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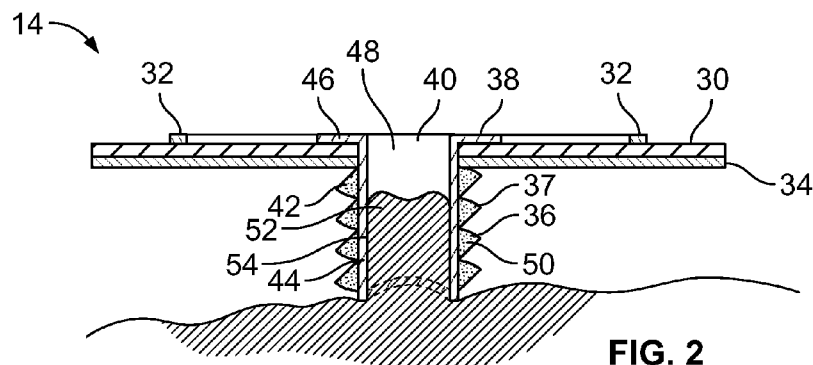


FIG. 2

(57) Abstract: A faceplate assembly for ostomy pouch systems is provided. The faceplate assembly includes a reservoir for containing a sealing material for sealing or adhering around an outer wall of a stoma and mucocutaneous junction at the stoma base. The faceplate may also include a removable sealant holder, which is configured to expose the stoma sealing material when a user withdraws the sealant holder from the faceplate assembly. Further, the removable sealant holder may facilitate raising and sealing a recessed stoma.



## OSTOMY FACEPLATE INCLUDING STOMA ADHESIVE RESERVOIR

## BACKGROUND

[0001] The present disclosure relates to a faceplate for ostomy appliances, and more particularly to a faceplate including adhesive reservoir.

[0002] An ostomy appliance or system is a medical device or prosthetic that provides a means for collecting waste from a stoma typically created as a result of a surgical procedure to divert a portion of the colon or small intestine. One type of ostomy appliance is a pouch that is attached to a user around the stoma or the peristomal area.

[0003] Two common types of pouch systems are available, a one-piece system and a two-piece system. In a one-piece system, a pouch is permanently attached to a faceplate on the opposite side of a skin barrier. The skin barrier is typically formed from a hydrophilic adhesive material that can provide a seal between the user's skin and the pouch. The pouch system is attached to a user via the skin barrier. Thus, when a user wants to replace the pouch, the entire appliance including the faceplate and the skin barrier is removed from the user.

[0004] A two-piece system also includes a faceplate and a pouch. However, the pouch and the faceplate are two separate devices, and are not permanently attached to each other. Instead, a two-piece system includes a pair of coupling rings, one of which is fixedly attached to a faceplate assembly, while the other is attached to a pouch assembly. The coupling rings are configured to mate with each other, such that the pouch assembly can be securely attached to the faceplate assembly by engaging the coupling rings together. In use, the faceplate assembly is first attached to a user via a skin barrier, and the pouch assembly is secured to the faceplate via the coupling rings. Thus, a two-piece pouch system allows a user to remove and replace the pouch without removing the faceplate that is adhered to user's skin. This can help to reduce the discomfort and irritation associated with removing skin barrier adhesive or gel from the user's skin. Typically, the faceplate is replaced with a new unit after 3 to 4 days of wear.

[0005] An ostomy pouch may be configured as a drainable pouch including a draining outlet to allow a user to empty pouch content as it gets filled with stoma output, which can be reused after closing the draining outlet. An ostomy pouch

may also be configured as a closed pouch, which is discarded after it is filled with stoma output.

**[0006]** A faceplate includes an inlet opening to receive a stoma. Leakage of stoma effluent can weaken the seal between a skin barrier and user's skin, and can irritate the peristomal skin causing skin damage and infection. Peristomal skin irritation and infection can be difficult to cure and expensive. Stoma effluent leakage can also result in accidents and user embarrassment. Thus, efforts have been made to provide a faceplate that can fit and seal around a stoma outer wall to reduce stoma effluent leakage. However, stoma effluent leakage remains as a serious problem for ostomates. Thus, any improvements to reduce the risk of stoma leakage are of great importance to ostomates. The present disclosure according to various embodiments provides an improved faceplate which seals around a stoma outer wall and its base to reduce the risk of leakage.

#### BRIEF SUMMARY

**[0007]** A faceplate assembly including a reservoir containing a sealing material for sealing around a stoma outer wall and mucocutaneous junction at the stoma base is provided according to various embodiments. The reservoir may contain a sealing material, such as an adhesive or a sealing gel for sealing around a stoma outer wall and mucocutaneous junction at the stoma base to reduce the risk of stoma effluent channeling under a skin barrier and damaging the peristomal skin. The faceplate assembly can also include a removable sealant holder, which is configured to operate with the adhesive reservoir to contain the sealing material, and allow the sealing material to come in contact with a stoma outer wall as a user withdraws the sealant holder from the faceplate assembly.

**[0008]** In one aspect, a faceplate assembly for an ostomy pouch system is provided. The faceplate assembly may include a faceplate, a skin barrier, and a reservoir for containing a sealing material or adhesive. The faceplate may include an inlet opening, a first surface and a second surface. The skin barrier may be displaced on the second surface. The reservoir may be arranged proximate the inlet opening and extend away from the second surface. The reservoir may be configured to contain a sealing material for sealing around a stoma outer wall and expose the sealing material when a stoma is received through the inlet opening.

**[0009]** In some embodiments, the reservoir may be defined by a collar, which may be attached to the faceplate and extend from the second surface. The collar may be formed from a soft flexible film, and may have an accordion-like or bellows-like shape. The faceplate assembly may also include a sealant holder, which may be removably arranged in the inlet opening. The sealant holder may include a head plate, a cylindrical wall and a center opening. In such embodiments, the reservoir may be defined between the collar and the cylindrical wall. The center opening, head plate and cylindrical wall may have a generally circular shape.

**[0010]** The sealant holder may be arranged in the inlet opening, such that the head plate seats on the faceplate about the inlet opening and the cylindrical wall is arranged adjacent the reservoir. A plurality of troughs, which have an accordion-like or bellows-like shape, may be defined between the cylindrical wall and the collar, thereby forming the reservoir. The reservoir may be filled with an adhesive or sealing gel, such as hydrophilic mucoadhesives or a waxy material, for sealing around a stoma outer wall. Once applied around the stoma, the adhesive or sealing gel may remain in place around the stoma outer wall throughout the course of use and effectively prevent stoma effluent from channeling under the skin barrier and damaging the peristomal skin.

**[0011]** The center opening of the sealant holder may be configured to receive a stoma. Further, the sealant holder may be configured such that the sealing material for sealing around a stoma outer wall is exposed as the sealant holder is withdrawn from the inlet opening and allow the sealing material to come in contact with the stoma to seal around the stoma outer wall and its base.

**[0012]** In one embodiment, the faceplate assembly according any of the above discussed embodiments may be used for a two-piece ostomy appliance. In such an embodiment, the faceplate may include a first coupling ring mounted on the first surface, which is configured to secure a pouch assembly by engaging with a second coupling ring mounted on the pouch assembly.

**[0013]** In another embodiment, the faceplate assembly according to any of the above discussed embodiments may be used for a one-piece ostomy appliance, in which a pouch may be fixedly attached to the second surface of the faceplate.

**[0014]** In another aspect, a method of attaching an ostomy appliance to a user is provided. The method includes a step of providing a faceplate assembly

including a faceplate, a skin barrier, and a reservoir. The faceplate may include an inlet opening, a first surface and a second surface. The skin barrier may be displaced on the second surface. The reservoir may be arranged proximate the inlet opening and extend away from the second surface. The reservoir may contain a sealing material for sealing around a stoma outer wall and mucocutaneous junction at the stoma base. The method also includes steps of placing the faceplate assembly on a user such that the reservoir is arranged around a stoma outer wall, and exposing the stoma sealing material in the reservoir to allow the stoma sealing material to seal around the stoma. Further, the method includes a step of adhering the skin barrier to a peristomal skin.

**[0015]** In some embodiments, the faceplate assembly may also include a removable sealant holder arranged in the inlet opening. The removal sealant holder may include a cylindrical wall and a center opening. In such embodiments, the step of exposing the stoma sealing material may include withdrawing the removable sealant holder from the inlet opening to expose the stoma sealing material. Further, the method may also include a step of pushing the sealant holder against the stoma to raise the stoma through the center opening of the sealant holder to facilitate sealing around a recessed stoma outer wall and its base.

**[0016]** Other aspects, objectives and advantages will become more apparent from the following detailed description when taken in conjunction with the accompanying drawings.

#### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

**[0017]** The benefits and advantages of the present embodiments will become more readily apparent to those of ordinary skill in the relevant art after reviewing the following detailed description and accompanying drawings, wherein:

**[0018]** FIG. 1 is a perspective illustration of a two-piece ostomy system including a pouch assembly and a faceplate assembly including an adhesive reservoir and a removable sealant holder according to an embodiment;

**[0019]** FIG. 2 is a cross sectional view of the faceplate assembly of FIG. 1 taken along line A--A;

**[0020]** FIG. 3 is a perspective view of the removable sealant holder of FIG. 2;

**[0021]** FIG. 4 is a perspective view of sealant holder according to a different embodiment;

**[0022]** FIG. 5 is a cross sectional view of a one-piece drainable ostomy pouch system including a reservoir assembly according to an embodiment; and

**[0023]** FIG. 6 is a cross sectional view of a one-piece disposable ostomy pouch system including a reservoir assembly according to a different embodiment.

## DETAILED DESCRIPTION

**[0024]** While the present disclosure is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described a presently preferred embodiment with the understanding that the present disclosure is to be considered an exemplification and is not intended to limit the disclosure to the specific embodiment illustrated.

**[0025]** FIG. 1 is an illustration of a two-piece ostomy system 10 according to an embodiment. The two-piece ostomy system 10 includes a pouch assembly 12 and a faceplate assembly 14. The pouch assembly 12 includes a collection pouch 16 which may be formed of a body side panel 18 and an outer panel 20, which are sealed together around their periphery 22. The pouch 16 may include an open neck portion 24 at the pouch's lower end, which may be provided with closure means, such as a suitable clamp for maintaining the pouch in a closed condition. In another embodiment, the neck portion 24 may be omitted entirely and the panels 18, 20 may be sealed around the full periphery of the pouch 16. The pouch assembly 12 may also include a first coupling ring 26, which may be secured to the body side panel 18 of the pouch 16 by heat sealing or any other suitable means.

**[0026]** As shown in FIGS. 1 and 2, the faceplate assembly 14 generally includes a faceplate 30, a second coupling ring 32, a skin barrier 34, a reservoir 36, and a removable sealant holder 38. FIG. 2 is a cross sectional illustration of the faceplate assembly 14 taken along line A--A. The faceplate 30 may be formed of a gas-permeable, water-resistant microporous material. Preferably, the faceplate 30 is highly flexible, so that it will conform readily to body contours and body movements, and relatively strong and durable.

**[0027]** The skin barrier 34 may be formed of a suitable pliable and tacky material capable of engaging and adhering to the peristomal skin. Such barrier materials are well known in the art. For example, the skin barrier 34 may be formed of a medical-grade pressure sensitive adhesive that can adhesively secure the faceplate assembly 14 to a patient's skin in the peristomal region.

**[0028]** The second coupling ring 32 may be mounted on the faceplate 30. The first coupling ring 26 and the second coupling ring 32 are configured to mate with each other, such that the pouch assembly 12 may be mechanically secured to the faceplate assembly 14 when the coupling rings 26, 32 are engaged together.

**[0029]** The faceplate assembly 14 also includes an inlet opening 40 for receiving a stoma 52, which may be sized to fit around a stoma outer wall 54. As shown in FIG. 2, the reservoir 36 is arranged proximate the inlet opening 40 and configured to contain a material 50 for sealing around the stoma outer wall 54. In this embodiment, the reservoir 36 is defined by an accordion-like or bellows-like collar 37, which may be attached to the faceplate 30. As shown in FIG. 2, accordion-like or bellows-like troughs 42 are defined between the collar 37 and the removable sealant holder 38, in which a material for sealing around the stoma outer wall 54, such as a suitable adhesive, sealant, or sealing gel, may be contained. The accordion-like collar 37 may be formed using a suitable soft flexible film.

**[0030]** The sealant holder 38 is removably arranged in the inlet opening 40. FIG. 3 is an illustration of the sealant holder 38 according an embodiment. As shown in FIGS. 1-3, the sealant holder 38 includes a cylindrical wall 44, a circular head plate 46, and a center opening 48. The sealant holder 38 is arranged in the inlet opening 40, such that the circular head plate 46 seats on the faceplate 30 about the inlet opening 40, and the cylindrical wall 44 is displaced adjacent the collar 37, such that the accordion-like troughs 42 are formed between the collar 37 and the cylindrical wall 44.

**[0031]** A material suitable for sealing around the stoma outer wall 54 may be filled in the accordion troughs 42. For example, a biocompatible adhesive or sealing gel, such as a mucoadhesive or a waxy material. Other biocompatible materials that do not get mushy or fall apart when exposed to stoma effluent during use, such as a silicone formulation, may also be suitable. An adhesive or sealing gel may be loaded into the accordion-like troughs 42 during manufacturing of the faceplate assembly 14, or by a user prior to donning the faceplate assembly 14. Thus,

a wide variety of tissue adhesives and gels may be used to fill the reservoir 36. The sealant holder 38 may be configured to operate with the accordion-like collar 37 to contain an adhesive in the accordion-like troughs 42, and prevent the accordion-like troughs 42 from prematurely collapsing during manufacturing, shipping and handling prior to donning of the faceplate assembly 14.

**[0032]** In use, the faceplate assembly 14 is placed on a user, such that the center opening 48 of the sealant holder 38 is arranged over the stoma outer wall 54. Thus, when a user pushes the sealant holder 38 against the stoma 52, the stoma 52 is raised through the center opening 48. As such, by using the sealant holder 38, a recessed stoma can be pushed out and raised through the center opening 48 to facilitate sealing of the recessed stoma. As the stoma 52 is raised through the center opening 48, the sealant holder 38 is slowly withdrawn from the inlet opening 40, which exposes an adhesive or sealant contained in the accordion-like troughs 42, allowing the adhesive or sealant to come in contact with and seal around the stoma outer wall 54. When the sealant holder 38 is completely withdrawn, the adhesive in the accordion-like troughs 42 is fully exposed to the stoma outer wall 54 to provide a good seal around the stoma 52 and its base to isolate the stoma 52 from the surrounding peristomal skin without blocking the stoma orifice. Once the sealant holder 38 is completely removed, and the faceplate assembly 14 is adhesively attached to the user via the skin barrier 34.

**[0033]** Some users may prefer pulling the sealant holder 38 and pressing the skin barrier 34 against the peristomal skin almost simultaneously or in small sequential steps. For example, a user may pull the sealant holder 38 little and push the skin barrier 34 little, and repeat these steps until the sealant holder 38 is completely removed and the skin barrier 34 is secured on the peristomal skin. Subsequently, the pouch assembly 12 is attached to the faceplate assembly 14 by engaging the coupling rings 26, 32.

**[0034]** Although the reservoir in this embodiment is defined by the accordion-like collar, in other embodiments, a reservoir can be formed in different shapes to contain a stoma sealing material. Further, a sealant holder may come in different shapes and sizes. For example, a sealant holder may be generally oval shaped.

**[0035]** A one-piece pouch system may also include such a reservoir. FIG. 5 is a cross sectional illustration of a one-piece drainable pouch system including

a reservoir assembly according to an embodiment. The one-piece pouch system 100 includes a pouch 102, a skin barrier 104, and a reservoir assembly 106. The pouch 102 is a drainable pouch including a drain opening 130. The reservoir assembly 106 is arranged proximate an inlet opening 108 defined in the pouch 102.

[0036] The reservoir assembly 106 may include a sealant holder 110, an accordion-like or bellows like collar 112, and accordion-like or bellows-like troughs 114 defined between the sealant holder 110 and the collar 112. The troughs 114 may be filled with a material for sealing around a stoma outer wall, such as a mucoadhesive, a gel material, or a biocompatible material which does not get mushy or fall apart when exposed to stoma effluent during use. FIG. 4 is an illustration of the sealant holder 110. As shown, the sealant holder 110 may include a cylindrical wall 116, a circular head plate 118, and an opening 120 defined in the head plate 118 and extending through the cylindrical wall 116. The cylindrical wall 116 may be attached to the circular head plate 118 along a snap-off joint 122. The cylindrical wall 116 may also include a bottom surface 124, on which one or more opening may be provided for equalizing pressure to prevent vacuum suction effect when cylindrical wall 116 portion is snapped off and removed after a stoma has been received through the cylindrical wall 116. The sealant holder 110 may also be provided with a string 128 for pulling and removing the cylindrical wall 116 portion of the sealant holder 110. The snap-off joint 122 is a weak joint configured to break and detach the cylindrical wall 116 portion from the circular head plate 118 upon a pulling force.

[0037] In use, a user can press the skin barrier 104 against the base of a stoma to attach the one-piece pouch system 100, wherein the stoma is received through the opening 108 and through the cylindrical wall 116. If needed, the user can push the sealant holder 110 against the peristomal area to facilitate placement of the stoma through the cylindrical wall 110. Once the stoma is received through the sealant holder opening 108, the user can access the string 128 through the opening 130 and pull the string 128 to snap off and detach the cylindrical wall 116 portion of the sealant holder 110, thereby exposing the stoma sealing material in the troughs 114 to seal around the stoma outer wall.

[0038] FIG. 6 is a cross sectional illustration a disposable one-piece pouch system 200 including a reservoir assembly 206 according to an embodiment. The disposable one-piece pouch system 200 and the reservoir assembly 206 are similar to the drainable one-piece pouch system 100 and the reservoir assembly 106

except a pouch 202 is closed pouch without a drain opening. Thus, a string 228 of a sealant holder 210 is attached to a bottom portion 230 of the pouch 202. Thus, in use, a user may snap off a cylindrical wall portion 216 of the sealant holder 210 by pulling the bottom portion of the pouch 202 to expose a stoma sealing material in troughs 214. In this embodiment, the cylindrical wall portion 216 may be formed from a softer or less rigid material than the sealant holder 38, 110 of the previously described embodiments to minimize discomfort of a user from the cylindrical wall portion 216 remaining in the pouch 202 during use. An example of such a softer material suitable for the cylindrical portion 216 is silicone. The cylindrical wall portion 216 may also be formed from a material that becomes softer when exposed to stoma output, such as polyvinyl alcohol (PVOH).

**[0039]** All patents referred to herein, are hereby incorporated herein in their entirety, by reference, whether or not specifically indicated as such within the text of this disclosure.

**[0040]** In the present disclosure, the words “a” or “an” are to be taken to include both the singular and the plural. Conversely, any reference to plural items shall, where appropriate, include the singular.

**[0041]** From the foregoing it will be observed that numerous modifications and variations can be effectuated without departing from the true spirit and scope of the novel concepts of the present invention. It is to be understood that no limitation with respect to the specific embodiments illustrated is intended or should be inferred. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

## CLAIMS

What is claimed is:

1. A faceplate assembly for an ostomy pouch system, comprising:  
a faceplate including an inlet opening, a first surface and a second surface;  
a skin barrier displaced on the second surface; and  
a reservoir arranged proximate the inlet opening and extending away from the second surface, wherein the reservoir is configured to contain a sealing material for sealing around a stoma outer wall and expose the sealing material when a stoma is received through the inlet opening.
2. The faceplate assembly of claim 1, wherein the reservoir is defined by a collar, wherein the collar is attached to the faceplate and extending from the second surface.
3. The faceplate assembly of claim 2, wherein the collar is formed from a soft flexible film and has an accordion-like shape.
4. The faceplate assembly of any of claims 1-3, further including a sealant holder removably arranged in the inlet opening, wherein the sealant holder includes a head plate, a cylindrical wall and a center opening.
5. The faceplate assembly of claim 4, wherein the reservoir is defined between the collar and the cylindrical wall.
6. The faceplate assembly of any of claims 4-5, wherein the sealant holder includes a circular center opening, a circular head plate and a circular cylindrical wall.
7. The faceplate assembly of any of claims 4-6, wherein the sealant holder is arranged such that the head plate seats on the faceplate about the inlet opening and the cylindrical wall is arranged adjacent the reservoir.

8. The faceplate assembly of claim 5, wherein a plurality of troughs having an accordion-like shape are defined between the cylindrical wall and the collar, thereby forming the reservoir.

9. The faceplate assembly of any of claims 1-8, wherein the reservoir is filled with a sealing material for sealing around a stoma outer wall, wherein the sealing material is a gel, sealant, and/or mucoadhesive.

10. The faceplate assembly of any of claims 4-9, wherein the center opening of the sealant holder is configured to receive a stoma, and the sealant holder is configured such that the sealing material is exposed as the sealant holder is withdrawn from the inlet opening and allow the sealing material to come in contact with the stoma to seal around an outer wall of the stoma.

11. The faceplate assembly of any of claims 1-10, wherein the faceplate assembly is for a two-piece ostomy appliance and comprises a first coupling ring mounted on the first surface, wherein the first coupling ring is configured to secure a pouch assembly including a second coupling by engaging with the second coupling ring.

12. The faceplate assembly of any of claims 1-10, wherein the faceplate assembly is for a one-piece ostomy appliance, and comprises a pouch attached to the second surface.

13. A method of attaching an ostomy appliance to a user, comprising the steps of:

providing a faceplate assembly, the faceplate assembly comprising;

a faceplate including an inlet opening, a first surface, and a second surface;

a skin barrier displaced on the second surface; and

a reservoir arranged proximate the inlet opening and extending away from the second surface, the reservoir containing a sealing material;

placing the faceplate assembly on a user such that the reservoir is arranged around a stoma outer wall;

exposing the sealing material and allowing the sealing material to seal around the stoma outer wall; and  
adhering the skin barrier to a peristomal skin.

14. The method of claim 13, wherein the faceplate assembly further includes a removable sealant holder arranged in the inlet opening, the removal sealant holder including a cylindrical wall and a center opening, wherein the removable sealant holder is withdrawn from the inlet opening to expose the sealing material.

15. The method of claim 14, further including pushing the sealant holder against the stoma to raise the stoma through the center opening of the sealant holder.

16. A one-piece ostomy pouch system comprising:  
a pouch including an inlet opening and a cavity;  
a skin barrier attached to the pouch around the inlet opening;  
a reservoir assembly arranged proximate the inlet opening and extending into the cavity, wherein the reservoir assembly is configured to contain a sealing material and expose the sealing material when a stoma is received through the inlet opening.

17. The one-piece ostomy pouch system of claim 16, wherein the reservoir assembly includes a sealant holder, a collar, and troughs, wherein the troughs are defined between the sealant holder and the collar, wherein the troughs contain a sealing material.

18. The one-piece ostomy pouch system of claim 17, wherein the collar is formed from a soft flexible film and has an accordion-like shape.

19. The one-piece ostomy pouch system of any of claims 17-18, wherein the sealant holder includes a head plate and a cylindrical wall portion, wherein the cylindrical wall is attached to the head plate via a snap-off joint, wherein the snap-off joint is configured to break and detach the cylindrical wall portion from the head plate when force is applied.

20. The one-piece ostomy pouch system of claim 19, further including a string attached to the cylindrical wall portion, wherein the cylindrical wall portion is configured to snap-off and detach from the head plate when the string is pulled to apply pulling force.

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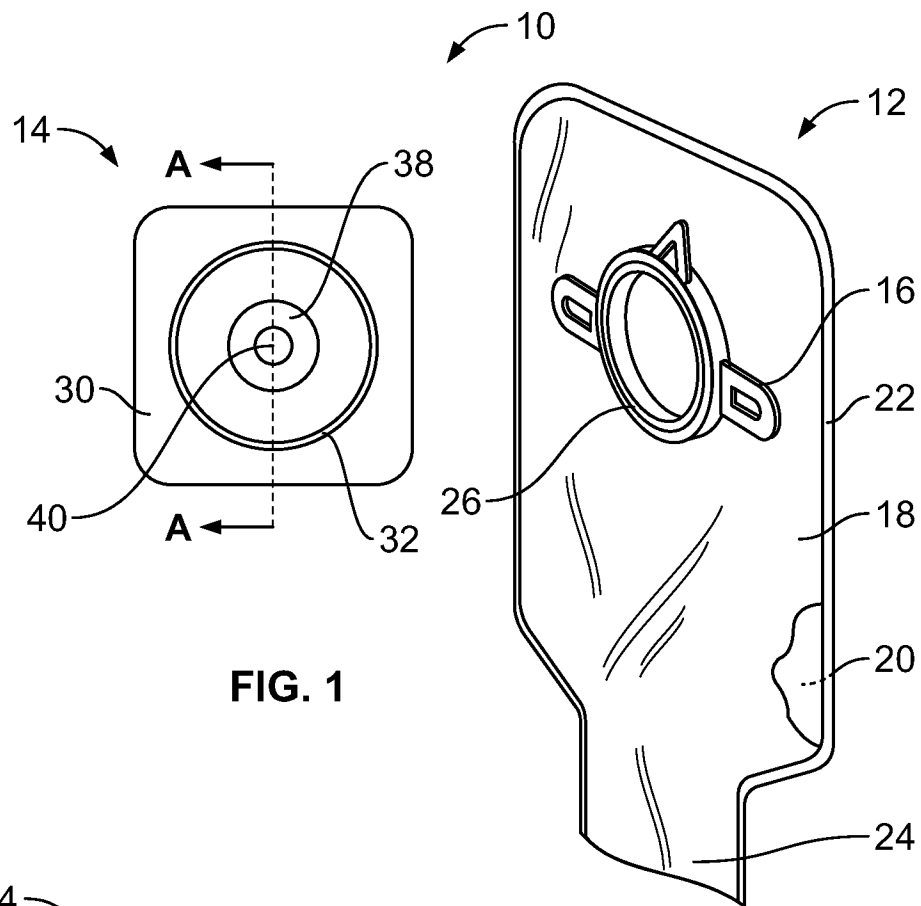


FIG. 1

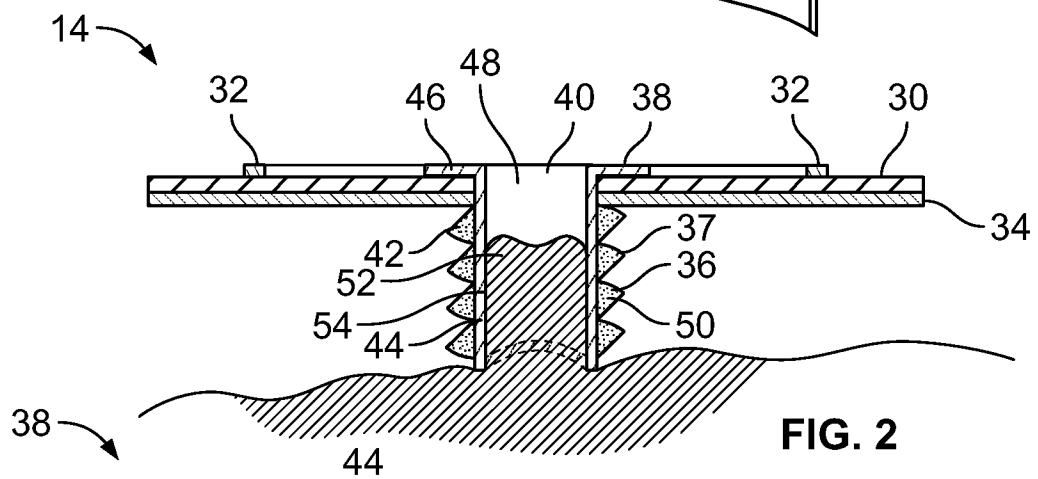


FIG. 2

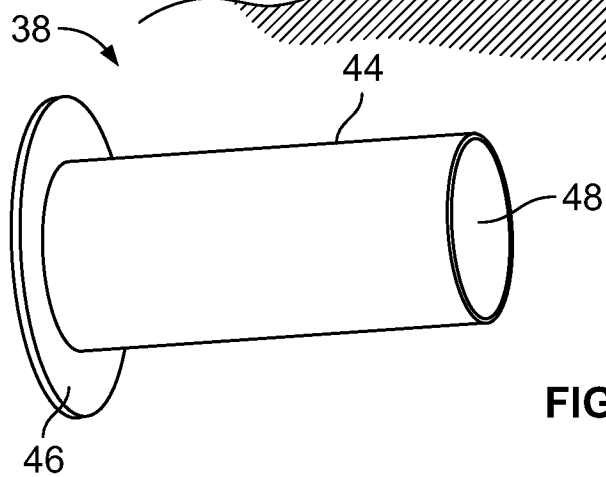
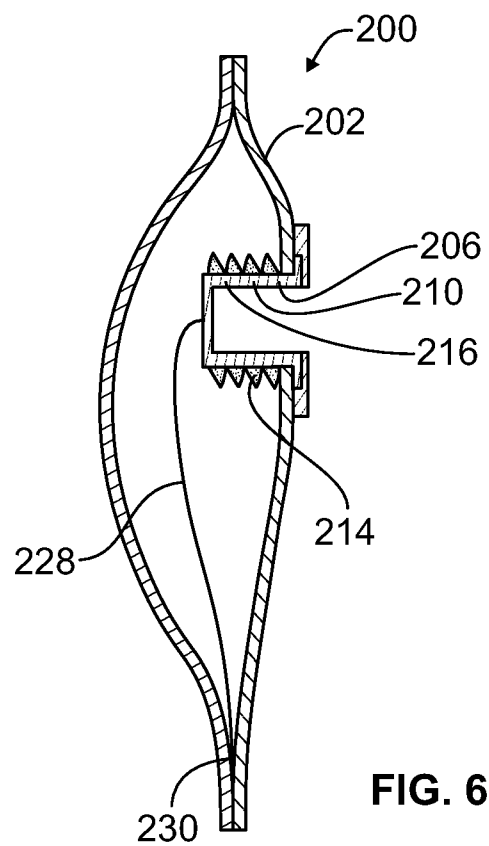
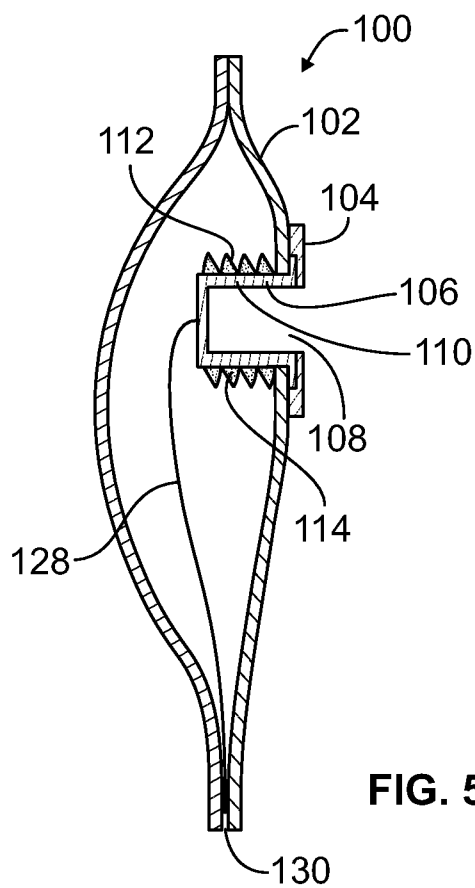
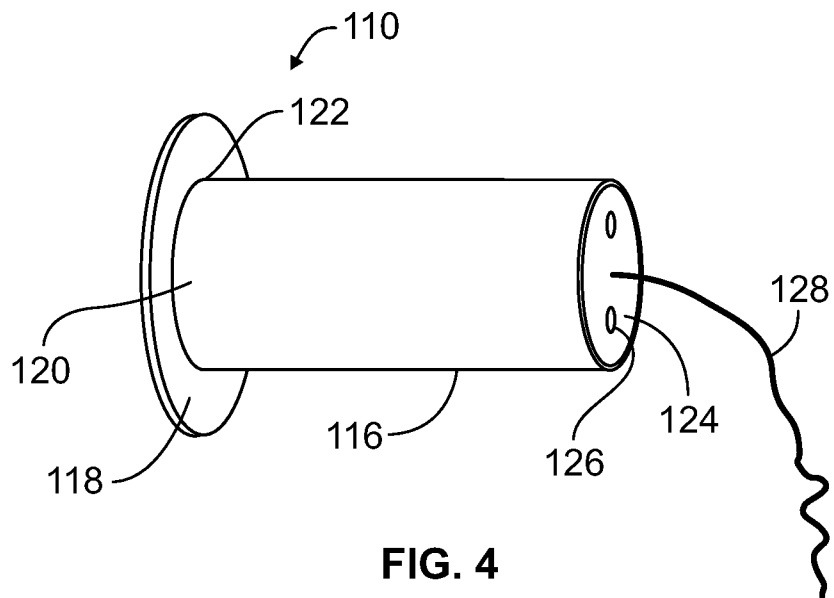


FIG. 3

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## INTERNATIONAL SEARCH REPORT

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| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>INV. A61F5/44 A61F5/443 A61F5/445<br>ADD.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                 |                                                                      |
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| According to International Patent Classification (IPC) or to both national classification and IPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                 |                                                                      |
| <b>B. FIELDS SEARCHED</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                 |                                                                      |
| Minimum documentation searched (classification system followed by classification symbols)<br>A61F                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                 |                                                                      |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                      |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>EPO-Internal                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                 |                                                                      |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                 |                                                                      |
| Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Citation of document, with indication, where appropriate, of the relevant passages                              | Relevant to claim No.                                                |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | US 3 805 789 A (MARSAN A)<br>23 April 1974 (1974-04-23)                                                         | 16                                                                   |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | column 3, line 66 - column 6, line 59;<br>figures 11-21                                                         | 1-15,<br>17-20                                                       |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | -----<br>US 5 125 916 A (PANEBIANCO THOMAS [US] ET<br>AL) 30 June 1992 (1992-06-30)<br>abstract; figures 1-4    | 1-15,<br>17-20                                                       |
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| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                 |                                                                      |
| * Special categories of cited documents :<br>"A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed<br>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<br>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone<br>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art<br>"&" document member of the same patent family |                                                                                                                 |                                                                      |
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