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a part interest

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[54] **STOMA ADAPTER**
9 Claims, 5 Drawing Figs.

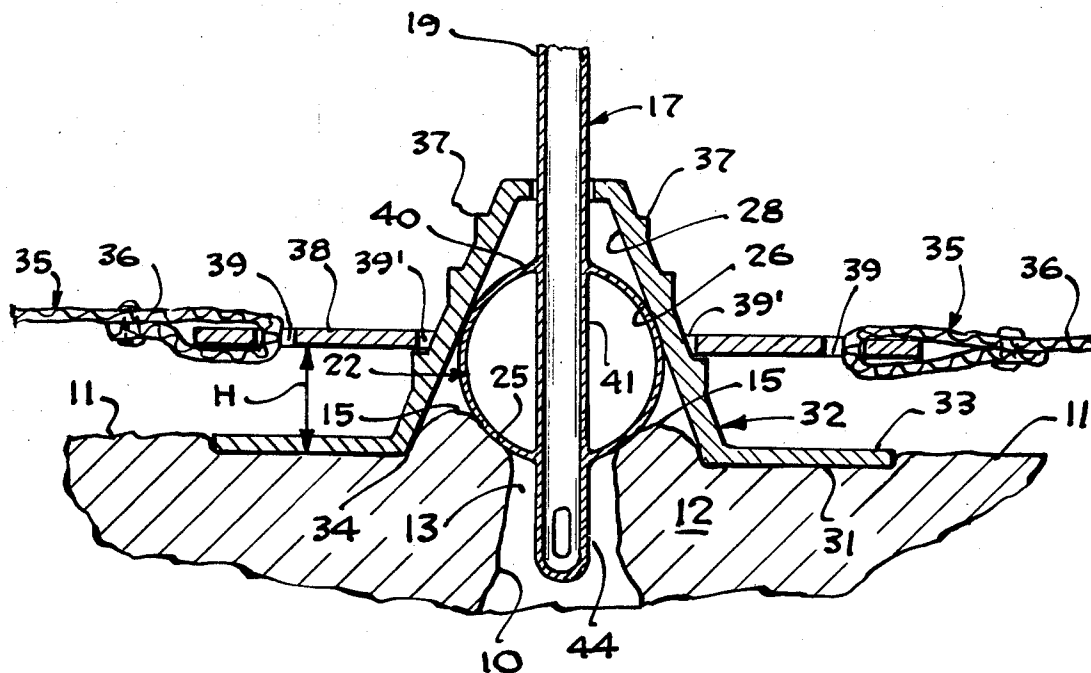
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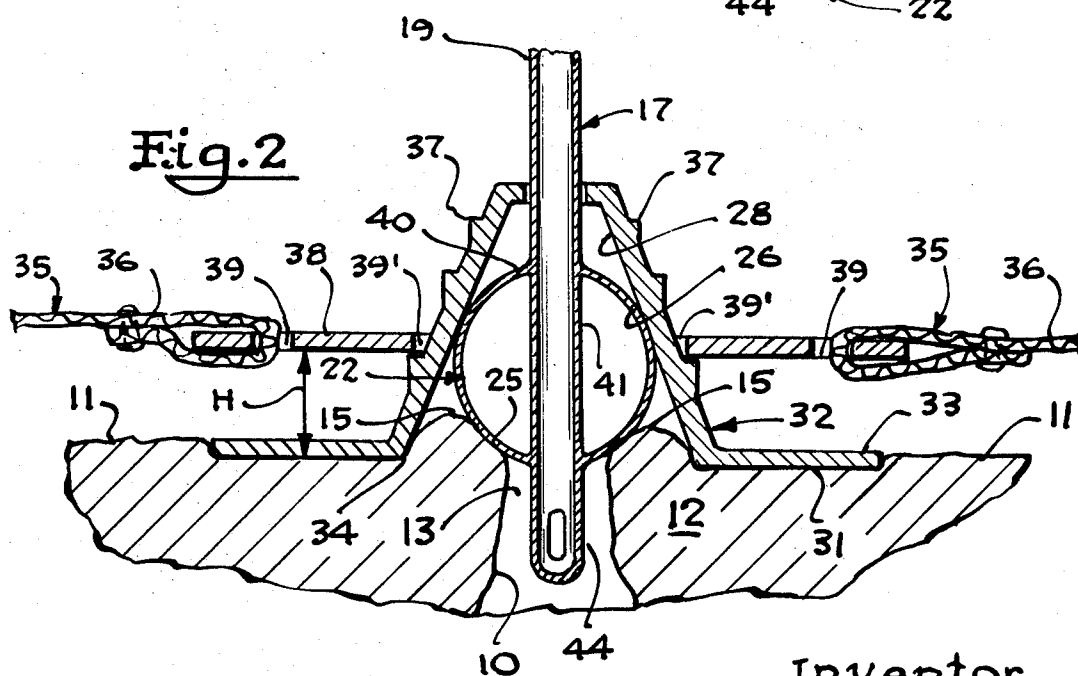
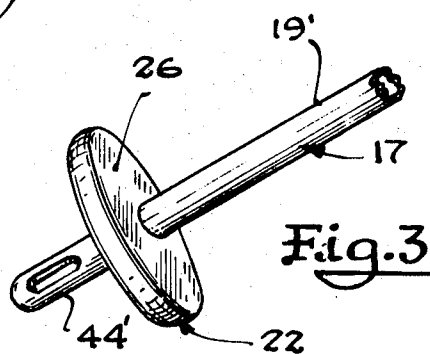
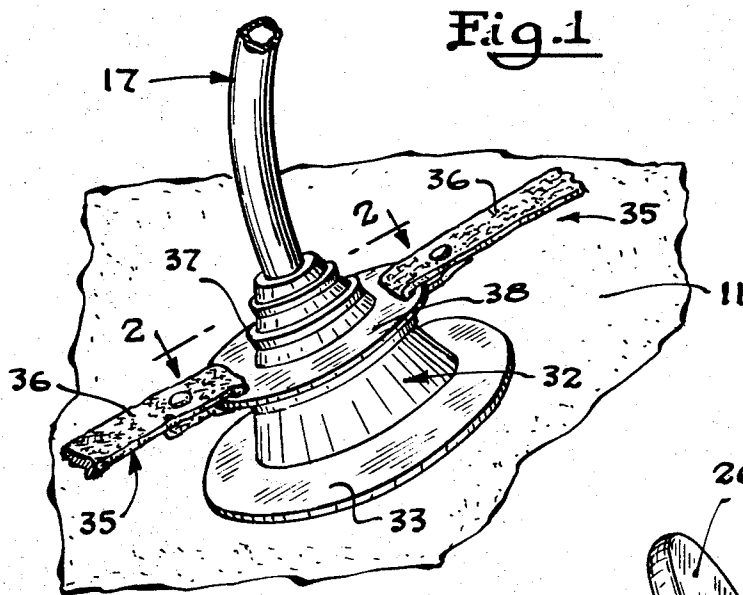
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ABSTRACT: A device for conveying fluids, such as aqueous suspensions of barium sulfate, into and out of a body opening such as a colostomy opening, including conduit means, a radial flange integral with the conduit means, pressure means for maintaining the flange in direct contact with a stoma, base means for engaging the abdominal wall, said base means being constructed to abut the abdominal wall closely adjacent the stoma, body-encircling means for maintaining the base means in place, said pressure means being fixed with respect to said base means, whereby the body cavity is sealed at the stoma and fluid communication between the cavity and the exterior abdominal wall is prevented.





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Fig. 4

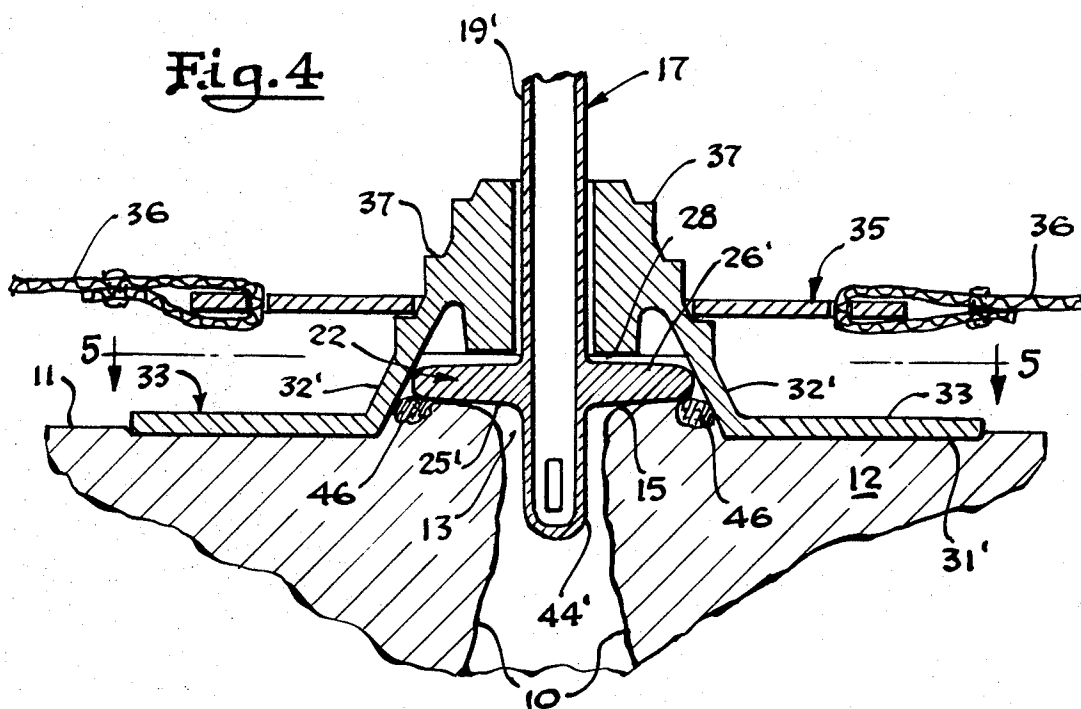
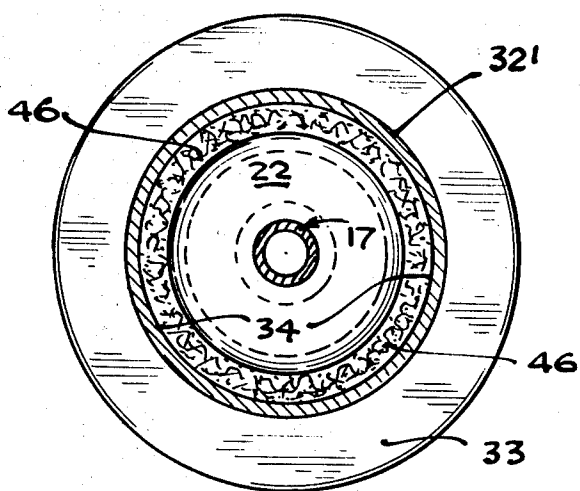


Fig. 5



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1

STOMA ADAPTER

BACKGROUND OF THE INVENTION

In the radiographic examination of colostomies it is necessary to transfer aqueous suspensions of barium sulfate through the body opening (i.e. the stoma) in sufficient quantities to permit observation of the structures involved during the examination. Frequently the patient is required to change positions several times during the course of the study. For example, at one point in the radiographic study the patient may be required to lie on his back, and at another point the patient may be required to lie on one or the other side. Moreover, devices heretofore available for inserting the barium sulfate suspensions into the involved organs through a stoma would usually permit substantial leakage at the stoma. Such leakage of the barium sulfate would generally be sufficient to cause the barium sulfate suspension to collect or drain around the stoma onto the body wall or into cloth packings. Cloth packing would often be pressed against the stoma to minimize such leakage or expulsion of the barium sulfate suspension. Shadows resulting from such indiscriminate distribution of the barium sulfate suspension against the outer body wall or into cloth packings may have a tendency to obscure observation of details involving internal organs in that area. Also, whenever the patient is required to change position the tendency for the barium sulfate suspension to leak from the stoma was increased.

Some of the devices heretofore provided for maintaining conduit means such as tubes in body openings required the expansion of a bulb or flange with the body to prevent the removal of the conduit means from the body opening. Such devices are totally unsuitable for use in connection with colostomies, ileostomies, and the like, because of the danger of rupture of the wall of the organ involved.

It is an object of this invention to provide a device for virtually leakproof transfer of fluids such as aqueous barium sulfate suspensions into the body through a stoma. It is a further object to provide a device which is readily maintained in leakproof condition during a radiographic examination, and especially during a change in position by the patient. It is another object of this invention to provide a device for the convenient, tidy and clean transferring of fluid into and out of the body through a stoma, which device is readily cleaned, sterilized, and simple to use.

SUMMARY OF THE INVENTION

In a device in accordance with this invention the conduit means has a radial flange for sealingly engaging the outer portion of the stoma the device includes means for pressing the flange against the surfaces of the stoma. It also includes base means which abut the abdominal wall closely adjacent the periphery of the stoma. The means for pressing the flange against the stoma is fixed with respect to the base means.

DESIGNATION OF THE FIGURES

FIG. 1 is a perspective view illustrating a preferred embodiment of this invention;

FIG. 2 is a cross-sectional view taken approximately along the line 2-2 in FIG. 1;

FIG. 3 is a fragmentary perspective view of an end portion of a catheter having integral therewith a flange near the end thereof;

FIG. 4 is a cross-sectional view taken approximately along the lines 2-2 of FIG. 1 illustrating the internal structure of an alternative embodiment of this invention; and

FIG. 5 is a view of the base component as it faces the body.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Although the following disclosure offered for public dissemination, in return for the grant of a patent, is detailed to ensure adequacy and aid understanding, this is not intended to

2

prejudice that purpose of a patent which is to cover each new inventive concept therein no matter how others may later disguise it by variations in form or additions or further improvements. The claims at the end hereof are intended as the chief aid toward this purpose; as it is these that meet the requirement of pointing out the parts, improvements, or combinations in which the inventive concepts are found.

In accordance with this invention the interior 10 of a body organ, such as the colon, is sealed with respect to fluid communication with the skin 11 on the abdominal wall 12 by way of the opening 13 in stoma 15. The conduit means, generally 17, such as a Foley catheter 19, or other catheter 19', has extending completely around a portion of the circumference thereof an enlarged portion, generally 22, which is sufficiently great in diameter to prevent insertion of the enlarged portion, generally 22, into the interior 10 of the organ involved. A lower surface 25, 25' sealingly engages stoma 15. An upper portion 26, 26' abuts against downwardly directed surface 28 which maintains pressure on the enlarged portion 22, which in turn causes pressure to be exerted at lower surface 25, 25' against stoma 15.

An alternative construction of the conduit means 17 and more particularly of the enlarged portions generally 22 will be discussed in greater detail hereinafter.

Preferably the lowermost edge of base 32 includes a radially extending flange 33 to increase the surface over which the pressures are distributed, and to increase the stability of the device when in position. While the flange 33 is shown as disposed in a plane, it is to be understood that it can be shaped to closely conform to the configuration of a particular region of the abdominal wall, and can be sized to conform to the degree of curvature of the particular patient's abdomen, e.g. for large or small people. Flange 33 is preferably thin enough to be slightly flexible, but thick enough to provide support.

The lowermost surface 31, 31' of base 32 abuts skin 11 in close proximity to the outer circumference of stoma 15. Thus the configuration of the opening 34 in base 32 at lowermost surface 31 is substantially circular. Skin 11 at surface 31, 31' is illustrated as being slightly depressed to signify the slight pressure exerted upon skin 11 by surface 31, 31'. Body encircling means generally 35 (which includes a body-encircling belt 36, preferably made of an elastic material and base-engaging means 38) maintains base 32 in position at stoma 15.

While the base-engaging means 38 is shown in the attached drawings to engage base 32 at a height approximately halfway up the height of the base 32, i.e. at the height indicated by the letter "H" in FIG. 2, it is not essential that the base-engaging means be at that particular height. While the base-engaging means may be fixed to base 32 closely adjacent the skin when the device of this invention is used in connection with stomata in the upper abdominal regions, it is preferred that the base-engaging means 38 be constructed to engage base 32 at a substantial distance above the abdominal wall 12 when the device of this invention is used in connection with a stoma in the lower abdominal region. The base-engaging means 38 which is illustrated is a flat piece having three openings. Two openings 39 receive the belt 36 and a larger central opening 39' fits over base 32 to securely fit thereon at a particular height above the skin. A smaller opening 39' causes higher engagement with a conical exterior. Thus it is not essential that steps 37 be provided to limit height of the base-engaging means 38, since availability of a number of different sized articles 38 will provide such flexibility in adjustment.

While the body-encircling means, generally 35, are shown to be relatively narrow for the purpose of clarity of illustration, it is preferred that the body-encircling means 35 be relatively wide, e.g. 3 inches or wider, and that they be relatively resilient, or elastic.

As illustrated in FIG. 2, a preferred embodiment of this invention utilizes a commonly available Foley-type catheter 19. The base 32 illustrated in FIG. 2 consists of a cup or conelike structure open at both ends and is readily cleaned and sterilized. The catheter illustrated in FIG. 2 is intended to suggest

the use of a wide variety of similar catheters having a bulb 40 which can be pneumatically expanded and which completely surrounds the conduit portion 41 of catheter 19. A large variety of these catheters are available, i.e. in different materials such as plastic, rubber, etc., and in different sizes of conduit portion 41 and bulb 40.

While a relatively short (e.g. 1 to 1½ inches) terminal portion 44, 44' beyond the enlarged portion 22 of catheter 19, 19' as illustrated in the accompanying drawings, the length of this portion may optionally be substantially longer. For example, when the device of this invention is intended for use in the radiographic examination of the signoidostomy, terminal portion 44, 44' is preferably about 4 inches long.

I have found that under actual hospital use conditions the device described above provides substantially leakproof transferring means for conveying aqueous barium sulfate solutions into and out of a body opening, such as a colostomy or ileostomy opening. Moreover, I have observed that the device in accordance with this invention permits the patient to change positions during the course of the study without causing substantial leakage or loss of the barium sulfate solution from the stoma.

It will be appreciated that the use of the device in accordance with this invention provides limited sealing pressure between the lower surface of the enlarged portion of the conveying means, such as the catheter, and the stoma, and yet permits excessive or possibly harmful pressures to be distributed against the abdominal wall. Moreover, the relatively close fitting of the base with the outer circumference of the stoma provides a degree of stability with respect to the relative positions of the catheter flange and the stoma.

Since not all stomata are of the same diameter, it is desirable and preferable to have available a set of different sized devices of this invention. It is preferable to use a device having an opening 34 which fits closely around stoma 15. Alternatively, if the opening 34 is somewhat oversized, I prefer to place a spongelike material or packing 46 around the stoma within opening 34. This not only assists in the stabilization, but in the event of a trace of inadvertent leakage, the liquid is diffused over a larger area, diminishing the likelihood that there will be interference with the radiographic examination. The quantity of such leakage, which is sometimes observed in using the device of this invention, is so low that no interference with the radiographic study has been reported. The spongelike packing 46 may be in the form of a thin doughnut, and may, of course, be disposable.

The relatively large diameter of the base means and also the wide diameter of the optional portion 26' provides stability with respect to the perpendicular orientation of the device with respect to the abdominal wall. This is an important factor in preventing inadvertent leakage. As indicated above it is preferred that the body-encircling means be relatively wide and in such embodiments the vertical stability of the device is even further enhanced, in spite of the movements which a patient is often required to make during the course of radiographic studies.

I claim:

1. An apparatus for use in conjunction with a catheter having a conduit to extend into a stoma in a person's body wall and having an enlargement surrounding the conduit and being larger than the stoma to contact the body wall with a portion of the conduit extending outwardly from said enlargement, said apparatus comprising:

a base having two ends and walls between said two ends, said walls defining a truncated conical internal opening relatively large at one end and relatively small at the other, said large end being of a size to receive said enlargement, said base having an outward peripheral flange at said one end of said walls of a configuration to fit flat against said body wall about said stoma, said base having an opening at said other end to receive said portion of the

conduit, whereby when said catheter is so positioned on said person's body wall said base may be placed over the catheter with the enlargement within the large end of the internal opening and said portion extending through said end opening, said internal opening being of a size that said base walls will, when said catheter and base are so positioned, bear against the periphery of said enlargement to hold said enlargement against said stoma, and means for holding said base with its flange firmly against the person's body and including a body-encircling band and a part in contact with the exterior of the base.

2. An apparatus as set forth in claim 1, wherein the exterior of said base defines a step of annular configuration between said ends and substantially parallel to said ends, and said part comprises a plate having an opening therein of a size to be received only over the portion of said base between said step and said other end.

3. An apparatus as set forth in claim 2, wherein there are a plurality of said steps with each step, commencing from said other end, being a larger annulus from that of the preceding step, whereby a plurality of said parts having openings therein of different sizes, may be interchanged one at a time to engage a respective sized step.

4. In the combination of a catheter and a device to hold it in place wherein the catheter has a conduit to extend into a stoma in a person's body wall and having an enlargement surrounding the conduit and being larger than the stoma to contact the body wall with a portion of the conduit extending outwardly from said enlargement, the improvement wherein said device comprises:

a base having two ends and walls between said two ends, said walls defining a truncated conical internal opening relatively large at one end and relatively small at the other, said large end receiving said enlargement, said base having an outward peripheral flange at said one end of said walls of a configuration to fit flat against said body wall about said stoma, said base having an opening at said other end receiving said portion of the conduit, said internal opening being of a size that said base walls will, when said catheter and base are so positioned, bear against the periphery of said enlargement to hold said enlargement against said stoma, and means for holding said base with its flange firmly against the person's body and including a body encircling band and a part in contact with the exterior of the base.

5. In the combination as set forth in claim 4, wherein the enlargement comprises a pneumatically expandable bulb.

6. In the combination as set forth in claim 5, wherein the exterior of said base defines a step of annular configuration between said ends and substantially parallel to said ends, and said part comprises a plate having an opening therein of a size to be received only over the portion of said base between said step and said other end.

7. In the combination as set forth in claim 6, wherein there are a plurality of said steps with each step commencing from said other end, being a larger annulus from that of the preceding step, whereby a plurality of said parts having openings therein of different sizes may be interchanged one at a time to engage a respective sized step.

8. In the combination as set forth in claim 4, wherein the exterior of said base defines a step of annular configuration between said ends and substantially parallel to said ends, and said part comprises a plate having an opening therein of a size to be received only over the portion of said base between said step and said other end.

9. In the combination as set forth in claim 8, wherein there are a plurality of said steps with each step commencing from said other end, being a larger annulus from that of the preceding step, whereby a plurality of said parts having openings therein of different sizes may be interchanged one at a time to engage a respective sized step.