June 3, 1969 R. J. SPICER 3,447,533

CLOSURE MEANS FOR ARTIFICIAL BODY OPENINGS

Filed Sept. 14, 1964 Sheet 1 of 2

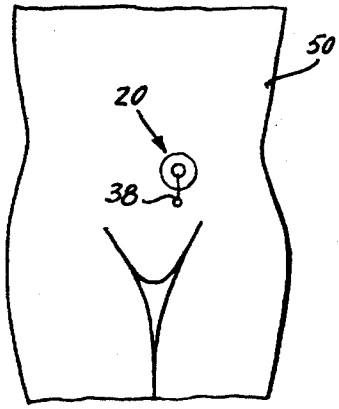

FIG. 3

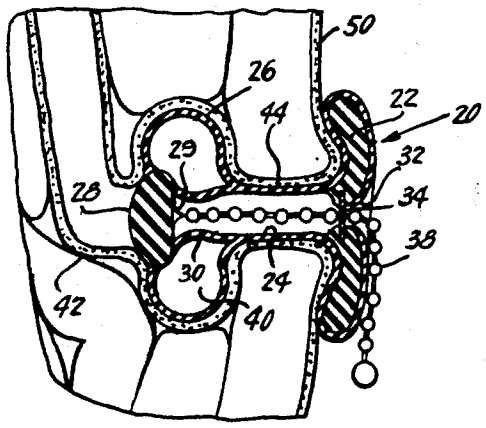

FIG. 2

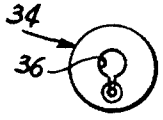

FIG. 4

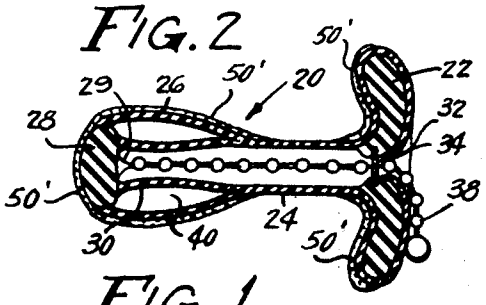

FIG. 1

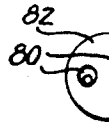

FIG. 7

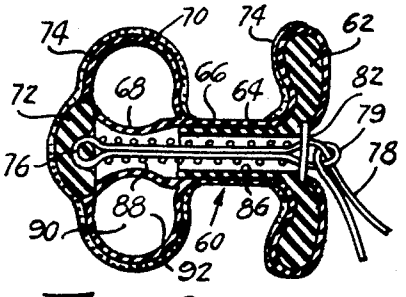

FIG. 6

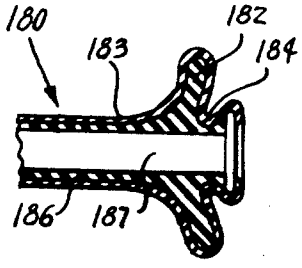

FIG. 12

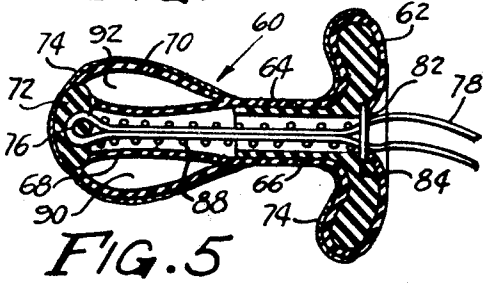

FIG. 5

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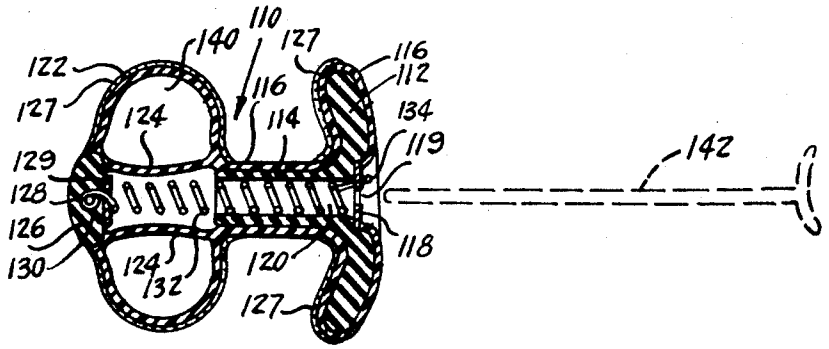

FIG. 10

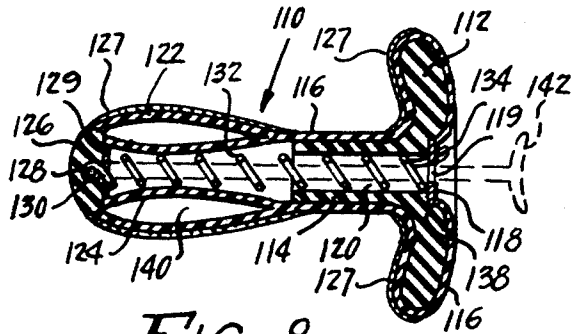

FIG. 8

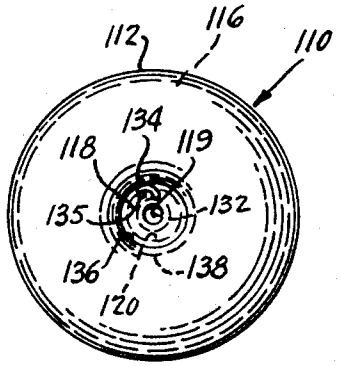

FIG. 9

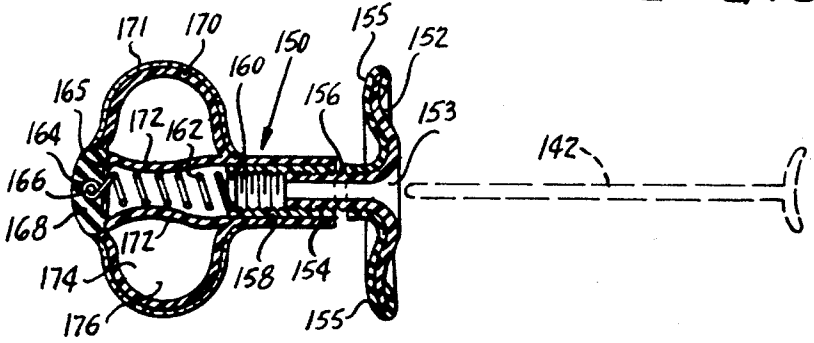

FIG. 11

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United States Patent Office 3,447,533 Patented June 3, 1969

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CLOSURE MEANS FOR ARTIFICIAL BODY OPENINGS

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Filed Sept. 14, 1964, Ser. No. 396,241
Int. Cl. A61b *19/00;* A61f *5/44;* B65d *39/12*
U.S. Cl. 128—1 10 Claims

ABSTRACT OF THE DISCLOSURE

A closure for body openings comprising an apertured support portion, an elastic contractable and expandable bladder portion circumferentially secured to one end of said support portion, an external plate portion secured to the other end of said support portion, said external plate portion conforming to the external anus of the body of the wearer and means for extending said bladder portion for sealable insertion into a body opening. In use, the device is contracted for insertion in the body opening and thereafter expanded to maintain the closure in sealing engagement with the body opening.

This invention relates to surgical appliances for closing artificial body openings, such as, rectal openings, artificial abdominal openings and the like, and in particular, to a surgical closure plug means adapted for ileostomy, colostomy, or rectal use which may be dependably, conveniently and comfortably used by a patient without a belt means and which will quickly rehabilitate a patient psychologically to a normal way of life and its pursuits with a minimum of time after the above operations.

Generally, colostomy patients are those individuals who have had their rectum waste elimination use removed surgically due to cancer or other malignant infections of the colon or of like areas. The lower bowel or colon is, therefore, brought out by the surgeon through an aperture of the side of the abdomen of the patient and surgically attached to the outer skin thereof as a skin grafted reinforced artificial body aperture for the purpose of serving as a means for the elimination of body wastes (stoma) which functions were formerly accomplished by the opening of the rectum. In the medical field, the artificial body aperture or opening is termed a "bud." Although a person can function quite well after this type of operation, there are no involuntary muscles or sphincter to control passage of body waste materials, liquids or gases. On the market today there are pads, various receptacles and several means of bag attachments which are either taped over the opening or attached thereto by means of a belt worn around the body to cover the bud to control the escape of gas and to muffle the noise of escaping gas therefrom. These means of waste elimination control are very inefficient and ineffective, and present a great physiological problem to a recovering patient or to the rehabilitating of a recovered patient who is accustomed to dealing with the public at conferences and other business or social activities, and does not want to be ostracized or embarrassed because of such noises or odors.

This invention solves the above problems by providing a restrictive self sealing surgical appliance for insertion into the artificial body opening and terminating end of the colon or duct to control and prevent the escape of gas, liquid and waste therefrom. This new surgical appliance may be made of various sizes and shapes to suitably seal and comfortably fit either single or double colostomies, or the like, as desired.

The method employed in this invention, in brief, permits a patient to insert the appliance in the extended position of the drawings into the "bud" or opening and adjust the radial expansion of the soft bulbous portion of the appliance against the internal walls of the colon and inside wall of the "bud" for comfort to be self sealing by further axial adjustments of the appliance to properly seal and bear against both sides of the "bud" as a substitute for the sphincter or involuntary muscles of the rectum opening formerly used by the patient. The various modifications of the invention as shown in the drawings permits the patient a choice in his preference in solving his problems and rehabilitating himself or herself to a normal way of life by being able to choose the appliance with the actuating means therefor that is desired by the patient, the details of which will be later described. The appliance would be of different flesh skin colors and made in different sizes and shaped to conform to the "bud" or artificial body opening for comfortable wearing, and made of sterilizable, non-toxic soft pliable surgical rubber, plastic or other desired materials supported therein by either captured air, semi-rigid or resilient materials as will best serve for use in the artificial opening of the body.

An object of the present invention is to provide a closure appliance for artificial body openings which avoids the drawbacks of the present known devices and which may be worn without a belt means surrounding the body of the patient.

A further object of the invention is to provide a closure appliance for artificial body openings which may be worn inconspicuously under the clothing and will not be uncomfortable to the patient during his normal day of activities.

A still further object of the invention is to provide a closure appliance which will comfortably seal from within various sizes and shapes of artificial body openings.

Another object of the invention is to provide a closure appliance for artificial body openings which is efficient, reliable and is relatively inexpensive.

A yet further object of the invention is to provide a closure appliance for artificial body openings which is radially expandable within the duct or intestine and is selectively contractable to bear against the internal and outer surfaces of the body opening.

A further object of the invention is to provide a method of sealing an artificial body opening by inserting a soft pliable and resilient material within a body duct and selectively expanding the material axially against the inside walls of the duct to seal the inside of the duct and adjusting longitudinally means cooperating with the soft material to sealably bear against the internal and outer surfaces of the body opening.

Another object of the invention is to provide a closure appliance for artificial body openings which is adapted to be easily cleaned and sterilized.

Another object of the invention is to provide a closure appliance for artificial body openings which is expandable to conform to the contour of the inside walls of the opening.

Another object of the invention is to provide a closure appliance for artificial body openings which may be expanded by air in sealing relationship with the inner walls of the opening and sealing clamp against the inside and outside walls of the artificial body opening.

With the above and other objects and advantageous features in view, the invention consists of various embodiments and a novel arrangement of parts therefor, more fully disclosed in the detailed description following, and more specifically defined in the claims appended thereto.

FIGURE 1 is a longitudinal sectional view of an embodiment of the invention showing an inner resilient portion cooperating with an outer cap portion and pull chain means;

FIGURE 2 is a partial sectional view of a human body and longitudinal sectional view of the device of FIGURE 1 after the appliance has been sealably positioned and expanded by adjusting pressure with chain tension within an artificial body opening;

FIGURE 3 shows a frontal view of the appliance after the appliance of FIGURE 1 has been installed in an artificial body opening of a colostomy patient;

FIGURE 4 is a frontal view of the keeper disc means for the pull chain of FIGURE 1;

FIGURE 5 is a longitudinal sectional view of a second embodiment of the invention, which employs an inner compressible spring means cooperating with cord laces therefor;

FIGURE 6 is a longitudinal sectional view of FIGURE 5, after the appliance has been inserted in an artificial body opening and expanded by draw cords therein preparatory to being worn by the patient;

FIGURE 7 is a frontal view of a tying keeper disc for the cord or laces of FIGURE 5;

FIGURE 8 is a third embodiment of the invention which employs a tension spring therein which is actuated by an individual tool to extend the appliance for insertion within the artificial body opening of a patient;

FIGURE 9 is a frontal view of the outer cap or plate means of FIGURE 8;

FIGURE 10 is a view of FIGURE 8 after insertion within the opening of a patient showing its self actuating radial expansion means for sealing the opening;

FIGURE 11 is a longitudinal sectional view of a fourth embodiment of the invention employing an inner tension spring means cooperating with a longitudinally adjustable screw thread means, as shown; and

FIGURE 12 is a modified form of the outer cap means of the various embodiments of the present invention which is adapted for rectal use.

In the drawings like reference numbers represent like parts.

Referring to FIGURES 1, 2, and 3, reference numeral **20** represents an exemplary embodiment of the device comprised of an outer plate like member **22** of a desired curvature to fit the outer surface of the "bud," joined to a semi-rigid neck portion **24** and connected to a flexible and resilient bulbous portion **26** secured to an inner supporting member **28** which is sealably attached by an inner flexible resilient tubular member **30** to the neck portion **24**. The space between membrane members **30** and **26** is filled by captured air inserted before or after molding or assembling thereof which serves to radially extend membrane **26** against intestine or canal walls when inserted in an artificial opening of a human body, as best shown in FIGURE 2. Plate means **22** contains a central opening **32** communicating with the tubular neck portion **24**. Opening **32** fixedly carries by groove means therein a suitable disc member **34** having a suitable shaped latch aperture **36** as shown in FIGURE 4 to receive and secure a pull chain **38**, as desired for proper adjustment of the extension of bulbous means **26** when extended longitudinally for insertion in a body opening or radially extended against the intestine or duct walls in an inside sealing relationship of the appliance with regard to the inner and outer peripheral surface of an artificial body opening, as best shown in FIGURE 2 which shows the sealing application of the new appliance **20**.

Pull chain **38** is secured to an anchor means **29** in a suitable manner to inner member **28**, as shown. Pull chain **38** may be of stainless steel or other suitable flexible noncorrosive material, as desired.

The bulbous portion **26**, members **24** and **28**, and the inner concave surfaces of plate **22** is covered by a soft latex material **50'** or other suitable material which is soft and very pliable, contributing to the comfort of the wearer of the new appliance of this invention. Bulbous portion **26** may be made of any suitable preformed shape yieldable and resilient material, as desired. Member **28** and plate **22** may be made of any suitable semi-yieldable material in accordance with use and functions of the membrane materials of the other portions of the new appliance, as desired.

In operation, when pull chain **38** is released from keeper disc like member **34**, the preformed resiliency of member **26** cooperating with the influence of compressible air **40** therein permits the bulbous portion **26** to extend longitudinally along the axis of the plug-like appliance for insertion in a body opening. When chain **38** is adjustably pulled taut, as desired by the wearer, and secured in disc means **34**, the flexible resilient bulbous portion extends radially outwardly against the inner walls of a duct **42** and against the inner wall of the body to sealably contact radially and longitudinally the inner surfaces of the artificial body opening, as best shown in FIGURE 2. In the latter operation of pull chain **38**, cap means **22** is sealably secured against the outer surface of the artificial body opening **44** (the bud).

To insert the appliance of FIGURE 1, the pull chain **38** is released from disc **34** to permit automatic longitudinal axial elongation of the bulbous portion **26** for comfortable insertion of this portion into artificial body opening **44** and duct or intestine means **42**. Then plate means **22** is held by the patient snugly against the body **50** while pull chain **38** is pulled taut and secured in latching aperture **36** of plate or disc means **34** by the patient to radially expand and longitudinally contract bulbous portion **26** in substantially the position shown in FIGURE 2, after which the appliance **20** may be comfortably worn by the patient in an artificial body opening, as best shown in FIGURE 3.

FIGURES 5, 6 and 7 disclose a second embodiment of the invention, in which reference numeral **60** designates the new appliance comprised of an outer plate like member **62** of a desired curvature sealably joined to a semi-rigid neck portion **64** covered by an outer flexible semi-rigid tubular neck membrane **66** attached, as desired, to an inner membrane **68** and an outer bulbous portion **70** of preformed resilient and flexible material secured to an intermediate inner membrane **72** of semi-rigid material and plate member **62** covered, at least partially, with soft latex or other suitable soft material **74**, as desired for the comfort and well being of the patient wearing the new appliance. Member **72** contains therein a suitable anchor means **76** adapted to receive a lace of nylon or other suitable material **78** adapted to be adjustably secured by knot means **79**, of FIGURE 6, through apertures **80** of keeper disc means **82** fixedly embedded by groove means **84** surrounding central aperture and conduit means **86** of plate means **62** and neck means **64**. The laces **78** are surrounded by a compression spring **88** which is secured to member **72** and disc means **82**, in a suitable conventional manner, to maintain the bulbous portion **70** in a longitudinally extended position preparatory to insertion into a body opening, as best shown by FIGURE 5. The recess **90** between inner membrane **68** and outer resilient bulbous portion **70** contains therein captured air **92** which cooperates with the inner membranes to extend the bulbous portion radially when drawn to desired pressure by patient, as best shown in FIGURE 6, which sealably coacts with artificial body opening **44** similarly to that of the appliance **20** as shown in FIGURE 2.

FIGURE 7 shows a front view of disc means **82** containing therein dual apertures **80** to receive each of the two ends of lace means **78**, as shown in FIGURES 5 and 6.

FIGURES 8, 9 and 10 disclose a third embodiment of the invention represented by reference numeral **110** comprised by outer plate means **112** of suitable curvature

connected to a tubular neck portion **114**, both being made of semi-rigid material covered by a soft membrane **116** of suitable flexible material. Plate means **112** contains therein a disc means **118** having an aperture **119** communicating with the aperture of inner neck walls **120**. Membrane **116** is sealably connected to an outer resilient and flexible bulbous membrane portion **122** secured to an inner tubular membrane means **124** secured to a closing end semi-rigid member **126** of a suitable shape as desired for insertion into a body canal. Member **126** contains therein an insert tool bearing disc means **129** and pin means **128** secured to the circular end loop means **130** of tension spring means **132** which is secured at the other end by curved loop spring means **134** in an aperture **135** of apertured disc means **118** secured in groove means **138** of plate means **112**. Bulbous portion **122** and inner tubular means **124** define a sealed toroidal like space filled with captured air **140** at a desired pressure inserted before or after assembly of the appliance by any conventional means, as desired. Bulbous membrane **122**, end member **126** and members **116** are covered by a soft latex like membrane **127**, as shown. This exemplary embodiment of the invention is self sealing and self securing in a body opening after insertion therein by an insertion tool **142** when manually inserted therein as shown in FIGURE 8 and released therefrom by the patient as shown in FIG-10. Appliance **110** after being placed in an artificial body opening is radially self expanding due to the preformed resilient shape of bulbous portion **122** coacting with captured air **140** axially against the inner walls of a body canal and longitudinally and axially controlled by tension spring means **132**.

FIGURE 11 is fourth embodiment of the invention which is not only self sealing by expanding radially but may be also adjusted to shorten the axial length of the appliance by coacting thread means to sealably contact the inner and outer surfaces of an artificial body opening reference numeral **150** represents this embodiment of the invention comprised of a concave-convex shape or other suitable shaped plate means **152** corresponding to the shape of the body opening, as desired, sealably connected to an externally threaded neck portion **154** which coacts with the internal threads **156** of an extending neck portion **158**. The distal end of extending neck portion **158** is attached by brazing or other conventional means to the outer end **160** of tension spring means **162** which is attached at the other end by an eyelet **164** passed through insert bearing disc **165** and surrounds pin means **166** conventionally embedded in closure end member **168** which is sealably connected to preformed resilient outer bulbous membrane portion **170** which is also sealably connected to both ends of inner flexible tubular member **172**. Plate means **152** is covered by pliable membrane **155**, as shown. Bulbous portion **170** and closure member **168** are covered with an impermeable soft latex material **171** or other non-irritating suitable material as desired, which is comfortable and helpful to the user of the present invention.

Plate means **152** is covered by a suitable semi-rigid material **155** and has a central aperture **153** communicating with the aperture of member **154**. The toroidal like sealed space **174** between outer bulbous membrane **170** and inner tubular membrane **172** is filled with captured air of a designated pressure inserted before or after assembly of the appliance, as desired. The longitudinal contraction of tension spring **162** together with the coaction of the captured air **176** and outer bulbous membrane **170** is radially self expanding against an inner body canal wall after insertion with insert tool **142**, the operation of which is similar to that illustrated in FIGURES 8 and 10, as understood by those skilled in the art. After insertion of the appliance in a body opening longitudinal axial adjustment is made by slowly turning plate means **152** in a desired direction to adjust the screw thread means **158** with that on the external surface of neck means **154** until bulbous portion **170** sealably contacts the inner surface and plate means **152** and sealably contacts the outer surface of the artificial body opening, as desired, for comfort of the wearer.

FIGURE 12 is an embodiment of the outer plate means of this invention adapted for use in a rectal opening or the like. Reference numeral **180** designates the plate and neck modification of the embodiments of the appliance which is comprised of apertured plate means **182** sealably connected to outwardly extending tubular end portion **184**, and inner tubular neck portion **186** defining a common aperture **187**, and having all outer contact surfaces covered by a soft latex type of material, or the like, to insure comfort and well being of the patient, as desired. Members **182**, **184** and neck portion **186** is covered in a conventional manner with a soft latex type of covering **183**.

In operation of this invention the following method steps may be generally defined for FIGURES 1 through 11, as follows:

The bulbous portion of the appliance is oblongated axially for insertion in a body opening, after which the external plate is snugly fitted against the external circumferential surfaces of the opening, then the internal portion of the appliance is radially expanded to sealably contact the inside wall surfaces of a body duct communicating with the opening. Then the appliance is axially shortened to compress or contact both inner and outer walls of the opening to insure a comfortable fluid or material seal of the artificial body opening as desired by a patient.

The bulbous portion, neck and plate means of the appliance may have one or more thicknesses of various soft materials applied thereto in a suitable conventional manner, within the purview of this invention, as desired.

From the foregoing it will now be seen that there is herein provided a novel and new closure appliance for artificial body openings which accomplishes all the objects of this invention during use, and others, including many advantages of great practical utility and hygienic importance.

As many embodiments may be made of the various embodiments hereinbefore shown and described as desired by those skilled in the art without departing from this inventive concept, it is to be understood that all matter herein is to be interpreted merely as illustrative, and not in a limiting sense, except as set forth in the following appended claims.

What is claimed is:

1. A closure appliance for artificial body openings comprising an elastically deflectable soft and multiple compartment bulbous bladder means, including a central open air compartment surrounded by a closed air compartment and an inner supporting bulbous member, a centrally apertured base plate means to sealably contact the outer surface of a human body opening including a neck portion cooperatively connected to said bladder means, said neck portion having a central aperture therein, means in said appliance for selectively and sealably expanding radially said bladder means against the inside walls of a duct communicating with a body opening, and means for radially contracting and longitudinally forwardly extending said bladder means to insert and remove the appliance from an artificial body opening.

2. A closure appliance for artificial body openings as in claim **1**, wherein said means for radially expanding said bladder means comprises a spring means cooperatively connected to said base plate means and said inner supporting member of said bladder means.

3. A closure appliance for artificial body openings as in claim **1**, wherein said means for radially expanding said bladder means comprises a spring and lace means for tying and biasing said bladder means in a radially expanded position.

4. A closure appliance for artificial body openings comprising a centrally apertured base plate means to contact

the outer body surface of a body opening, said plate means having an elongated apertured tubular support portion adapted for insertion in a body opening, an elastically deflectable soft inflated bladder means surrounding said tubular support portion, and aperture neck means securing said bladder means to said plate means in sealing contact with the inner surface and the outer surface of a body opening, said plate means and said bladder means comprising a common central aperture, an elongation means secured in said central aperture, and means for axially extending said bladder means to permit insertion of said bladder means into a body opening, said means thereafter permitting radial expansion of the bladder means to sealably secure the bladder means in a body opening.

5. A closure appliance for artificial body openings as in claim **4**, wherein the plate means and the bladder means contains therein a central spring means for sealably maintaining said bladder means in a body opening.

6. A closure appliance for artificial body openings as in claim **5**, wherein said spring means is a compression spring.

7. A closure appliance for artificial body openings as in claim **5**, wherein said spring means is a tension spring.

8. A closure appliance for artificial body openings comprising an outer plate means secured to an elongated neck portion of semi-rigid material having a central aperture in said portion communicating with the outer surface of said plate means and a centrally apertured and inflated bladder portion fixedly and adjustably secured by means to said neck portion to comfortably seal an artificial body opening, said outer plate means consisting of semi-rigid material externally covered with a thin impermeable skin or film material fixedly secured thereto, said bladder means being externally covered with a thin impermeable film material fixedly secured thereto, said bladder means having a light type chain means fixed thereto and whereby said bladder means can be radially expanded to maintain said bladder means in sealing relationship to the internal wall surfaces of a body duct, said light type chain means being secured by an apertured keeper plate means secured in said plate means.

9. A closure appliance for artificial body openings comprising a centrally apertured plate means conforming to the shape of a body opening and having an extending neck portion attached thereto adapted to extend within the canal of a body opening, said plate and neck portion being covered with a soft thin impermeable film material attached thereto to conform in shape and to contact the body opening surfaces; an elastically multiple compartment deflectable soft bulbous bladder means having a central longitudinal open air compartment, a surrounding closed air compartment and an inner supporting bulbous compartment member therein and adapted to be inserted into a body canal and radially expanded therein in sealing engagement with the walls thereof, and adjustable means longitudinally securing said neck portion to said bladder means to seal a body opening, means wherein said adjustable means comprises longitudinally adjustable comating thread means between said neck portion and said bladder means.

10. A closure appliance for artificial body openings according to claim **9**, wherein said bladder means includes captured air in said closed air compartment for radial expansion and longitudinal expansion thereof, said bladder means being externally covered with a suitable soft thin impermeable film material attached thereto to sealably contact the internal walls of a body canal.

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U.S. Cl. X.R.

128—283; 215—52