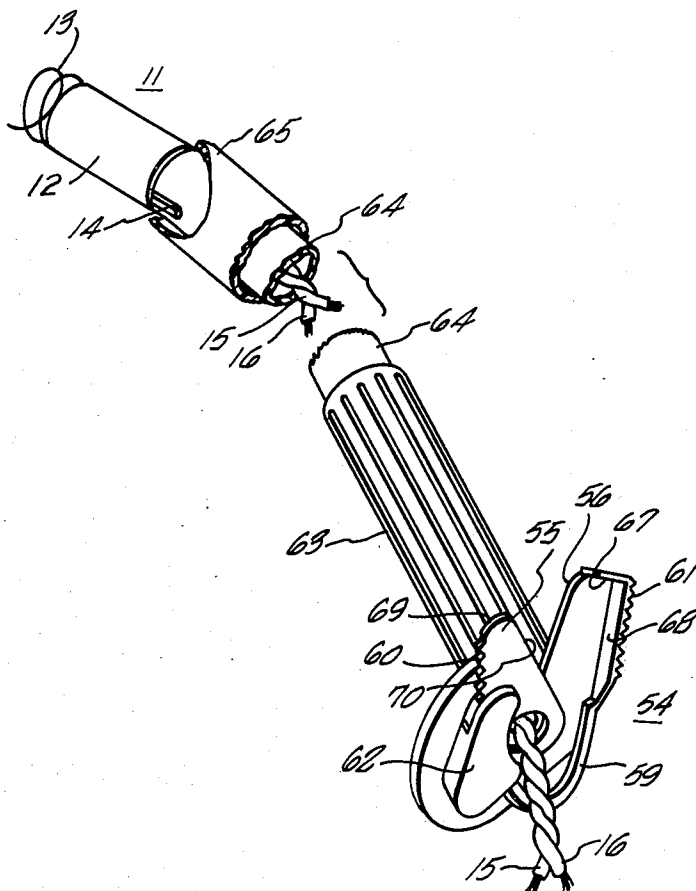
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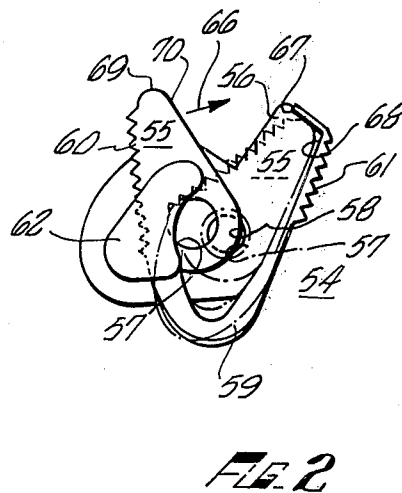
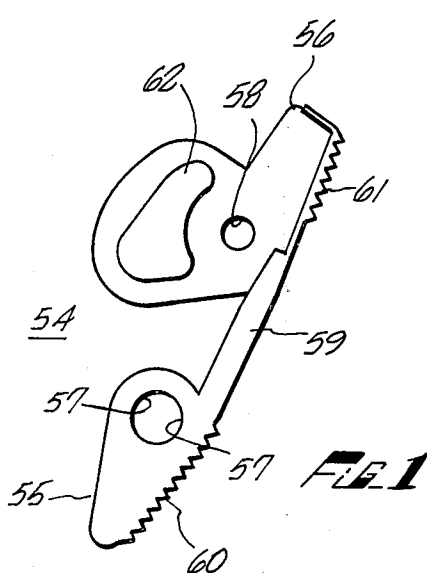
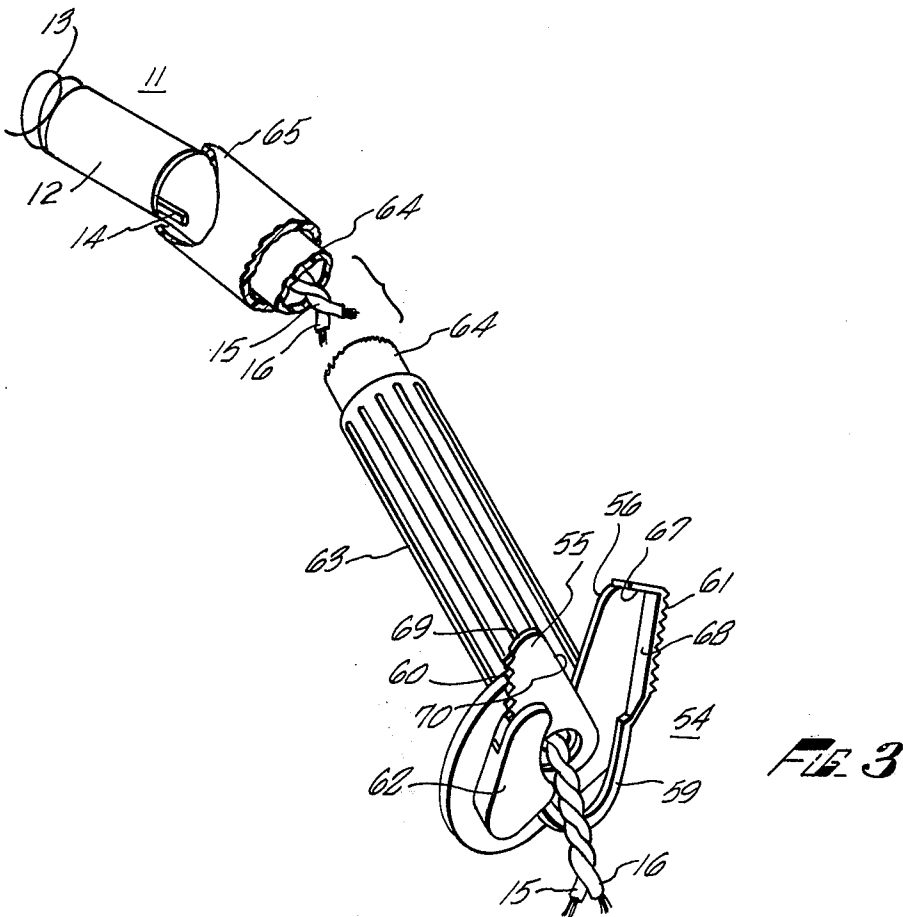
[57]

ABSTRACT

A retainer and drive clip, the clip being secured to a flexible drive tube dimensioned for insertion through the vagina and cervix of a woman in, or about to be in labor, and containing a pair of conductors having means for effecting electrical contact with the fetus by rotation of the drive tube, the drive clip carrying a fixed clamp element, a movable clamp element and yieldable means to cause the clamp elements to secure and retain the conductors whereby the drive tube may be manipulated to effect contact and the conductors may be restrained.

5 Claims, 3 Drawing Figures





METHOD OF MAKING A BIPOLAR ELECTRODE STRUCTURE

This application is a division of application Ser. No. 366,701, filed June 4, 1973, now abandoned.

BACKGROUND OF THE INVENTION

Monitoring fetal heartbeat by means of electrode elements attached to the fetus at or near the time of labor, have proven to be of substantial importance in connection with child birth. However, the problem of making and maintaining good electrical contact so that dependable monitoring of the fetal heartbeat has been difficult to attain.

SUMMARY OF THE INVENTION

The present invention is directed to a retainer and drive clip for use with a fetal monitoring device having a flexible drive tube, electrical contact elements and conductors extending therefrom through the drive tube which is summarized in the following objects:

First, to provide a retainer and drive clip for a fetal monitoring device, which provides dependable control of the device under difficult conditions of use to insure maintenance of good electrical contact with the fetus.

Second, to provide a retainer and drive clip as indicated in the previous object, which involves a novelty arranged drive means adapted to be secured to the flexible drive tube to facilitate manual rotation of the flexible drive tube and effect penetration of an electrode into the fetus, and a novel clip retainer for securing the conductors, including a clamp element fixed to the clip and a movable clamp element connected to the clip by a yieldable element.

Third, to provide a retainer and drive clip as indicated in the other objects, wherein all elements thereof are portions of a single molded part.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is made to the accompanying drawings, in which:

FIG. 3 is a perspective view of the retainer and drive clip shown attached to a monitoring device, the monitoring device being shown fragmentarily.

FIG. 2 is an end view of the retainer and drive clip in position to engage a pair of conductors.

FIG. 1 is a side view of the retainer and drive clip in its extended position as when molded.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the upper portion of FIG. 3, is illustrated a bipolar electrode structure 11 formed by an injection molding process utilizing a plastic such as a low density polyethylene under a pressure of approximately 20,000 lbs. per square inch. The bipolar electrode structure includes a polyethylene body 12 having a first spring or electrode 13 at the forward end thereof and a second or wafer electrode 14 at the rear end thereof. The first and second electrodes are made of a conductive metal such as stainless steel or the like. The exposed surface area of the wafer electrode 14 is approximately twice the exposed surface area of the spring electrode 13. Leading into the rear end of the body 12 of the bipolar electrode structure 11 are a first wire or conductor 15 and a second wire or conductor 16. Conductors 15 and 16 at their first ends are electrically connected in the body 12 of the bipolar electrode 11

to the spring electrode 13 and the wafer electrode 14 respectively. The second end of the conductors 15 and 16 are connected in a manner well known in the art to monitoring equipment (not shown) suitable for monitoring fetal heartbeat, heartrate or the like.

FIG. 1 illustrates a retainer and drive clip having a head portion 54 of an integrally molded, one-piece assembly. The head portion 54 comprises a first ear portion 55 having a first aperture or pathway 57 located therein and a second ear portion 56 having a second aperture 58 located therein. First ear portion 55 is integrally connected to the second ear portion 56 by means of a flexible arm 59. An outer or gripping edge 60 and 61 of the first and second ear portion respectively are provided with grooves serrations or a general roughening to aid in the use of the clip as previously described. The second ear portion 56 includes an integrally formed elbow or stop 62 which allows the first ear portion 55 to be engaged therein when in a first or relaxed position as shown in FIG. 9.

FIG. 2 illustrates the head portion 54 in its relaxed position and in its second or flexed position. First ear portion is positioned under the top portion of stop 62 in its relaxed position. First ear portion 55 is illustrated as being positioned over a surface of the second ear portion 56 in the clips second position.

In operation, the conductors 15 and 16 are positioned through a collar of the clip and second aperture 58 of the second ear portion 56 and the first aperture 57 of the first ear portion 55 when the clip is in its flexed position. The flexed position is accomplished by gripping the outer surface of gripping surfaces 60 and 61, respectively, of the first and second ear portions and squeezing or urging them together thereby flexing flexible arm 59 and providing substantial alignment of first and second apertures 57 and 58.

When the grip is relaxed from the gripping surface 60 and 61, the flexible arm 59 urges the ear portions apart and the first ear portion 55 is never allowed to relax beyond a side member of stop 62. This relaxed position will grip or hold the conductors 15 and 16 in a manner to provide for a sufficient force to urge the bipolar electrode structure 11 to remain in its grooves or slots or a driving tube as previously described.

FIG. 3 illustrates the clip including the previously described head portion 54 and an attached elongated tubular collar 63 which is formed integral therewith. The head portion 54 is illustrated to be in its relaxed position, that is, engaging the first and second conductors 15 and 16 which are passed through the respective apertures of second ear portion 56 and the first ear portion 55 to provide a sufficient gripping or holding force on the conductors to assure a prevention of relative slippage between the conductors 15, 16 and a driving tube 64. The first ear portion 55 is illustrated as being positioned by allowing the flexible arm 59 to substantially relax, but still desire to approach its fully opened position as in FIG. 1. In any event, the side member of stop 62 will prevent the head portion 54 from returning to the position of FIG. 1.

The elongated tubular collar or neck portion 63 includes an inner diameter which provides a frictional engagement with the surface of the driving tube 64 to provide control of the rotational and longitudinal movement thereof. An internal ridge member is optionally provided in the interior of the collar portion 63 to act

as a stop for the driving tube 64 at a predetermined depth.

As has been previously described, the driving tube 64 includes at its farthest end, slots or the like in which the wafer electrode 14 may be mounted, thereby aligning the bipolar electrode structure 11 in the proper position. A guide tube 65 is provided to perform the functions previously described.

The clip is preferably made of a low density polyethylene using an injection molding technique with an approximate pressure of 20,000 lbs. per square inch. The clip has the advantages previously described and provides for the control of the relative sliding between the conductors and the driving tube in an improved way while also being relatively easy to manufacture and mass produce.

When the clip is further compressed as indicated by arrow 66 in FIG. 2, the two apertures or holes 57 and 58 become exactly aligned to prevent any drag on the conductors 15 and 16 as the tubes 64 and 65 are removed from the conductors 15 and 16. A stop for accomplishing this alignment is provided by faces 67 and 68 of ear portion 56 being contacted by edges 69 and 70 of ear portion 55.

While embodiment and application of this invention has been shown and described it will be apparent to those skilled in the art that many more modifications will be possible without departing from the inventive concepts herein described.

I claim:

1. The combination with a fetal monitoring device, having a flexible guide tube dimensioned for insertion through the vagina and cervix of a woman in labor; electrode means disposed initially at the inner end of the guide tube for attachment and electrical contact with a fetus upon rotation thereof; a flexible drive tube slidable and rotatable in the guide tube and removably attachable to the electrode means to effect rotation thereof; and conductors extending from the electrode means through and beyond the drive and guide tubes for connection to an electrical monitoring apparatus, of a drive and clamp means disposed at the outer ends of the guide and drive tubes, and comprising:

- a. a tubular drive means secured to the flexible drive tube to receive the conductors extending there-through;
- b. a first conductor clamping element fixed to the tu-

bular drive means, extending laterally therefrom and having a perforation aligned with the drive means to receive the conductors;

- c. a second conductor clamping element also extending laterally from the drive means, overlying the first clamping element and perforated to receive the conductors;
- d. and yieldable means tending to cause relative off-setting movement of the perforations thereby to clamp the conductors.

2. A drive and clamp means as defined in claim 1, wherein:

- a. the clamping elements extend in angular relation and their distal edges are manually engageable to move the perforations toward alignment thereby to free the conductors.

3. A drive and clamp means as defined in claim 2, wherein:

- a. the yieldable means is a connecting strap integral with both clamping elements.

4. A drive and clamp means as defined in claim 3, wherein:

- a. a retaining element extends from one of the clamping elements over the other clamping element to retain the clamping elements in mutual engagement and to limit arcuate spreading movement of the clamping elements.

5. A single piece conductor retaining clip, comprising:

- a. a tubular portion adapted to receive a conductor;
- b. a fixed laterally extending perforated handle portion at one end of the tubular portion;
- c. an arcuately movable laterally extending perforated handle portion;
- d. an integral resilient strap connecting the handle elements;
- e. a retainer element extending from one of the handle portions over the other handle portion to maintain the handle portions in mutual engagement and limit arcuate movement of the movable handle;
- f. the handle portions having distal edges for manual engagement to cause alignment of their perforations for insertion of a conductor, the connecting strap causing misalignment of the perforations to clamp the conductor.

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