United States Patent

Cimber

[15] **3,658,057**

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[54] DIAPHRAGM

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[21] Appl. No.: **873,848**

[52] **U.S. Cl.** **128/129**

[51] **Int. Cl.** **A61f 5/46**

[58] **Field of Search** 128/127–130; 9/316; 152/340, 341; 46/87–90

[56] **References Cited**

UNITED STATES PATENTS

2,118,165	5/1938	Christopher et al.	9/316
3,126,936	3/1964	Beckadolph	152/341

FOREIGN PATENTS OR APPLICATIONS

108,261	3/1899	Germany	128/129
487,197	5/1928	Germany	128/129

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[57] **ABSTRACT**

A self inflating diaphragm having an inner tube containing air or gas under pressure and an outer flexible tube; a plug removable by a string from the inner tube permits the air or gas from the inner tube to expand the outer tube to occlude the passage; an occluding membrane may be used across the inner tube to facilitate retention of fluids and for contraception. With or without the membrane the device may constitute a supporting structure.

5 Claims, 7 Drawing Figures

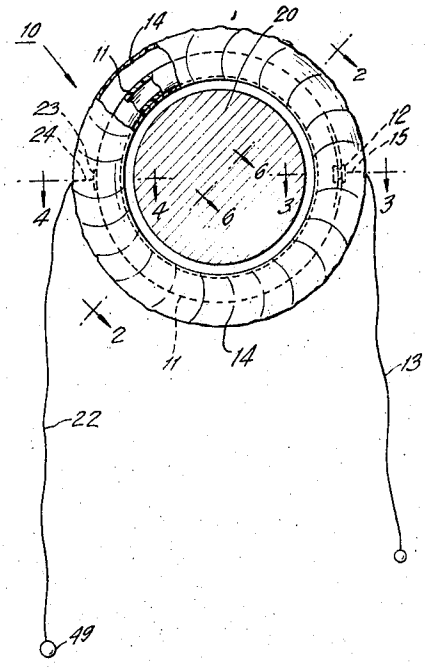


FIG. 1.

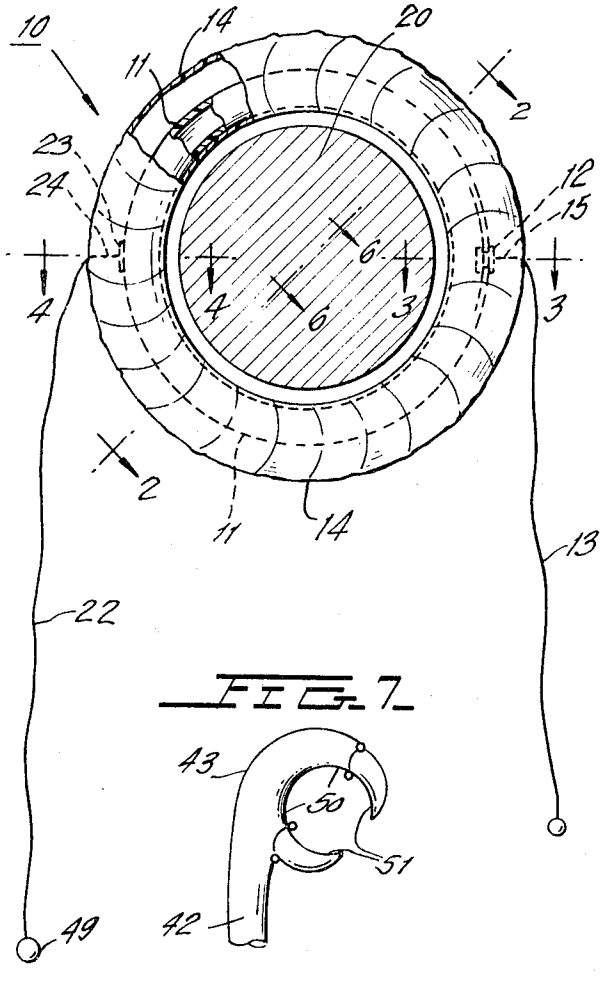


FIG. 7.

FIG. 2.

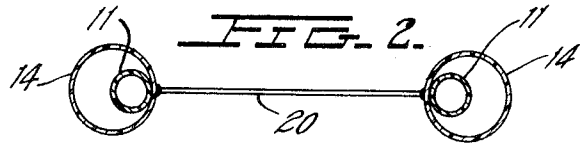


FIG. 3.

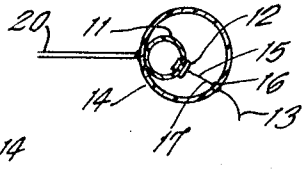


FIG. 4.

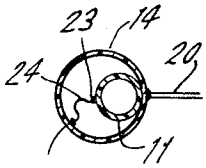


FIG. 6.

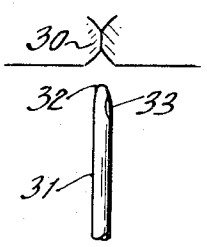
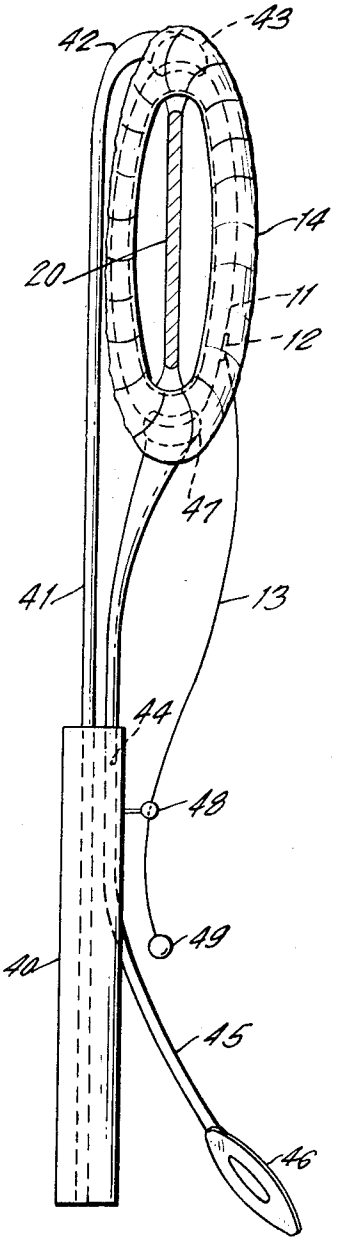


FIG. 5.



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DIAPHRAGM

My present invention relates to a vaginal diaphragm and more particularly to a self inflating diaphragm which may readily be placed in position and which will be inflated by means associated with and in the diaphragm form an appropriate seal and an air tight occlusion of the passage when in position. Inflatable structures for insertion in the vagina have been known but have required external additional means for apparatus for effecting the inflation.

My novel diaphragm consists essentially of an inflatable annular tubular envelope having enclosed therein another tubular annular container of smaller cross section than the envelope. The inner tubular container is charged with air or other selected gas under appropriate pressure so that when the air is vented from the inner tube it will inflate the annular inflatable outer tube to seal and occlude the passage and to position and retain the device.

A removable plug is provided for the inner tube; a string is attached to the plug and passed through an appropriately sealed opening in the outer tube. When the device is in the appropriate position in the passage extension of the string and a pull on the string will pull the plug from the inner tube permitting the air in the inner tube to expand into the outer flexible tube thereby expanding the ring to position it firmly in place and to occlude the passage.

A membrane may be extended across the area bounded by the inner surface of the inner tube. This membrane may be an extension of the material of the outer tube or may be a separate piece of material secured in place and will serve also to seal the passage in which the device is located. Where desired under appropriate circumstances the membrane may be provided with a valved opening that will permit the withdrawal of discharge fluid without removing the device from the passage.

An appropriate friction surface may be provided for the outer tube to ensure retention of the occluding position when the outer tube is expanded.

In addition, an appropriate removal string or other attachment may be provided for the entire device; said removal string preferably being in addition to the plug removal string or device.

It is, therefore, the principal object of my invention to provide a self inflating diaphragm ring which, after it is positioned in the passage, may by a very simple malipulation be caused to inflate without the utilization of external inflating means and, therefore, serve to seal and occlude the passage.

The foregoing and many other objects of my invention will become apparent in the following description and drawings in which:

FIG. 1 is a plan view partly in phantom of my novel diaphragm.

FIG. 2 is a cross sectional view taken on line 2—2 of FIG. 1 looking in a direction of the arrows.

FIG. 3 is a cross sectional view taken on line 3—3 of FIG. 1 looking in a direction of the arrows.

FIG. 4 is a cross sectional view taken on line 4—4 of FIG. 1 looking in a direction of the arrows.

FIG. 5 is a view showing one method of using an applicator to insert my novel diaphragm.

FIG. 6 is a cross sectional view taken on line 6—6 of FIG. 1 looking in the direction of the arrows indicating a modification of the diaphragm to permit the drawing off of fluids where the diaphragm is utilized primarily to retain fluids.

FIG. 7 is a view in perspective of the diaphragm engaging portion of the applicator of FIG. 5.

Referring now to FIGS. 1, 2, 3 and 4, my novel diaphragm comprises a relatively stiff and preshaped annular tube 11 which is sufficiently flexible, however, to permit simplified insertion of the diaphragm structure. The tube 11 is provided with a removable plug 12 to which is attached a string 13; the plug may have any desired shape preferably one where internal air or gas pressure inside the annular tube 11 will maintain the plug in air blocking arrangement. The plug is arranged in an appropriate opening in the tube 11 so that it may be pulled

out by a pull on the string 13 which is attached to the plug 12. The tube 11 is surrounded by the highly flexible tubular envelope 14 which when expanded is of larger cross sectional area than the tube 11 and which is air tight or nonpermeable to any gas that may be included in the tube 11. Preferably the annular envelope or tube 14 is made of polyethylene or any other thin plastic which will resist body fluids and will be impermeable to the air or gas which will be used as hereinafter explained to inflate it.

The string 13 may pass through the material of outer envelope or tube 14 in any of various selected ways. The portion 15 of the string 13 between the plug 12 and the inner wall of the envelope 14 may be sufficiently long so that a pull on the end of string 13 will result in extending the string 13 to pull out the plug without overextending the envelope 14 thereby permitting the gas or air to escape from the inner tube 11 to inflate the outer tube or envelope 14. If it is desired because of the dimensional arrangements involved to ensure that the string 13 may slide with respect to the outer envelope 14 then as shown in FIG. 4 the string 13 may pass through an opening 16 in the outer envelope the inner surface of which is provided at the opening 16 with an appropriate sealing adhesive 17 which will engage the outer surface of the plug 12 when it is pulled against the adhesive element 17 in order to seal the opening at that point. If, however, the polyethylene or other material for forming the outer envelope or tube 14 is simply sealed to the string with sufficient slack in the string in the area 15 to permit an extension thereof to pull out the plug then such sealing arrangement will not be needed.

Where the unit is to be used entirely as a support device rather than as a diaphragm an additional membrane is not needed. Where, however, its primary use is as a diaphragm then a membrane or film 20 may be supported inside the tubular elements 11 and 14. The membrane 20 may be either separately sealed to the inner surface of the tubular element 14 or may constitute a two layer extension of the tubular element 14.

In addition, as seen also in FIG. 4, a string 22 may be anchored at 23 to the other end of tube 11 to provide a means for removing the diaphragm. The string 23 will pass through the outer envelope 14 being, however, sealed thereto. A sufficient additional run of string may be provided at the section 24 thereof between the two tubes to permit full expansion of the outer envelope 14. When, however, the string 22 is pulled the inner section 23 will straighten out under the pull and transmit the mechanical pulling force to the diaphragm to assist in its removal.

The outer surface of the envelope 14 may be appropriately treaded or otherwise marked or formed to provide a good frictional fit against the inner walls of the passage in which it is positioned.

In operation, the entire unit 10 is inserted in the passage and rotated through approximately 90° so that it is appropriately positioned with respect thereto. A pull on the string 13 will then remove the plug 12 from the inner tube 11 which as above pointed out has been filled either with compressed air or other compressed gas. The compressed air or gas escaping from the opening from which the plug 12 has been removed will now expand into the envelope 14 and, therefore, expand the envelope 14 so that the outer surface of the envelope 14 will bear against the inner surfaces of the passage and provide a sufficient seal with respect thereto. The outer envelope 14 or outer tube will thus seat appropriately in the passage in which it is inserted conforming to any irregularities of the passage and because of the resilience of compressed air or any compressed gas that may be used will exert an even pressure on all the inner surfaces of the passage which it engages thereby providing a seal under substantially predetermined pressure and distributing the forces evenly over all elements of the passage. This will serve to support the entire ring structure including the inner stiffer tube 11 in position so that where it is desired to utilize the device as a support structure it will perform the function. Where, however, it is desired to utilize the

device as a sealing structure, as well, the presence of the membrane **20** in the unit provides appropriate sealing for retention of fluids and for contraceptive purposes.

In the event of irregularities in the passage or the projection of the cervix into the passage in an area where it is desired to obtain the seal the membrane **20** may be made sufficiently loose or sufficiently resilient to accommodate to such irregularity including the projection of the cervix. Where it is made sufficiently loose for this purpose additional material will be provided in the diaphragm section **20** to permit the diaphragm to conform itself either to the shape of the cervix or to form a pocket big enough to receive the cervix with room to spare.

My novel device thereby creates an air tight occlusion of the vaginal passage and can be placed at any desired level in the passage. It may be used as a contraceptive ring. It may also, if placed at a lower level, be used to block off the menstrual flow and may be used to control the incontinence that may result from a vaginal fistula.

The utilization of the air tight fit and the self contained arrangement for creating the air tight fit makes it possible for my novel device to be fully effective and accommodate itself readily to women of different size. The insertion is much easier than prior devices, less uncomfortable both to insert and to wear and more hygienic since it is readily disposable. As an advantage over a tassette, it is easier to introduce, better fitting and no leak should be possible as opposed to a tassette which has no contraceptive value.

The string **13** may be formed so that after it removes the plug it may be pulled out entirely utilizing the sealing element **17** on the inside of the tubular envelope **14** to seal the opening. As a preferred alternative, the string may be pulled through the sealing element **17** to effect inflation with the plug **12** sealing against the seal **17**; thereafter when it is desired to remove the diaphragm, the string **13** may be pulled to break the seal and deflate tube **14**. The string **22** remains in position at all times so that it may be used to provide a simplified means for removing the unit.

My novel device may also be used as a pessary structure as previously described. It can also be used as a plug to contain fluids; in the event of the presence of a fistula it may be placed just below the opening to contain the fluid. If desired, in its use as a device for containing fluids, the diaphragm element **20** may be modified as shown in FIG. **6** to provide valve means for drawing off any fluid that might be present after a predetermined minimal quantity has been reached. For this purpose a sphincter valve **30** may be placed in an appropriate area of the diaphragm which will not interfere with any of the organs. The sphincter valve is a well known type of valve which is elasticized to maintain a closure but which may be opened when an object is inserted therein. A draw off tube **31** having a tip **32** which may be inserted through the sphincter valve may then be passed through the valve **30**, the sphincter valve engaging the sides of the tube until the opening **33** in the tube passes through the valve thereby providing a passage from above the membrane **20** through the tube **31** through which fluids held above the membrane **20** may be drawn off.

Since appropriate valve arrangements for this purpose are well known no specific valve is contemplated herein other than the fact that a valve may be provided to permit the drawing off of fluids should that be desirable or necessary in the specific use of the device.

In FIG. **5** I have shown a simplified means for inserting my novel diaphragm and support into the vaginal canal. A handle **40** is provided with an extension **41** having a curved end **42** with a groove **43** therein. The handle is also provided with a longitudinal opening **44**.

An applicator rod which is preferably of relatively flexible material may be slidably retained in the longitudinal opening **44**. The diaphragm rim is supported in the groove section **43** of the curved end **42** of handle extension **41** and is inserted at one side of the vagina until it reaches the proper position. The groove section **43**, as seen in FIG. **7** is a bifurcated element having members **50, 50** in which are held the flexible tips **51** so arranged as to engage the tubes **11-14** to hold the diaphragm in position; the tips **51** are sufficiently flexible and resilient that, when the diaphragm is positioned, the withdrawal of the handle will permit the tips **51** to deflect and disengage the diaphragm. Thereafter the applicator handle **45** is pushed up by a finger engagement against its lower handle section **46** while the upper saddle **47** pushes against the lower end of the suspended diaphragm. The pushing up of the applicator rod **45** with the upper end of the applicator section **42** at one side of the vagina now rotates the diaphragm so that the lower end of the diaphragm is rotated into position against the other side of the vagina.

When the diaphragm is then in position a pull on the string **13** will result in removing the plug **12** and, therefore, result in expansion of the outer tube **14** as previously described thereby locating the device in position. The handle member is then pulled out.

The pulling of the string **13** may be made relatively automatic by having the string **13** pass through a hook **48** on the side of the handle **44**, the string being provided with a pull knob **49**. The hook arrangement **48** is, of course, of smaller diameter than the pull knob **49** but the string may be placed in the hook and as the applicator rod **45** is moved up into the desired position the larger end or ball end **49** of the string **13** engages a semi-circular portion of the hook thereby exerting a pull on the string so that as the handle rod **45** is pushed up further plug **13** is removed and expansion of the unit occurs.

In the foregoing I have described my invention in connection with illustrative embodiments thereof. Since many variations and modifications will now be obvious to those skilled in the art, I prefer to be bound not by the specific disclosure herein contained but only by the appended claims.

I claim:

1. A diaphragm comprising a continuous inner annular tube and a concentric continuous outer annular tube of flexible material containing the inner tube; said inner tube being adapted to retain a gas under pressure, a passage between the inner and outer tube; means for sealing said passage and means for removing said seal from said passage to permit the gas under pressure in the inner tube to pass into the outer tube and expand the outer tube to a dimension larger than the inner tube; and an occluding membrane supported across the opening formed by the annulus of the outer tube.

2. The diaphragm of claim **1** wherein said passage between the inner and outer tubes is formed by an opening in the inner tube; and said sealing means for said passage comprises a plug removable from said opening; and a string attached to said plug; said string being accessible outside the diaphragm for removal of said plug.

3. The diaphragm of claim **3** wherein an additional string is attached to said inner tube to facilitate removal of the diaphragm.

4. The diaphragm of claim **1** wherein a valved normally closed opening is provided in said membrane.

5. The diaphragm of claim **1** wherein the outer surface of the outer tube is treaded to provide a frictional surface.

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