United States Patent [19]

Chen James Ling

[11] **3,906,951**

[45] **Sept. 23, 1975**

[54] **STOMAL DEVICE INCLUDING MEANS TO PROLONG ATTACHMENT OF FLANGE**

[75] Inventor: **Chen James Ling,** East Brunswick, N.J.

[73] Assignee: **E. R. Squibb & Sons, Inc.,** Princeton, N.J.

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[21] Appl. No.: **494,781**

[52] **U.S. Cl.** **128/283;** 128/260

[51] **Int. Cl.²** **A61F 5/44**

[58] **Field of Search** ..... 128/1 R, 154–157, 128/163, 171–172, 260–261, 268, 272, 275, 283, 350 R, 2 F, 294–295

[56] **References Cited**

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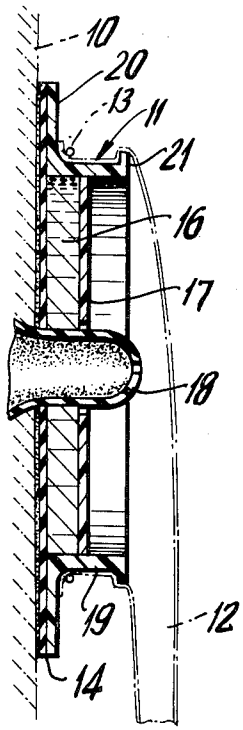
Primary Examiner—Richard A. Gaudet
Assistant Examiner—Rick Opitz
Attorney, Agent, or Firm—Lawrence S. Levinson; Merle J. Smith; Stephen B. Davis

[57] **ABSTRACT**

Cover disc located in the area between a flange and the stoma is employed to periodically deliver a hydrocolloid containing ointment or non-aqueous paste to seal off the area around the stoma. Seepage of fluid passing from the stoma to a bag attached to the flange is absorbed by the ointment and prevented from weakening the adhesive bond attaching the flange to the skin.

13 Claims, 3 Drawing Figures



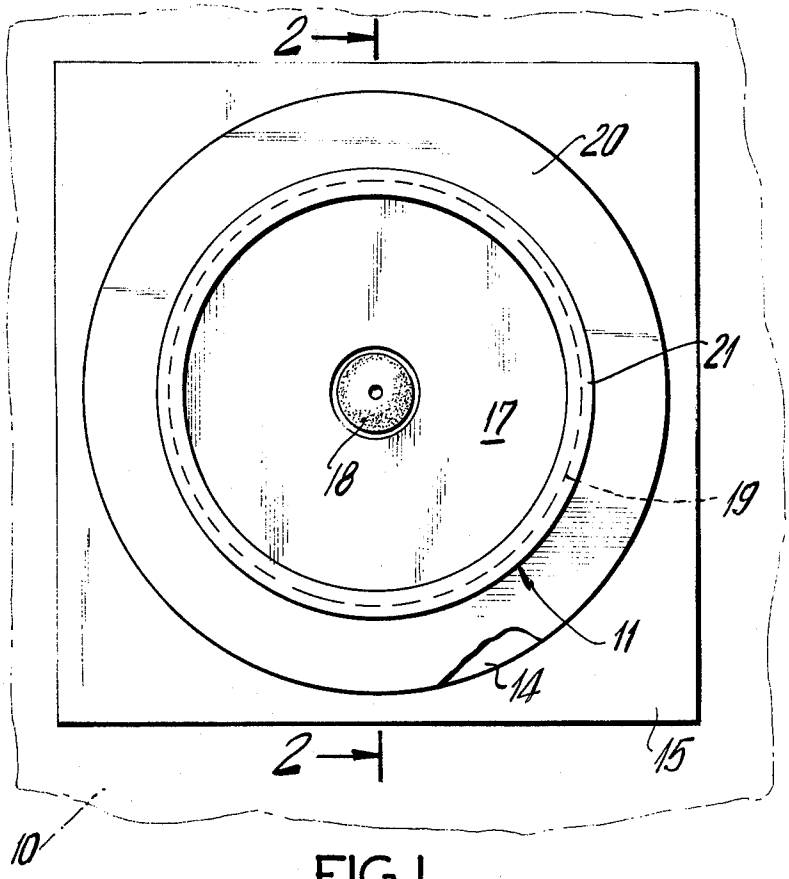


FIG.1

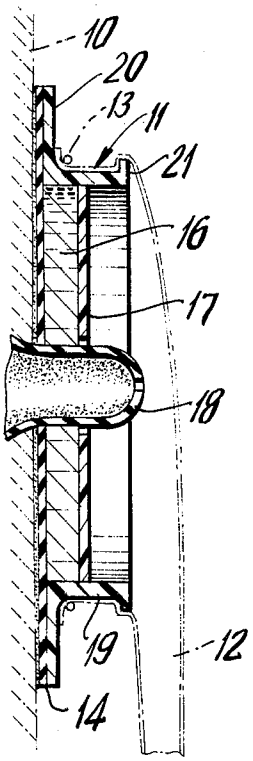


FIG.3

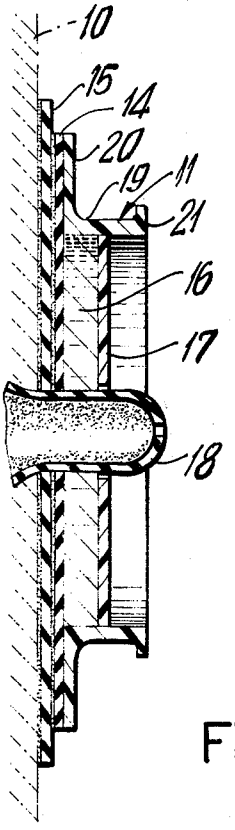


FIG.2

STOMAL DEVICE INCLUDING MEANS TO PROLONG ATTACHMENT OF FLANGE

BACKGROUND OF THE INVENTION

Stomal devices comprising a flange which is affixed to the skin and a disposable stoma bag attached to the flange by means of an elastic band are known. The flange is affixed to the skin by means of a double-sided pressure adhesive disc which is adhered either directly to the skin or to a peristomal covering which is adhered to the skin. The period of time for which the flange remains affixed to the skin is limited due to the fact that seepage occurs in the area of the stoma which weakens the adhesive bond.

SUMMARY OF THE INVENTION

This invention relates to an improvement over the stomal device described above. It relates to means whereby the seepage of fluid from the area of the stoma is retarded thus permitting the flange to remain affixed to the skin for a longer period of time. This result is achieved by the use of a disc located within the periphery of the flange which is manipulated to release amounts of a fluid absorbing ointment or non-aqueous paste in the area around the stoma.

FIG. 1 is a top view of the stomal device without the attached bag.

FIG. 2 is a side view along the line 2—2 of FIG. 1 without the attached bag.

FIG. 3 is the same as FIG. 2 except the peristomal covering is omitted and the attached bag is shown.

DETAILED DESCRIPTION

Referring now to the drawings in more particular detail, the stomal device comprises flange **11** to which stoma bag **12** is attached by suitable means such as an elastic band **13** (see FIG. 3). The flange **11** is bound to one side of a double-sided pressure sensitive adhesive member **14**. The adhesive member **14** can be formed in the shape of a disc comprising polymer film or closed-cell plastic foam having a pressure sensitive adhesive coating on both sides. The adhesive disc **14** has a centrally located hole adapted to fit around the stoma **18**. The other side of the pressure sensitive adhesive disc **14** can be pressed firmly against the skin **10** as shown in FIG. 3. Alternatively, the other side of adhesive disc **14** can be affixed to a peristomal covering **15**, as shown in FIG. 2, which can be pressed firmly against the skin **10**. The peristomal covering **15** also has a centrally located hole adapted to fit around the stoma **18**.

The peristomal covering **15** consists of an adhesive bonding composition comprising a pressure-sensitive rubbery elastomer adhesive component having intimately dispersed therein a water soluble or swellable hydrocolloid and a thin pliable water insoluble film secured to one side. Such coverings or bandages are described in U.S. Pat. No. **3,339,546** whose disclosure is incorporated herein by reference. The adhesive disc **14**, of course, is attached to the film side of covering **15**, see FIG. 2. The covering **15** can be of any shape although rectangular as shown in FIG. 1 is preferred. It is also possible to form the adhesive member **14** directly from the adhesive bonding composition described above by omitting the thin water insoluble film.

The flange **11** is formed from relatively rigid material such as various polymeric materials including polyethylene, polycarbonate, polyvinyl chloride, linear polyethylene, polystyrene, etc., or metals such as aluminum and stainless steel. Flange **11** includes side wall **19**, bottom wall **20**, and upper lip **21**, as seen in FIGS. 2 and 3. The flange can be of any shape such as rectangular or oval although circular as shown in FIG. 1 is preferred. The side wall **19** is generally straight as shown in FIGS. 2 and 3 although it can also be formed with a slight slope. The bottom wall **20** is generally perpendicular to side wall **19**, see FIGS. 2 and 3, and extends outwardly therefrom. Bottom wall **20** can also be constructed so that it extends inwardly from side wall **19** provided that a sufficiently large opening remains for passage of stoma **18**. The bottom wall **20** attached to the adhesive member **14**. Upper lip **21** functions to prevent accidental detachment of stoma bag **12** due to slippage of elastic band **13**.

The disposable stoma bag **12** is formed from any suitable flexible polymeric film such as polyethylene or polypropylene.

This invention is the inclusion of cover disc **17** which releases an amount of ointment or non-aqueous paste **16** in the area of the stoma **18**. As can best be seen in FIGS. 2 and 3, the ointment or paste **16** is located in the space between cover disc **17**, flange side wall **19**, and adhesive member **14**.

The ointment or non-aqueous paste **16** is formed of a mixture of an oil component such as mineral oil or vegetable oil and a water soluble or swellable hydrocolloid or mixtures thereof, such as polyvinylalcohol, powdered pectin, gelatin, sodium carboxymethylcellulose, high molecular weight carbowax, carboxypolymethylene and other like substances. The hydrocolloid is present at a level of from about **25** to about **75%** by weight, with about **30** to about **55%** by weight being preferred. Medicaments such as antiinflammatory agents and deodorants can also be included within the ointment or non-aqueous paste **16**.

The cover disc **17** is rigid or semi-rigid and about **1** to about **3** mm. thick. The rigidity is such that the cover disc **17** will not bend or deform when pressed by hand. The cover disc **17** is formed from materials which are oil resistant and compatible with the ingredients in ointment **16**. Polypropylene, polystyrene, polycarbonate, aluminum, and stainless steel are examples of materials suitable for this purpose. The cover disc **17** is shaped according to the shape of flange **11**. Its dimensions are such that it will fit snugly within the flange side wall **19** and around stoma **18**. Enough space should remain between cover disc **17** and stoma **18** so as to avoid rubbing of the inner edge of the cover disc on the stoma. Upon pressing cover disc **17** towards adhesive member **14** a quantity of ointment **16** will be forced upwards along the sides of stoma **18** and fill the space between cover disc **17** and stoma **18**.

After the flange **11** has been attached to adhesive member **14** which in turn can optionally be attached to peristomal covering **15**, a quantity of hydrocolloid containing ointment or paste **16** is loaded into the area between flange wall **19** and adhesive member **14**. The properly sized cover disc **17** is inserted and the entire device is affixed to the skin. The covering disc **17** is pressed slightly to squeeze the hydrocolloid ointment **16** so as to seal off the space around the stoma **18**. The disposable flexible stoma bag **12** is then attached to the flange by means of elastic band **13**. After a period of time, the ointment or non-aqueous paste **16** will become a soft hydrated mucilaginous paste due to the ab-

sorption of aqueous fluid from the excreta or urine which passed through the opening in stoma **18.** The covering disc **17** is then pressed down with the fingers through the wall of the flexible stoma bag **12** without removing the bag or by pressing directly after the bag has been removed causing an amount of fresh ointment or paste **16** to reseal the space around the stoma **18.** Thus, the aqueous fluid is continuously blocked and prevented from seeping to the adhesive member **14** or peristomal covering **15** and weakening the adhesive bonds which keep the device in place.

What is claimed is:

1. A stomal device comprising an adhesive member, a rigid flange means including a continuous side wall, outwardly extending bottom wall perpendicular to said side wall and an upper lip, said flange means affixed to one side of said adhesive member by an adhesive bond between said bottom wall and said adhesive member, both said adhesive member and said bottom wall having a centrally located opening to permit the device to encircle a stoma, a quantity of hydrocolloid containing ointment or non-aqueous paste located interior of said flange side wall and supported by said adhesive member, a rigid or semi-rigid covering disc having a centrally located opening sized and shaped so as to snugly fit in the space between said flange side wall and said stoma with said covering disk opening in line with said adhesive member opening, whereby movement of said covering disc toward said adhesive member will force a portion of the hydrocolloid containing ointment or paste to fill the space between the stoma and said covering disc.

2. The stomal device of claim **1** including a flexible stoma bag attached to said flange by means of an elastic band whereby said flange upper lip prevents accidental detachment of said bag.

3. The stomal device of claim **1** wherein said ointment or non-aqueous paste comprises an oil component selected from mineral oil or vegetable oil and from about **25** to about **75%** by weight of a water soluble hydrocolloid, a water swellable hydrocolloid, or mixtures of water soluble and water swellable hydrocolloids.

4. The stomal device of claim **3** wherein said ointment or non-aqueous paste comprises from about **30** to about **55%** by weight of hydrocolloid.

5. The stomal device of claim **3** wherein said cover disc is from about **1** to about **3** mm. thick and from materials which are resistant and compatible with the ingredients in the ointment or non-aqueous paste.

6. The stomal device of claim **1** wherein said adhesive member is a bonding composition comprising a pressure sensitive rubbery elastomer adhesive having intimately dispersed therein a water soluble or water swellable hydrocolloid.

7. The stomal device of claim **1** wherein said adhesive member is an adhesive disc comprising a polymer film or closed-cell plastic foam having a pressure sensitive adhesive coating on both sides.

8. The stomal device of claim **7** wherein the other side of said adhesive disc is attached to a peristomal covering comprising a bonding composition having a thin water insoluble backing film, said adhesive disc attached to said film.

9. The stomal device of claim **8** wherein said adhesive disc and said cover disc are circular and said peristomal covering is rectangular.

10. The stomal device of claim **8** including a flexible stoma bag attached to said flange by means of an elastic band whereby said flange upper lip prevents accidental detachment of said bag.

11. The stomal device of claim **10** wherein said ointment or non-aqueous paste comprises an oil component selected from mineral oil or vegetable oil and from about **25** to about **75%** by weight of a water soluble hydrocolloid, a water swellable hydrocolloid, or a mixture of water soluble and water swellable hydrocolloids.

12. The stomal device of claim **11** wherein said ointment or non-aqueous paste comprises from about **30** to about **55%** by weight of hydrocolloid.

13. The stomal device of claim **12** wherein said cover disc is from about **1** to about **3** mm. thick and from materials which are resistant and compatible with the ingredients in the ointment or non-aqueous paste.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 3,906,951

DATED : Sept. 23, 1975

INVENTOR(S) : James L. Chen

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

The inventor's name should read --James Ling Chen--.

Col. 2, line 13, "attached" should read --attaches--.

Col. 3, line 27, "disk" should read --disc--.

Signed and Sealed this

Third Day of August 1976

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks