

July 14, 1970

L. FENTON
STOMATIC APPLIANCE
Filed May 12, 1966

3,520,301

Fig. 2

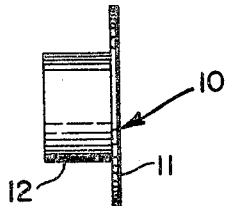


Fig. 3

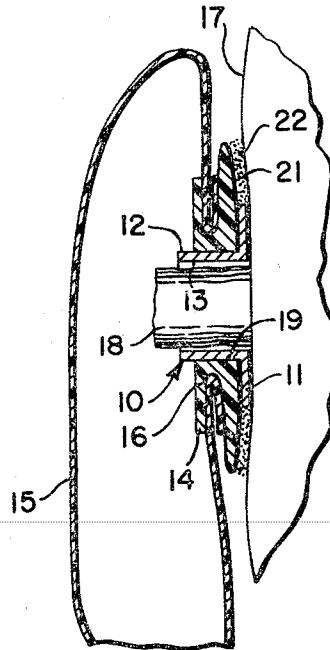
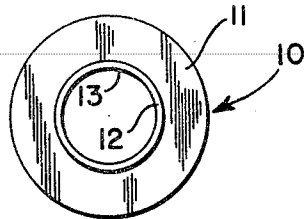


Fig. 1

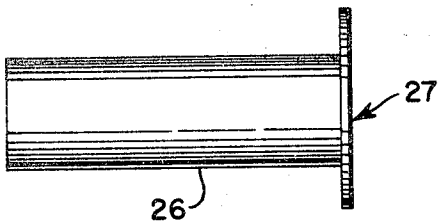


Fig. 5

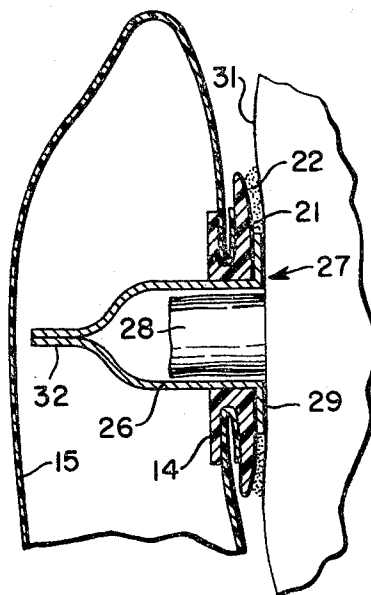


Fig. 4

INVENTOR
LEONARD FENTON

BY McNenny, Farrington, Pearne & Gordon

ATTORNEYS

1

3,520,301

STOMATIC APPLIANCE

Leonard Fenton, % 5156 Richmond Road,
Beachwood, Ohio 44014

Filed May 12, 1966, Ser. No. 549,591

Int. Cl. A61f 5/44

U.S. Cl. 128—283

5 Claims

ABSTRACT OF THE DISCLOSURE

A device for facilitating the attachment of a drainage bag to the stoma of a patient. The device has a tubular portion and a radially extending rim portion adjacent one end of the tubular portion. The device is formed of a non-irritating material which is soft and pliable and which softens in use to form a jelly-like mass. The tubular portion is proportioned to extend into the inlet opening of a drainage bag and surrounds the stoma and the rim portion is sealed against the body around the stoma.

This invention relates to stomatic appliances and, more particularly, to a device for facilitating the application of a drainage bag to the stoma of a patient having an ileostomy, ureterostomy or the like.

As a result of an anomalous intestinal or urinary condition, such as an ileac or ureter obstruction, it is often necessary to establish an artificial opening in the patient to permanently expose a short piece of ileum or the ureter which constitutes a stoma about which a receptacle or pouch-like bag is secured. Such a pouch or receptacle is usually flexible and is formed of rubber or plastic material. The pouches are provided with an inlet opening in which a mounting ring is secured. The mounting ring is formed with an inlet opening which fits over the stoma and a face which fits against and seals with the body around the stoma.

In the past it has been customary to coat the face of the mounting ring to secure the appliance in position. fore it is positioned against the skin around the stoma. It has also been customary to use a belt which attaches to the mounting ring to secure the appliance in position. Reference may be made to my U.S. Letters Pat. No. 2,818,069, dated Dec. 31, 1957, for a complete description of one preferred mounting ring structure.

In some instances a pliable washer is first placed around the stoma against the skin before the mounting ring is secured in place. These washers are usually formed of karaya washers tend to hold their shape but are soft. One such binder which may be used is glycerin. Such karaya washers tend to hold their shape but are soft and pliable. They also have sufficient adhesive properties so that they adhere to the skin and the mounting ring, providing a good seal which prevents odor and the like. While in use, they tend to soften under body heat and form a jelly-like mass which functions to protect the skin against irritation and forms a lasting seal between the mounting ring and the body.

When mounting rings are properly positioned, such prior arrangements have been found to be quite satisfactory. However, it has been found in many instances that the patient has encountered difficulty in properly locating the mounting ring around the stoma because the bag or pouch covers the mounting ring and prevents the patient from determining if the mounting ring is properly centered around the stoma. As a result, the mounting rings are often improperly positioned and press against the side of the stoma. Since there are no nerve endings in the stoma, the patient is usually unaware of the condition and may wear the improperly positioned appliance for some time. This causes irritation of the stoma and, in some

2

extreme cases, ulcerates the stoma to a degree requiring corrective surgery.

With an appliance incorporating the present invention, a washer-like device is formed with an integral cylindrical projection which extends along and around the stoma. Preferably, the device is formed of karaya powder and a binder. However, other suitable materials may be used. The cylindrical projection serves two functions. First, it provides a guiding surface which is sufficiently stiff to guide the ring as it is moved into proper position. Second, it provides a protective coating between the stoma and the walls of the inlet opening of the mounting ring to prevent irritation or damage to the stoma. The proper positioning of the washer device presents no difficulty since it is open so that the patient can see or use his sense of touch to insure its proper location.

In a second embodiment of this invention, an additional problem is eliminated. Some patients have difficulty caused by an almost constant drainage from the stoma, which can cause contamination around the stoma before the appliance can be secured in position. Since such contamination can result in both skin irritation and odor, this presents a serious problem to patients having this difficulty. The second embodiment of this invention substantially eliminates this difficulty by providing a temporary closure of the stoma to hold back drainage until the appliance can be properly secured in position. This is accomplished by forming the cylindrical portion with a length so that it extends beyond the end of the stoma. As soon as the washer device is positioned over the stoma, the patient merely pinches the end closed and drainage is temporarily stopped. The mounting ring is then secured in position without danger of drainage contamination. After the appliance is properly positioned, the body heat and the heat of the drainage cause the washer device material to soften and open to permit normal drainage.

It is an important object of this invention to provide a novel and improved device which facilitates the attachment of a drainage pouch around the stoma of a patient and which protects the stoma while the appliance is in use.

A further object of this invention is to provide a novel and improved device according to the preceding object which provides temporary means to prevent drainage from spilling on the abdomen and surrounding skin, so that contamination will not occur during the mounting of the appliance.

Further objects and advantages will become apparent from the following detailed description and accompanying drawings, wherein:

FIG. 1 is a cross-sectional view of a stomatic appliance incorporating this invention, showing the appliance attached to the patient;

FIG. 2 is a side elevation of one washer device according to this invention;

FIG. 3 is an end elevation of the washer device of FIG. 2;

FIG. 4 is a cross sectional view similar to FIG. 1 but showing a washer device according to a second embodiment of this invention wherein means are provided to temporarily prevent drainage; and

FIG. 5 is a side elevation of the second embodiment of the washer device.

Referring now to the drawings, and in particular to FIGS. 1 through 3, the first illustrated embodiment of this invention includes a washer device 10 preferably made from karaya powder mixed with a binder to form a soft, pliable and adhesive material. Such material tends to hold its shape under room temperatures but softens to a jelly-like mass under body heat and moisture. It should be understood that in its broader aspects this invention is not limited to a device formed of this material and that other

3

suitable materials may be used. The washer device 10 has a flat washer-shaped rim 11 and an integral, hollow tubular or cylinder portion 12 which projects from one face of the rim 11. The hollow cylinder 12 and rim 11 define an aperture 13. The washer device may be made in various sizes so that the device can be selected to properly fit any given stoma. Preferably, the device should be sized so that the aperture 13 fits loosely over the stoma. Preferably the rim 11 is about one half an inch in radial width regardless of the size of the cylinder portion 12.

To attach a drainage bag or pouch 15, the patient first secures a relatively rigid plastic mounting ring 14 in the opening 16 of the bag 15. He then cleans the skin 17 around the stoma 18 and slips the washer device 10 over the stoma 18, positioning the rim 11 against the skin 17. The rim is sufficiently adhesive or sticky to form a seal with the skin and hold the device 10 in place. The patient does not have difficulty in properly positioning the device 10 since it is open at its rearward end and he can observe the stoma 18 or determine if the device is in the proper position by his sense of touch.

With the washer device properly in position, the patient usually coats the face 21 of the mounting ring 14 with a suitable adhesive 22 and then slips the mounting ring over the cylindrical portion 12 with the surface of the inlet opening 19 in the mounting ring 14 guided by the cylindrical portion 12 until the mounting ring is in the position illustrated in FIG. 1. The belt (not shown) is then attached to the mounting ring 14 and the appliance is properly secured in position.

In its mounted position, the washer device 10 effectively spaces and cushions the opening 19 from the stoma 18 to eliminate any possible irritation of the stoma by the mounting ring. In addition, the rim section 11 provides a tight seal between the skin 17 and mounting ring, preventing the escape of any drainage and also preventing odor. After the appliance is in position a short time, the material forming the washer device softens under body heat and forms a jelly-like substance, providing a lasting seal and lasting protection against irritation.

FIGS. 4 and 5 illustrate the second embodiment of this invention, which differs from the first embodiment in that the cylindrical portion 26 of the washer device 27 is sufficiently long so that it extends beyond the end of the stoma 28. Here again, a washer-like rim 29 is integrally formed with the cylindrical portion 26 and is positioned against the patient's skin 31 in the same manner as the washer device 10 of the first embodiment.

The cylindrical portion 26 is longer than the stoma 28 by a sufficient amount to permit the outer end thereof to be pinched closed, as illustrated at 32. Since the material is slightly sticky, it remains closed until the ring can be properly positioned. Generally, a stoma is about one half inch long, and the cylindrical portion 26 should be at least about one and one half inch long. Here again, the material of the washer device 27 is preferably karaya powder mixed with a suitable binder to form a soft, pliable device which is sufficiently rigid to guide the mounting ring 14 into the proper position with respect to the stoma 28. The mounting ring 14 and bag or pouch 15 may be of the identical structure illustrated in the first embodiment and an adhesive 22 may be coated on the face 21 of the mounting ring 14 to provide additional sealing between the skin 31 and mounting ring 14.

Because the end of the cylindrical portion 26 is closed at 32, the stoma 28 is effectively sealed against drainage while the ring 14 is positioned. This prevents drainage from contaminating the area around the stoma while the ring is positioned. Shortly after the appliance is attached, the body heat and the heat of the drainage soften the

4

material of the cylindrical portion 26, causing it to open so that drainage into the pouch is unrestricted. Here again, the cylindrical portion 26 provides a jelly-like coating around the stoma which cushions the stoma and prevents irritation thereto.

Although preferred embodiments of this invention are illustrated, it is to be understood that various modifications and rearrangements of the parts may be resorted to without departing from the scope of the invention as defined in the following claims.

I claim:

1. A device for use with stomatic appliances having an inlet opening comprising a tubular portion and a radially extending rim portion substantially adjacent to one end of said tubular portion, said device being substantially inelastic and being substantially inelastic and being formed of a non-irritating, soft and pliable material which softens in use to form a jelly-like mass and which is adapted to seal against the body around a stoma and with said appliance around said inlet opening, said tubular portion being proportioned to extend into said inlet opening and around but radially spaced from a stoma, said tubular portion being sufficiently stiff to guide the walls of said inlet as the appliance is positioned over said stoma.

2. A device as set forth in claim 1 wherein said material is karaya powder mixed with a binder.

3. A device for use with stomatic appliances having an inlet opening comprising a tubular portion and a radially extending rim portion substantially adjacent to one end of said tubular portion, said device being substantially inelastic and being formed of a non-irritating material adapted to seal against the body around a stoma and with said appliance around said inlet opening, said tubular portion being proportioned to extend into said inlet opening and around but radially spaced from a stoma, said tubular portion being sufficiently stiff to guide the walls of said inlet as the appliance is positioned over said stoma, said tubular portion being longer than the stoma and the material forming the tubular portion being sufficiently flexible and adhesive so that the end of the tubular portion may be pinched to temporarily prevent drainage from the stoma.

4. A device as set forth in claim 3 wherein said tubular portion is at least about one and one-half inches long.

5. A stomatic appliance comprising a washer device having a tubular portion and a radially extending rim substantially adjacent to one end of said tubular portion, a drainage receiving assembly including a mounting ring having an inlet opening therein positioned around said tubular portion and a face section positioned against the adjacent surface of said rim portion, said tubular portion being proportioned to fit over a stoma with the outer surface of said rim against the patient's skin around such stoma, said washer device being formed of a material which is soft and pliable at room temperature and which is sufficiently adhesive to seal with said mounting ring and the patient's skin, said tubular portion extending for a distance greater than the length of the stoma and being pinched closed to temporarily prevent drainage from the stoma, said material being adapted to soften and open in use.

References Cited

UNITED STATES PATENTS

2,684,676	7/1954	Perry	128—283
2,818,069	12/1957	Fenton	128—283
3,021,843	2/1962	Perry	128—283
3,302,647	2/1967	Marsan	128—283

CHARLES F. ROSENBAUM, Primary Examiner

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,520,301 Dated July 14, 1970

Inventor(s) LEONARD FENTON

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 1, line 28, change "lieac" to --ileac--.

Column 1, lines 40 and 41, delete "to secure the appliance in position, fore" and substitute therefor --with an adhesive sealing material before--; and

line 50, cancel "washers tend to hold their shape but are soft" and substitute therefor --powder mixed with a suitable plasticizing binder.--

Column 3, line 18, change "properly" to --properly--.

Column 4, line 16, cancel "substantially inelastic and being".

SIGNED AND
SEALED
DEC 15 1970

(SEAL)

Attest:

Edward M. Fletcher, Jr.

Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents