United States Patent [19]

Nolan

[11] **3,910,274**

[45] **Oct. 7, 1975**

[54] **STOMA IRRIGATING SYSTEM**

[75] Inventor: **John L. Nolan,** Glenview, Ill.

[73] Assignee: **Hollister Incorporated,** Chicago, Ill.

[22] Filed: **Mar. 18, 1974**

[21] Appl. No.: **451,942**

[52] **U.S. Cl.** **128/227;** 128/283

[51] **Int. Cl.²** **A61M 3/00**

[58] **Field of Search** 128/227, 240, 241, 245, 128/283, 251

[56] **References Cited**

UNITED STATES PATENTS

2,741,247	4/1956	Marsan	128/283
2,888,925	6/1959	Philips	128/251
2,902,036	9/1959	Perry	128/283
2,928,393	3/1960	Marsan	128/283
3,292,625	12/1966	Marsan	128/283
3,577,982	5/1971	La Par	128/245
3,672,370	6/1972	Marsan	128/227
3,771,522	11/1973	Waysilk et al.	128/227

Primary Examiner—Richard A. Gaudet
Assistant Examiner—J. Yasko
Attorney, Agent, or Firm—Wegner, Stellman, McCord, Wiles & Wood

[57] **ABSTRACT**

The present invention provides a stoma irrigating system including an irrigating cone which is soft on the inserted apex end but firm on the base end and is easily cleansed, a reservoir for irrigating fluid, a bag to be secured to the body of an ostomy patient, the bag having an opening surrounding the stoma of the patient, and with the bag having closeable means which permits the irrigating cone to be inserted into the stoma, and to which cone a tube communicating with the reservoir may be attached to direct irrigating fluid into the stoma and hence into the intestinal tract of the patient.

5 Claims, 6 Drawing Figures

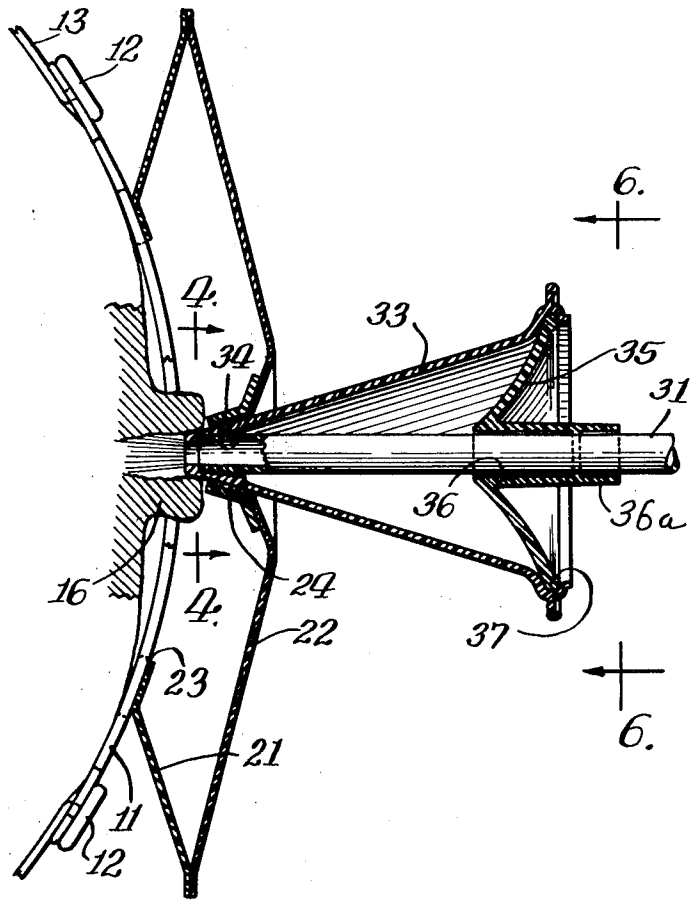


Fig. 1.

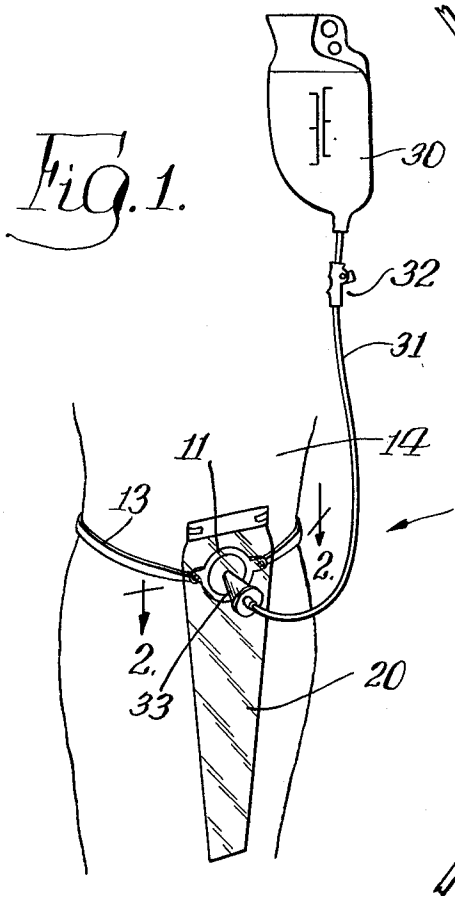


Fig. 2.

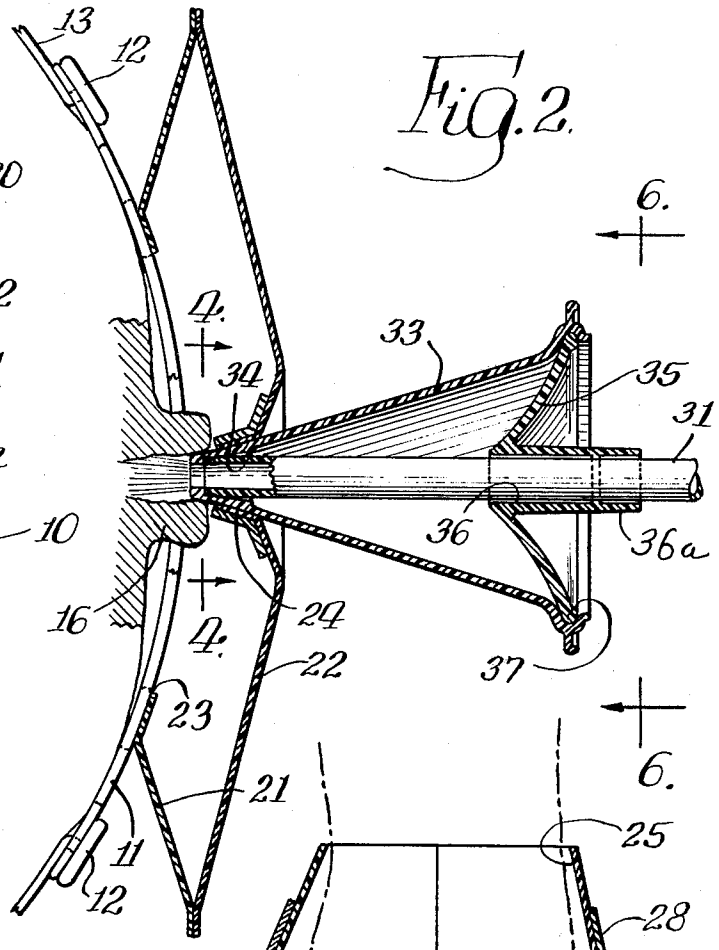


Fig. 4.

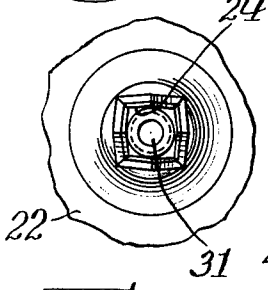


Fig. 5.

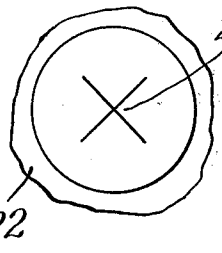


Fig. 3.

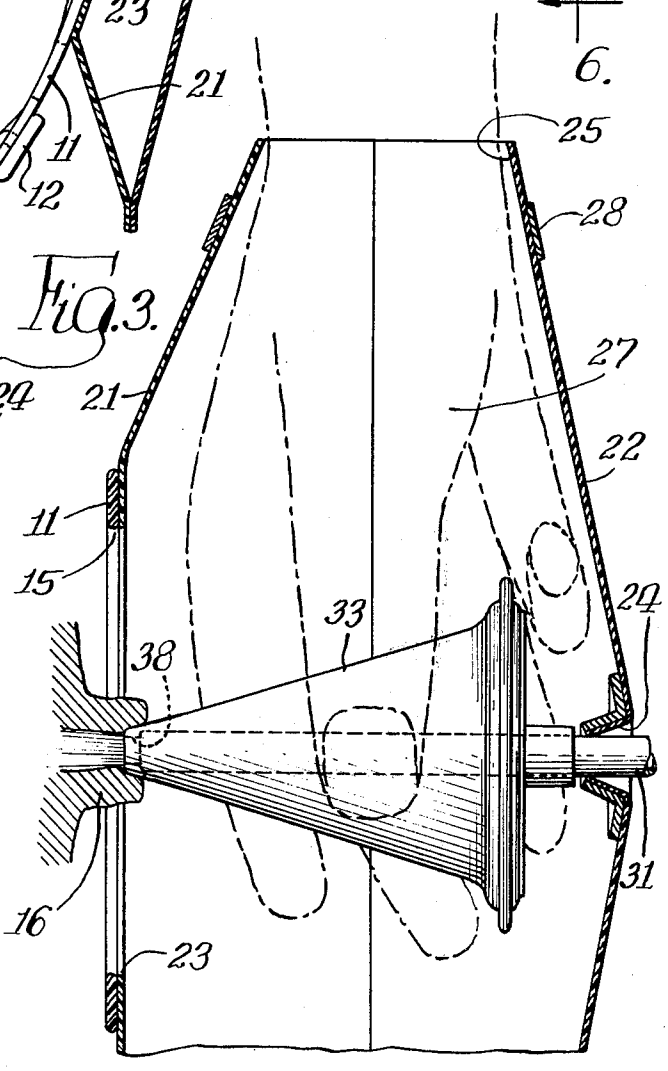
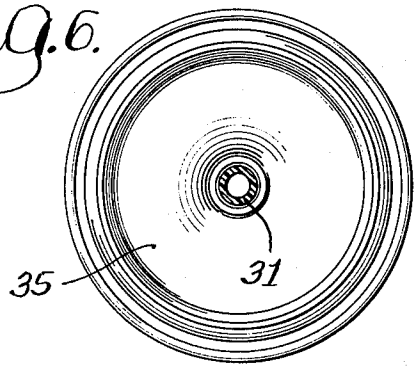


Fig. 6.



STOMA IRRIGATING SYSTEM

BACKGROUND OF THE INVENTION

Patients who have had a colostomy operation are left with a stoma extending through the abdominal wall, from which waste material is discharged into a bag or container. In the care and treatment of many such patients, it is necessary routinely to irrigate the intestine and for that purpose it has been customary to use a cone, the apex of which is inserted into the stoma, with the apex having a hole therein connected to a tube, in turn connected to a source of irrigating fluid. With the cone inserted in the stoma, irrigating fluid may be introduced into the intestine for irrigating purposes. After a suitable length of time, the cone is removed, permitting irrigating fluid to drain out, cleansing the bowel. It has also been customary to provide a suitable bag adapted to be secured to the patient, into which such discharge is directed.

In the devices of the prior art designed to accomplish the foregoing irrigation, difficulty has been experienced in providing a cone which is soft and pliable, easy to clean, and which prevents the attached tube from penetrating into the stoma beyond the tip of the cone, a condition which can cause damage to the intestine. Difficulty has also been experienced in providing a structure which will permit the cone to be properly positioned in the stoma and yet which is arranged to catch and retain fluids draining from the intestine, including the irrigation fluid and other material which may be discharged therewith. The present invention is particularly designed to provide an irrigation system wherein a soft, easily cleanable cone may be easily, properly and safely positioned, and at the same time ample security for the retention of discharged fluid is provided.

BRIEF SUMMARY OF THE INVENTION

Colostomy patients differ in a wide variety of ways. Not only are the physical characteristics of each patient different, the size, shape, and location of the stoma varies significantly from patient to patient. According to the present invention, there is provided an irrigation system which may be used by the patient in several ways in order to effect proper irrigation of the intestinal tract, while at the same time providing means for catching and retaining fluids discharged after the irrigation has been accomplished. Thus, the present invention contemplates a unique type of cone to facilitate irrigation and a bag of transparent or translucent plastic material which may be secured to the body of a patient and having an opening surrounding the stoma, with the bag having an open top through which the separate plastic cone may be inserted into the end of the stoma, or alternate means to permit insertion of the cone into the stoma. The outer wall of the bag is provided with a self-sealing opening opposite the opening surrounding the stoma, and through which self-sealing opening a tube connected to a source of irrigating fluid may be inserted. When so inserted, the tube is directed through the base of the cone and into communication with an aperture in the apex of the cone so that irrigating fluid is directed therefrom into the stoma and hence into the intestinal tract of the patient.

In some cases, or occasionally from time to time with an individual patient, it may be advantageous to insert the apex of the cone into the stoma by inserting the apex through the self-sealing opening mentioned above, and the present invention provides for this alternate method of use. In other cases, or occasionally from time to time with an individual patient, it may be advantageous to insert the entire cone, with its tube connected, into the bag through the open top and then to insert the apex of the cone into the stoma, and the present invention provides for this alternate method of use as well.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view showing a portion of a body of an ostomy patient with the device of the present invention shown in one operating (irrigating) position, with the cone penetrating the resealable opening in the receptacle bag;

FIG. 2 is an enlarged horizontal sectional view taken along line 2—2 of FIG. 1;

FIG. 3 is a vertical sectional view of the upper portion of the apparatus shown in FIG. 1 showing the cone inside the receptacle bag, which is shown in open position; FIG. 4 is a sectional view taken along line 4—4 of FIG. 2;

FIG. 5 is a view of a portion of the outer surface of the bag showing the self-sealing opening therein in closed position; and

FIG. 6 is a view partially in section taken along line 6—6 of FIG. 2.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, there is shown an irrigating system **10** which includes a retaining device **11** provided with means **12** to be secured to a belt **13** for holding the retaining device in position on the body of a patient **14.** The retaining device **11** is provided with a central aperture **15** which surrounds the stoma **16** of the patient.

The irrigating system includes a bag **20** of transparent or translucent plastic material having an inner wall **21** and an outer wall **22.** The inner wall **21** has an opening **23** sealed at its edges to the retaining device **11.** Opposite the opening **23** in the inner wall of the bag is a self-sealing or self-closing opening **24** formed in the outer wall of the bag, with the opening **24** being directly opposite the center of the aperture **15.**

The walls **21** and **22** are sealed together along their edges, but not at the top portion so that the walls may be separated at the top to provide an access opening **25** large enough to permit the entry of the hand **27** of the patient. The walls of the bag may be folded at the top to close the opening **25,** and the walls may be secured in closed position by means of bendable soft metal clips **28.**

A reservoir **30** is provided for use in conjunction with the apparatus thus far described, with the reservoir being connected to a tube **31** extending through a hand-operated valve **32,** with the valve serving to control the flow of fluid through the tube.

The tube **31** is adapted to be used in conjunction with a separate cone **33** of soft plastic material, with the cone having a hole at its apex and being provided with a relatively rigid diaphragm-like member **35** at its base. The diaphragm has a guide opening **36** extending therethrough and a guide cylinder **36***a* aligned therewith and extending along the axis of the cone. The diaphragm is

snapped into position around the base of the cone by virtue of a mating of its outer edges with an inner recess **37** formed in the cone. The hole **34** at the apex of the cone is designed so that the tip of the tube **31** will not pass through it, thus preventing the tube from accidentally entering the stoma. Thus, the inner diameter of the hole is less than the outer diameter of the tube. As a further insurance against the patient forcing the tube through the hole in the apex of the cone and into the stoma, the apex is provided with an in-turned flange **38** providing a shoulder which acts as a positive stop for the tube, thus preventing the tube from extending beyond the apex of the cone.

As indicated earlier, the device of the present invention may be used in either of three ways, one way being that illustrated in FIG. **3** wherein the clips **28** are loosened to permit the bag to be opened as shown at **25** and the hand of the patient inserted into the opening to position the cone **33** in the stoma. After the cone has been so positioned, the tube **31** is inserted through the opening **24** in the outer wall **22** of the bag, through the guide opening **36** to the opening **34** in the apex of the cone. The tube cannot be pushed beyond the apex of the cone as it has a larger diameter than the opening **34.** Thus, the tube cannot be pushed beyond the cone into the stoma, which might injure the patient. With the tube and cone so positioned, the valve **32** may be opened and irrigating fluid will flow into the intestinal tract. When the irrigation has been completed, the cone is withdrawn from the stoma and the tube is withdrawn from the cone. At this point the opening **24** will automatically seal and the cone may be withdrawn from the bag and the latter closed by means of the clips **38.** Fluid released by the irrigation process will then flow into the bag **20.**

An alternate method of use of the bag which a patient may employ from time to time is shown in FIGS. **1** and **2** wherein the tube **31** is inserted through the diaphragm **35** into the cone **33** to position the end of the tube at the opening **34** in the apex of the cone. With the tube and cone so assembled, the apex of the cone is inserted through the opening **24** and moved toward the body of the patient to cause the apex of the cone to enter the stoma **16.** When irrigation has been completed, the valve **32** is closed and the tube and cone removed simultaneously to permit fluid to drain into the bag. The opening **24** will automatically seal to prevent the stoma discharge from following the apex of the cone when it is removed from the opening.

Still another method of using the apparatus of the present invention and probably the one that will most frequently be employed, is to assemble the tube and cone as shown in FIG. **1** and then insert the same so assembled through the opening **25** in the top of the bag after first releasing the clips **28.** The hand of the patient can guide the cone and tube into the opening of the bag and insert the apex of the cone into the stoma. After being so inserted, the valve **32** is opened and irrigation proceeds. During irrigation, the cone may be held in place by hand, which may be either inside or outside of the bag. When irrigation has been completed, the cone and attached tube are removed through the opening **25** which can then be closed by folding the top half of the bag **20** and securely bending the soft metal clips **28** to hold the bag in closed, folded position. The irrigating fluid and other bowel contents which will be expelled after the cone has been removed will flow into the bag.

One of the important features of the present invention is the fact that the cone **33** is made of soft plastic material. Thus, it will neither injure nor cause pain to the patient when it is inserted into the stoma. The cone is sufficiently flexible so as to adapt itself to the contours of the stoma and thus not only assure a good seal, but also assure the comfort of the patient. If the cone were made entirely of soft material, it would not possess sufficient strength to be inserted at least partially into the stoma and held there firmly enough to effect a seal. Thus, according to the present invention, the base of the cone, i.e., the diaphragm **35,** is made of relatively stiff plastic material. As the diaphragm is snapped onto the base of the cone it is in contact with the entire circumference of the base and provides support at that end sufficient to permit insertion and retention of the apex of the cone. Because the diaphragm **35** may be snapped onto and off of the base of the cone, cleaning of the interior of the cone is made possible.

I claim:

1. A device for irrigating the stoma of an ostomy patient comprising, a reservoir for irrigating fluid, a tube communicating with the reservoir, a cone of plastic material having an apex to be inserted into the stoma, said cone being of relatively soft pliable plastic material having an opening at its apex, a flange on the inner surface of the cone adjacent said opening and surrounding the same, said flange providing an annular stop having an inner diameter smaller than the outer diameter of said tube, a diaphragm of relatively stiff plastic material secured to the base of the cone, a hollow guide cylinder extending through the diaphragm along the axis of the cone to guide the tube to be inserted therethrough to the apex of the cone, said tube and cone delivering irrigating fluid from the reservoir into the stoma.

2. A device for irrigating the stoma of an ostomy patient comprising, a plastic bag having inner and outer walls secured together at their edges, a retaining device having an aperture therein, an opening in the inner wall of the bag having its edges secured to the edges of the aperture in the retaining device, means on the retaining device adapted to be secured to a belt for retaining the bag in position on the body of an ostomy patient with the stoma extending through said aperture, said walls being unsecured to each other at their tops to provide access means to the interior of the bag with said access means extending entirely across the top of the bag, retention means secured across the top of one of said walls and extending along the length of said access means, the upper portion of said walls adjacent said access means being adapted to be rolled to close said access means and said access means being retained in said closed position by said retention means.

3. A device for irrigating the stoma of an ostomy patient comprising, a transparent plastic bag having inner and outer walls secured together at their edges, a retaining device having an aperture therein, an opening in the inner wall of the bag having its edges sealed to the edges of the aperture in the retaining device, means on the retaining device adapted to be secured to a belt for retaining the bag in position on the body of an ostomy patient with the stoma extending through said aperture, a self-sealing opening in the outer wall of the bag located opposite the center of said aperture, a reservoir for irrigating fluid, a tube communicating with the reservoir and insertable through the opening in the outer wall, a cone of plastic material having an apex to

be inserted into the stoma, a closeable opening in the top of the bag to permit the cone to be inserted therethrough into the bag and to be positioned with the apex of the cone in the stoma, said tube being insertable through the opening in the outer wall and placed into communication with a hole in the apex of the cone when the cone is so positioned for delivering irrigating fluid into the stoma.

4. A device for irrigating the stoma of an ostomy patient comprising, a transparent plastic bag having inner and outer walls secured together at their edges, a retaining device having an aperture therein, an opening in the inner wall of the bag having its edges sealed to the edges of the aperture in the retaining device, means on the retaining device adapted to be secured to a belt for retaining the bag in position on the body of an ostomy patient with the stoma extending through said aperture, a reservoir for irrigating fluid, a tube communicating with the reservoir, a cone of plastic material having an apex to be inserted into the stoma, said cone being of relatively soft pliable plastic material having an opening at its apex with the inner diameter of said opening in the apex being smaller than the outer diameter of said tube, a diaphragm of relatively stiff plastic material secured to the base of the cone, said diaphragm being provided with an opening to permit the tube to be inserted therethrough to the apex of the cone, a closeable opening in the top of the bag to permit the cone to be inserted therethrough into the bag and to be positioned with the apex of the cone in the stoma, said tube being insertable through the opening in the top of the bag and placed into communication with the hole in the apex of the cone when the cone is so positioned for delivering irrigating fluid into the stoma.

5. A device for irrigating the stoma of an ostomy patient comprising, a transparent plastic bag having inner and outer walls secured together at their edges, a retaining device having an aperture therein, an opening in the inner wall of the bag having its edges sealed to the edges of the aperture in the retaining device, means on the retaining device adapted to be secured to a belt for retaining the bag in position on the body of an ostomy patient with the stoma extending through said aperture, a reservoir for irrigating fluid, a tube communicating with the reservoir, a cone of plastic material having an apex with a hole therein, said apex being adapted to be inserted into the stoma, a closeable opening in the top of the bag to permit the cone to be inserted therethrough into the bag and to be positioned with the apex of the cone in the stoma, said tube being insertable through the base of the cone and placed into communication with the hole in the apex of the cone when the cone is so positioned for delivering irrigating fluid into the stoma.

* * * * *