Ostomy devices, for example for use in ileostomy and colostomy but not limited to these applications. The specification discloses a sealing device (1) for a body channel, comprising an inflatable bung (2) for insertion into the body channel (3) and a reservoir (4) for fluid in communication with the interior void of the bung. The volume of the reservoir (4) can be selected such that compression of the reservoir (4) displaces sufficient fluid into interior void (5) of the bung (2) to seal the body channel (3) without the application of undue pressure thereto. In the embodiment shown, the reservoir (4) comprises bellows of adjustable volume.
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Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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Closure for ostomy device.

The present invention is concerned with closure devices, for use in the closure of body channels such as those produced as a result of ileostomy and colostomy surgery, but is not limited to these applications.

Ostomy surgical procedure comprises severage of the intestine and redirection of the intestinal tract to a stoma, which is formed as an artificial opening in the skin. In certain aspects the present invention falls into the general class of inventions in which an annular member is attached or held against the body such that a stoma is alligned with the central aperture, and wherein matter passing out of the stoma and through the aperture is received in a collection vessel, such as a bag.

Although the invention is generally intended for use with artificial openings, it should be understood that it is applicable to any natural or artificial opening of the human body, or to a corresponding opening of the animal body, refered to hereafter as "body channels".

Closure devices of the prior art have comprised a pad of polymeric material, such as karaya gum, for contact with the body and a radially extending flange permanently
bonded to the other side thereof, in which both the flange and the pad have an aperture as described above. Means disposed about the periphery of the aperture secure an external bag in place to receive waste matter.

Our own patent GB1522391 provides an apparatus for collecting human waste which comprises a tubular member, one end of which is adapted for connection to a human to receive waste from a body channel, the other of which is surrounded by a flexible tube which has been contracted in a longitudinal direction into a container or holder disposed circumferentially of the tubular member. The said patent further discloses the use of an inflatable bung for the closure of a body channel, and provides for a funnel-like bung in certain embodiments.

A further inflatable bung is disclosed in GB2108848 (Prager), wherein an annulus is implanted below the skin around the outside of a body channel and an inflatable bung is placed in the channel.

A non-inflatable but expandable bung is disclosed in US 4210132 and US 4210131 (Perlin). In this specification there is disclosed an artificial sphincter for closure of a body channel having an annulus implanted below the surface of the body and around the channel and a plug having elongated flexible side walls of an elastic material. The plug pushes a collection bag for wastes
in the channel, the open edge of the bag being secured to a flange around the periphery of the opening of the channel.

In addition to the requirement for the generally irreversible surgical implantation of an annulus below the skin, further disadvantages are known to occur with the apparatus of the prior art.

Firstly, one problem with ostomy devices stems from the generation of gas within the digestive tract. Such gas or "flatus" may be produced naturally or as a result of illness in quantities which vary from time to time. It is known to provide filters for this gas. In one known ostomy device having an outer wall extending upwardly of the flange, a filter compartment is affixed to a portion of the outer periphery of this wall and communicates with the interior by means of openings provided in the wall. It is known to provide valves in these openings to control the flow of flatus. Known filters for ostomy devices tend to be too small to provide effective filtration when manufactured from conventional materials. Attempts to overcome this difficulty by employing additional filter material fail as the filters must pass a large quantity of flatus in a short time, otherwise ballooning of the bag occurs. Thus, effective filters made from conventional materials are excluded by their large dimensions.
Secondly, care must be taken in inflating bungs placed in body channels as under-inflation will result in leakage while over-inflation could result in rupture of the walls of the channel or in embolism. It is important to note that geriatric, senile, drugged or otherwise mentally incompetent persons are considered especially prone to damage themselves when inflating a bung placed in a body channel. Furthermore, devices of the prior art have relied on the use of separate pumps, such as hypodermic syringes (see Silvanov GB 1522391 and Prager GB 2108848); ambulant patients may not wish to carry such evidence of their condition about, while some patients may tend to lose additional apparatus.

Thirdly, the channel wall, for example the bowel or intestinal wall, may be severely pinched between the device and an implanted annulus, causing some pain and damage. Moreover, the long term effects of contact between a rigid object, such as the annulus, and the bowel wall have not been fully determined and it is believed that continued pressure and occasionally excessive pressure could cause bruising and possibly even atrophy or carcinoma could result. It will be understood that surgical techniques for use upon some body channels, such as the urethra, do not involve the use of such annuli.
Fourthly, faecial matter compacted against the innermost end of the bung may assume a shape which makes evacuation both difficult and painful.

The present invention has among its objectives the solution of some or all the above difficulties.

According to a first aspect of the present invention there is provided a closure device for a body channel, comprising a hollow inflatable bung for insertion into the body channel and a reservoir for fluid in communication with the interior void of the bung, CHARACTERISTED IN THAT the volume of the reservoir can be selected such that compression of the reservoir displaces sufficient fluid into interior void of the bung to seal the body channel without the application of undue pressure thereto.

By providing a hollow inflatable bung in connected to a reservoir, such that a known volume of fluid, preferably air, is contained within the reservoir and the bung it is believed possible to ensure that a predetermined inflation of the bung will occur when the reservoir is compressed. The total "balanced volume" of air can be preselected to give a particular inflation of the bung.

Typically, the reservoir comprises bellows of adjustable volume, by which it is possible to ensure that the
interior void of the bung is not over-inflated.

Conveniently, the bung is inserted within a bag located within the body channel, whereby it is possible to ensure that the bung does not come into direct contact with waste matter, and that waste matter is ejected into the interior of the bag as it emerges from the body channel.

Preferably, the bag is secured at or around the opening thereof to a substrate located outside of the body, which both facilitates the hygienic operation of the present invention and allows replacement of the bag with ease.

More preferably, the bag comprises one end of a flexible tubular member which has been contracted in its longitudinal direction and which is provided with closure means at the said end, whereby successive portions of the bag may be filled with waste matter and removed, thus allowing the bag to be replaced occasionally rather than each time evacuation occurs.

In an embodiment of the invention for use with the body channel formed as the stoma of a colostomy the inflated bung comprises a generally conical body having a re-entrant base to ensure that stools compacted against the bung are tapered at a forward end thereof and
thereby to facilitate evacuation without excessive strain and discomfort. Moreover, this shape produces a more even and gentle pressure on for example the bowel wall, by gently forming to its irregular contours, rather than spherically shaped inflatables which generally distort the bowel to fit their contour.

In a further embodiment of the invention a vent tube is provided along or substantially parallel to the long axis of the closure device, to allow the exchange of fluid between the ambient and the interior of the body channel, thus enabling either the release of fluid from the body channel without removal of the closure device, such as the release of gasses (for example flatus) or the release of liquids (for example urine) or to allow the introduction of substances into the body channel, for example for medical treatment.

A particular embodiment of the present invention, more particularly intended as a urethral catheter, comprises a first tube for insertion along the urethra into the bladder and an inflatable hollow bung attached to the inserted end. The bung may be inflated by the compression of an exterior reservoir. A further tube disposed either internal to, circumferential or alongside the first tube opens into the bladder to allow the escape of urine and or the introduction of medicaments.
It is possible to place a filter device in such a vent-tube to prevent the release of solid matter, and to adsorb noxious fluids.

According to a second aspect of the present invention there is provided an ostomy appliance comprising:

a) an annular flange to fit around the stoma and an upwardly extending annular wall provided on the flange.

b) a filter chamber affixed to the said flange and a conduit communicating at one end thereof with the chamber, and,

c) one or more vents communicating with the conduit.

CHARACTERISED IN THAT, the vents are located at or near the uppermost edge of the annular wall and do not pass through the annular wall.

It is important to note that gas must pass along the entire axial length of the annular wall before entering the vents.

Typically, the conduit is provided on the outer surface of the annular wall and upon the uppermost surface of the flange and conveniently, a filter is located either in a chamber or in a portion of the conduit which serves as a chamber. The conduit may be partly formed by a chordal
modification of the annular wall. In an embodiment of the invention, the conduit follows a peripheral path around the annular wall and is provided with an internal filter and one or more apertures for the release of gas. An advantage of such a peripheral path is that a greater time of passage through the filter is obtained without a substantial increase in the size of the device.

Preferably the filter comprises charcoal cloth, more preferably the charcoal cloth is that disclosed in UK Patent No. 1301101.

In order that the invention may be further understood, it will be illustrated by way of example and with reference to the accompanying figures wherein:

Figure 1 shows a cross section through a device according to the present invention with the bellows extended, further detail of the filter is shown in figures 1a, 1b and 1c,

Figure 2 shows a cross section through a device according to the present invention with the bellows compressed,

Figure 3 shows a plan view of a device according to the present invention,
Figure 4 shows the invention in use as a colostomy device, and,

Figure 5 shown an alternative embodiment to that shown in figures 1-4, wherein the flatus conduit is modified.

Turning to figure 1, there is shown a sealing device (1) for a body channel, comprising an inflatable bung (2) for insertion into the body channel (3) and a reservoir (4) for fluid in communication with the interior void of the bung. The illustrated device will be explained with particular reference to a colostomy or illeostomy sealing device. The volume of the reservoir (4) can be selected that compression of the reservoir displaces sufficient fluid into interior void (5) of the bung (2) to seal the body channel (3) without the application of undue pressure to the walls of the channel. In the embodiment shown, the reservoir (4) comprises bellows of adjustable volume.

The interior void (5) of the bung (2) communicates with the reservoir (4) via the tube (20). This tube is provided at the upper end thereof with a fluid tight closure (21) for the retention of a fixed quantity of fluid within the reservoir, and slides sealingly within the grommet (25a). Thus, as the bellows (4) are compressed, air is forced into the tube (20) via port (20b) flows down the tube and enters the interior void
(5) of the bung (2) via port (20¢), inflating the bung.

The illustrated embodiment further employs a bag (6) located within the body channel, within which the bung is inserted. The bag (6) comprises one end of a flexible tubular member (7) which has been contracted in its longitudinal direction and which is provided with closure means at the end (8).

A holder (9) is provided for the contracted tube. The holder (9) further comprises an annular flange (10) to fit around the stoma and an upwardly extending annular wall (11) provided on the flange. A filter chamber (12) is affixed to the flange (10) and a conduit (13) communicates with both the chamber (12) and one or more vents (14) provided in the annular wall (11), at or near the uppermost edge of the annular wall.

It can be seen that conduit (13) is provided on the outer surface of the annular wall and upon the uppermost surface of the flange.

A filter material (15) is located in the chamber and extends into the conduit. The filter material comprises charcoal cloth.

Figure 1a shows a detail of the filter assembly of figure 1. The filter chamber (12) is affixed to the
flange (10) as in the figure, but the ascending inner
wall of the conduit (11a) is formed by a chordal
diversion of the annular wall (11). In this embodiment
the filter cloth (13a) follows a serpentine path within
the filter chamber (12). Flatus may be filtered both by
passage through the cloth and over the surface thereof.

Figure 1b shows an alternative filter configuration to
that of figure 1a. In this embodiment, the filter 13b
is folded within the filter chamber, and its resilience
urges it against the walls of the chamber. Also shown
in figure 1b are structures (28) provided to cause
turbulence in the gas flow and aid absorption.

Figure 1c shows an alternative configuration in which
the filter has been removed and caps inserted to close
the vents (14) and the chamber. It is envisaged that
such caps would be applied by the user when bathing, or
when sleeping, in order to prevent liquid entering the
filter chamber, either from the vents (14) or from the
ambient.

Returning to figure 1, in the embodiment shown an
annulus of a suitable gum material (16) (such as gum
karaya) is located beneath the holder (9) to ensure
adhesion of the holder to the body wall. Furthermore,
the illustrative embodiment uses a ring (17) implanted
beneath the body wall (18) and around the outer
periphery of the body channel to ensure that the wall (19) of the body channel is adequately supported. It should be noted that the ring is optional, and is not necessary to put the invention into practice, however certain patients may already have such a ring in situ following the fitting of one of several types of ostomy devices. The surface of the ring is rounded to as to reduce the likelihood of pressure damage to wall of the body channel. The ring may be made from any suitable, i.e bio-compatable material.

The top plate (22) of the bellows forms a cover for the holder and the dependant flange (23) is capable of an interlocking engagement with the bottom plate (11) to maintain the bellows in an exhausted state.

As can be seen from figures 1 and 2, as the top plate (22) is urged towards the holder (9), fluid is expelled from the bellows and driven along the tube (20) to inflate the bung (2). This urges the bag (6) against the wall (19) of the body channel and effects sealing. It is advantageous to select the volume of the bellows such that the correct pressure between the wall (19) and the bag (6) is attained when the bellows are at or near to exhaustion. This correct pressure is sufficient to ensure that waste material in the body channel does not seep between the channel wall and the bag. It should be noted that the pressure should not be so great that
damage is caused to the channel wall.

As can be seen from figures 1, 2, 3 and 4, the upper surface of the top plate (22) is both substantially flat and lies close to the body surface, making the device inconspicuous when in use.

It will be further noted that the innermost surfaces of the bung, and of the bag are re-entrant when inflated, this ensures that the stools accumulating against the innermost surface of the bag are tapered at their forward ends, thereby aiding evacuation. Moreover, the use of such a re-entrant surface promotes an effective seal between the bung and the wall of the body channel.

Turning now to figure 4, there is shown a sealing device according to the present invention in use as a colostomy sealing device.

When a quantity of waste-matter has accumulated in the body channel, the top (22) and bottom (11) plates of the bellows are disengaged, allowing the bellows to be extended and the bung (2) to deflate. The bag (6), is then removed from the body channel with the waste-matter inside it, and a sufficient length of tube (7) drawn from the holder (9) to contain all of the waste-matter (24) and allow the tube to be tied-off and cut, as illustrated in the figure.
As is shown in the figure, it is preferable to employ two fastenings to tie-off the tube, and to cut the tube between the fastenings, thus allowing the tube to be pushed back inside the body channel to form another bag, and the package of waste matter to be disposed of.

Turning back to figure 2, it is noted that in this particular embodiment of the invention the vents (14) are closed by the bag (6) when the bung (2) is inflated. Upon the deflation of the bung (2) there may be a release of flatus accumulated in the body channel, this is vented through the filter material (15) where selected components of the gas stream are absorbed. As an alternative to the release of flatus only upon deflation of the bung, there may be a continuous or discontinuous release of flatus through the filter material.

Turning now to figure 5 there is shown an alternative embodiment to that shown in figures 1-4, wherein the flatus conduit is modified. In this embodiment the conduit (13) follows a peripheral path around the annular wall (11) and is provided with an internal filter and one or more apertures (30) for the release of flatus.
CLAIMS:

1) A closure device for a body channel, comprising a hollow inflatable bung for insertion into the body channel and a reservoir for fluid in communication with the interior void of the bung. CHARACTERIZED IN THAT the volume of the reservoir can be selected such that compression of the reservoir displaces sufficient fluid into the interior void of the bung to seal the body channel without the application of undue pressure thereto.

2) The device of claim 1, wherein the reservoir comprises bellows of adjustable volume.

3) The device of either of claims 1 or 2, wherein the bung is inserted within a bag located within the body channel.

4) The device of claim 1, wherein the inflatable bung comprises a generally conical sac, in which the base thereof adopts a re-entrant shape when inflated.

5) The device of claim 1, wherein a vent tube is provided at least in part along or substantially parallel to the long axis of the closure device, to allow the exchange of fluid between the ambient and the interior of the body channel.
6) The device of claim 5, wherein a filter is located in the vent-tube to prevent the release of solid matter.

7) The device of claim 6, wherein the vent tube comprises a conduit provided on the outer surface of the annular wall communicating with a chamber upon the uppermost surface of the flange.

8) The device of claim 7, wherein the chamber is disposed spirally upon the flange.

9) The invention of claim 6, 7 or 8 wherein a filter comprising charcoal cloth is located either in the chamber or the conduit.

10) A closure device for a body channel, comprising a hollow inflatable bung for insertion into the body channel and a reservoir for fluid, said reservoir being of variable volume, external to the body and in communication with the interior void of the bung, whereby a predetermined volume of fluid may be contained in the reservoir and the bung such that upon compression of the reservoir sufficient fluid is displaced into the interior void of the bung to inflate the bung and seal the body channel without the application of undue pressure to the walls of the body channel.
11) A closure device as claimed in claim 10, further comprising an annular plate provided with means for securing the said reservoir thereto, means for securing the said plate against an outer surface of the body and means for collecting and storing waste material.
INTERNATIONAL SEARCH REPORT

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 8

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC 4: A 61 F 5/445

II. FIELDS SEARCHED

Classification System       Classification Symbols

IPC 4                              A 61 F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

III. DOCUMENTS CONSIDERED TO BE RELEVANT 9

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"M" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search 22nd December 1986

Date of Mailing of this International Search Report 16 Jan. 1987

International Searching Authority EUROPEAN PATENT OFFICE

Signature of Authorized Officer

M. VAN MOL
This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 11/12/86.

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