(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 June 2004 (17.06.2004)

PCT

(10) International Publication Number
WO 2004/049984 A2

(51) International Patent Classification[7]: A61F 5/442, 5/445

(21) International Application Number: PCT/ZA2003/000179

(22) International Filing Date: 1 December 2003 (01.12.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
02/9700 29 November 2002 (29.11.2002) ZA

(71) Applicant *(for all designated States except US)*: **SIBIYA, BONGINKOSI, Victor** [ZA/ZA]; 75 The Augustus, 51 Linden Road, Sandown, Johannesburg (ZA).

(71) Applicant and
(72) Inventor: **SIBIYA, DUMISANI ITUMELENG, Anthony** [BW/BW]; 22274, Phase 4, Gabarone (BW).

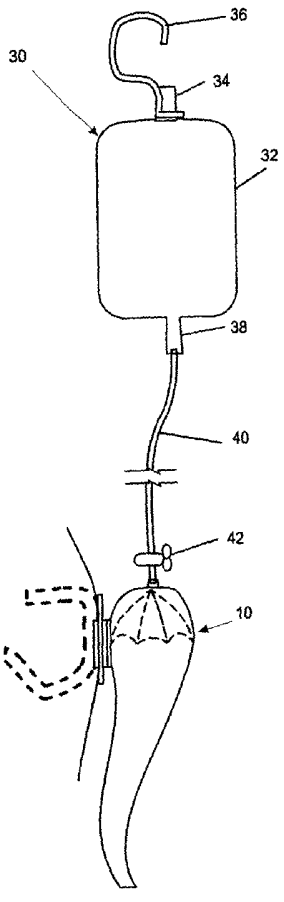
(74) Agent: **FISHER, LES T**; Les Fisher & Co, P.O. Box 391864, 2018 Bramley (ZA).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: OSTOMY BAG, FLUSHING KIT AND METHOD



(57) Abstract: An ostomy device comprising a flexible bag (10, 80) for receiving body fluid has a separable wafer 12 for attaching the bag to a user and a closable flushing inlet (18, 82) for introducing liquid to flush the bag while it is still fitted to a user. Guide means (22, 82) is provided to the flushing liquid around the walls of the bag. A plurality of such devices (10, 80) are provided in a kit including a collapsible container (32) for liquid, means (36) for suspending the container and a hose for connecting the outlet to an ostomy bag via a valve (42).

WO 2004/049984 A2

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*

— *of inventorship (Rule 4.17(iv)) for US only*

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

OSTOMY BAG, FLUSHING KIT AND METHOD

TECHNICAL FIELD:

This invention relates to ostomy bags and cleaning such bags, and is particularly but not exclusively concerned with enterostomy bags.

BACKGROUND ART:

Several thousand intestinal ostomies are created worldwide each year for a variety of conditions including cancer, inflammatory bowel disease, diverticular disease of the colon and injuries to the bowel from penetrating abdominal trauma. Such ostomies permit bowel contents to pass into an external bag. The ostomy comprises suturing an opening in the intestine to an opening in the abdominal wall such that the intestinal contents exit via this orifice rather than through the normal anal orifice. An ostomy base consisting of an adherent wafer with a central orifice is positioned over the stoma such that any intestinal effluent flows through the central orifice. In use, for enterostomies, an ostomy bag is fitted to the base via an inlet annulus on the bag that sealingly engages an outlet annulus around the central orifice. The bag has an outlet tube that is turned over and clipped to seal the bag in use. The bag is cleaned by removing it from the base, opening the outlet tube, draining the contents into a toilet and washing the bag.

Removing and reconnecting the bag from its base is a difficult process, especially for the elderly who may have coordination or fine motion impairment. Improper reconnection of the bag to its base leads to leakage of odours and in some cases, stomal effluent. Often faecal matter passes into the space between the wafer and the body; this leads to irritation and can result in serious infections.

The invention seeks to resolve these problems in a reasonably satisfactory manner.

DISCLOSURE OF THE INVENTION:

One aspect of the invention provides an ostomy device comprising a flexible bag for receiving body fluids, an inlet port for admitting body fluids, a closable outlet for discharging fluids accumulated in the bag in use, and a closable flushing inlet through which liquid can pass to flush the bag.

Preferably the device includes a wafer base that adheres to the skin of a user. The bag may be permanently or releasably attached to the wafer base.

The flushing inlet is preferably positioned to be above the inlet port in use. The flushing inlet is preferably positioned adjacent the inlet port. The flushing inlet may be attached to the wafer base. A removable closure may be provided for closing the flushing inlet, such as a suitable stopper or cap. Alternatively or additionally the flushing inlet may be provided with a suitable valve; the valve provides a convenient means to release gas accumulated in the bag in use.

Preferably guide means is provided to distribute fluid flowing through the flushing inlet around the interior walls of the bag. The guide means may comprise a deflector inside the bag adjacent the flushing inlet. The deflector may have a plurality of distribution channels and, conveniently for this purpose, has an umbrella like shape. Alternatively, the guide means may comprise a body defining a fluid passage inside the bag, the body being formed with a plurality of suitably distributed perforations forming outlets from the fluid passage into the bag. Preferably the body is a tube closed at one end and forming the flushing inlet at the other end, the tube having a longitudinal and circumferential array of openings.

Another aspect of the invention provides an ostomy bag flushing kit comprising a collapsible container for fluid, means for suspending the container, an opening into the container, an outlet from the container, and a hose for connecting the outlet to an ostomy bag.

The hose and outlet may be permanently connected to each other.

A valve may be provided for controlling the flow of fluid out of the container. The valve may be provided in the hose at a suitable position along its length, preferably near the outlet from the hose.

Yet another aspect of the invention provides an ostomy kit comprising flushing kit and a plurality of ostomy devices as described above.

Still yet another aspect of the invention provides a method of flushing an ostomy bag that is fitted to a person including the steps of: opening a lower region of the bag to discharge fluids in the bag; opening the bag at an upper region thereof while it is attached to the person; and directing a liquid through the bag to clean the interior walls of the bag. The liquid may be water. Optionally a sterilising solution is added to the water.

Further features, variants and/or advantages of the invention will emerge from the following non-limiting description of examples of the invention made with reference to the accompanying schematic drawings.

BRIEF DESCRIPTION OF THE DRAWINGS:

Figure 1 shows a schematic side view of a person fitted with a colostomy device of the invention;

Figure 2 shows a detail of the lower end of the bag of Figure 1 that is closed by being folded over and clipped;

Figure 3 shows a sectioned side view of a portion of the device of Figure 1 that is attached to the person;

Figure 4 shows a front view of the portion of Figure 3;

Figure 5 shows a side view of a guide means provided in the device of Figure 1;

Figure 6 shows a plan view of the guide means of Figure 5;

Figure 7 shows a the bag of Figure 1 in use with a flushing kit of the invention; and

Figure 8 shows a side view of a variant of guide means for a colostomy device of the invention.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS:

In the drawings the same or similar parts have the same reference numbers, certain parts having sub-numbers to identify them as part of a component or as substantially equivalent parts in different embodiments.

Figures 1 and 2 show an ostomy bag 10 having a wafer base 12 that adheres to the skin around an intestinal stoma 14 of a person 16. The wafer base may be sutured to the colon if desired.

The wafer base has a flat pad 12.1 that adheres to the skin around the stoma and has a boss 12.2 with a central orifice 12.3 trimmed with scissors to fit the stoma when it is worn. The bag has a wide mouth at its free end which is closed by a clip 10.2 during normal wear, as shown in Figure 2, allowing temporary storage of the stomal effluent without spillage. A flushing inlet 18 is formed at the top of the bag adjacent to the wafer base. A plug 20 is provided for closing the flushing inlet. The inlet opens onto an umbrella shaped guide 22 that forms channels 22.1 opening into the lumen of the bag in such a way as to allow fluid flowing into the inlet to be distributed around the wall of the bag. Figures 5 and 6 show the guide 22 in more detail.

Referring to Figures 3 and 4, the bag and wafer are separate, but connectable by two annular rings 30.1 on the bag that fits sealingly with two annular ribs 30.2 formed on the boss 12.2. If desired, the ostomy bag may be permanently connected to the wafer base.

Figure 7 shows flushing system 30 comprising a collapsible, re-usable plastics container or water bag 32 with a filler opening 34 at its top for storing water, a hook 36 for suspending the bag from a suitable elevated support, an outlet 38 at the base of the bag, and a hose 40 secured to the outlet. A valve 42 is provided near the free end of the hose.

Figure 8 shows a variant of ostomy bag 80 in which the flushing inlet is formed by a stiff tube 82 of plastics heat welded to the bag to have a portion 82.1 outside the bag and a portion 82.2 inside the bag. A stopper 84 on a plastics tie 84.1 engaged with the portion 82.1 tube is provided for releasably closing the inlet. The free end 86 of the inside portion of the tube is flattened and welded closed. Circumferentially and longitudinally spaced holes 88 are formed in the inside portion 82.2 of the bag. A valve 90 is fitted to the tube for conveniently releasing stomach gasses.

In practice, the ostomy bag is cleaned as follows. The water bag is filled with water at a suitable temperature, optionally with a cleansing and/or sterilising solution, with the valve of the hose being in its closed position. The bag is then hung at a suitable height using the hanging hook on the bag. The free end of the hose is then attached to the flushing inlet of the ostomy bag, while it is still on the wearer. The clip at the outlet of the ostomy bag is released when the bag is positioned above or hangs

over a suitable receptacle such as a toilet bowl. The valve on the hose is then opened, allowing the water to run into the bag and out of its free end into the receptacle, emptying and cleaning the bag and cleansing the skin around the stoma. The ostomy bag may be squeezed, folded, rubbed, etc. to ensure good cleaning. The hose is disconnected when water flow ceases. The outlet from the ostomy bag is then closed by folding it over itself and replacing the clip.

There are several benefits of the described embodiments. The ostomy bag does not have to be removed with each cleaning, making improper replacement with its attendant leaks impossible. Since there is minimal manipulation of the bag and its wafer base during cleaning, the base stays attached to the skin longer, reducing the chances of leakage under the wafer which would otherwise occur with frequent removal and attachment of the bag to the base in conventional ostomy systems. There is less irritation of the skin on which the base is placed since the base does not have to be removed and replaced often. The skin around the stoma is washed free of stomal effluent each time the appliance is emptied, reducing irritation of the skin from prolonged contact with stomal effluent.

The invention is not limited to the precise details described above and shown in the drawings. Modifications may be made and other embodiments developed without departing from the spirit of the invention. For example, the metal hook 36 may be replaced by a reinforced plastics loop or eye formed in or at the periphery of the bag 32. The hose 40, instead of being connected to the cleaning water bag, may be fitted with an elastomeric coupling adaptor so that it can be connected directly to a tap or other water source. While an example of the invention illustrates and describes a colostomy bag, the principles apply to all enterostomies and ostomy bags.

CLAIMS:

1. An ostomy device comprising a flexible bag (10, 80) for receiving body fluids, an inlet port (12) for admitting body fluids, a closable outlet (10.1) for discharging fluids accumulated in the bag in use, and a closable flushing inlet (18, 82) through which liquid can pass to flush the bag.

2. The ostomy device of claim 1, wherein the device includes a wafer (12.1) base that can adhere to the skin of a user.

3. The ostomy device of either of claims 1 or 2, wherein the bag is releasably attached to the wafer base (30.1 and 30.2).

4. The ostomy device of any one of claims 1 to 3, wherein the flushing inlet (18, 82) is positioned to be above the inlet port in use.

5. The ostomy device of any one of claims 1 to 4, wherein the flushing inlet (18, 82) is positioned adjacent the inlet port (12.1).

6. The ostomy device of any one of claims 1 to 5, wherein the flushing inlet (18, 82) is attached to the wafer base (12).

7. The ostomy device of any one of claims 1 to 6, wherein a removable closure (20, 84) is provided for closing the flushing inlet.

8. The ostomy device of any one of claims 1 to 7, wherein a suitable valve (90) is provided for closing the flushing inlet.

9. The ostomy device of any one of claims 1 to 8, wherein guide means (22, 82) is provided to distribute fluid flowing through the flushing inlet around the interior walls of the bag.

10. The ostomy device of claim 9, wherein the guide means comprises a deflector (22) inside the bag adjacent the flushing inlet.

11. The ostomy device of claim 10, wherein the deflector 22 has a plurality of distribution channels (22.1).

12. The ostomy device of claim 9, wherein the guide means comprises a body (82) defining a fluid passage inside the bag, the body being formed with a plurality of suitably distributed perforations (88) forming outlets from the fluid passage into the bag.

13. The ostomy device of claim 12, wherein the body is a tube (82) closed at one end (86) and forming the flushing inlet (82.1) at the other end, the tube having a longitudinal and circumferential array of openings.

14. An ostomy bag flushing kit comprising a collapsible container (32) for liquid, means (36) for suspending the container, an opening (34) into the container, an outlet (38) from the container, and a hose (40) for connecting the outlet to an ostomy bag (10, 80).

15. The kit of claim 14, wherein the hose (40) and outlet (38) are permanently connected to each other.

16. The kit of either of claims 14 or 15, wherein a valve (42) is provided for controlling the flow of fluid out of the container (32).

17. The kit of claim 16, wherein the valve (42) is provided in the hose at a suitable position along its length.

19. The kit of claim 7, wherein the valve (42) is provided near the outlet from the hose.

20. An ostomy kit comprising a plurality of ostomy devices as claimed in any one of claims 1 to 13 and a flushing kit as claimed in any one of claims 14 to 19.

21. A method of flushing an ostomy bag that is fitted to a person including the steps of: opening a lower region (10.1) of the bag to discharge fluids in the bag; opening the bag at an upper region (18, 82) thereof while it is attached to the person; and directing a liquid through the bag to clean the interior walls of the bag.

22. The method of claim 21, wherein the liquid is water, optionally with a sterilising solution.

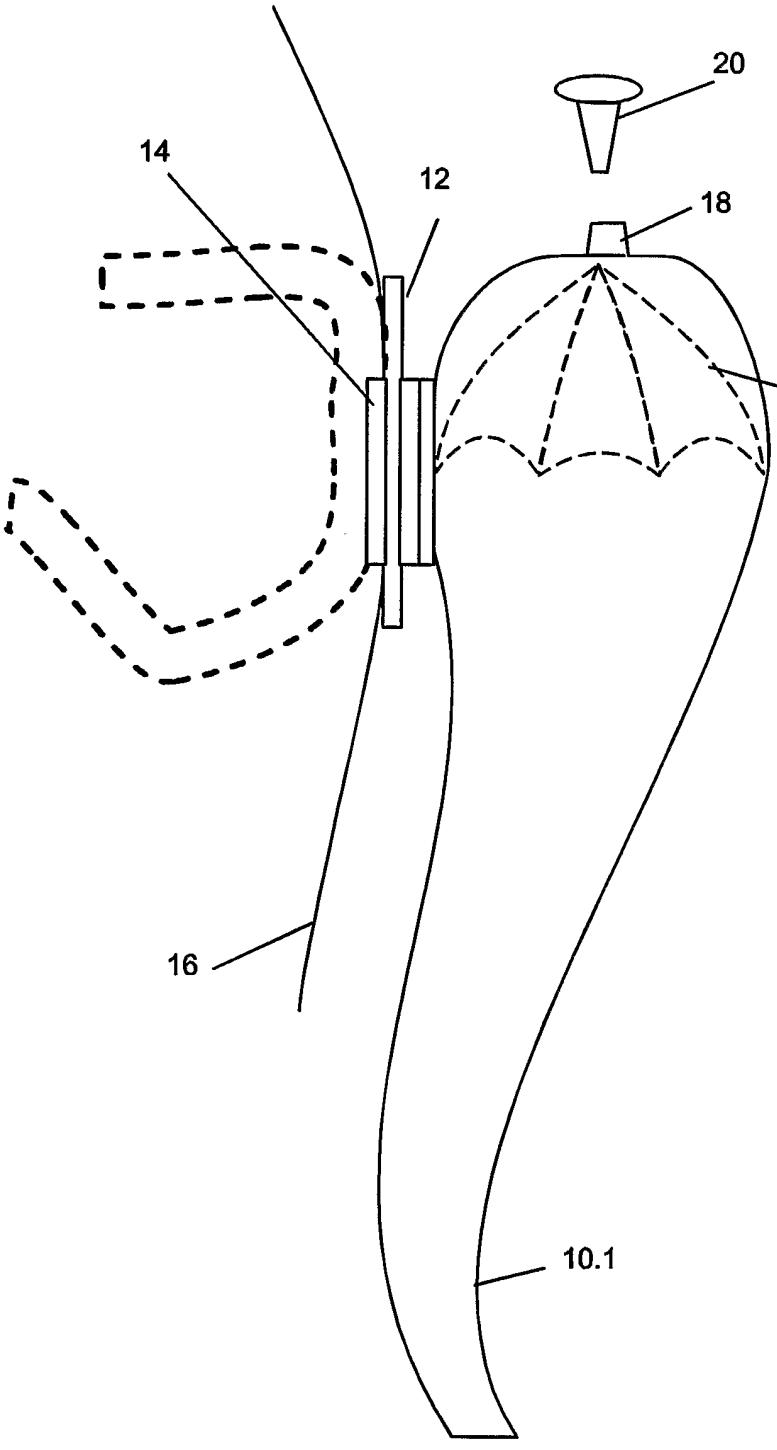


Figure 1

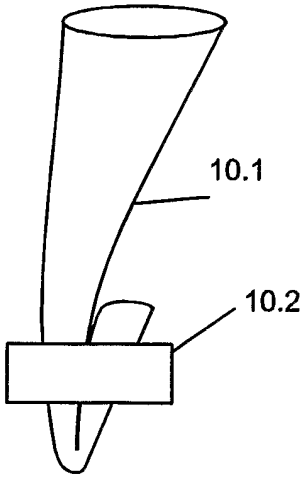


Figure 2

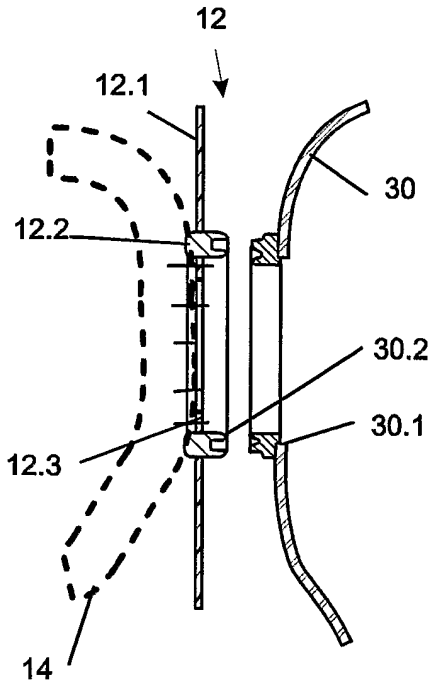


Figure 3

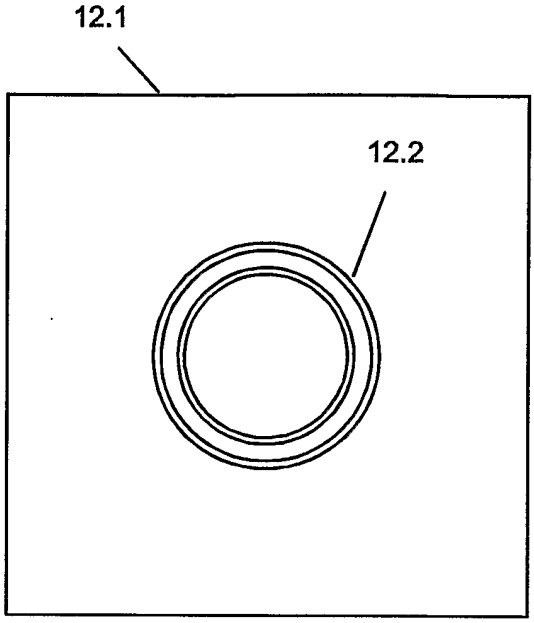


Figure 4

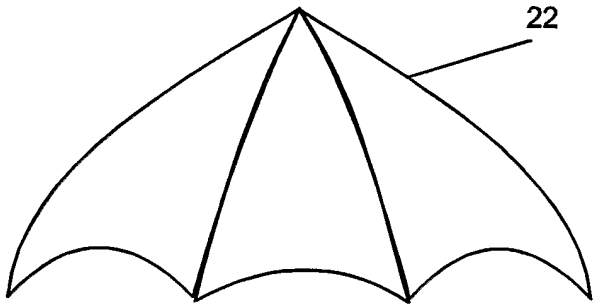


Figure 5 22.1

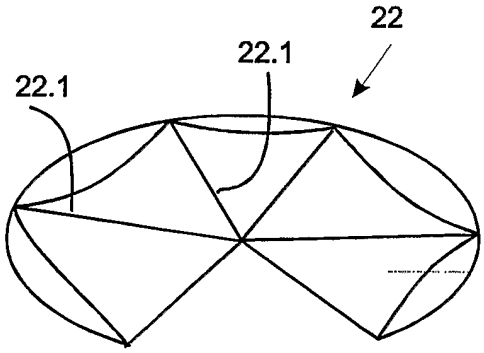


Figure 6

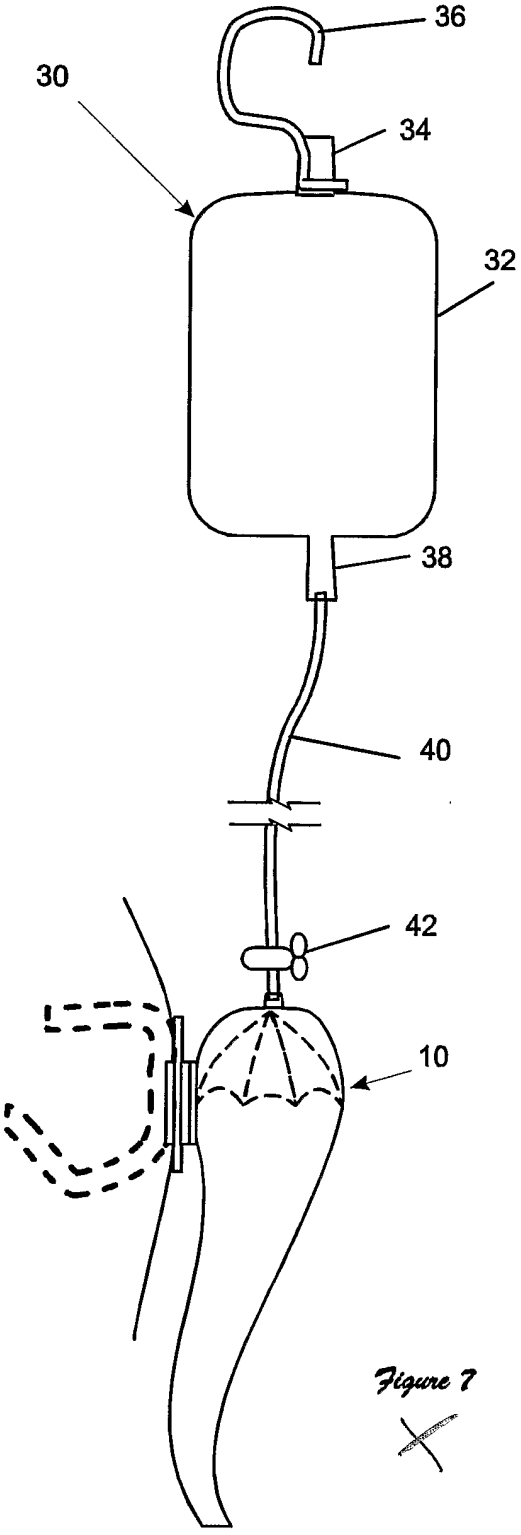


Figure 7

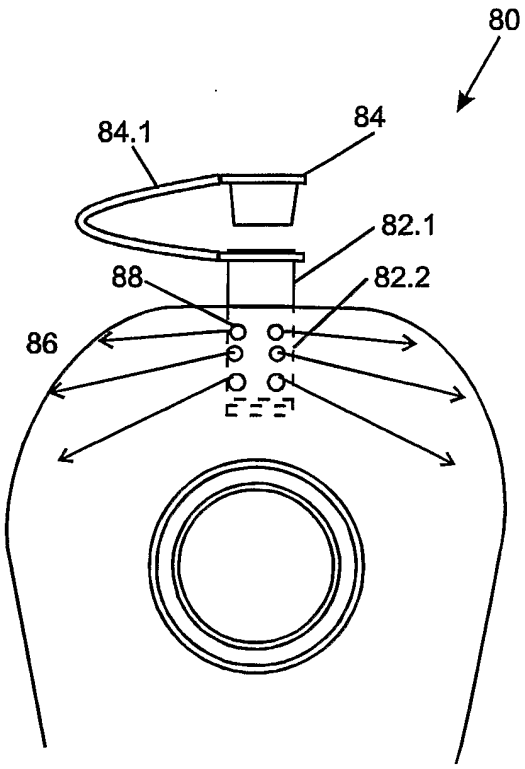


Figure 8