

- [54] **CERVICAL CUFF**
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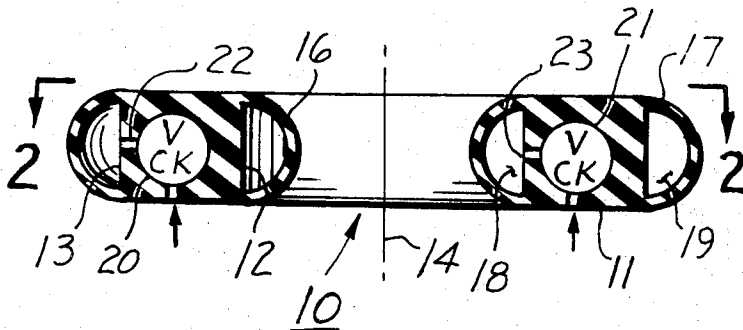
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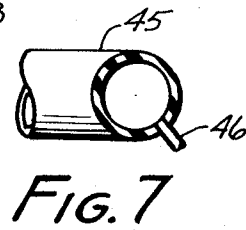
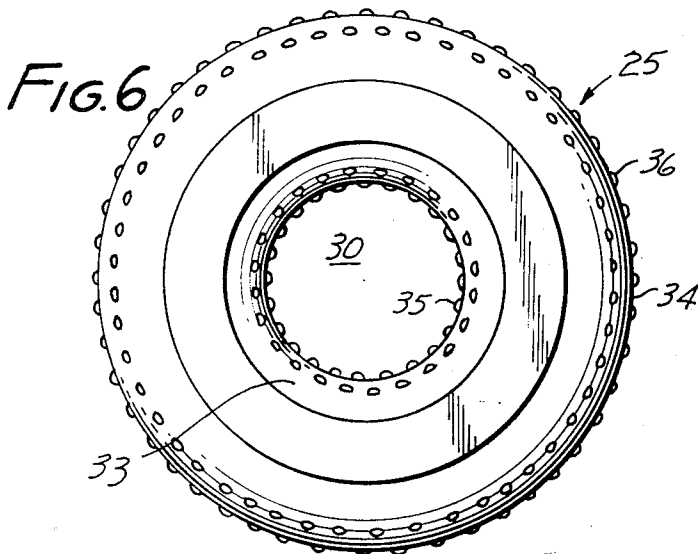
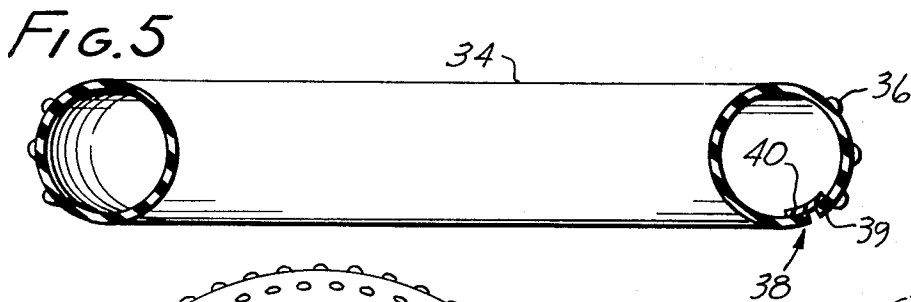
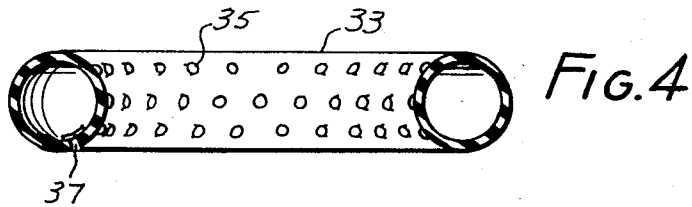
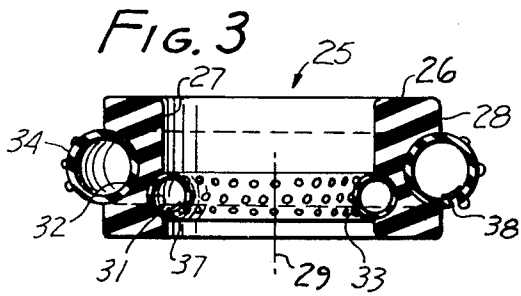
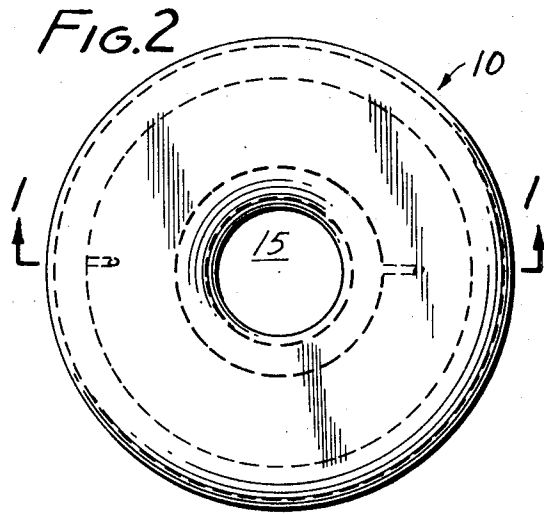
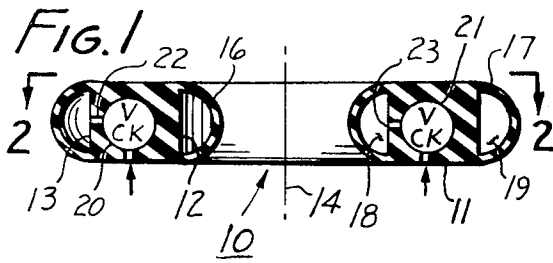
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[57] **ABSTRACT**

A cervical cuff for holding closed an incontinent cervix, comprising a stiffly flexible substantially inelastic support ring having a central axis and an inner and an outer peripheral wall. The inner wall forms an opening to receive the neck of the cervix. A first and second elastic impermeable membrane extends around and is mounted to the inner and outer walls respectively so as to form a first and second laterally expansible chamber. Inflation of the chambers extends the membranes so that the inner membrane engages the cervical neck inside the opening, and the outer membrane engages body tissue surrounding and spaced from the cervical neck. The ring is thereby retained in the body and the neck is held closed inside the ring.

9 Claims, 7 Drawing Figures





CERVICAL CUFF

This invention relates to a cervical cuff for an incontinent cervix.

The problem of incontinent cervixes has been a nagging one in the surgical field for a long time. Speaking generally, an incontinent cervix is one which cannot contain the products of conception during the second trimester. Its clinical manifestations including bulging of the fetal membranes, absence of uterine contractions, and absence of bleeding, leading to rapid and painless second trimester abortion. There have been extensive attempts to manage the incontinent cervix which have generally been centered on three approaches. The first approach is surgical, which includes the techniques of cerclage, trachelorrhaphy, and isthmorrhaphy. The second approach is hormone therapy using progestational agents and the third approach is mechanical devices such as certain kinds of pessaries.

There are disadvantages in all of the above methods. For example, surgical complications of cerclage include the risk of uterine rupture due to failure to remove the restraint in the presence of strong uterine contractions and amnionitis, endometritis, sepsis, anesthesia risks to both mother and fetus, and cervical amputation. Hormonal therapy has met with only moderate success. The use of a pessary may involve problems of discharge, discomfort, erosion, and bleeding.

In all of the foregoing three approaches, there is also involved the significant factor of economic cost, both as to the time required for the procedure, and the expenses surrounding it. To a person with limited funds, however successful any of these techniques may be, it is simply too expensive.

The inflatable cuff of this invention has been designed to provide the obstetrician with a safe and easy method of treating cervical incompetence. The device is simple to insert; it lacks the major complications listed above, and it is very economical. It can be inserted in the doctor's office and does not require hospitalization.

A cervical cuff according to this invention comprises a stiffly flexible substantially inelastic support ring having a central axis and an inner and an outer peripheral wall. The inner wall forms an opening to receive the neck of the cervix. A first and a second elastic impermeable membrane extends around and is mounted to the said inner and outer wall respectively, forming a first and a second laterally expansible chamber. Inflation of the chambers extends the membranes laterally so that the inner membrane engages the cervical neck inside the opening and closes the neck. The outer membrane engages body tissue surrounding and spaced from the cervical neck whereby to retain the ring in the body.

According to a preferred but optional feature of the invention, valve means is provided in fluid communication with each of said chambers to admit and retain fluid under pressure therein.

The above and other features of this invention will be fully understood from the following detailed description and the accompanying drawings in which:

FIG. 1 is an axial cross-section taken at line 1—1 of FIG. 1;

FIG. 2 is a top view taken at line 2—2 of FIG. 1;

FIG. 3 is an axial cross-section of the presently preferred embodiment of the invention;

FIGS. 4 and 5 are axial cross-sections of portions of FIG. 3;

FIG. 6 is a top view of FIG. 3 taken at lines 6—6 therein; and

FIG. 7 is a fragmentary cross-section showing another means for supplying fluid to the chambers.

In FIG. 1 there is shown a cervical cuff 10, according to the invention which includes a stiffly flexible, substantially inelastic support ring 11, having an inner wall 12 an outer wall 13 and a central axis 14 with which the inner and outer walls are coaxial. The inner wall forms an opening 15 to receive the neck of the cervix.

A first and a second membrane 16, 17 are attached to the ring at the inner and outer wall respectively so as to form therewith an inner and an outer chamber 18, 19 respectively. The membranes are flexible and elastic so that the chambers are expansible when fluid is introduced therein. They are also impermeable.

The entire device is preferably made of silicone rubber because of the tolerances of tissue to this material of construction. The support ring will be substantially inelastic and stiffly flexible because of its relatively heavy cross-section, while the membranes are laterally expansible because of their relatively thinner cross-section. These sections will be selected with a view to the tensile properties of the particular formulation of silicone rubber which is used. A suitable ring will have an inner diameter of 1 1/2 inches, an outer diameter of 2 1/2 inches and an axial thickness of 3/8 inch. The inner membrane will inflate to a 1 1/2 inch diameter and the outer membrane will inflate to a 3 inch diameter.

In case a self-sealing structure is used, the chambers may be inflated simply by piercing the support ring or either of the membranes with a fine needle and then injecting a fluid such as saline solution, relying upon tendency of the rubber to close on itself to keep the fluid confined. Alternatively, check valves 20, 21 of any desired construction can be built into the ring and connected by channels 22, 23 to the chambers. These are only two examples of the many alternative means by which the chambers may be filled with fluid under pressure. Another will be shown in connection with the embodiment of FIGS. 3-6.

The device of FIGS. 3-6 is the presently preferred embodiment of the invention. It is a cervical cuff 25 with a support ring 26 having an inner wall 27 an outer wall 28, and a central axis 29. The inner wall forms a central opening 30.

Peripheral grooves 31, 32 are formed in an inner and outer walls respectively. These are semi-circular in cross-section and receive first and second membranes 33, 34 in the form of continuously sealed circularly sectioned flexible peripheral tubes whose outer dimensions are congruent to those of the groove into which they fit. The first membrane 33 is shown in FIG. 3 seated in groove 31 with a plurality of protuberances 35 facing inwardly. The second membrane 34 is shown in FIG. 5 with a plurality of protuberances 36 on its outside periphery, whereby the protuberances will face outside the ring and engage and improve the contact with the tissues against which it abuts when in use. When not filled with fluid (either gas under pressure, or a trapped liquid), the membranes will yield to pass adjacent objects, but when filled they become rigid at or even beyond their illustrated size to fix the cuff in place.

Suitable dimensions for the ring are: inner diameter, 1 1/2 inches, outer diameter, 2 1/2 inches, axial thickness 1 inch. Relaxed outer tubular diameter of outer membrane one-half inch, its peripheral diameter equally 3 inches. Relaxed outer tubular diameter of inner membrane, three-eighths inches, diametrical central opening, 1 1/8 inches. Protuberance one-sixteenth inch spherical domes on 1/4 inch centers.

Valves 37, 38 are provided in the membranes 33, 34 respectively and may be typical bladder type valves such as found in basketballs and footballs. These may be vulcanized in place and typically will include a base 39 and an overlying diaphragm 40 which can be displaced by a needle to pass the fluid. Alternatively, the membranes may be provided with tubings integral therewith which can be led and connected to a source of fluid under pressure and then the tube may be tied, fused or otherwise closed with the excess tube cut off to size after installation.

In FIG. 7, a tubular membrane 45 is shown with a conduit 46 connected to it to pass fluid. This conduit may be closed in any desired manner.

In the device of FIGS. 3-6, the materials of construction may again be silicone rubber, the cross-sectional area of the support ring being such as to render it stiffly flexible and substantially inelastic while the wall thickness of the membranes is such as to permit the chambers to be expanded so as to accomplish the purpose of the invention.

The fluid for insertion may be gas or liquid, but liquid is preferred. The term "inflation" as used herein encompassed not only a stretching of the membrane, but also the rigidity of a membrane in its normal configuration, its prior condition having been slack, such as by there being air in the membranes of FIG. 3, followed by filling them full of liquid.

The use of the devices are extremely simple. While the membranes are uninflated, the neck of the cervix is grasped and pulled through the central opening and the ring is thrust upwardly to its final location. Then the chambers are inflated so as to bring the membranes into contact with the tissue which they are to engage. The fluid is retained either by check valves, by cutting, tying or fusing the conduits, or simply by withdrawing the needle from a self-sealing structure. The cuff is then in place and will remain fixed there until it is time for it to be removed. The technique of insertion is simple, does not require hospitalization and the device itself is elegantly simple and inexpensive.

This invention is not to be limited by the embodiments shown in the drawings and described in the de-

scription, which are given by way of example and not of limitation, but only in accordance with the scope of the appended claims.

We claim:

5 1. A cervical cuff for holding closed the neck of an incontinent cervix comprising: a stiffly flexible, substantially inelastic support ring having a central axis and an inner and an outer peripheral wall, the inner wall forming an opening to receive the neck of the cervix; a first and a second elastic fluid-tight membrane extending around and mounted to the said inner and outer wall respectively, forming a first and a second laterally expansible chamber, means permitting the inflation of said first and second chambers whereby inflation of said chambers extends said membranes laterally so that the inner membrane engages a cervical neck inside the opening, and the outer membrane engages body tissues surrounding and spaced from the cervical neck, whereby to retain the ring in the body while the inner membrane holds closed the cervical neck.

20 2. A cervical cuff according to claim 1 in which said means permitting the inflation of said chambers is valve means provided in fluid communication with each of said chambers to admit and retain fluid under pressure therein.

3. A cervical cuff according to claim 1 in which the membranes comprise bodies of revolution joined at parallel edges to the ring.

4. A cervical cuff according to claim 1 in which the membranes comprise continuous closed tubes an in which the inner and outer walls have grooves to receive said tubes.

5. A cervical cuff according to claim 1 in which the inner one of said membranes has protuberances on its inner surface and in which the outer membrane has protuberances on its outer surface.

6. A cervical cuff according to claim 1 in which said means permitting the inflation of said chamber is valve means provided in each of said membranes comprising a check valve.

7. A cervical cuff according to claim 6 in which the valve means comprises a deflectable diaphragm.

8. A cervical cuff according to claim 1 in which said means permitting the inflation of said chamber is conduit means provided to the respective chambers for filling the same.

9. A cervical cuff according to claim 1 in which said means permitting the inflation of said chambers comprises a self-sealing wall provided to the respective chambers.

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