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(54) **Ostomy appliance; pad for same, attachment means for same and kit of parts for assembling same**

(57) An ostomy appliance comprises a body-attachable pad (10) of skin-compatible adhesive material having a stomal orifice, and means whereby a plurality of ostomy bags can be attached in sequence to the pad by exposing a fresh region of adhesive each time it is desired to attach a clean ostomy bag. This is achieved by providing a series of sequentially sealable adhesive rings (34) provided with tabs (36).

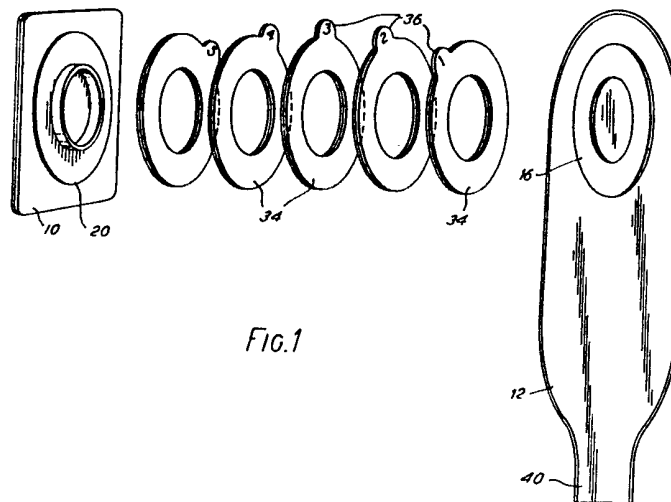


Fig.1

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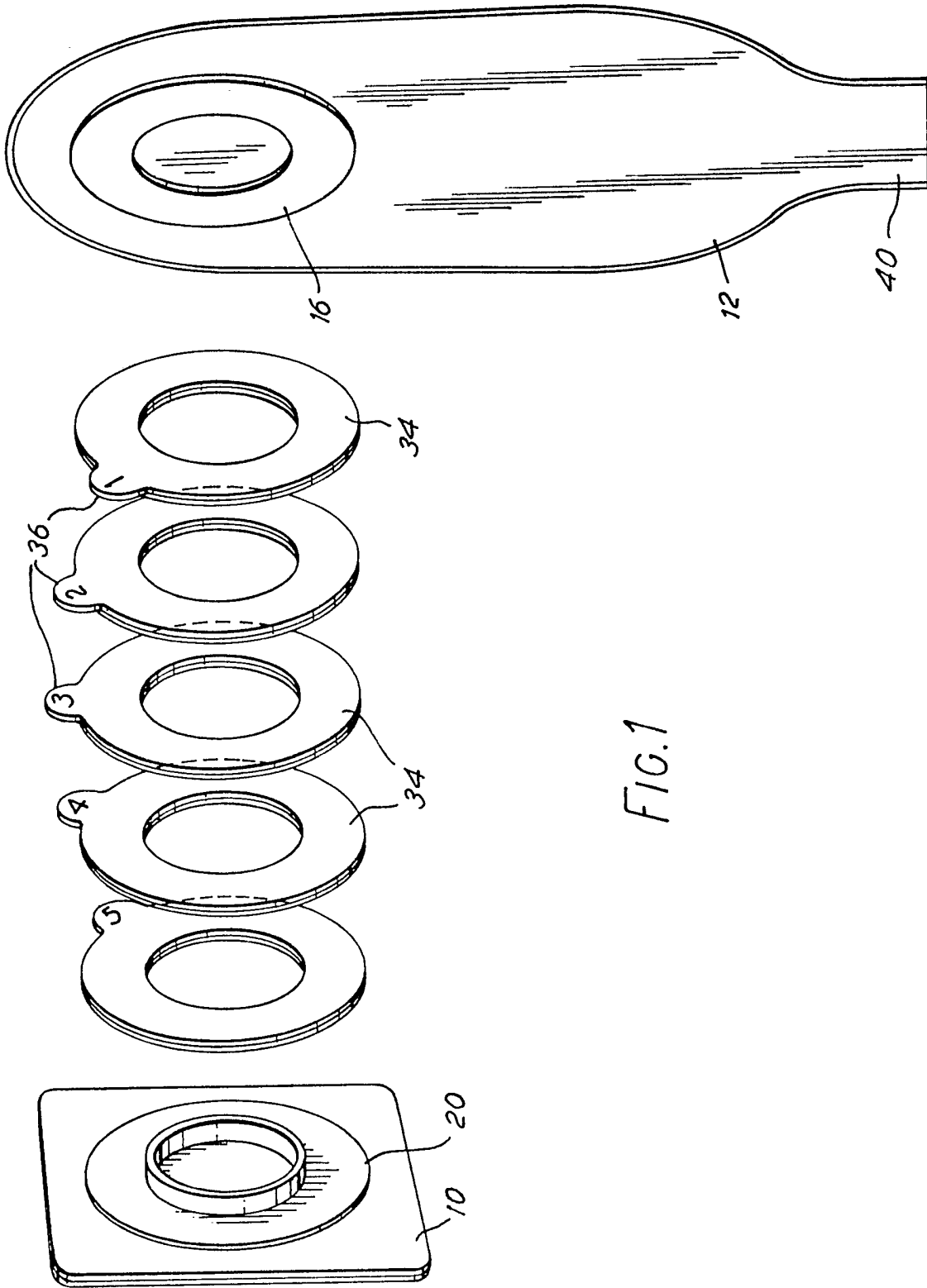


FIG.1

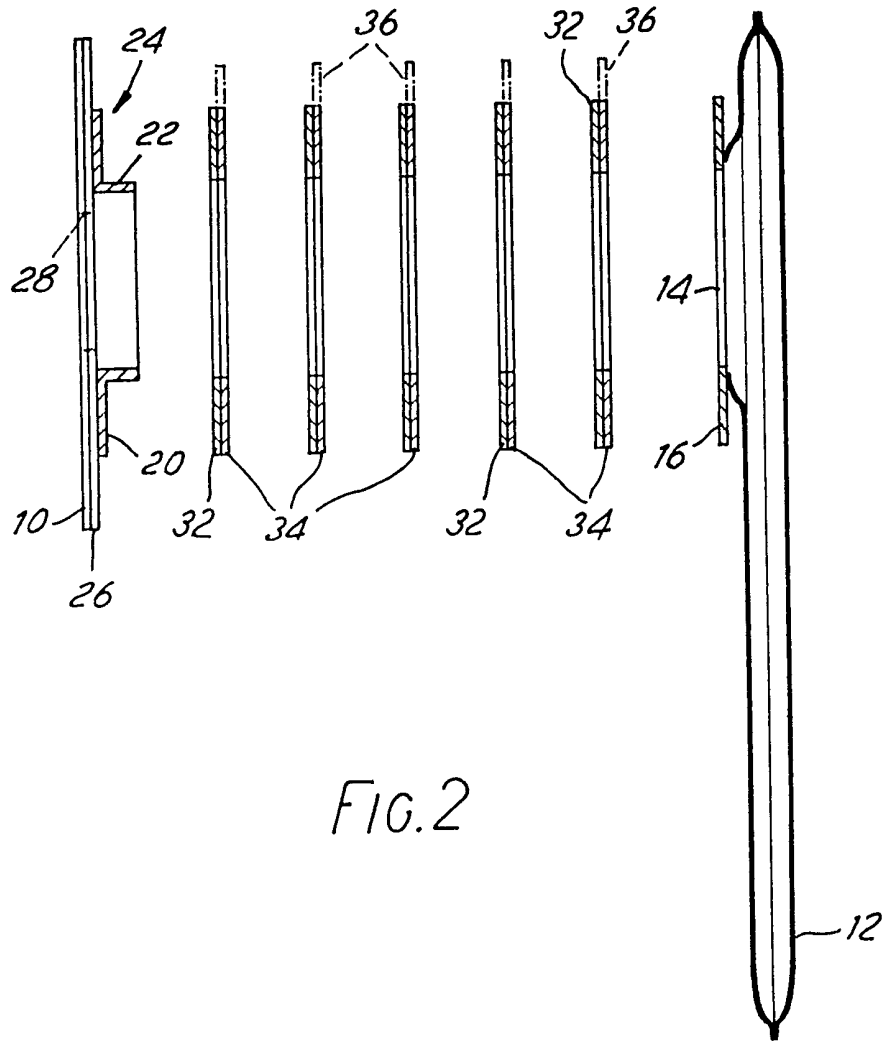


FIG. 2

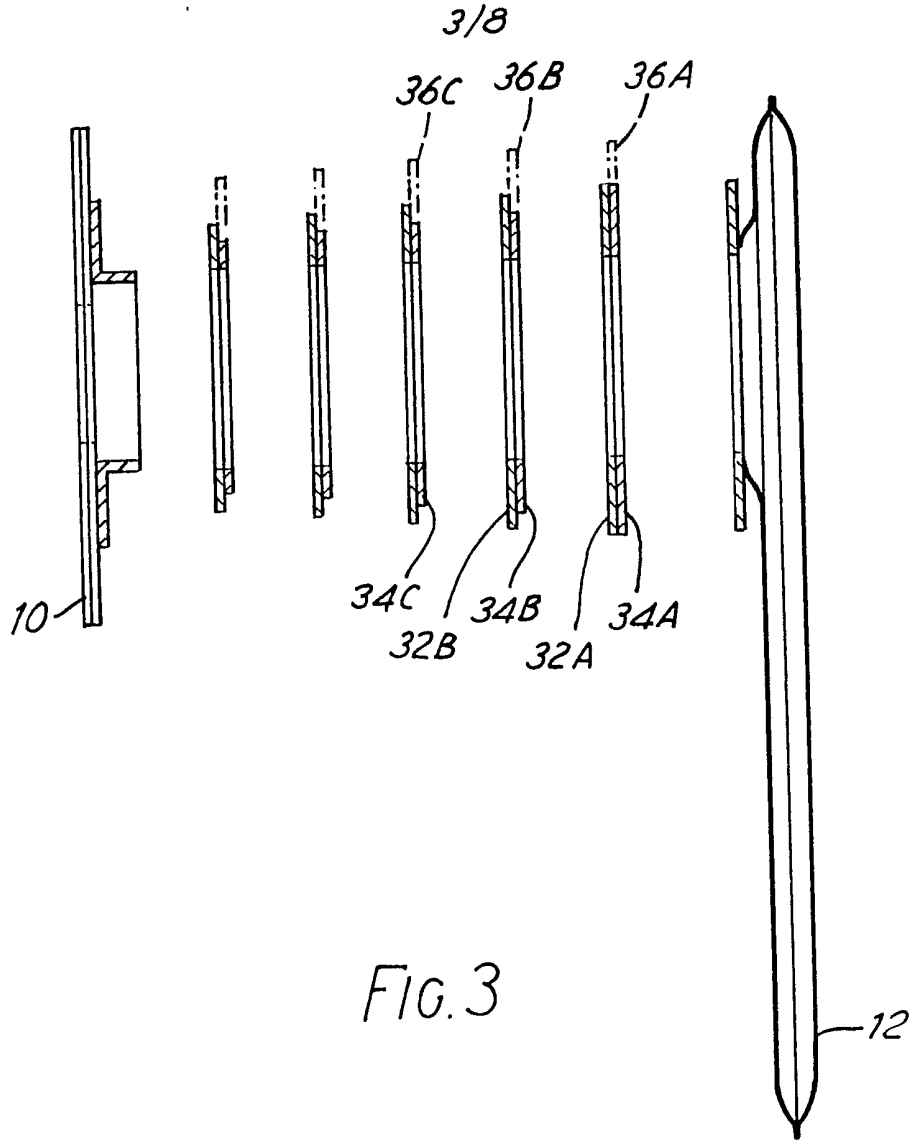


FIG. 3

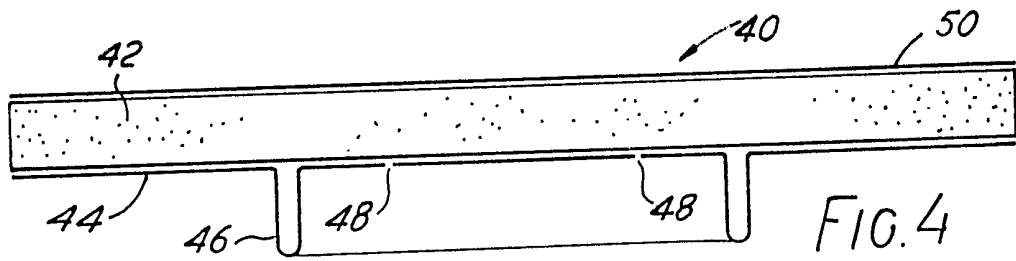


FIG. 4

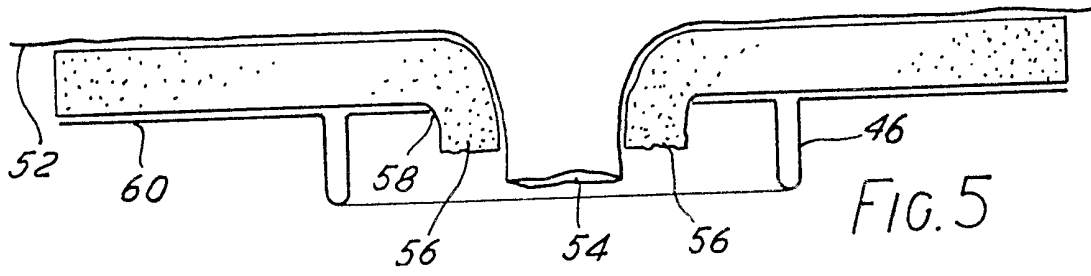
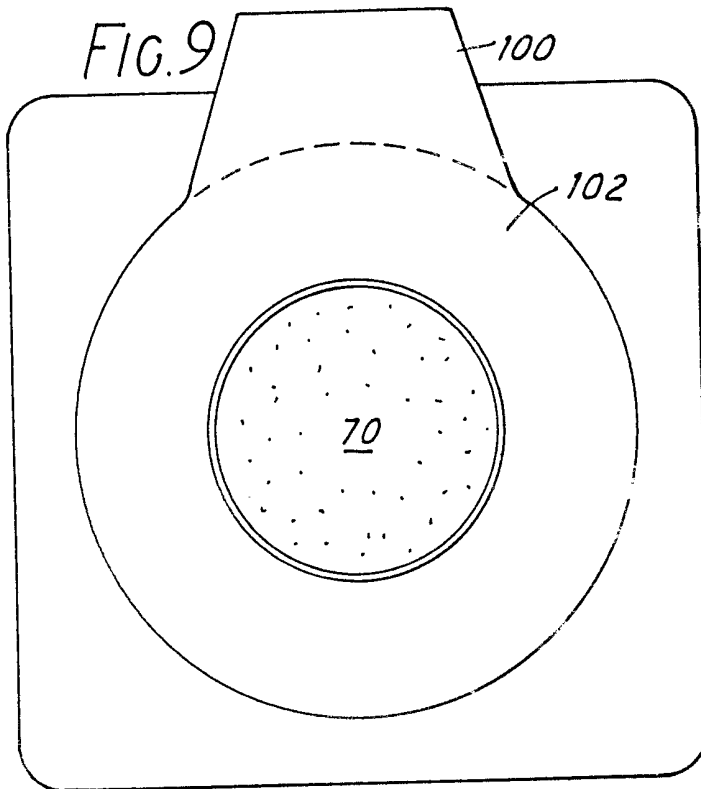
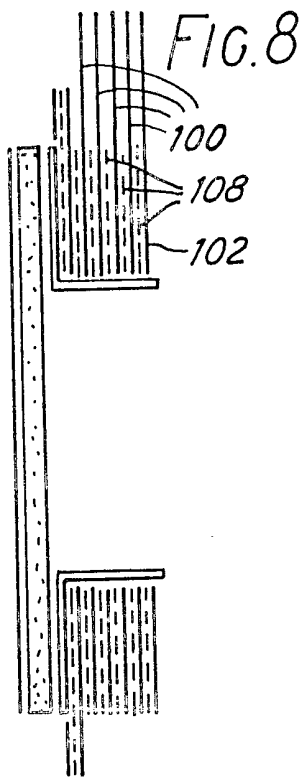
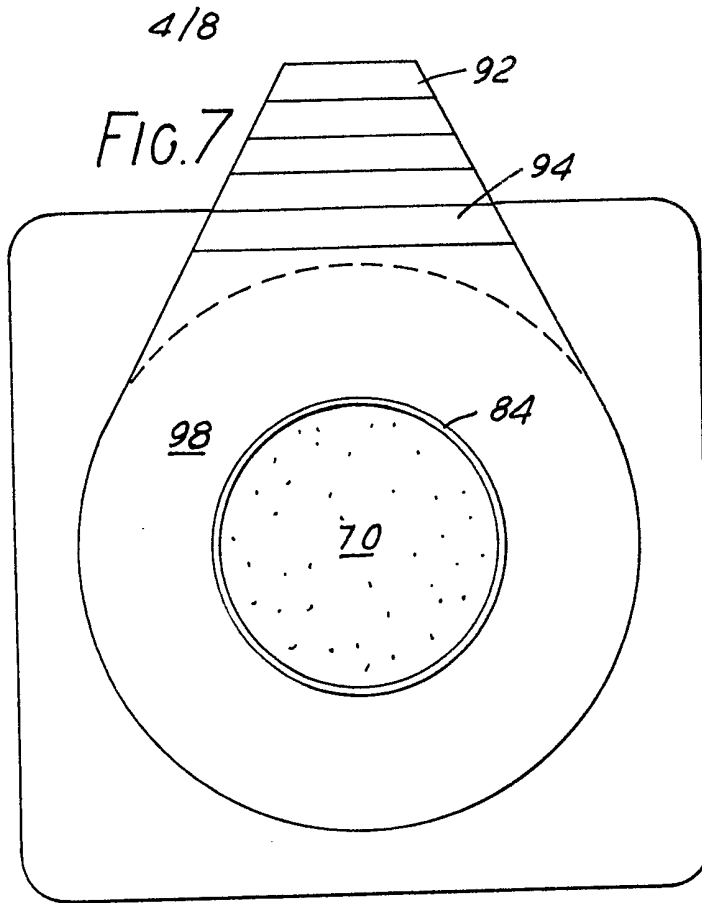
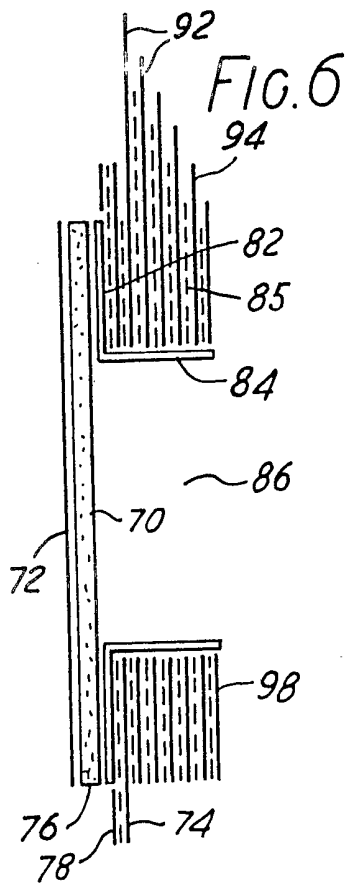


FIG. 5



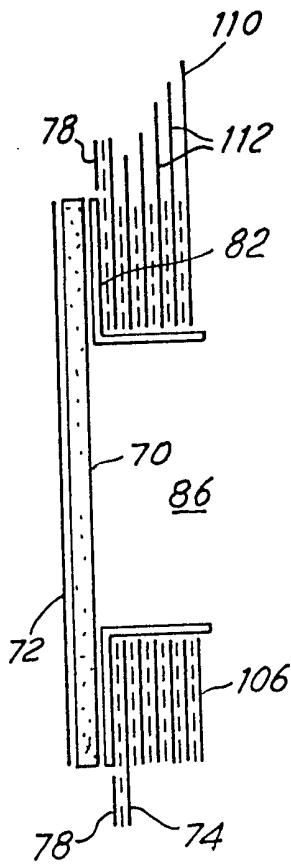


FIG. 10

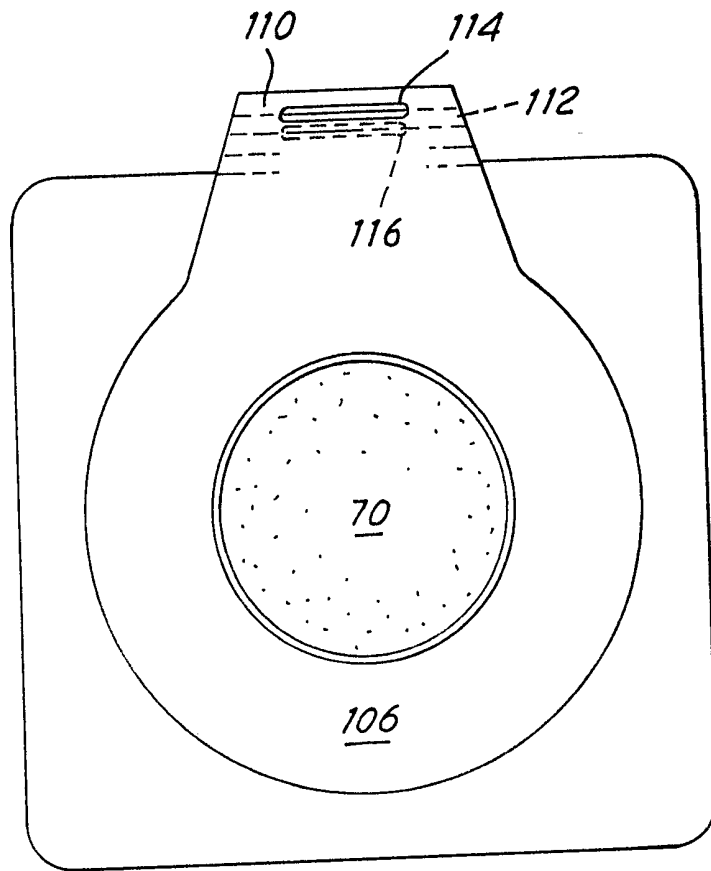


FIG. 11

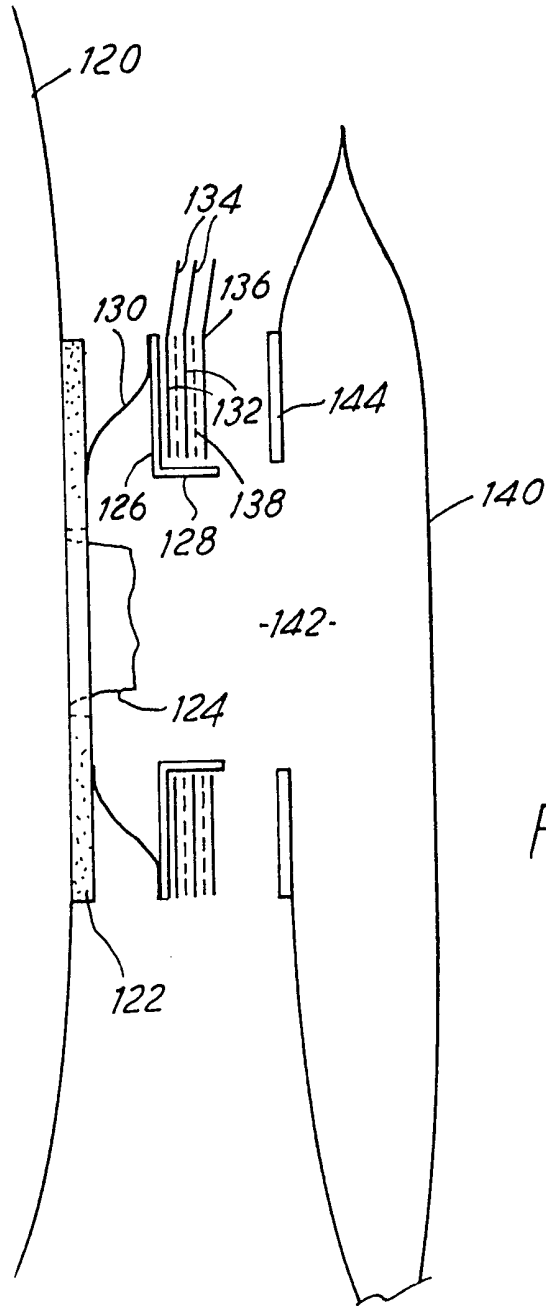
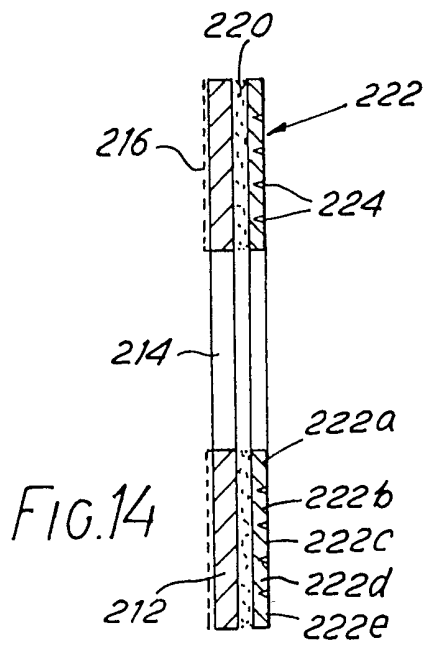
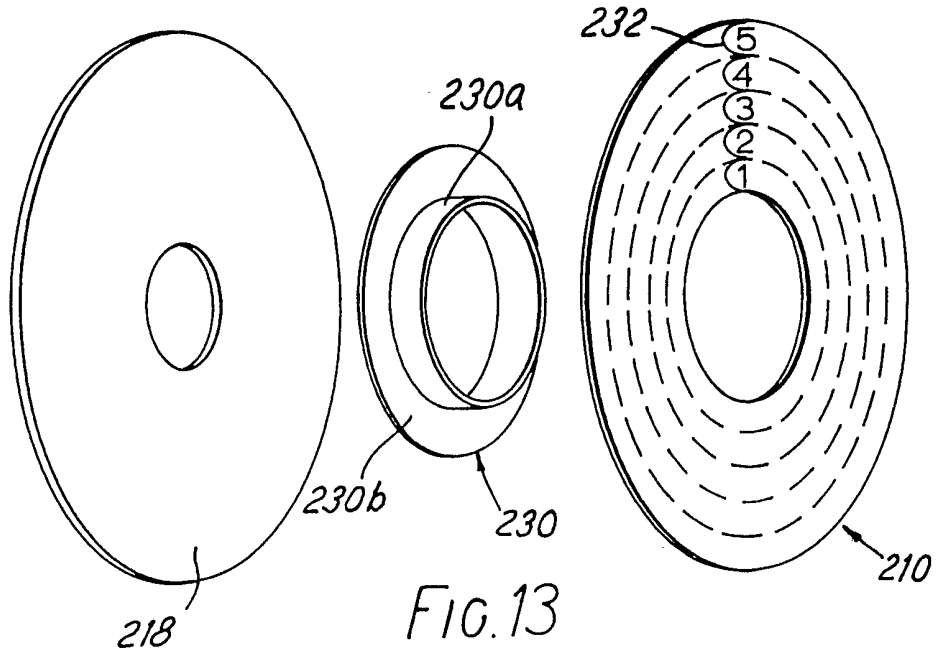


FIG.12



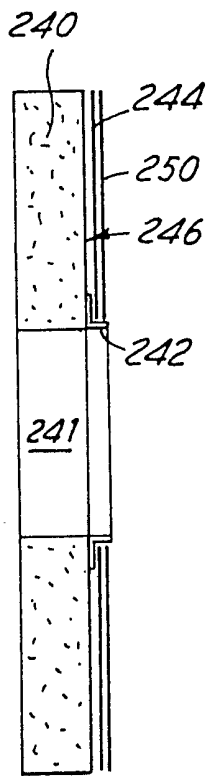


FIG.15

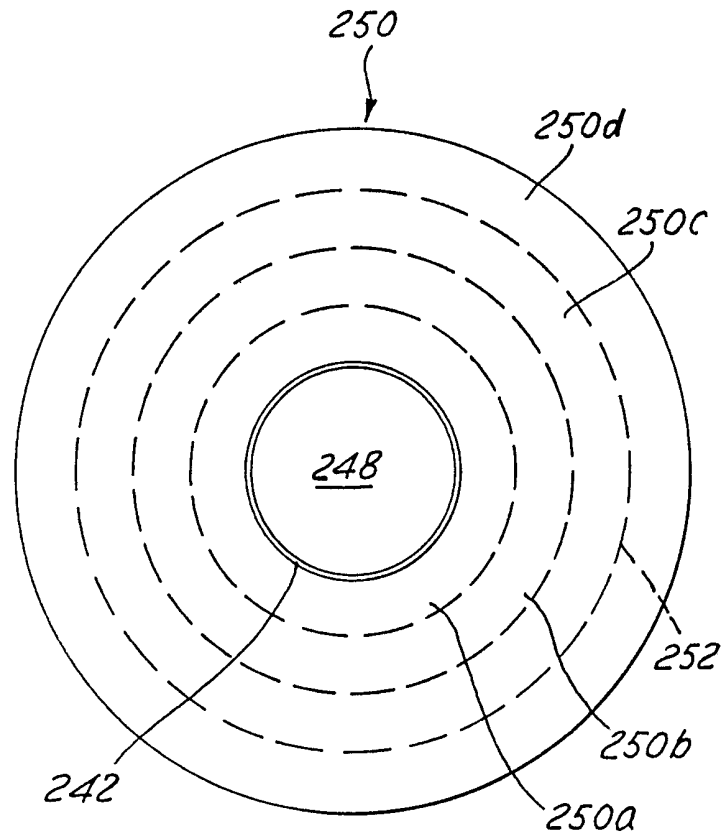


FIG.16

SPECIFICATION

Ostomy appliance pad for same attachment means for same and kit of parts for assembling same

This invention relates to an ostomy appliance, pad for same, attachment means for same, and kit of parts for assembling same.

10 In a successful known system, described and illustrated in British Patent No. 1 571 657, an ostomy bag is attached to a skin-compatible medical grade adhesive pad by a releasable coupling. In the case of some ostomates, however, it may be desirable to provide a lightweight, simple adhesive attachment system.

According to the present invention, there is provided an ostomy appliance comprising a body-attachable pad of skin-compatible adhesive material having a stomal orifice, and means whereby a plurality of ostomy bags can be attached in sequence to the pad by exposing a fresh region of adhesive each time it is desired to attach a clean ostomy bag.

According to one embodiment of the invention there is provided an ostomy appliance comprising a bag for receiving discharged wastes, a stomal orifice in one wall of the bag, a flange having a flat surface, intended to face towards the body of the wearer when the appliance is worn, surrounding the orifice, a medical grade adhesive pad, and a plurality of double sided adhesive annuli, separated by peelable cover annuli carried by the pad, each of the double sided adhesive annuli having a peripherally projecting portion.

The double-sided adhesive annuli are intended for sequential use in attaching the bag, via its flange, to a pad of medical grade adhesive material which the wearer has attached to his (or her) skin at the peristomal region. The reason for having a plurality of adhesive layers separated by peelable cover annuli is so that a new double sided annulus can be exposed by peeling off the outer cover layer. Hence each time a bag is emptied or changed it can be securely re-attached to the medical grade adhesive pad and there is no need to remove frequently. This is a considerable advantage in that the operation of removing and replacing such a pad is one of some difficulty and is often painful.

Such an appliance can be used as a 4-day bag or a 5-day bag by providing a corresponding number of double sided adhesive annuli. Each cover layer may have a radially projecting finger tab which serves two purposes, firstly it can carry a number or indication (e.g. "Monday") and secondly it enables the cover layer to be readily stripped off to expose the adhesive surface of the underlying double sided adhesive layer so that the flat surface of the flange on the bag can be brought into face-to-face contact with the so

exposed adhesive surface.

In accordance with one preferred embodiment of the invention, an ostomy bag is attached to a body-attachable pad by a series of sequentially peelable adhesive members each of which has a grasping tab, the tabs being arranged so that peeling off a first tab exposes a second tab, the latter not being accessible to the user until the first tab has been peeled off.

Alternatively, double sided adhesive layers may be alternated with peelable cover layers, and the cover layers may be shaped and arranged so that they are sequentially peelable, that is to say, each cover layer has a grasping tab and these tabs are so arranged that peeling off one tab exposes an underlying tab. Each cover layer is peeled off when it is desired to expose a fresh region of adhesive in order to attach a clean bag to the pad of skin-compatible material which is adhesively attached to the peristomal region.

In accordance with another preferred embodiment of the invention, there is provided a body-attachable pad carrying a flange to which is adhesively secured a stack of sequentially peelable adhesive members for attaching an ostomy bag to the flange, and the flange and the pad are connected by a flexible web which permits limited relative movement therebetween in a direction substantially perpendicular to the pad. Using such an arrangement, an ostomate can place his/her fingers behind the flange (i.e. between the flange and his body) so as to absorb the pressure which is applied to fix the bag to the exposed one of the stack of plasters.

In accordance with a further alternative embodiment of the invention, a kit of parts for making an ostomy appliance includes an apertured pad of body-attachable, skin-compatible material, and a plurality of ostomy bags to each of which is attached a peelable cover layer which when removed exposes an annular region of adhesive surrounding a stomal orifice in a wall of the bag, the said region of adhesive being arranged in use to adhesively secure each bag in turn to the pad.

In accordance with yet another preferred embodiment of the present invention, the body-attachable, skin-compatible pad is attached to a disc of plastics material (e.g. a vacuum-formable material) having an upstanding rim, there being a closed loop line of weakening within the rim so that a central region of the disc can be manually removed by the user. The aperture so produced serves as a stoma aperture.

In use the user cuts or punctures a hole for his stoma in the pad of skin compatible material and removes the central area of the plastics material; then when the member is applied to the body an inner marginal edge portion of the pad takes up a position closely surrounding the stoma, and forms both a

protective pad and a seal. The skin-compatible material then covers the exposed inner edge of the disc and avoids any pain or irritation being caused to the stoma by the inner edge
5 of the disc.

Also according to the invention an adhesive plaster for use in attaching an ostomy bag to a body-attachable member has an adhesive-protecting cover layer which is constructed so
10 that successive separate regions of the cover layer can be torn off in turn, so exposing a fresh adhesive for the attachment of a fresh ostomy bag.

The invention will be better understood
15 from the following nonlimiting description of examples thereof given with reference to the accompanying diagrammatic drawings in which:

Figure 1 is an exploded perspective view of
20 a medical grade adhesive pad, a plurality of double sided adhesive annuli, and intervening cover annuli;

Figure 2 is a side view corresponding to
Figure 1;

Figure 3 is a side view of an alternative
25 embodiment of the invention;

Figure 4 is a cross-sectional diagrammatic
view, somewhat enlarged from full size, of an
example of a body attachable member accord-
30 ing to the invention;

Figure 5 is a view similar to Figure 4
showing the member in position on a wearer
and illustrating the cushioning and sealing
effect of a marginal portion of the pad;

Figures 6 and 7 show, in cross-section and
35 in front elevation respectively, one embodi-
ment of a skin-compatible medical grade ad-
hesive pad carrying a plurality of 'peel off'
adhesive annuli;

Figures 8 and 9 show, in cross-section and
40 in front elevation respectively, a second embodi-
ment of a pad carrying a different ar-
rangement of 'peel off' adhesive annuli;

Figures 10 and 11 show, in cross-section
45 and in front elevation respectively, a third
embodiment of pad carrying yet another ar-
rangement of 'peel off' adhesive annuli;

Figure 12 diagrammatically shows a further
embodiment of body-attachable pad together
50 with an ostomy bag;

Figure 13 is an exploded view illustrating
another embodiment of the invention;

Figure 14 is a cross-section taken in a
vertical plane through the adhesive plaster
55 shown in—Figure 13 with the thickness exag-
gerated for clarity of illustration;

Figures 15 and 16 illustrate another man-
ner of use of a plaster according to the
invention, Figure 15 being a cross-sectional
60 view taken in a vertical plane and Figure 16 a
front view of a plaster applied to a bodyatta-
chable member.

In the drawings, like parts bear like refer-
ence numerals.

65 Referring firstly to Figures 1 and 2, the

illustrated ostomy appliance includes a medi-
cal grade adhesive pad 10 and an ostomy bag
12. The ostomy bag has a stomal orifice 14
which is surrounded by a flange, e.g. of
70 synthetic plastics material, having an annular
flat surface which is intended to face towards
the body of the wearer when the appliance is
in use. This surface is indicated at 16. The
medical grade adhesive pad 10 also has se-
75 cured thereto a flange 20 which optionally
includes an inner peripheral rib 22. The
flange 20 has an outwardly facing flat annular
surface 24, intended to receive a stack of
double sided adhesive annuli which are inter-
80 leaved with annular cover layers. The medical
grade adhesive pad 10 may be bonded to a
plastics film layer 26, in conventional manner.
In use, a hole indicated by the dotted lines 28
is cut in the pad 10 and the film 26 so that
85 the user's stoma can be passed therethrough.

The double-sided adhesive annuli are indi-
cated at 32, and for example, five are here
shown. This would be appropriate for a 5-day
ostomy appliance. The fifth one in order of
90 use is directly adhesively attached by one of
its adhesive surfaces to the surface 24 and by
its other surface to a peelable annular cover
layer 34. Like cover layers are located be-
tween adjacent double sided adhesive annuli,
95 and these cover layers as seen best in Figure
1 each have a radially projecting finger tab 36
useful firstly for peeling off the layer 34 and
secondly for carrying a numeral or other vis-
ible indication to assist the user of the appli-
100 ance.

The bag 12 may be either a bag having a
drain outlet 40 as seen in Figure 1, or may
alternatively be a closed bag intended to be
thrown away when full, as seen in Figure 2.

105 The words "annulus" and "annuli" are
used in the application without a strict geo-
metrical meaning. That is to say, a 'double
sided annulus as used in this invention need
not be geometrically circular; a double sided
110 adhesive layer of any shape which surrounds
the stomal orifice and which can be peeled off
from an adjacent layer to expose a region of
adhesive would be suitable.

Referring now to Figure 3, the ostomy bag
115 12 and medical grade adhesive pad 10 are as
shown previously. The double sided adhesive
annuli interleaved with peelable cover annuli
however have a gradually diminishing outside
diameter as one moves from the first to be
used (nearest to the bag) to the last to be
120 used (nearest to the pad). The reason for this
is to ensure that when one peelable cover
layer (e.g. 34A) is removed, it exposes an
area of fresh adhesive on the double sided
adhesive annulus 32A, and then when the
125 next cover layer 34B is removed, a fresh layer
of adhesive on the annulus 32B is exposed.
Deterioration of the outer edges of the adhe-
sive annuli is thereby minimised.

130 Another feature of difference compared to

the Figures 1 and 2 embodiment is that the O.D. of the adhesive layers is greater than that of the cover layers (except for the peel tabs thereof). Consequently narrow outer rims of the adjacent adhesive annuli tend to stick together and prevent any peel apart occurring except at the surface where the outermost peel-off cover annulus is being removed.

Referring now to Figures 4 and 5, a body-attachable member or pad 40 comprises a pad 42 of medicated skin compatible adhesive fixed to a disc 44 of plastics material. The disc 44 has an upstanding rim 46, and a closed loop line of weakening, which may be circular, indicated at 48 to define an area within the rim 46 which can readily be removed by a user without the use of a tool.

A strippable protective layer 50 is applied to the rear surface of the pad 52. This layer 50 is stripped off to expose an adhesive surface of the pad 52 when the pad 40 is to be applied to the patient's body.

Figure 5 illustrates the member 40 in position, the skin of the patient being indicated at 52 and the stoma of the patient at 54. As will be seen, the inner marginal edge portion 56 of the pad 42 has been deformed somewhat so that it closely surrounds and is in contact with the periphery of the patient's stoma 54; this provides a cushioning effect preventing the relatively sharp inner rim 58 of the disc 44 from painfully digging into the patient's stoma, and moreover the good adhesive contact between the pad 42 and the stoma 54 provides a sealing effect preventing any migration of liquid waste products towards the peristomal skin area 52. The annular surface 60 of the disc 14 serves for adhesive attachment of an ostomy bag in any of the various ways described in this patent application.

In a preferred form of the present invention, the rim 46 is produced by vacuum forming.

By use of the manufacturing procedure disclosed in Figure 3, of our Patent Application No. 84 10231 a large number of body attachable members can be readily produced without the need for individual moulding of plastics discs having rim parts.

An alternative embodiment of the present invention is illustrated in Figures 6 and 7. As seen in Figures 6 and 7, a pad 70 of skin-compatible medical grade adhesive material such as "Stomahesive" defined above, and carrying a strippable rear cover layer 72 supports a front cover sheet 74 whose function is to cover over the edges 76 of the pad 70 which would otherwise be exposed, there being a strippable annular paper or like layer 78 which protects adhesive on the rear surface (left hand side as seen in Figure 6) of the protective layer 74 where this extends beyond the pad 70. As illustrated, the pad 70 is in the form of a flat disc and the protective layer 74 is substantially rectangular. Attached to the pad 70 is a plastics disc 82 carrying a

central circular rim 84 which defines a stomal aperture 86. The disc 82 carries, stacked over the layer 74, a stacked pile of annular adhesive attachment members, herein called plasters, each plaster being constituted by a layer of tough paper or flexible plastics film bearing adhesive 85 and having a grippable tab 92. The tab arrangement as illustrated in Figure 6 is such that the rearmost plaster has the largest tab and the forwardmost plaster has a relatively small tab as seen at 94. The assembly is protected by a front cover annular layer of release paper or other suitable material which is identified at 98.

It will be seen that by peeling off firstly the cover layer, an annular region of adhesive is exposed to which an ostomy bag may be applied, and after that bag has been filled, then by peeling off the first adhesive plaster 94 further fresh adhesive on the so-exposed face of the next underlying plaster is made available for attaching a subsequent ostomy bag to the appliance.

Figures 8 and 9 show an alternative version of this embodiment of the invention, the difference being that in this embodiment the tabs of the adhesive plasters 100 are all of the same size. As seen in Figures 8 and 9, no adhesive is provided between the plasters outside the annular region, so that one tab can readily be separated from the next and so that the cover sheet 102 can be removed at the beginning of the use of the appliance.

Another variation of this embodiment of the invention is illustrated in Figures 10 and 11. According to this advantageous version, each of the cover layer 106 and the plasters 108 is annular in form with an upwardly projecting tab, the tab being denoted 110 in the case of the cover layer and 112 for each of the plasters. Each of the plasters has a tab of progressively increasing height, moving from the plaster closest to the disc 82 to the plaster furthest from the disc 82. Moreover, each tab has an elongated slot cut therein, near to the top of the tab, to enable a user to insert his fingernail in the slots so as to more readily separate one tab from the next. The slot in the cover layer is indicated at 114 and the aperture in the front tab 112 is indicated at 116. For simplicity of illustration in Figure 11, the other apertures in the tabs 108 are not shown.

Referring to the versions of the invention shown in Figures 6-11, it will be realised that any convenient number of separate plasters may be employed. Although five plasters have been illustrated in Figure 6, and four plasters in Figures 8 and 10, any selected number of plasters, e.g. one for each day of the week, can be included in the appliance. Moreover, while in some instances it may be preferable for the ostomy bag which is to be used with the illustrated appliances to have a relatively stiff plastics flange surrounding the stomal

orifice in one of its walls, in other instances no such stiff flange would be needed and the bag wall could be adhesively secured directly to the exposed adhesive surface.

5 An alternative embodiment of the invention is shown in Figure 12, which is diagrammatic cross-section illustrating the skin 120 of a wearer of a body-attachable pad 122 of medical grade adhesive material such as the "Stomaheasive" (Registered Trade Mark) referred to
10 above. The stoma of the patient is seen at 124, projecting through a suitable hole in the pad 122. A disc 126 carrying a circular rim 128 is connected to the pad 122 by a flexible
15 annular sheet 130. The sheet 130 may be of fabric or of a thin flexible plastics film.

The disc 126 carries a stack of annular plasters 132, each of which has a tab 134. A
20 strippable protective front cover layer 136 protects the adhesive 138 on the outermost plaster. An ostomy bag 140 having a stomal aperture 142 surrounded by a flat thin plate of annular form 144 cooperates with the
25 body-attachable appliance including the pad 122. In use, the protective layer 136 is stripped off exposing the adhesive layer 138 and the bag is brought in face to face manner up against this adhesive, the rim 128 then
30 extending just within the confines of the stomal orifice 142. The bag is consequently held firmly in position on the disc 126 and during the assembly, the user can if he wishes place his fingers behind the disc 126 to support the
35 disc 126 against the pressure needed to press the plate 144 onto the adhesive 138. When the bag 140 is full, it is removed, the used plaster is also removed so exposing a fresh adhesive surface on the plaster beneath. A
40 new bag can then be applied in a similar way.

The illustrated adhesive plaster 210 (Figures 13 and 14) includes a substrate 212 (which may for example be a conventional fabric substrate as found in conventional sticking plasters) having a central hole 214 therein
45 to constitute a stomal aperture. The rear (body side) surface of the substrate carries adhesive 216 whereby the plaster can be fixed to a body-attachable member 218, not shown in Figure 14. The front (or bag side) surface
50 carries adhesive 220 which is covered by a peelable protective layer 222. The layer 222 is divided into five annular regions 222a to 222e by circular partial cuts 224 which extend through, for example, about 3/4 of the
55 thickness of the protective layer 222. These cuts may be made by a punching or stamping operation. Alternatively the cuts may extend completely through the layer 222, or lines of weakening may be produced by having rows
60 of perforations. Other expedients will occur to a man of average skill in the art.

While a circular hole 214 and circular cuts 224 have been described, it will be appreciated that a non-circular, e.g. oval, configuration could be employed although circular is

preferred.

In use of the assembled appliance, an intervening member 230 herein called a chute member is fixed to a body-attachable pad 218
70 of medical grade adhesive and the cylindrical wall 230a of the chute is passed through the hole 214, the latter being of a sufficient size to accommodate the chute. The chute functions to guide any waste products issuing
75 from the stoma into the interior of an ostomy bag and to minimise the chance of any of them coming into contact with the adhesive 216 or the adhesive 220. If such contact were to occur, the security of attachment
80 provided by the adhesive would be made less reliable. However, in some instances, e.g. when a very simple and inexpensive ostomy system is desired, the chute 230 can be omitted and the plaster 10 attached directly
85 by the adhesive 216 to the pad 218.

In use, the inner ring 222a is peeled or stripped off, so exposing an annular area of adhesive 220, and the wall of an ostomy bag having a stomal orifice therein is brought in
90 face to face contact with the exposed area of adhesive 220, with the stomal orifice in the bag wall substantially in registry with the hole 214. To facilitate stripping off the rings 222a to 222e, each ring may carry a tab or projection 32 which can be grasped between finger
95 and thumb. The tabs may if desired be numbered as shown in Figure 13.

The ostomy bag employed may be of the kind which has a flat annular flange on its
100 rear wall surrounding the stomal orifice therein, or such a flange may be omitted and the bag rear wall directly applied to the adhesive 220.

The intermediate member 230 may advantageously be made by vacuum forming a synthetic plastics film, and its flange 230b is preferably ultrasonically welded to a plastics film forming the outer surface boundary of the
105 pad 218.

110 In an advantageous embodiment of the invention, the adhesive 16 may be such as to have a higher "peel strength" than the adhesive 20. This ensures that the attachment of the plaster 210 to the pad 18 remains secure
115 when force is applied to peel off one of the rings 222a to 222e.

Figure 15 illustrates a body-attachable medical grade skin-adherable pad 240 which is disc-shaped with a central hole 241, i.e. is
120 annular in shape. To the pad 240 is attached a vacuum formed plastics rim 242. An adhesive plaster 244 according to the invention is directly fixed in any suitable way, e.g. by adhesive, to the front face 246 of the pad
125 240. The plaster 240, 242 has a central hole 248 of a diameter slightly greater than the O.D. of the rim 242. A protective layer 250 can be manually peeled or stripped from the plaster 242. The layer 250 is separated by
130 cuts 252 into concentric rings 250a to 250 d

(Figure 15). Each of these rings can be separately stripped from the plaster 244. While the plaster 244 and pad 240 are shown as circular in shape, they could have other configurations.

5 The pad 218 or the pad 240 may be made of the material known by the Registered Trade Mark STOMAHESIVE and may be obtained in U.K. from E.R. Squibb & Sons limited, of Hounslow, Middlesex.

10 An advantageous form of body-attachable pad consists of three layers, namely a skin compatible medical grade adhesive, a plastics film thereon, and a fasson fabric plaster layer covering the film and having its marginal edge portions extending somewhat beyond the outer edges of the adhesive and the film. The adhesive and the film will normally be coextensive. The purpose of the fasson fabric layer is to shield the edges of the adhesive so that, for example, these edges do not slide to the clothing of the wearer.

15 While there have been suggestions in the past, e.g. in British Patent Specification No. 1 256 866, that an ostomy bag can be attached to a body-attachable ring by adhesive, there has been (to the best of Applicants' knowledge and belief) no means hitherto suggested or obtainable other than recent patent applications of the present Applicant whereby a series of ostomy bags can be adhesively attached in turn to a single body-attachable member, while the member remains attached to the body of the wearer.

20 Moreover, the arrangement according to the invention is light in weight, has a very flat configuration, does not produce an unsightly bulge under the clothes, and is easily and inexpensively manufactured.

40 CLAIMS

1. An ostomy appliance comprising a body-attachable pad of skincompatible adhesive material having a stomal orifice, and means whereby a plurality of ostomy bags can be attached in sequence to the pad by exposing a fresh region of adhesive each time it is desired to attach a clean ostomy bag.

2. An ostomy appliance comprising a bag for receiving discharged wastes, a stomal orifice in one wall of the bag, a flange having a flat surface, intended to face towards the body of the wearer when the appliance is worn, surrounding the orifice, a medical grade adhesive pad, and a plurality of double sided adhesive annuli, separated by peelable cover annuli carried by the pad, each of the double sided adhesive annuli having a peripherally projecting portion.

3. A series of sequentially peelable adhesive members for attaching an ostomy bag to a body-attachable pad, each member having a grasping tab, the tabs being arranged so that peeling off a first tab exposes a second tab, the latter not being accessible to the user until

the first tab has been peeled off.

4. An ostomy appliance according to Claim 1 or 2 in which double sided adhesive layers are alternated with peelable cover layers, and the cover layers are shaped and arranged so that they are sequentially peelable, that is to say, each cover layer has a grasping tab and these tabs are so arranged that peeling off one tab exposes an underlying tab.

5. A body-attachable pad carrying a flange to which is adhesively secured a stack of sequentially peelable adhesive members for attaching an ostomy bag to the flange, and the flange and the pad are connected by a flexible web which permits limited relative movement therebetween in a direction substantially perpendicular to the pad. Using such an arrangement, an ostomate can place his/her fingers behind the flange (i.e. between the flange and his body) so as to absorb the pressure which is applied to fix the bag to the exposed one of the stack of plasters.

6. A kit of parts for making an ostomy appliance includes an apertured pad of body-attachable, skin, compatible material, and a plurality of ostomy bags to each of which is attached a peelable cover layer which when removed exposes an annular region of adhesive surrounding a stomal orifice in a wall of the bag, the said region of adhesive being arranged in use to adhesively secure each bag in turn to the pad.

7. An ostomy appliance according to Claim 1, 2 or 4 in which the bodyattachable, skin-compatible pad is attached to a disc of plastics material (e.g. a vacuum-formable material) having an upstanding rim, there being a closed loop line of weakening within the rim so that a central region of the disc can be manually removed by the user.

8. An appliance according to Claim 7 constructed so that in use the user cuts or punctures a hole for his stoma in the pad of skin compatible material and removes the central area of the plastics material; then when the member is applied to the body an inner marginal edge portion of the pad takes up a position closely surrounding the stoma, and forms both a protective pad and a seal, with the skin-compatible material then covering the exposed inner edge of the disc to avoid any pain or irritation being caused to the stoma by the inner edge of the disc.

9. An adhesive plaster for use in attaching an ostomy bag to a bodyattachable member having an adhesive-protecting cover layer which is constructed so that successive separate regions of the cover layer can be torn off in turn, so exposing a fresh adhesive for the attachment of a fresh ostomy bag.

10. An ostomy appliance substantially as herein described with reference to and as illustrated in the accompanying drawings.

11. Any novel combination or sub-combina-

tion disclosed and/or illustrated herein.

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