

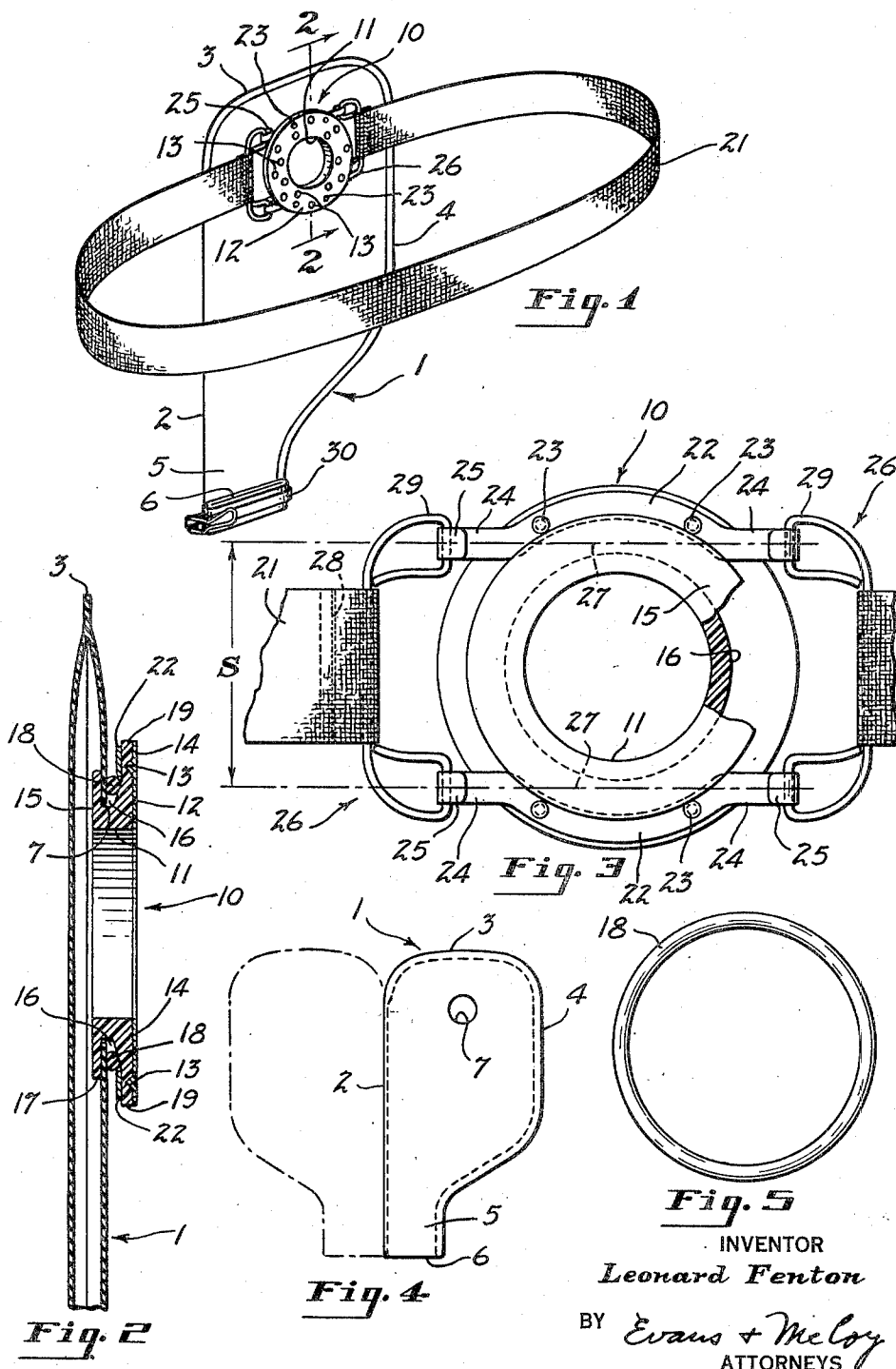
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ILEOSTOMY RECEPTACLES

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ILEOSTOMY RECEPTACLES

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This invention relates to medical appliances and particularly to ileostomy receptacles.

The problem of designing devices of this character which can be manufactured in standard sizes and worn comfortably by all patients requiring them, without bodily discomfort or danger of accidental dislodgement of the receptacle, has received considerable attention. However, devices of this character heretofore available have had numerous objectionable features. Among these are undue restriction of bodily movement by the patient while wearing such a device, inconvenient or unreliable means for attaching the pouch to a mounting ring and for holding the mounting ring securely in place, poor adhesion of the mounting ring to the patient's skin, difficulty in emptying and cleaning the pouch, and bulkiness of the device causing noticeable bulging of clothing under which it is worn.

The principal object of the present invention is to provide an ileostomy receptacle that is improved in all of the foregoing respects and that is also simple and inexpensive to manufacture.

A particular object of the invention is to provide a reliable and simplified arrangement for attaching the pouch to a mounting ring of minimum thickness so that the attachment is secure in use and easily and quickly assembled and disassembled, and so that the device is not unduly thick where the attachment is made.

Another object of the invention is to provide an improved arrangement for securing a belt to the mounting ring so that any tendency for the mounting ring to slip or tilt during bodily movement and be pulled away from the skin will be minimized.

Still other objects of the invention is to provide an improved mounting ring having a minimum diameter to avoid interfering with stooping and twisting bodily movement by the patient, and to provide a mounting ring having an improved body attaching face that makes secure adhesion to the skin possible with the relatively small attaching surface available because of the small diameter of the ring.

One feature of the invention is characterized by a novel relationship of the edge of a pouch opening with a groove in a mounting ring and an elastic O-ring.

Another feature of the invention is characterized by a novel hook arrangement for attaching a belt to a pouch mounting ring.

Still another feature of the invention is characterized by an improved mounting ring design that provides a multiplicity of small adhesive reservoirs between the mounting ring and the body against which the ring is to be adhered, to secure better adhesion and permit safe reduction in the body-contacting area of the ring.

The foregoing and still other objects, advantages, and characteristic features of the invention will be more fully understood from the following detailed description of a preferred embodiment of the invention and from the accompanying drawing in which:

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Fig. 1 is a perspective view of a device embodying the invention, including a supporting belt, the view showing the side of the pouch and mounting ring normally disposed against the right side of the abdomen for receiving a projecting stoma;

Fig. 2 is a fragmentary vertical section through the pouch and mounting ring of Fig. 1, showing the manner in which the pouch is attached to the mounting ring;

Fig. 3 is a fragmentary elevation of the mounting ring with the belt attached thereto, but with the pouch removed, this view showing the side of the mounting ring opposite the side shown in Fig. 1 and illustrating the manner in which the belt is attached to the ring, a portion of the ring being broken away to illustrate in more detail the construction of the ring;

Fig. 4 is an elevation of the pouch looking at one side thereof with the opposite side of the pouch shown in phantom outline adjacent thereto for illustrating how the two sides are cut out from a single sheet of material; and

Fig. 5 is an elevation of the elastic O ring employed for securing the pouch to the mounting.

Referring to the drawing, a device embodying the invention may include a normally flat pouch 1 having the configuration in elevation shown in Fig. 4. As shown, this configuration involves one straight side edge 2 joined along a gradual curve to a substantially straight top edge 3 which is in turn joined along a gradual curve to an opposite side edge 4. The latter side edge 4 extends downwardly from the top edge 3 over a major portion of the height of the pouch and then curves and extends toward the straight side edge 2 for the major portion of the width of the pouch. The side edge 4 then curves in the opposite direction and extends downwardly substantially parallel to the straight side edge 2 to form a restricted neck portion 5 terminating in an open bottom end 6 from which the contents of the pouch may be discharged.

A pouch of this character may be cut as an integral piece from a sheet of suitable sheet material, a synthetic rubber-like material, such as neoprene being preferred. A layout of this integral piece is illustrated in Fig. 4 by the conventional outline of one side wall and the phantom outline of the opposite side wall joined thereto along the straight side edge 2. The piece of material is folded along a vertical center line to form two identical side wall portions which may be sealed together by any conventional procedure from the upper end of the straight edge 2, around the top edge 3 and opposite side edge 4, to a point at the bottom of the pouch that is spaced from the straight edge 2 so as to leave the bottom opening 6 unsealed. A circular aperture 7 is cut in one side wall of the pouch substantially midway between the side edges 2 and 4, and about the same distance below the top edge 3.

A mounting ring or annulus 10 for the pouch 1 is preferably formed from a suitably rigid plastic material, such as nylon, with an axial thickness of about 1/4 inch, an inner diameter for a stoma receiving opening 11 between about 3/4 and 1 1/4 inches, and an outer diameter not exceeding 2 3/4 inches and preferably less than 2 1/2 inches. The particular range of dimensions specified for the mounting ring are determined by the fact that the various sizes of stomas encountered range from a minimum of 3/4 inch to a maximum of 1 1/4 inches and by the desirability of keeping the outside diameter of the ring as small as possible while still providing an annular attaching surface 12 of sufficient radial width to be sealed and adhered tightly to the skin of the abdomen surrounding the stoma. An adult of normal size can usually tolerate a diameter up to about 2 3/4 inches with-

out serious interference by the mounting ring with the relative movement of the upper portion of the pelvic bone toward the lower rib caused by bending, stooping, and twisting the torso in the course of normal bodily activity. With stoma receiving openings 11 that are smaller in diameter than the normal maximum of $1\frac{1}{4}$ inches, outer diameters correspondingly less than $2\frac{3}{4}$ inches may be employed to give the body maximum freedom of movement. However, I have found that the great majority of patients can easily tolerate an outer mounting ring diameter of $2\frac{3}{8}$ to $2\frac{1}{2}$ inches, and I prefer to maintain a standard outer diameter of, say, $2\frac{3}{8}$ inches as a manufacturing convenience. Mounting ring thicknesses of about $\frac{1}{4}$ inch give adequate rigidity for supporting the pouch 1 without rendering the device too bulky under the patient's clothing.

While annular attaching surfaces having radial widths well over 1 inch have heretofore been considered necessary to secure adequate adhesion to the skin, I have found that the radial width of the attaching surface 12 may be reduced to as little as $\frac{1}{2}$ inch while still obtaining reliable adhesion, if the attaching surface is provided with a multiplicity of depressions 13 formed therein and distributed substantially uniformly thereover, as best shown in Fig. 1. I prefer to provide a minimum radial width of about $\frac{5}{16}$ inch, and an outer diameter of $2\frac{3}{8}$ inches will suffice to provide this width with the largest size of opening 11 commonly required.

The purpose of the depressions 13 is to serve as adhesive reservoirs for supplementing a thin layer 14 of adhesive that is spread over the surface 12 for adhering and sealing the mounting ring to the patient's skin. The exact diameter and depth of these depressions is not critical, and they may suitably range from about $\frac{1}{16}$ to $\frac{3}{16}$ inch in diameter and have a depth sufficient to materially increase the thickness of the layer 14 of adhesive at each of the depression locations, as shown in Fig. 2.

The mounting ring 10 preferably has a face 15 opposite the attaching face 12 that is of lesser outside diameter than the attaching face, and a peripheral groove 16 is formed in the mounting ring between the opposite faces 12 and 15 thereof. As shown in Fig. 2, the opposite side walls of the groove 16 converge radially inwardly toward the bottom of the groove so that the groove is appreciably narrower at its bottom than it is at its open end. The angle of convergence of the side walls of the groove may vary considerably, but is preferably in the range of about 8 to 20°. This convergence may be provided by inclining either or both of the side walls of the groove with respect to a plane normal to the axis of the annulus. Preferably, however, the side of the groove closest to the attaching face 12 is inclined to provide the desired convergence and the opposite wall of the groove is substantially normal to the axis of the annulus.

The edge of the pouch material surrounding the aperture 7 in one side wall thereof is stretched and fitted over the mounting ring flange 17 of smaller outside diameter, and the stretching is then relieved so that this portion of the material is disposed in the groove 16, preferably against the wall of the groove defined by the flange 17. An O ring 18, that is preferably made substantially circular in cross section from a substantially incompressible elastic material, is elastically expanded to permit the mounting ring flange 19 of larger diameter to pass therethrough. The ring 18 is then allowed to elastically contract and seat itself in the groove 16 with a wedging fit between one wall of the groove and the pouch material against the opposite wall of the groove. The axial thickness and the unstretched inner diameter of the O ring 18 are selected so that the ring will be elastically wedged in the groove 16 with sufficient force to securely lock the pouch material in the groove and support the pouch on the mounting ring without danger of its being accidentally dislodged.

The mounting ring 10 is preferably held firmly against the abdomen by means of a belt 21 that surrounds the waist of the patient with the ends of the belt attached to opposite sides of the mounting ring. In order to minimize any tendency for the mounting ring to slide out of its proper position or to tilt away from the skin at any point around its periphery during bodily movement of the patient, two pairs of widely spaced attaching arms are preferably provided. Each pair of attaching arms may suitably be formed from a single flat strip of metal 22, the central portion of the strip having an arcuate configuration conforming to the curvature of the mounting ring. The flat strip 22 may be secured against the face of the flange 19 of the mounting ring opposite the attaching face thereof by means of a pair of flat-head rivets 23, or the like. If desired, the rivets 23 may be slightly countersunk in the strip 22 to eliminate any interference with positioning of the O ring 18. The opposite ends 24 of the strip 22 project beyond the periphery of mounting ring and may be bent back upon themselves to provide hooks 25 for receiving a belt attaching bracket 26. As shown in Fig. 3, each metal strip 22 provides a pair of belt attaching arms 24 that extend in opposite directions along a chord 27 located outwardly well beyond the periphery of the stoma receiving opening 11. The chords 27 defined by the oppositely extending pairs of arms 24 are parallel and spaced apart by a distance substantially greater than the diameter of the stoma receiving opening 11, and the arms 24 form parallel pairs of tension members acting along the widely spaced tension application lines represented by the chords 27.

The belt attaching brackets 26 may be formed of a suitably stiff wire, and each bracket may be attached to one end of the belt 21 by folding the end of the belt around the central portion of the bracket 26 and back upon itself and by stitching the overlapped belt portions together along the line 28. Symmetrically disposed loop portions 29 on each bracket 26 are adapted to be engaged and disengaged with the hooks 25 on the arms 24 for exerting tension on the arms 24 along the lines of the chords 27. Because of the wide spacing of the pairs of attaching arms 24, proper tension in the belt 21 will hold the mounting ring firmly against the abdomen and resist any tendency of the mounting ring to slip about its own axis or to tilt away from the skin to which the attaching face 12 is adhered.

The opening 6 in the neck of the pouch 5 may be closed by folding the neck back upon itself and applying any suitable form of clip 30, as shown in Fig. 1. To permit quick and convenient attachment and detachment, the clip 30 may be one of the snap-acting type.

From the foregoing description of a preferred embodiment of the invention, it will be observed that the device may be quickly assembled by inserting the flange 17 of the mounting ring through the opening 7 in the pouch 1, and then applying the O ring 18 in the manner described to securely fasten the mounting ring to the pouch. The adhesive 14 may then be applied to the attaching face 12 of the mounting ring, and the mounting ring may be placed against the body with the opening 11 surrounding the stoma. The device may be securely supported in this position by passing the belt 21 around the waist and attaching the belt brackets 26 to the two pairs of attaching arms 24. The straight edge 2 of the pouch is normally positioned toward the front of the torso with the restricted neck 5 disposed well forwardly adjacent the groin where the bulk of the pouch will cause the least possible bulging of clothing under which the device is worn. The pouch may be emptied from time to time, without removal of the pouch from the mounting ring 10 and without removing the mounting ring 10 from the body, by actuating the clamp 30 to open the same and permit the contents of the pouch to be drained. Complete drainage and cleaning of the inside of the

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pouch is facilitated by the straight edge 2 of the pouch which, being merely a loose fold between opposite sides of the pouch, provides an unrestricted drainage channel. The configuration of the pouch also facilitates the employment of a brush to clean the inside of the pouch while flushing with water.

Removal of the pouch from the mounting ring is generally necessary only when the pouch is so worn out as to require replacement. This is done when the mounting ring has been removed from the body. At such time, it is a simple matter to insert the tip of a thin, blunt instrument (not shown) having a hooked end between the O ring 18 and the flange 19 of the mounting ring for pulling the O ring out of the groove 16 and off of the mounting ring.

From the foregoing description of the construction and operation of a preferred device embodying the present invention, it will be apparent that I have provided a simple and inexpensive structure for accomplishing the various objects of the invention. While an illustrative embodiment of the invention has been shown and described in detail, it will be recognized by those skilled in the art that many variations of this specific embodiment may be made without departing from the true scope of the invention as defined in the appended claims.

Having disclosed my invention, I claim:

1. An ileostomy pouch of elastic sheet material having an aperture in a wall thereof, a rigid mounting ring for said pouch having an annular body-engaging face, an annular peripheral groove in said ring extending radially inwardly toward the axis of the ring, one of the side walls of said groove tapering toward the other in a radially inward direction, whereby the bottom of said groove is narrower than the opening thereof, the edges of the sheet material of said pouch around said aperture being received in said groove against one side wall thereof, and an annular elastic ring received under tension in said groove entirely around the mounting ring and seated against said sheet material and the opposite wall of the groove, the axial thickness and unstretched inner diameter of said elastic ring being selected to elastically wedge the ring firmly in said groove between said sheet material and the opposite wall of the groove and spaced from the bottom of the groove for locking the sheet material in the groove entirely around the mounting ring.

2. An ileostomy pouch according to claim 1 in which said elastic ring is substantially solid and incompressible.

3. A mounting ring for an ileostomy pouch having a substantially flat, annular, body-engaging face and a multiplicity of depressions formed in and distributed substantially uniformly over said body-engaging face for receiving an adhesive composition, each of said depressions being in the range of about $\frac{1}{16}$ inch to $\frac{3}{16}$ inch in width, and the radial width of said body-engaging face being between about $\frac{1}{2}$ inch and $\frac{3}{8}$ inch.

4. A mounting ring for an ileostomy pouch having a substantially flat, annular, body-engaging face and a multiplicity of depressions formed in and distributed substantially uniformly over said body-engaging face for receiving an adhesive composition, each of said depressions being in the range of about $\frac{1}{16}$ inch to $\frac{3}{16}$ inch in width, the inner diameter of said body-engaging face being from $\frac{3}{4}$ to $1\frac{1}{4}$ inches, and the outer diameter of said

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ring and of said body engaging-face being from $1\frac{3}{4}$ inches to $2\frac{3}{4}$ inches.

5. A mounting ring for an ileostomy pouch comprising a rigid annulus having a substantially flat body-engaging face surrounding a centrally disposed stoma receiving opening, and two symmetrically disposed pairs of belt attaching arms secured to the opposite face of the annulus, the arms of one of said pairs extending in opposite directions beyond the outer periphery of the mounting ring along a chord thereof and terminating in hook-shaped end portions aligned with said chord, the arms of the other of said pairs extending in opposite directions beyond the outer periphery of the mounting ring along another chord thereof and terminating in hook-shaped end portions aligned with said other chord, and said chords being parallel and spaced radially outwardly beyond the inner periphery of said body-engaging face, whereby said arms form parallel pairs of tension members having widely spaced tension application lines with belt attaching hooks at the ends thereof.

6. A mounting ring for an ileostomy pouch having an axial thickness not exceeding $\frac{5}{16}$ inch and an outer diameter not exceeding $2\frac{3}{4}$ inches, said ring having a substantially flat, annular, body-engaging face, the outer diameter of said body-engaging face being substantially equal to the outer diameter of the mounting ring and the inner diameter of said body-engaging face being between about $\frac{3}{4}$ inch and $1\frac{1}{4}$ inches, and two symmetrically disposed pairs of belt attaching arms secured to the opposite face of the annulus, the arms of one of said pairs extending in opposite directions beyond the outer periphery of the mounting ring along a chord thereof and terminating in hook-shaped end portions aligned with said chord, the arms of the other of said pairs extending in opposite directions beyond the outer periphery of the mounting ring along another chord thereof and terminating in hook-shaped end portions aligned with said other chord, and said chords being parallel and spaced radially outwardly beyond the inner periphery of said body-engaging face, whereby said arms form parallel pairs of tension members having widely spaced tension application lines with belt attaching hooks at the ends thereof.

7. A mounting ring for an ileostomy pouch having a substantially flat, annular, body engaging face and a multiplicity of depressions formed in and distributed substantially over said body engaging face in spaced apart relationship for receiving an adhesive composition.

8. A mounting ring for an ileostomy pouch in the form of an annulus of substantially rigid material having an annular body engaging face and a multiplicity of depressions formed in and distributed substantially over said body engaging face in spaced apart relationship for receiving an adhesive composition.

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