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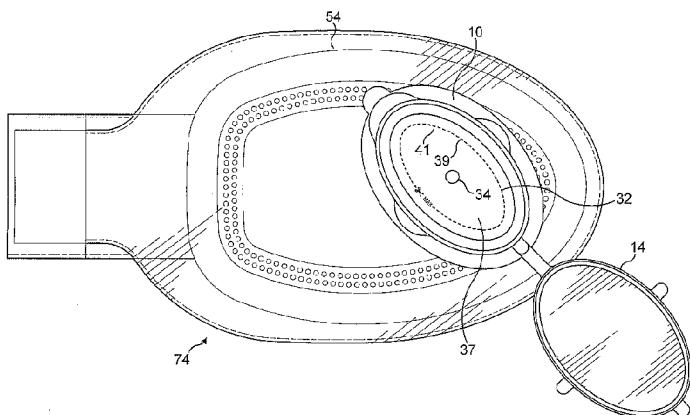
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(54) Title: ACCESS PORT FOR A MEDICAL APPLIANCE AND METHOD



(57) Abstract: A medical access port (10) has a base (12) and a lid (14). The base (12) has an adhesive layer (26) which may be exposed by pulling a peel layer (28). The port may be stuck onto a bag (54) and an access aperture (34) may be enlarged, if desired, by cutting through a mounting substrate of the port (10) and a substrate (58) of the bag. The lid (14) may be opened and closed as desired and the access port may be located in the most suitable configuration for the particular use application concerned.

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ACCESS PORT FOR A MEDICAL APPLIANCE AND METHOD

The present invention relates to an access port for use with medical appliances, such as medical bag systems such as those comprising fistula bags, pouches or wound managers.

- 5 When a patient has a wound or fistula, it may be desirable to cover the wound or fistula in order to provide a barrier. Some such wounds and fistulas may be covered with a bag which may be sealed to the patient to collect material such as fluid at the wound or fistula while also providing a barrier.

Any discussion of the prior art throughout the specification should in no way be
10 considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

US-A-6015399 discloses a small circular gas vent for a colostomy pouch which may be attached by the user to a conventional ventless colostomy pouch - this small vent is not therefore used for the therapy of the patient. This addresses a
15 venting problem associated specifically with colostomy pouches and does not provide access for patient tissue care or inspection. The vent has a plug with a sharp point which extends below a lower flange surface of a socket of the vent for preventing buildup of material in the colostomy bag at the entrance to the vent.

- 20 An example of a known fistula bag is the EAKIN ® F12 fistula bag which has a layer of COHESIVE ® sealing material which seals the bag to the patient and a drainage tube for emptying the bag when necessary. This bag has proved extremely successful but needs to be removed from the patient whenever the wound, fistula or otherwise troubled part of the patient requires attention.

Another known fistula bag includes a central circular access port welded to the centre thereof. The access port provides access to the part of the patient to which the bag is attached. However, the access port is by its nature in a fixed position relative to the bag's periphery. The therapist/user has therefore limited

5 freedom in placing the bag to provide access in the most desirable position for access port function. Inspection also always requires the port to be opened and then closed again, potentially causing patient discomfort.

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

10 Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising", and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

According to a first aspect of the present invention there is provided a therapy

15 access port for a medical appliance for allowing therapy of a patient therethrough, the port comprising a base, an openable closure for the base, and a seal arranged to be located on the base for sealingly connecting the port to a medical appliance. The port may be connectable to the medical appliance in a user-chosen or in a therapist or end user-chosen location position such that the

20 access port may be located on the appliance wherever desired.

According to a second aspect of the invention there is provided a medical bag system comprising a medical bag and an access port according to the first aspect, wherein the seal is arranged to be located on the base for sealingly connecting the port to the medical bag in one of a choice of locations.

25 According to a further aspect of the invention there is provided an access port according to the first aspect for a medical appliance, the closure co-operating with an access aperture with a minimum cross-dimension over 2 cm. The

access aperture may be circular, oval or elongate. The access aperture may have a maximum cross dimension greater than 4cm, for example about 7 cm to 12 cm. When the access aperture is oval, in one embodiment it may have a minimum cross dimension (along a short axis thereof) of about 4 to 6 cm and a maximum cross dimension (along a long access thereof) of about 8 to 11 cm.

5 This configuration may provide easy hand or tool access through the access aperture for patient therapy.

According to a further aspect of the invention there is provided an access port for a medical appliance according to the first aspect, the closure including an 10 inspection window. This advantageously allows a wound or the like to be inspected through the port without the need to open the port, thereby minimizing patient discomfort.

According to a further aspect of the invention there is provided an access port for a medical appliance according to the first aspect, the closure having a lower 15 surface spaced above the lower surface of the base. This advantageously reduces the risk of contact between the closure and structure such as a wound of a patient to which the port has been applied.

Advantageously, in accordance with these aspects of the invention, the access port may be located on the bag or appliance wherever desired. For example, a 20 nurse may inspect the patient and then choose where to site the access port on the appliance or bag based on such observations. For example, when a nurse would consider it most appropriate to site the access port in the middle of a medical bag such a fistula bag, the access port may be so located.

Alternatively, if it appears most appropriate for access or other reasons to locate 25 the access port near an edge of a medical bag, this may be done instead. These aspects of the invention therefore provide increased flexibility and choice ultimately leading to improved patient comfort.

A number of optional features in connection with either or both of the above aspects of the invention will now be discussed.

The appliance may comprise a bag having a membrane surface on a first side thereof, and the membrane surface may be arranged for the formation of an

5 inspection hole therein. The port may be arranged to sealingly engage around the inspection hole. The inspection hole may be formed after the port has been applied to the appliance or bag, or before as desired. The bag may have a sealing layer on a second side thereof, opposite the first side, which is adapted to seal the bag to a substrate of a patient. The sealing layer may be a self

10 adhesive layer.

The bag may be arranged to be mounted on a patient, for example to skin of a patient around a wound or fistula.

The base may be non-circular, for example oval. This has the substantial advantage that the base may be formed with a relatively small overall size, but

15 the base may be provided with a central oval aperture which allows access therethrough by a hand, thereby allowing a nurse or other operator greater and more flexible access therethrough.

The base may have a generally flat base plate having an access aperture formed in or near the centre thereof. The seal may comprise an adhesive layer

20 located adjacent the base plate. This may provide a convenient structure in which the base plate may be pushed on to a bag or other appliance to connect the two together in a simple way near the point of use and without requiring complicated welding apparatus as in the prior art.

The adhesive layer may be located upon and cover an area of, or all of a lower

25 surface of, a mounting substrate, the mounting substrate being secured to the base, the adhesive layer facing away from the base plate.

The mounting substrate may include a cutting tool access aperture formed therethrough. Therefore, the mounting substrate may be cut as desired, for example by a nurse, to form an access aperture of desired size and overall configuration, for example based upon patient observations.

- 5 The adhesive layer, in a pre-use configuration, may be protected by a peel-off layer.

The mounting substrate may include indicia thereon for indicating a maximum suitable aperture dimension therefor. Accordingly, this may warn the user, such as a nurse, from making an unsuitably large aperture.

- 10 At least one of the base plate and enclosure member may include a pinch flange arranged to assist in manual closure of the port with a pinching action, and to assist in opening. Accordingly, it may not be necessary to press down upon the patient to open and/or close the access port, thereby avoiding discomfort to the patient.
- 15 The closure member may have an outer edge arranged to snap-lockingly seal on to a connector part of the base plate and the outer edge may comprise a hoop of material. A closure substrate may sealingly close the hoop. The closure substrate may be transparent. This has the advantage the wound may be clearly inspected through the access port without opening the port: in a prior art fistula bag known to the inventor, a unitary opaque closure is provided, thereby requiring potentially uncomfortable opening thereof for inspection of the area of the patient located behind the access port.
- 20
- 25

In another embodiment, the port may comprise an access bag and the base plate thereof may comprise a first flexible substrate layer thereof. This allows an access port with a lightweight construction.

The access bag may have a second flexible substrate and the flexible substrate layers may be joined at respective edges thereof. The bag may comprise a rectangular bag. The first flexible layer may have a slit formed therethrough for communication with the interior of a medical bag.

- 5 The closure may comprise at least one elongate component arranged to releasably join the first and second flexible substrates together therealong for releasably closing the access bag.

According to a further aspect of the invention there is provided a method of assembling a medical appliance system having a medical appliance and an

- 10 access port according to the first aspect, the method comprising selecting a desired location for mounting the access port on the appliance and mounting the access port on the appliance in the desired location with an adhesive component. This has the advantage that the system may be assembled as desired by an individual near the point of use. However, this need not
- 15 necessarily be the case and the whole method may if desired be completed in some embodiments earlier, for example in the manufacturer's works e.g. before any details of any patients are known. The method may include providing the appliance in the form of a bag and forming a communication aperture in the bag once the port is mounted on the bag. The access port may be as set out in the
- 20 first aspect of the invention. The bag system may comprise a system as in the second aspect of the invention.

According to a further aspect of the invention there is provided a method of operating a medical bag system having a medical bag and an access port according to the first aspect, the method comprising observing a patient,

- 25 selecting a location for the access port on the medical bag based upon observations of a patient, mounting the access port on the medical bag in the selected location, and mounting the system on a patient.

The access port may be mounted on the bag once the bag is on the patient.

The method may include opening the access port while the system is mounted on the patient.

According to a further aspect of the invention there is provided an access port according to the first aspect for a medical bag, the access port having a non-

5 circular yet curved configuration. The non-circular yet curved (for example oval or elongate) configuration may advantageously provide that an overall relatively small access port may be provided, yet one through which access by hand may be more conveniently obtained than with a circular or rectangular port.

The present invention may be carried out in various ways and two embodiments

10 of access ports and medical bag systems in accordance with the invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a front view of a first embodiment of an access port in accordance with the present invention;

15 Figure 2 is a section on the line II-II';

Figure 3a is a front view of a known medical bag with a drainage tube thereof in an open extended configuration;

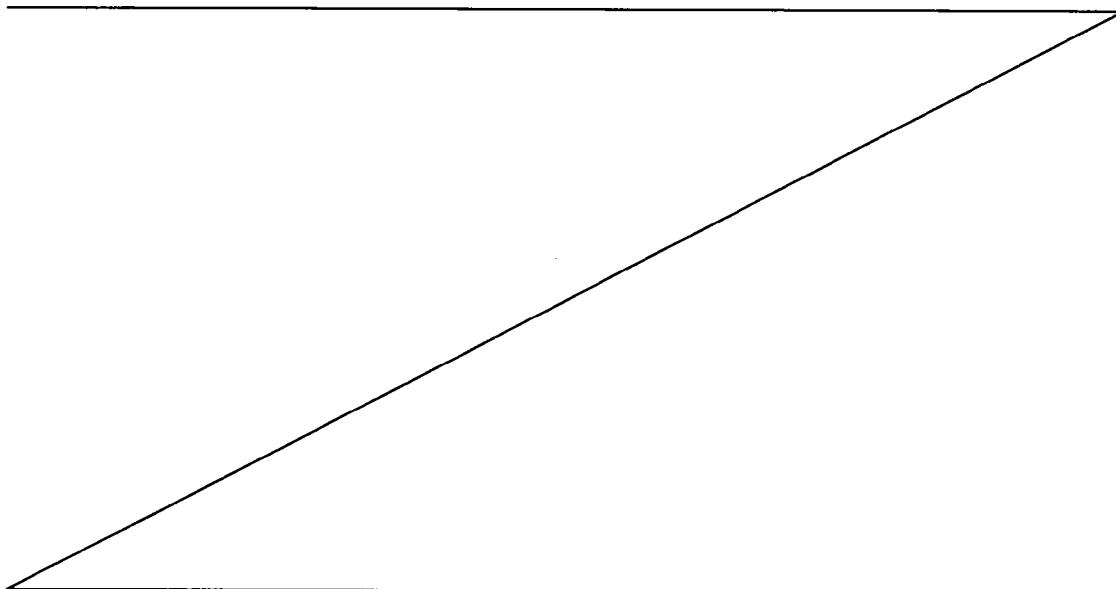


Figure 3b shows the bag of Figure 3a with the drainage tube closed and stowed;

Figure 4a is a side view corresponding to Figure 3a;

Figure 4b is a side view corresponding to Figure 3b;

Figure 5 shows the access port of Figure 1 attached to the bag of Figures 3 and

5

4;

Figure 6 shows a second embodiment of an access port in accordance with a second preferred embodiment of the present invention; and

Figure 7 is a section on the line VII-VII' in Figure 6

10 As shown in Figure 1, a first embodiment of an access port 10 in accordance with the present invention has a base 12 and closure or lid 14. The base has an oval flange 16 having an upstanding connector part or rim 18. The flange 16 is in the form of a base plate for the base 12 and is attached by adhesive or a weld 20 to a thin mounting substrate whose lower surface 24 is entirely covered with adhesive 26. A removable peel layer 28 may be removed from the mounting substrate 22 at the point of use by pulling on the peel tab 30 in order to expose the adhesive 26. Visible from the top or front of the access port is an indicia line 32 which indicates the maximum extent of any aperture which may be cut in the mounting substrate 22 (optionally by enlargement of optional aperture 34 as will be described below). The mounting substrate includes the aperture 34 formed therethrough, through which scissors or another cutting tool may be inserted in order to enlarge the aperture 34 towards the maximum extent line 32 as will be described below.

15

20 25 The lid 14 is connected to the base 12 by a flexible hinge 36 (or by other means). The lid 14 has an outer edge 38 having a sealing formation 40 which is arranged to sealingly connect in a releasable manner to a sealing formation 42 on the rim 18 of the base 12. The outer edge 38 is sealed by an oval window 44 made of transparent substrate material.

The sealing formations 40, 42 are designed to releasably snap lock together. Flanges 46, 48 are provided on the lid 14 and base 12 respectively for assisting in opening the lid 14 and flanges 46 and/or flanges 48 may be optionally omitted in other embodiments if desired. In other embodiments, not so many pinch flanges may be provided and indeed none may be necessary since the weld 20 only extends partially radially across the lower face 50 of the oval flange 16 such that a user may in some cases slide one or more fingers below the flange 16 for pinch closing purposes.

10

The known fistula bag 54 (an example only – the port is also suitable for use with other forms of appliance with different shape and/or dimensions) shown in Figures 3a to 4b is an EAKIN ® F12 fistula bag and includes two layers 56, 58 of thin membrane material which have a generally oval planform as shown in Figure 3a terminating at one end at a drainage tube 60 which may be extended as shown in Figure 3a or wrapped up and stowed in a sealing manner in a stowage pouch 62 as shown in Figure 3b. The membrane material layers 56, 58 are flexible and although shown as very close together and parallel in Figures 4a and 4b, due to the fact that the two membrane layers 56, 58 are only joined to one another at peripheral weld seam 64, the space between the two membranes 56, 58 may be inflated in to a bag shape, such as by the ingress of fluids into the bag 54.

Attached to the lower membrane surface 56 is a layer of COHESIVE ® sealing material 66 which is suitable for sealing the bag 54 onto a patient (not shown) once a peel strip 68 has been removed, thereby exposing the sealing material 66.

In use, a nurse or other operative may examine a patient's wound or fistula and select the bag 54. Next, starting at access aperture 70 which passes through sealing material 66 and lower layer 56 scissors may be used to enlarge the aperture 70 to an appropriate size to surround the wound, but not to a larger 5 size than a weld 72 which joins the sealing material 66 to the membrane sheet material 56 in a sealing manner. Next, the bag 54 may be laid on a flat surface (not shown). Next, the peel layer 28 may be removed, exposing the adhesive 26 which is a self-adhesive and covers the entire lower surface 24 of the mounting substrate 22. Next, the access port 10 may be positioned on the bag 54 10 wherever desired and pressed down as required to ensure a secure bond. The view in Figure 5 shows the access port 10 and bag 54 in this configuration with the lid 14 open. Next, the operative may use scissors or another suitable tool enlarge the optional aperture 34 by cutting through the mounting substrate 22 and membrane material 56 together to cut an enlarged access aperture of any 15 convenient shape or size up to the border line of maximum extent shown by the indicia 32. As an alternative to enlargement of optional aperture 34 by cutting, aperture 34 may be absent and optional perforations 35 may be placed (for example at position of indicia 32) to allow the therapist or other user to push out and remove an inner part 37 of the substrate (or film) 22. Bag 54 may then 20 be cut as desired to form an aperture 39 and example of whose location is shown in Figure 5 at the same position as aperture 41 to be formed by pushing out part 37 of substrate defined by perforations 35. It will be appreciated that push out part 37 is shown for clarity in Figure 5 whereas in many cases it may actually be removed before applying port 10 to bag 54. Perforations may also 25 extend through peel layer 28. The combined bag system 74 consisting of the assembled bag 54 and port 10 may then (after removing peel layer 68 and preparation of the bag 54 and layer 66 in accordance with manufacturer's instructions) be carefully pressed on to and sealed on to the patient using the adhesive layer 66. The lid 14 may then be closed and due to the transparent

nature of the window 44 the wound or fistula, (not shown), if located below the window 44 or in the region thereof, may be easily inspected through the window 44. Also, due to the oval shape of the access port/ aperture 34 once enlarged up to or near its maximum extent, i.e. to the indicia line 32, access 5 through the port 10 by hand is possible without making the overall size of the port 10 very large.

Figures 6 and 7 show another embodiment of an access port for use with the same type of bag as that shown in Figures 3a to 4b. The access port 100 shown 10 in Figures 6 and 7 has a base 110 and a closure 112. The base consists of a flexible rectangular layer of membrane material welded at three edges thereof 114, 116, 118 to a similar layer of membrane material 120. The outer surface 122 of the base 110 has a rectangular self adhesive layer of material 124 thereon which is initially protected by a peel strip 126. The base 110 and 15 adhesive layer 124 also have an optional rectangular access aperture 127 formed therein.

The closure 112 consists of an elongate fastener 128 joining the two edges 114, 118, the fastener 128 consisting of an elongate projection 130 on the base 110 20 which is adapted to releasably seal into elongate sealing channel 132 on the substrate 120.

The port 100 is used in a similar manner to the port 10 of Figure 1. The rectangular aperture 127 may be enlarged to form a larger access aperture or 25 the user may stick port 100 on to the bag 54 and then enlarge the aperture 127 using scissors or the like, cutting simultaneously through the layer 58. Instead of enlarging the aperture 127 in that way, the user may simply decide to cut an elongate slit 132' through the base layer 110 and membrane material 58 to

provide an elongate flexible access port. Slit 132' may be pre-formed by the manufacturer, such as in cases when optional aperture 127 is absent.

The embodiments described in these and other preferred embodiments provide
5 an access port with a self-adhesive layer which allows the port to be positioned
in an ideal place on a pouch, bag or other medical appliance by a therapist or
nurse. The access ports allow access to wounds, fistulas or stomas by
therapists/nurses or other operators to observe/clean and treat the same either
by looking through the window 44 or transparent base 110 and layer 120, or by
10 opening the closure, i.e. the lid 14 or the closure 112. The therapist or nurse
may install the access port on almost any type of plastic-based appliance that
would benefit from an access port in a medical environment. The access port
may be supplied in a range of sizes such that larger or smaller access ports than
those shown in Figures 1 and 6 may be provided but having the same or similar
15 overall configuration. The opening 34, 132', 127 may be made large enough to
accommodate a hand for cleaning and treatment purposes. In the example
shown in Figure 5 the access aperture 34 once enlarged to the indicia 35 may
have a cross-dimension along the short access of the port of about 5 to 7 cm
and a cross-dimension along the long axis of the port of about 8 to 11 cm, thus
20 allowing easy access by hand, tool or other media through the port for patient
therapy.

Instead of using a self adhesive layer to attach the port as in the embodiments
described, the access port could in other embodiments be glued or clamped on
25 to the medical bag 54 or other appliance.

It is envisaged that in some cases port 10, 100 may be used with a bag or other
medical appliance and in a method of operation intended to and actually
producing a solely cosmetic effect, such as a beauty treatment for skin (e.g.

tanning), hair (e.g. tinting) or the like. It is also envisaged that the invention extends to ports and methods of operation used in relation to deceased humans or animals.

- 5 Apart from the peel layer 28, 126 the materials in the port 10, 100 may all be plastics and relatively flexible. However, a reliable seal is needed between the outer edge 14 and rim 18, as well as between the corporating closure parts 130, 132.
- 10 Various modifications may be made to the embodiments described without departing from the scope of the invention as defined by the accompanying claims as interpreted under Patent Law.

Claims

1. A therapy access port for a medical appliance for allowing therapy of a patient therethrough, the port comprising a base, an openable closure for the base, and a seal arranged to be located on the base for sealingly connecting the port to a medical appliance, wherein the access port is configured to be connected to the medical appliance in a user-chosen location position such that the access port may be located on the appliance wherever desired.
5
2. A medical bag system comprising a medical bag and an access port as claimed in claim 1, wherein the seal is arranged to be located on the base for sealingly connecting the port to the medical bag in one of a choice of locations.
10
3. Apparatus as claimed in claim 1 or claim 2 in which the appliance comprises a bag having a membrane surface on a first side thereof, and in which the membrane surface is arranged for the formation of an inspection hole therein, and in which the port is arranged sealably engage around the inspection hole.
15
4. Apparatus as claimed in claim 3 in which the bag has a sealing layer on a second side thereof opposite the first side which is adapted to seal the bag to a patient.
5. Apparatus as claimed in any one of claims 2 to 4 in which the bag is arranged to be mounted on a patient.
20
6. Apparatus as claimed in any one of the preceding claims in which the base is oval.
7. Apparatus as claimed in any one of the preceding claims in which the base has a generally flat base plate having an access aperture formed in the centre thereof.
25

8. Apparatus as claimed in claim 7 in which the seal comprises an adhesive layer located adjacent the base plate.
9. Apparatus as claimed in claim 8 in which the adhesive layer is located upon and covers an area of a mounting substrate, the mounting substrate being secured to the base plate, the adhesive layer being on a surface of the substrate facing away from the base plate.
10. Apparatus as claimed in claim 9 in which the mounting substrate includes perforations therethrough enabling a pre-defined part of the substrate to be removed by tearing the substrate.
- 10 11. Apparatus as claimed in claim 9 or claim 10 in which the mounting substrate includes indicia thereon for indicating the position of a tearline at the edge of the pre-defined part.
12. Apparatus as claimed in claim 8 or claim 9 in which the adhesive layer in a pre-used configuration is protected by a peel off layer.
- 15 13. Apparatus as claimed in any one of the preceding claims in which the closure member has an outer edge arranged to snap-lockingly seal onto a connector part of the base plate.
14. Apparatus as claimed in claim 13 in which the outer edge comprises a hoop of material, and in which a closure substrate sealingly closes the hoop, the closure substrate preferably being transparent.
- 20 15. Apparatus as claimed in any one of claims 1 to 8 in which the access port comprises an access bag and the base plate comprises a first flexible substrate layer of the access bag.

16. Apparatus as claimed in claim 15 in which the access bag has a second flexible substrate layer and the flexible substrate layers are joined at respective edges thereof.
17. Apparatus as claimed in claim 16 in which the closure comprises at 5 least one elongate component arranged to releasably join the first and second flexible substrates together therealong for releasably closing the access bag.
18. Apparatus as claimed in claim 15 or claim 16 or claim 17 in which the first flexible layer has a slit formed therethrough for communication with the interior of a medical bag.
- 10 19. A method of assembling a medical appliance system having a medical appliance and a therapy access port as claimed in claim 1 or any preceding claim when dependent on claim 1, the method comprising selecting a desired location for mounting the therapy access port on the appliance and mounting the access port on the appliance in the desired location with an adhesive 15 component.
20. A method as claimed in claim 19 which includes providing the appliance in the form of a bag and forming a communication aperture in the bag once the port is mounted on the bag.
21. A method as claimed in claim 19 or claim 20 in which the bag is a 20 component of the bag system as claimed in claim 2 or any preceding claim when dependent on claim 2.
22. A method of operating of a medical bag system having a medical bag and a therapy access port as claimed in claim 1 for allowing patient therapy therethrough, the method comprising observing a patient, selecting a location 25 for the access port on the medical bag based upon observations of the patient,

mounting the access port on the medical bag in the selected location, and mounting the bag on the patient.

23. A method as claimed in claim 22 in which the access port is mounted on the bag once the bag is on the patient.

5 24. A method as claimed in claim 22 or claim 23 which includes opening the access port while the system is mounted on the patient.

25. An access port as claimed in claim 1 for a medical bag, the access port having a non-circular yet curved configuration

10 26. A medical bag system comprising a medical bag and an access port as claimed in claim 25 located thereof.

27. A medical bag system as claimed in claim 26 in which the medical bag is arranged to be mounted on a patient.

15 28. An access port as claimed in claim 1 wherein, the closure member co-operating with an access aperture having a minimum cross-dimension greater than 2 cm.

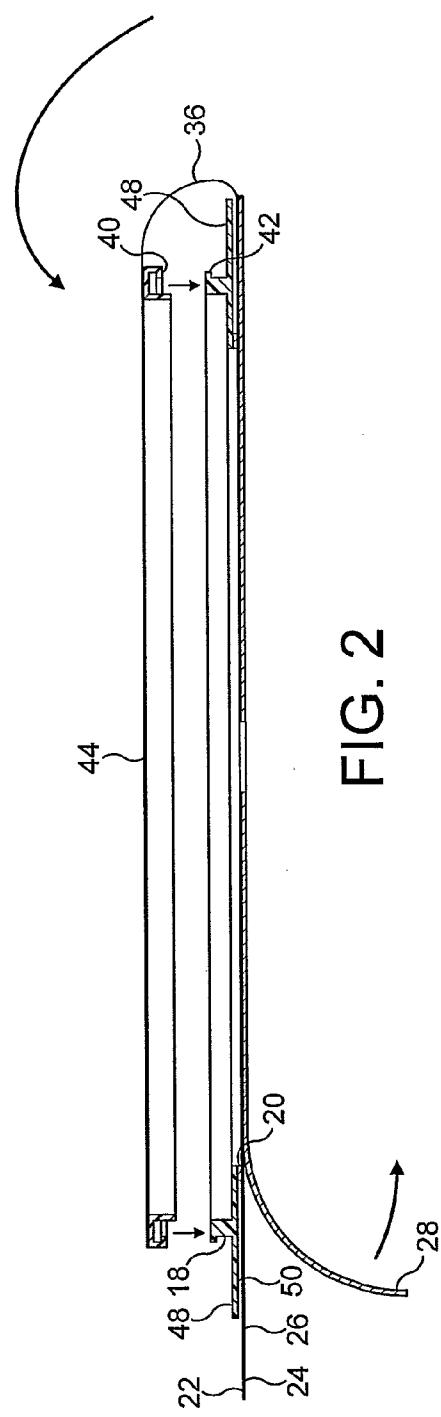
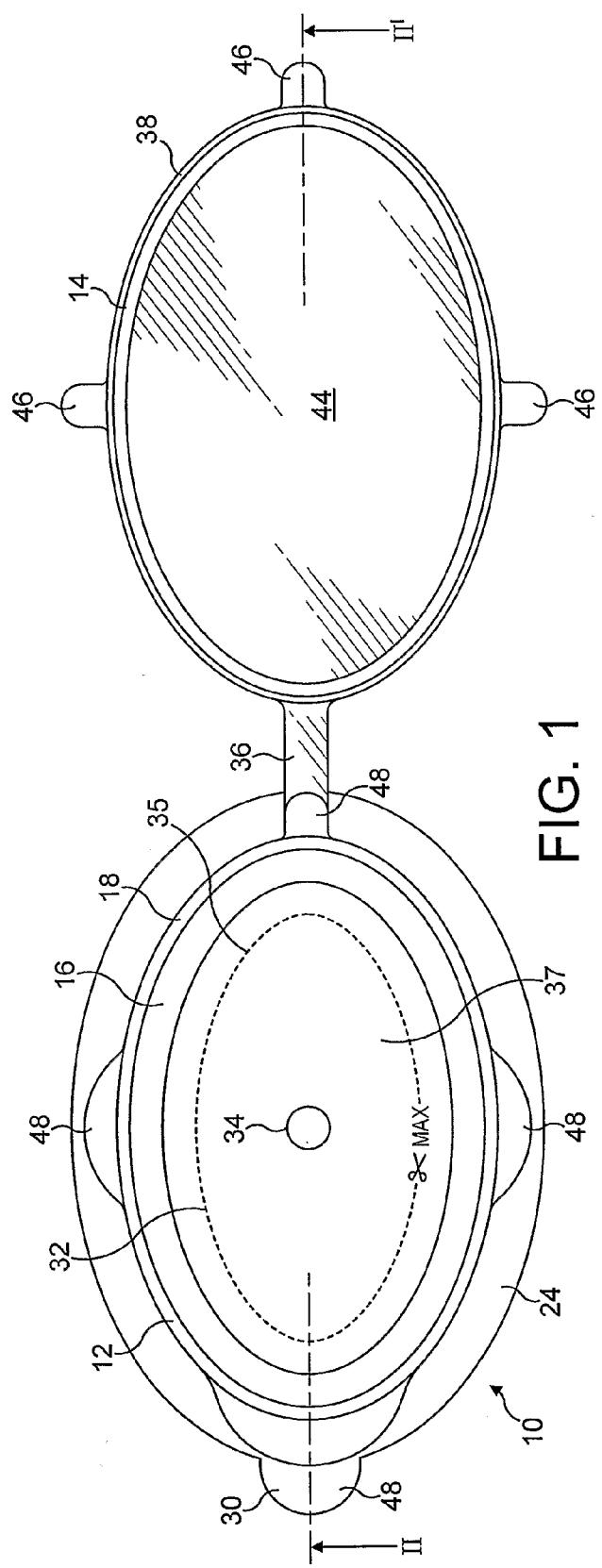
29. An access port as claimed in claim 1 wherein, the closure including an inspection window.

30. An access port as claimed in claim 1 wherein, the closure having a lower surface being spaced above the lower surface of the base

20 31. An access port substantially as described herein with reference to figures 1 to 5 or 6 and 7 of the accompanying drawings.

32. A medical bag system substantially as described herein with reference to Figures 1 to 5 or 6 and 7 of the accompanying drawings.

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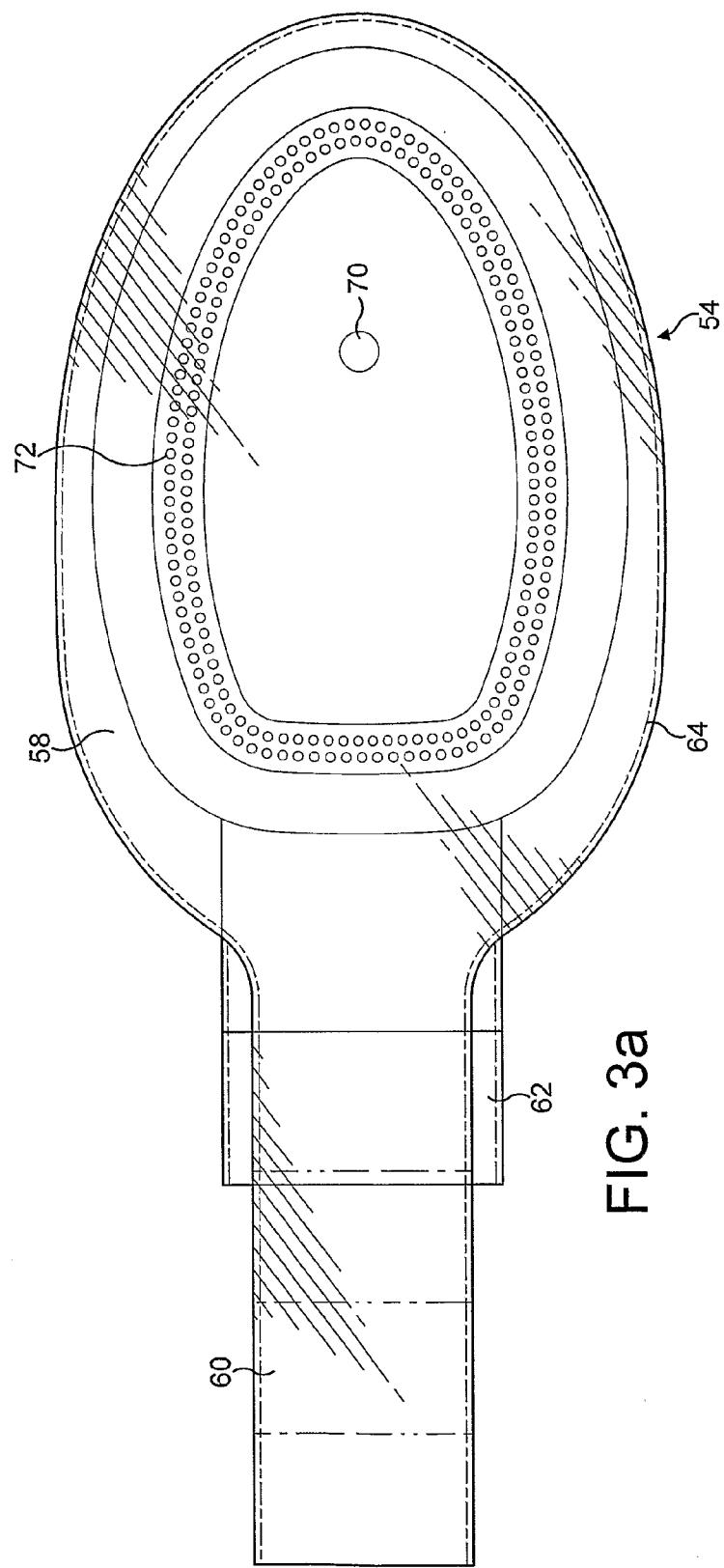


FIG. 3a

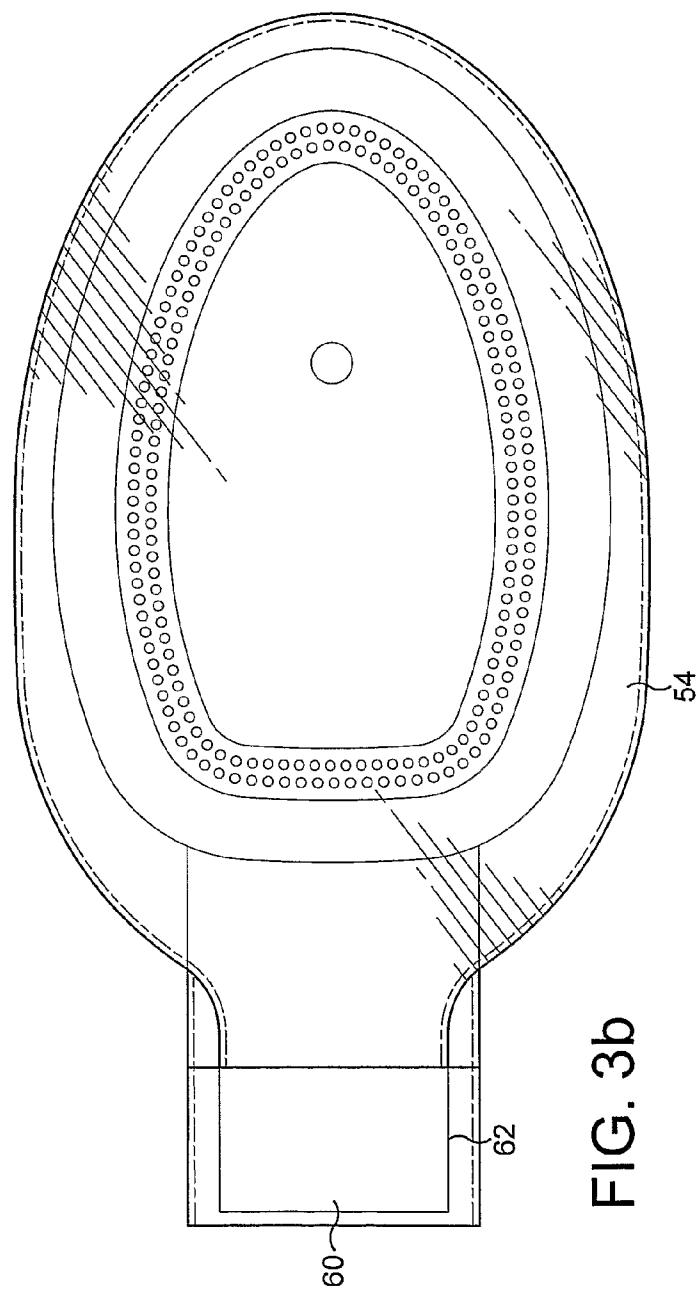
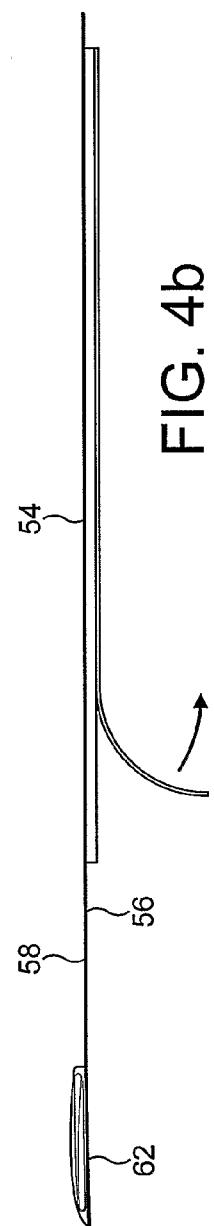
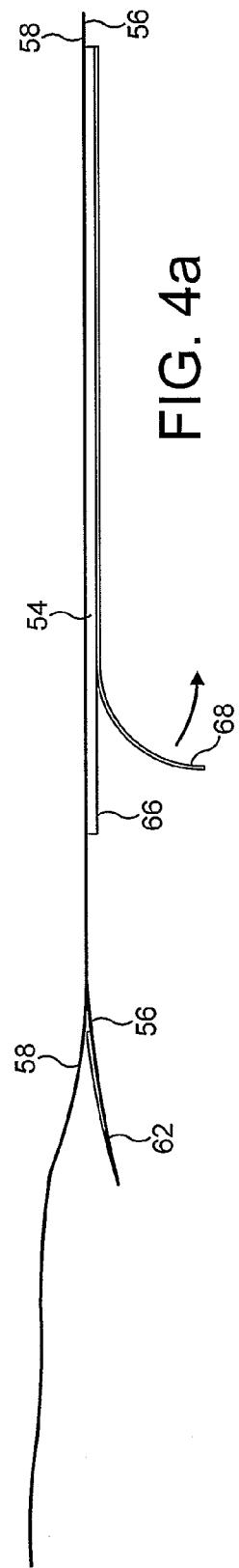
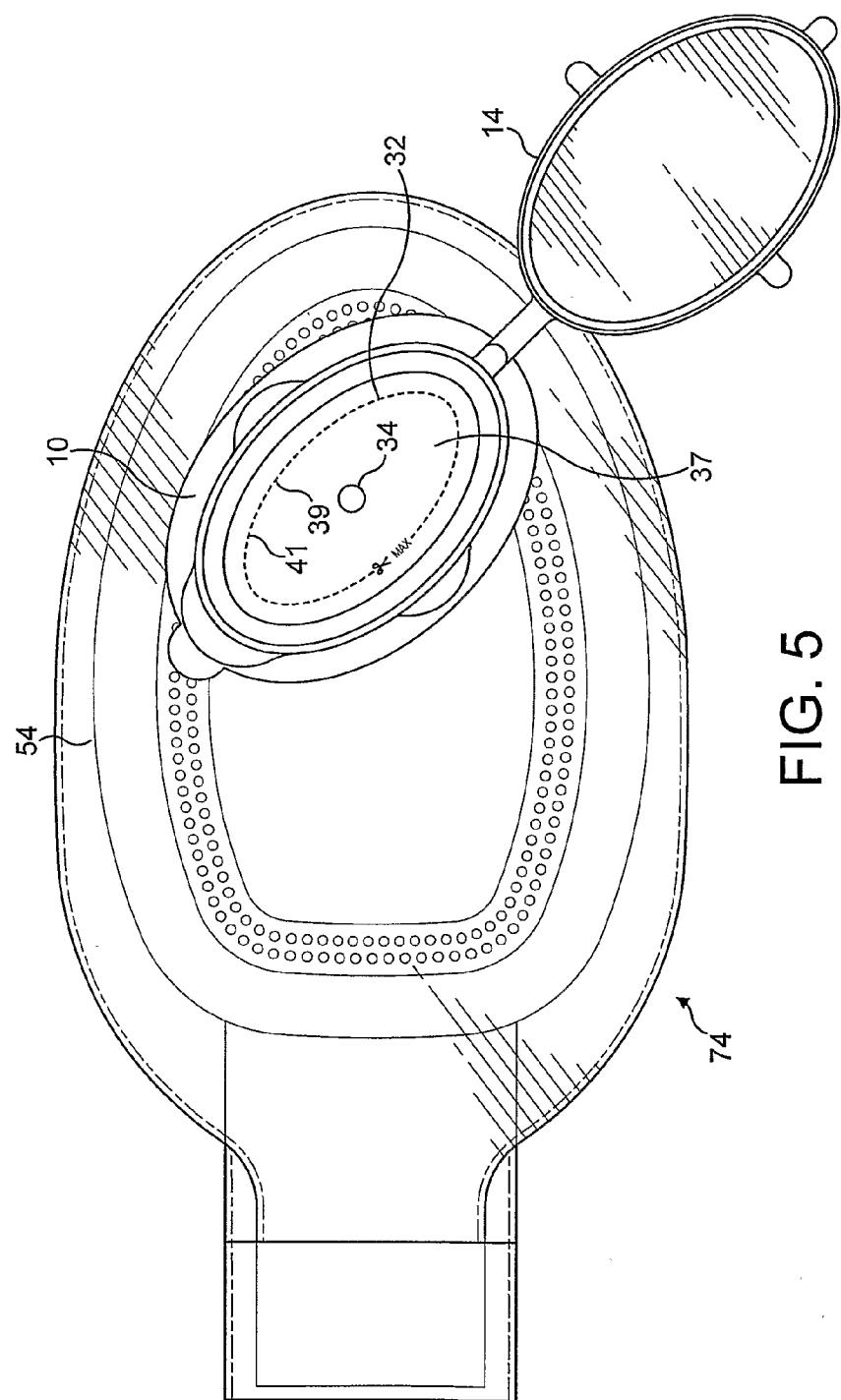


FIG. 3b





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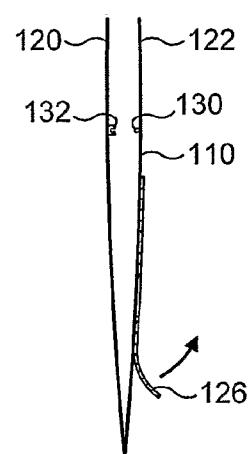
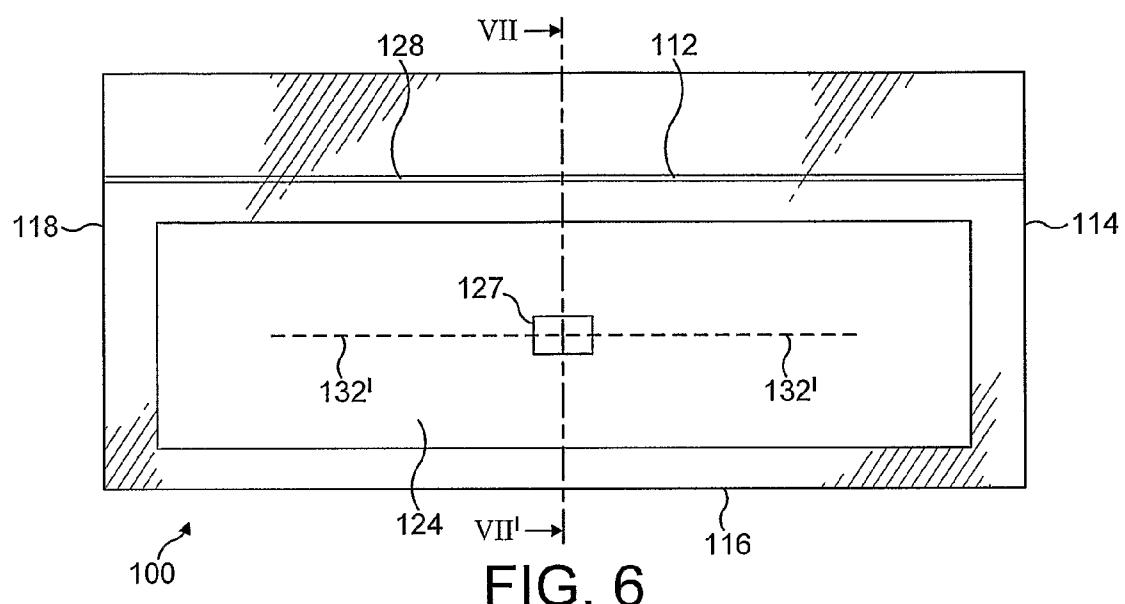


FIG. 7