

March 19, 1968

J. R. BENFIELD ETAL

3,373,745

MEDICAL DEVICE SUCH AS FOR ILEOSTOMY AND COLOSTOMY

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2 Sheets-Sheet 1

Fig. 1

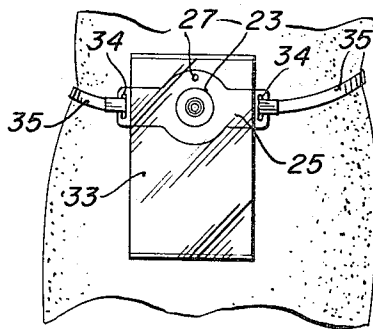


Fig. 2

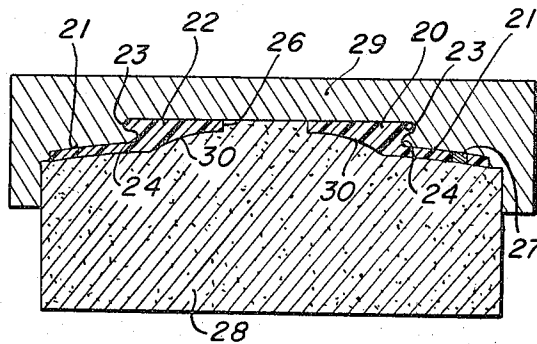


Fig. 3

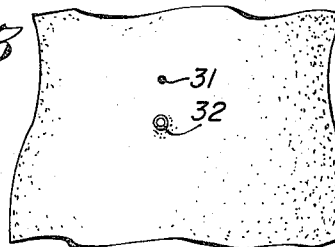


Fig. 5

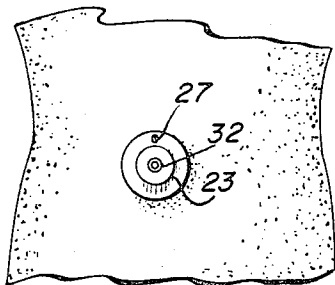
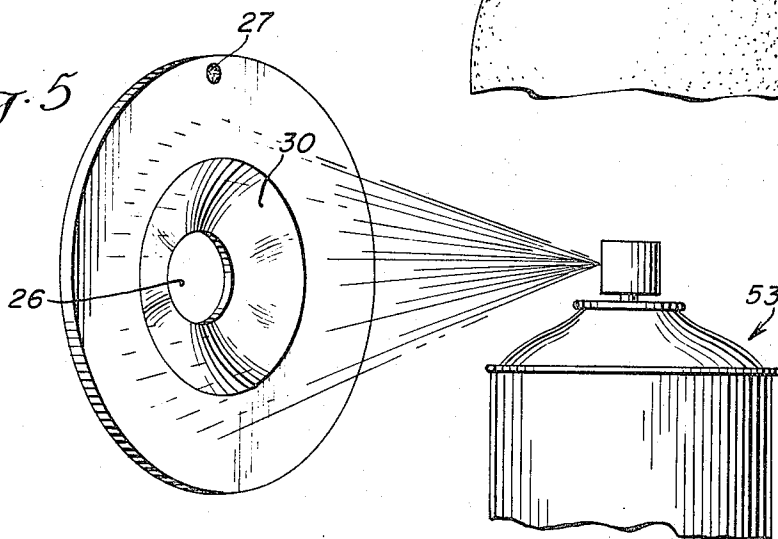


Fig. 4

INVENTORS.
John R. Benfield
George W. Barnhart
By Merriam, Smith & Marshall
Attorneys

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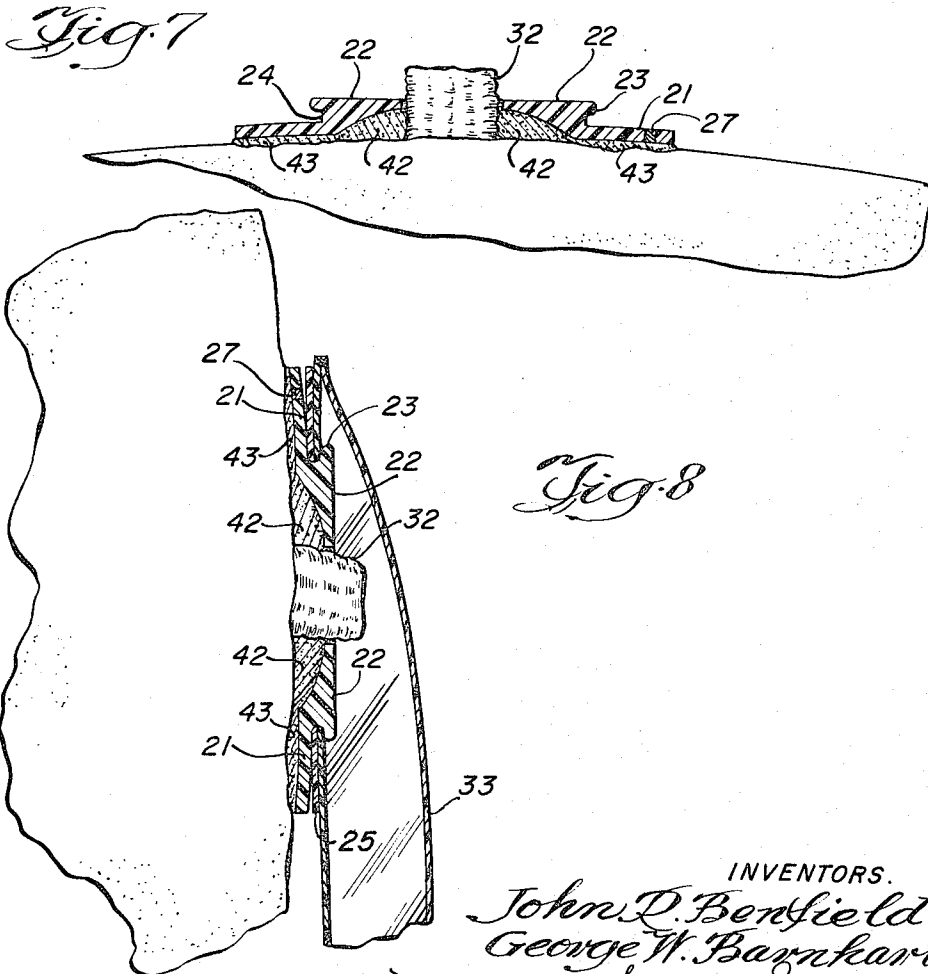
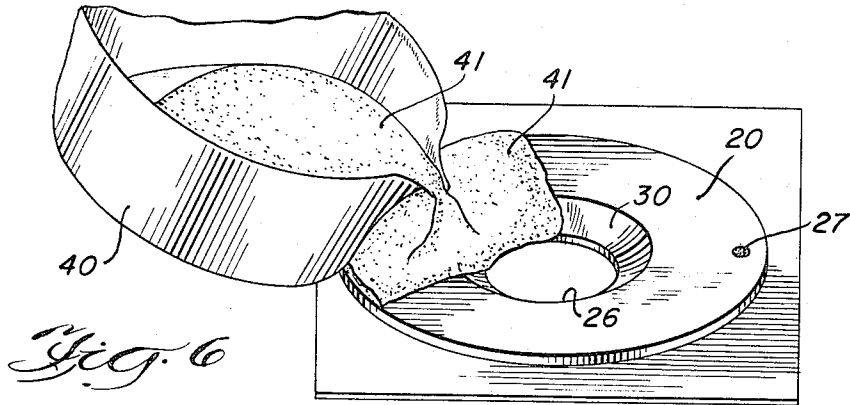
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INVENTORS.

John D. Benfield
George W. Barnhart

By Merriam Smith & Marshall
Attorneys

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MEDICAL DEVICE SUCH AS FOR ILEOSTOMY AND COLOSTOMY

John R. Benfield, 4801 Sheboygan Ave., Madison, Wis. 53705, and George W. Barnhart, P.O. Box 1151, Ogden Dunes, Ind.

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ABSTRACT OF THE DISCLOSURE

Disclosed is a device to hold a bag to receive bodily discharge from a stoma such as formed by a colostomy operation. The device comprises a flexible disk, such as of silicon rubber, with a flange to hold the bag and a rear surface molded in contact with the body to the body contour in and about the stoma.

This invention relates to medical devices. More particularly, this invention is concerned with devices used in ostomy management.

The creation of an ostomy, such as an ileostomy, colostomy or urinary diversion, is often part of a lifesaving or curative operation. Following the operation, the patient frequently has many years of active, useful life ahead. Although there are on the market devices for use in ileostomies, colostomies and urinary diversions that are suitable for a number of patients, they leave considerable to be desired, particularly in those patients who have unique, irregular or difficult stomas. In order to function properly on such patients, an ileostomy, colostomy or urinary diversion device is needed which fits perfectly.

Generally following an ileostomy, colostomy or urinary diversion, most of the recovery regime during the post-operative period is usually directed to maintaining the patient's fluid and electrolytic balance, nutrition, wound healing and general postoperative management. Insufficient attention is directed at that time to the function of the ostomy. This, however, is the subject upon which the patient focuses most attention. Patient opinion generally favors the earliest possible fitting of a suitable device and bag to accumulate the bodily discharge. Indeed, the period between operation and acquisition of a satisfactory appliance or device is often quite trying for the patient because of the frequency of dressing change required and because presently available disposable bags used with such devices are not generally adequate for continued use because they often allow contact with the highly irritating bodily waste products.

Applicants have, accordingly, provided by the subject invention a novel ostomy device which can be used satisfactorily on normal stomas as well as those which are of difficult or unusual shape, such as involved in ileostomy, colostomy and urinary diversion management. The device is of simple fabrication and can be custom fitted rapidly to each patient's body contour and stoma either immediately after operation or any time postoperatively.

According to one aspect of their invention, applicants provide a stock plate of flexible, elastic material resistant to body fluids which in unitary form comprises a thin, flexible layer of the material with a stoma-receiving hole therein spaced from the peripheral edges of the layer, a collar outwardly projecting from and integrally part of the layer and surrounding the hole, and a lateral flange on the side of the collar. Such stock plate can be used to form a custom-molded plate device for a patient as will be subsequently discussed. For further illustration, the invention will be described in conjunction with the attached drawings in which:

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FIGURE 1 is a front view showing an ostomy appliance strapped around the waist of a patient.

FIGURE 2 is a vertical sectional view through a mold used for making the stock plate;

FIGURE 3 shows a stoma on a patient;

FIGURE 4 shows the stock plate positioned over the stoma of a patient with the marking dot of the plate above the stoma;

FIGURE 5 shows adhesive being applied to the rear or back surface of the stock plate;

FIGURE 6 shows a room temperature, vulcanizable material being coated on the rear surface and in the hole of the stock plate;

FIGURE 7 shows the stock plate coated with the room temperature, vulcanizable material applied to a patient's body with a stoma protruding through the plate hole for making a custom contoured plate; and

FIGURE 8 is a side vertical section through a complete appliance showing the custom contoured plate positioned around a stoma with the collecting bag hanging from the supporting collar and flange.

In all of the figures of the drawings, the same numbers will be used to describe the same or similar elements, parts, or areas.

With reference to FIG. 2, the stock plate 20 is made of a flexible, elastic material resistant to body fluids. It has a thin, flexible layer 21 with a collar 22 as an integral part thereof and of the same material. The collar 22 projects outwardly and upwardly from the layer 21. The collar is relatively wide and has a flat outer surface. On the side edge of the collar is a lateral flange or lip 23. This flange 23 is more or less in a plane spaced apart from and parallel to the plane of the layer 21. Between the flange 23 and the layer 21 is a groove 24 into which there can be seated a bag hanger 25 as shown in FIGS. 1 and 8.

Spaced from the peripheral edge of the collar is a hole 26 which goes through the stock plate. This hole is of a size adequate to accommodate reception of stomas normally encountered in ileostomy, colostomy and urinary diversion operations. There is also generally included in the stock plate a marking dot 27 generally of a different color than the plate material. This dot serves to guide application of the plate to a person's body after it has been removed so as to re-register the plate in the same position to obtain a close fit.

The lower half 28 of the mold shown in FIG. 2 and the upper half 29 of the mold in the same figure have cooperating inside surfaces which mold the stock plate when the two parts of the mold are brought into position.

The stock plate provided by this invention can be produced in a mold as described by use of a room temperature, vulcanizable silicone rubber base ingredient having a fluid viscosity of between about 8,000 centistokes and about 12,000 centistokes at 77° F. with a viscosity of about 10,000 centistokes being ideal. Such materials are described in U.S. Patents Nos. 2,833,742 and 2,927,907. The silicone rubber base ingredient is available from the Dow Corning Corporation under the trade name Silastic RTV 382. This material, before catalyzing, is white in color. As commercially available, it has a higher than desirable viscosity and therefore it is thinned before use. For thinning purposes, a silicone fluid is advisably used such as Dow Corning 360 fluid (also called Fluid 200—20 centistokes). Further details regarding this can be found in "Silicones and Their Uses," McGraw-Hill Book Company, Inc., New York 1954, at pages 37 et seq. Generally, about one part of silicone fluid to about three parts of silicone rubber base ingredient on a volume basis gives a suitable mixture for use in making the stock plate. The silicone rubber base ingredient can be catalyzed with a

number of known catalysts including stannous octoate to initiate the vulcanizing process. The working time and setting time of the rubber can be varied by the amount of catalyst employed. A reinforcing material such as a nylon mesh cloth can be molded in the stock plate for increasing its strength. For further details concerning the preparation of room temperature, vulcanizable silicone rubber base ingredients and their use in molding, reference is made to the copending application of George W. Barnhart, one of the applicants here. Ser. No. 145,963, filed Oct. 18, 1961. It should be understood, however, that other suitable materials besides silicone rubbers can be used in practicing the invention and, furthermore, the stock plate can be preformed of silicone rubbers which are heat vulcanizable, such as of Dow Corning Medical Silastic 372 or 373, since they need not be formed in contact with the body. The heat vulcanizable silicone rubber is preferred for the stock plate since it is stronger than the room temperature vulcanizable silicone rubber. Because of their inertness, the silicone rubbers are particularly useful in this invention.

The stock plate also advisably has a recessed rear area 30, desirably with a concave contour, surrounding the stoma-receiving hole in the plate.

In properly positioning the plate to the body of the patient, a marking dot 31 is applied to the skin above the stoma 32 as shown in FIG. 3. A suitable adhesive which will permit adherence of the plate to the body, such as Dow Corning adhesive 269 (medical adhesive B) or 274, is applied to the back surface of the plate such as by spraying from an aerosol container 53 as shown in FIG. 5. After the adhesive has been applied, the so-coated plate can be placed in position on the patient's body with the marking dot 27 on the plate placed upwardly on the patient's skin. The stoma 32 is centered in the plate hole 26. Once the plate has been applied, the remaining parts of the appliance can be affixed to the plate to complete it. Thus, as shown in FIG. 1, the bag hanger 25 with a central hole just slightly smaller than the circular flange 23, is squeezed over the flange and into the groove 24. Suspended from the hanger 25 is a bag 33 of an impervious material resistant to body fluids such as polyethylene film. At each end of hanger 25 are grooves 34 through which belt 35 is affixed and which then encircles the body of the patient.

The device can be left affixed in place so long as it functions suitably and the adhesive holds the plate securely to the skin. If the plate is worked loose, it can be readily re-adhered into position by applying another layer of adhesive to the rear surface of the plate and then re-applying the plate against the body. The stock plate can be readily used as described for colostomy management where the feces are liquid.

In those patients who have difficult stoma and in ileostomy and urinary management, it is advisable for the plate to be custom molded to the patient's body contour. Furthermore, it is also advisable, even where the stoma involved is normal and presents no problem, for the rear surface and stoma-receiving hole of the plate to be custom molded to the body contour against which it will adhere in use. Both of these objects can be readily achieved by use of the described stock plate. Thus, the stock plate 20 is placed on a piece of paper with the rear side of the plate up. The purpose of the paper is to prevent the molding material from flowing through the hole 26. From ladle 40 as shown in FIG. 6, there is poured a room temperature, vulcanizable material 41, such as described in the patents identified above, over the rear surface of the stock plate and into the hole 26 as well as the recessed area 30. The room temperature, vulcanizable material can be of the same material used for the stock plate, and advisably is a silicone rubber. The so-coated plate is then positioned onto the patient's body as shown in FIG. 7 with the stoma protruding through hole 26, taking care to place the marking dot 27 upwardly. The collar 22 is in

the front. The plate is then pressed lightly against the patient's body and light pressure maintained thereon until the room temperature, vulcanizable material has set to a form-retaining state. In order to firmly adhere the molded layer to a stock plate made of heat vulcanized silicone rubber, a suitable layer of adhesive is applied onto the rear surface and hole of the stock plate before the molding material is coated thereon. Such use of an adhesive is usually not needed when the stock plate is made of room temperature, vulcanizable silicone rubber because the molded layer will readily bond to it.

With further reference to FIG. 7, the molded material occupies the recessed area 30 in the rear of the stock plate and thus provides an added core 42 therein and in the hole 26 as well as parts 43 on layer 21 which follow the body contour. Once the molding material has set, the custom-molded plate is removed from the body and off the stoma and the excess molding material trimmed away from the peripheral edges and from around the stoma-receiving hole. After this trimming has been done, a layer of adhesive is applied to the rear of the custom-molded plate in the same manner as described with reference to FIG. 5. The plate is then re-positioned on the body as shown in FIGS. 1 and 8 with the guiding dot 27 above the stoma. Once the custom-molded plate has been so positioned, bag 33, suitably affixed to the supporting hanger 25, is then positioned in place over the collar on the custom-molded plate and the strap 35 secured around the patient.

The stock plate or the custom-made plate can be employed immediately after the operation. There need be no delay in making use of the device as provided herewith. In fact, the custom-made plate can be formed immediately after an operation because none of the ingredients employed need affect the area of the operation or the stoma. The molding material, particularly when of medical grade silicone rubber, will not irritate the stoma or operated area. Thus, the benefits of this invention can be made use of immediately and need not be delayed.

Generally, the stock plate is circular of about 3 to 3½ inches diameter with a collar outer dimension of about 2 inches and a stoma-receiving hole of about 1 inch. The overall thickness of the plate is about ¾ of an inch with the thinner layer 21 being about ⅓ of an inch or less.

While the size and configuration of a stoma changes rapidly in the postoperative period due to edema and later to shrinking, the plate can be easily adapted and fitted over and over again as necessary by the described techniques. Since the device can be employed immediately after the operation, the anxiety and multiple dressing and bag changes required by previous methods can be avoided using this invention.

The foregoing detailed description has been given for clearness of understanding only, and no unnecessary limitations should be understood therefrom, as modifications will be obvious to those skilled in the art.

We claim:

1. A flexible elastic stock plate of material resistant to body fluids for medicinal uses such as in ileostomy, colostomy and urinary diversion management comprising a unitary plate having a thick central portion and a thin peripheral sheet portion extending planar therefrom, said thick portion being raised at its periphery from one side of the thin portion to form a circular collar, a stoma-receiving central hole through the collar in the normal direction, a flange around the side of the collar, and a concave recessed back surface surrounding the hole and terminating about at the diameter of the collar.

2. The plate of claim 1 made of silicone rubber.

3. The plate of claim 1 in circular form having about a 3 to 3½ inches diameter, a stoma-receiving hole of about 1 inch diameter, a collar diameter of about 2 inches, and an overall thickness of about ¾ inch.

4. A custom formed flexible elastic plate of material resistant to body fluids for use in ostomy management.

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comprising (a) a stock plate of such material in unitary form having a collar with a stoma-receiving hole therein spaced from the peripheral edges of the collar, a thin flexible layer projecting from the lower periphery of the collar, and a lateral flange on the side of the collar, and (b) a separately applied layer of such material bonded on the back of the stock plate and in the stock plate hole molded and contoured to a particular patient's stoma and surrounding body area.

5. An elastic plate according to claim 4 in which the stock plate collar has a recessed back surface, surrounding the hole, which is filled with the separately applied layer of material.

6. A custom formed elastic plate according to claim 4 in which a layer of adhesive is between and in contact

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with the surface of the stock plate and the separately applied layer on the back thereof.

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RICHARD A. GAUDET, *Primary Examiner*.

C. F. ROSENBAUM, *Examiner*.