Feb. 17, 1970 S. HERMAN 3,495,592

ENTEROSTOMY MEANS

Filed April 17, 1967

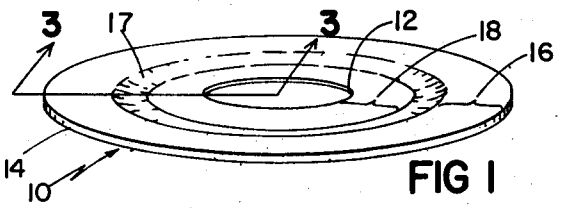


FIG 1

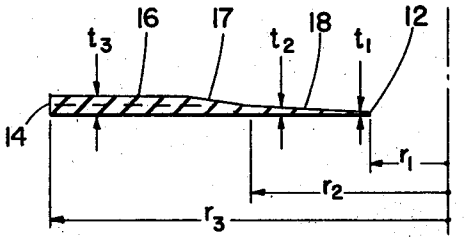


FIG 3

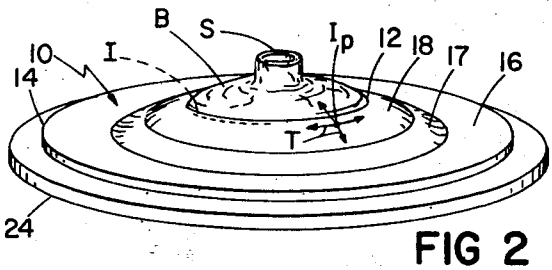


FIG 2

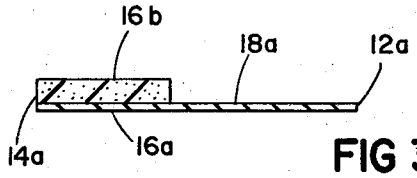


FIG 3a

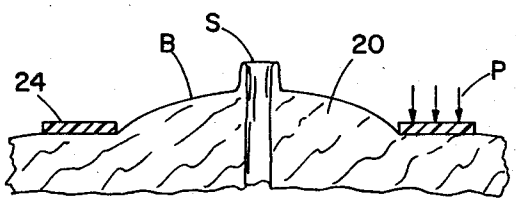


FIG 4

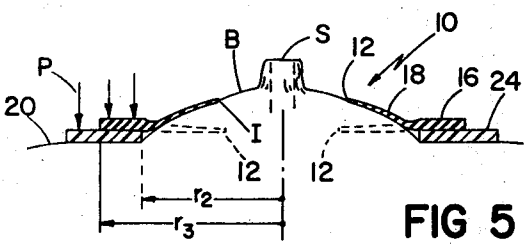


FIG 5

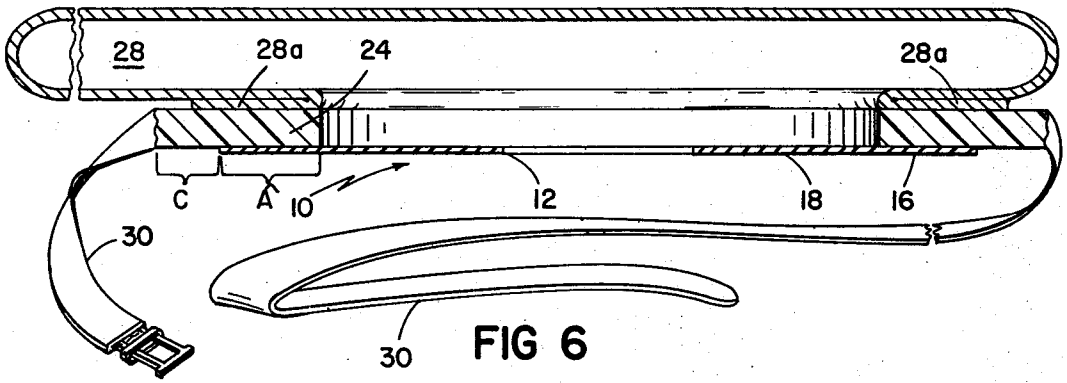


FIG 6

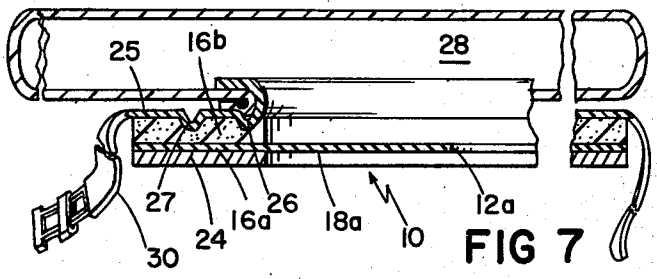


FIG 7

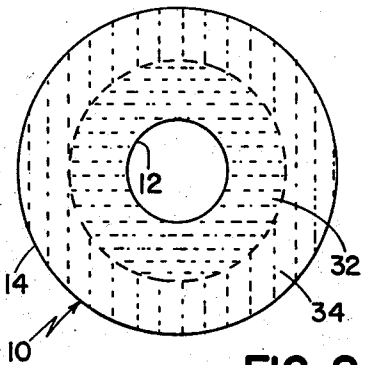


FIG 8

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3,495,592

ENTEROSTOMY MEANS

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U.S. Cl. 128—283 6 Claims

ABSTRACT OF THE DISCLOSURE

Adaptable enterostomy appliances. At the point of initial contact with the body an annular surface defined about the stoma substantially assumes the curvature of the undisturbed flesh and moves with the flesh. Embodiments employ a thin annular diaphragm of highly flexible and extensible material. Its inner margin, advantageously of membrane properties, engages the flesh in face-to-face contact, and may be readily stretched and distended by the flesh while its outer periphery is held against movement. A rigid ring pressed against the flesh can create a stabilized bulge of flesh to which the diaphragm can conform. An improved two piece appliance is presented.

This invention relates to enterostomy appliances for the collection of solid or liquid matter from a stoma.

An object of the invention is to provide an improved seal against penetration of matter and moisture under the edges of the appliance. It is known that such penetration causes damage to body tissue, irritation and discomfort, requires frequent attention to the appliance, and prevents the wearer from leading a normal life.

Another object is to provide better adapted enterostomy appliances to permit longer use without disturbing the basic seal.

Further objects of the invention are to provide such adapted appliances which in a few standardized forms may be used in a wide variety of instances: for persons having stomas of varying sizes and shapes without necessitating difficult fitting procedures; for persons having irregularities in the tissue surrounding the stoma; and for persons who wish to be active, or whose flesh for other reasons makes the use of an appliance difficult.

A further object is to provide an improved two-part appliance which employs a base member more-or-less permanently secured to the body, and a bag member which can be released for discharge of the collected matter.

According to the invention it has been discovered that prior appliances, although intended to give protection, have themselves created conditions which eventually induced penetration of the collected matter or moisture beneath appliance, or otherwise caused irritation. In the case of cushions or other devices incorporating a convex surface or edge which contacts oppositely convexly-shaped flesh, minute wrinkling of either surface may occur. Between such surfaces, as a result of the relative pressing and relaxing movement of the body flesh there may occur a pumping-like action, or a seeping or liquid surface tension effect, or other irritating action.

According to the present invention the appliance is provided with a member defining an annular surface constructed and arranged to conform to the curvature of the flesh and movable with the flesh at the line of initial contact, which lies closest to the stoma.

The invention features a diaphragm of flexible material surrounding the stoma. Its inner margin, advantageously of membrane properties, lies face-to-face with the tissue of the body, uniformly to the edge of the diaphragm. This margin is highly flexible, and has the ability to readily conform to the flesh, thereby resisting the formation of

pockets and deleterious relative movement. Its effectiveness is enhanced when stressed outwardly by a convex bulge of flesh which places the diaphragm under tension, and causes the initial edge to even more closely conform with the flesh. The invention features a relatively rigid outer ring member adapted to be pressed against the flesh of the patient to form a substantially stabilized outward bulge of the flesh to which the diaphragm readily conforms.

The invention features an inwardly extending diaphragm having a flexible inner margin on the order of ¼ inch or greater radial extent, formed of material of such properties as latex sheet of about 0.10 inch thickness. The invention features a smooth flesh-contacting surface of the diaphragm, ending in an edge adapted to conform intimately to the skin, and highly flexible and extensible, free to move in all directions with the skin at the critical region of intersection.

These and other objects, features and advantages will be understood from the following detailed description of presently preferred embodiments, taken in connection with drawings, wherein:

FIG. 1 is a perspective view of a diaphragm according to the invention;

FIG. 2 is a view similar to FIG. 1 showing the diaphragm conforming to an outwardly bulged portion of flesh;

FIG. 3 is a cross-sectional view of the diaphragm of FIG. 1 taken on line 3—3;

FIG. 3*a* is a view similar to FIG. 3 of another preferred embodiment;

FIG. 4 is a cross-sectional view of a relatively rigid ring member being pressed against the flesh surrounding the stoma;

FIG. 5 is a view similar to FIG. 4, showing the diaphragm adapting to the stoma region;

FIG. 6 is a partially cross-sectional view of an enterostomy appliance incorporating the diaphragm of FIG. 1;

FIG. 7 is a cross-sectional view similar to part of FIG. 6 of another preferred enterostomy appliance according to the invention;

FIG. 8 is a plan view of another preferred embodiment of the invention.

Referring to FIGS. 1 and 3 the adaptor **10** is of annular form comprised of two annular flat portions. Outer annular portion **16**, terminates in outer edge **14** and is formed with sufficient thickness t_3 to permit it to be pressed against a cooperating member of the appliance or against the body of the wearer. At the inner extremity of the outer annulus **16** is a transition zone **17** to inner annulus **18** which forms a diaphragm, terminating at an abrupt inner edge **12**, the surface of the diaphragm immediately adjacent the edge **12** being capable of lying flat, or conforming, without divergence, to the contour of the flesh. In this preferred embodiment the diaphragm tapers inwardly in thickness. Preferably, when made of solid material (i.e. no air bubbles or foam), and depending upon the nature of the material, and the particular design, the outer thickness t_3 is between about .030 to .010 inch thickness, and the inner thickness t_1 is between about .025 and .001 inch thickness. The radial width (r_2-r_1) of the diaphragm **18** should be about ¼ inch or larger.

While shown of integral form in FIG. 3, in FIG. 3*a* the outer portion is formed by annulus **16***a* of the same material and integral with the annulus **18**, and a second outer member **16***b* is bonded face to face therewith.

For either embodiment the diaphragm is highly flexible and resilient, common latex rubber sheet presently being preferred. (The first embodiment was made of latex sheet #470, .010 inch thickness, Green Rubber Company, Cambridge, Mass.) When constructed with properties of latex

of a thickness no greater than about .015 inch the inner portion of the diaphragm (see I, FIG. 5) in essence constitutes a membrane that is capable of behaving like the skin or flesh of the wearer. Thicker diaphragms may provide an adequate living fit.

Generally for the embodiment, it can be stated that rubber, or rubber-like materials, impermeable to gas, should be employed, and if solid material, the material should have a modulus of elasticity of no more than 1000 p.s.i. over its region of elastic strain. The particular latex mentioned above demonstrates a modulus of 200 p.s.i. at a strain of 5%, a modulus of 122 p.s.i. at a strain of 41%, and a modulus of 218 p.s.i. at a strain of about 300%. For a one inch wide strip, of .010 inch thickness of this material, two points initially spaced apart 1 inch were stretched apart a distance of 1⅝ inches under a lengthwise tension of 1 pound. Generally it can be stated that a one inch wide strip of a material to be employed should be able to extend elastically lengthwise one-quarter of an inch per inch, advantageously substantially more, under a load of one pound. It will be understood that where a foam material (including material containing air bubbles) is employed it must be judged in its foam, and not its solid state, and where the foam is made of solid material that has a modulus on the order of 200 p.s.i., the permissible thicknesses at the most critical region may increase as much as two times over that specified above.

Referring to FIG. 4 the flesh **20** of a wearer, for instance flesh in the region of the abdomen, is shown formed into a stabilized bulge B by the action of a rigid hollow ring **24** which is pressed by pressure P against the flesh. The stoma S is shown protruding through the ring **24** at the center of the bulge B.

Referring to FIGS. 2 and 5, the adaptor **10** is shown with outer annulus **16** lying upon a matching outer surface of the ring **24**, the ring **24** forming the stabilized bulge of flesh B as shown in FIG. 4 by pressure P. The inner edge of the ring **24** has a radius generally corresponding to radius r_2, the radius of the inner edge of annulus **16**, whereby the diaphragm portion of the adaptor extends freely inwardly of the hole of the ring. Its unstressed position is shown in dotted lines in FIG. 5. In the solid line position the diaphragm can be seen to conform to the curvature of the stabilized bulge of flesh B, and in particular the surfaces of the flesh and the diaphragm **18** at region I, adjacent the initial line of contact, are conformed together, with the diaphragm assuming substantially the outwardly convex curvature of the unflattened flesh. For any given point I_p in that reigion, the substance of the diaphragm is stretched, and subjected to tension T, with the result that the diaphragm exerts a desirable pressure against (normal to) the flesh. This not only ensures that a seal will be maintained, but perhaps more importantly increases the degree of engagement or grip of the diaphragm with the flesh to ensure that the diaphragm will follow any further bulging movements of the flesh, as may occur when the intestine becomes filled.

In the embodiment of FIGS. 2 and 5 the ring **24** extends outwardly beyond the adaptor **10**, providing a region for attachment of a bag support device. This bag support device may be of various detachable forms, and can be formed to exert pressure P, e.g. by means of a supporting belt. Alternatively, a belt can be attached to the ring **24**, and the detachable bag means need only press against annulus **16** in a manner sufficient to hold the adaptor **10** in place, to resist movement of the outer periphery during the stretching action of the inner periphery, and to create therewith a seal to prevent leakage between the adaptor and the bag. In this respect the embodiment of FIG. 3*a* is advantageous in providing the second outer member **16***b* of soft, but non-permanently-dentable, impervious foam such as polyvinyl latex foam (adhesively bonded to a latex annulus **16***a*) which can conform to the edge of the detachable bag support to effect the seal and security.

Referring to FIG. 6 there is shown an ostomy appliance comprising the adaptor **10**, as described above, a rigid outer ring **24**, e.g. of rigid or semi-rigid plastic, permanently secured to the outer annulus **16** of the adaptor, and a collection bag **28**, permanently secured at **28***a* to the outer surface of the ring. A belt **30** is secured to the rigid outer ring, and is adapted, when fitted about the wearer, to exert the pressure P by which the ring, in this example exerting its pressure through the thickness of the adaptor, may form a stabilized bulge of flesh to which the diaphragm may conform. In the region A or C an adhesive, such as rubber cement, may be applied to prevent the device from slipping, however, the seal will be formed against the flesh in the region of edge **12**.

The embodiment of FIG. 7 is like that of FIG. 6 except that it is an improved two-part appliance. The adaptor I is a separate unit comprising a diaphragm **10**, as above, permanently secured to the upper surface of a rigid ring **24**, the latter having lower surface **24***a* adapted to be adhered to the flesh of a wearer. The adaptor is more or less permanently applied to the flesh, followed by second part II, comprising a rigid ring **25**, e.g. of stainless steel, to which the collection bag **28** is attached. In this embodiment the diaphragm is of the form of FIG. 3*a*, with the thickness of resilient sealing foam as part of the outer annulus. Inner and outer annular ridge formations **26** and **27** in the stainless steel ring member **25** indent into the foam, providing a seal and secure the two parts together.

Advantageously the various adaptors and appliances described above may be provided with adhesive or other adaptive or treatment substances. Referring to the preferred embodiment of FIG. 8, the skin-contacting surface of adaptor **10** is provided with an outer band of pressure sensitive adhesive **34** compatible with the skin and adapted to hold the adaptor in place, and an inner band of karaya gum. It will be appreciated that this and the other adaptors according to the invention may be more-or-less permanently secured to the flesh of the wearer and the remainder of the appliance may be detachable to enable the bag to be emptied.

Unlike certain prior stoma pads, the size of the hole in the membrane need not be pre-established. Instead the wearer may simply trim the edge **12** to the desired size and shape. In many instances the size may be much less critical than was the case with prior devices. In any event, it becomes possible with the adaptor of the present invention to supply a single style of appliance to wearers having various sizes of stomas.

It is to be noted that the seal between the flesh and diaphragm may improve with use through the self-elimination or squeezing-out of any air bubbles that exist therebetween. Iit is also to be noted that the diaphragm itself, or its contacting surface may be formed by moisture-absorbent or therapeutic materials, including karaya gum, or its substitute, in the usual or modified form, and to the extent it is effective, the tolerances for the physical properties of the materials of the diaphragm can be somewhat relaxed.

What is claimed is:

1. An adaptor constructed and arranged to relate an enterostomy appliance to the body, said adaptor comprising an annular member having a surface defined, at the line of initial contact with the flesh, by means permitting said surface to substantially assume the curvature of the undisturbed flesh and to extend with the flesh when the flesh moves, said adaptor being in the form of a thin, highly flexible diaphragm, said line of initial contact being defined by a free inner edge of said diaphragm, said diaphragm arranged to engage the flesh in face-to-face contact over a substantial margin adjacent said edge, said diaphragm having joined therewith an outer annular member of resilient foam constructed and

arranged to be squeezed into sealing contact with a bag-supporting member.

2. The adaptor of claim 1 wherein said margin is defined by a freely extending annulus formed of material having a modulus of elasticity of less than 1000 p.s.i. over its elastic range.

3. The adaptor of claim 1 wherein said diaphragm has a radial width of at least ¼ inch.

4. The adaptor of claim 1 wherein the thickness of said diaphragm decreases in the direction of said inner edge.

5. The adaptor of claim 1 including a coating of pressure-sensitive adhesive on at least a portion of the surface of said adaptor, adapted to secure said diaphragm in sealing relation to the flesh of a wearer.

6. The adaptor of claim 5 having a coating in the vicinity of said inner edge having the protective properties of karaya gum, and the adhesive outside of said vicinity comprises a pressure sensitive rubber cement.

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