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Shulman et al.

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(54) **VENTED EMERGENCY WOUND DRESSINGS**

USPC 602/41, 42, 47, 48, 52, 54, 57-59;
604/304-307, 122

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See application file for complete search history.

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(Continued)

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filed on Mar. 26, 2010, now abandoned.

(60) Provisional application No. 61/915,198, filed on Dec.
12, 2013, provisional application No. 61/163,613,
filed on Mar. 26, 2009.

(57) **ABSTRACT**

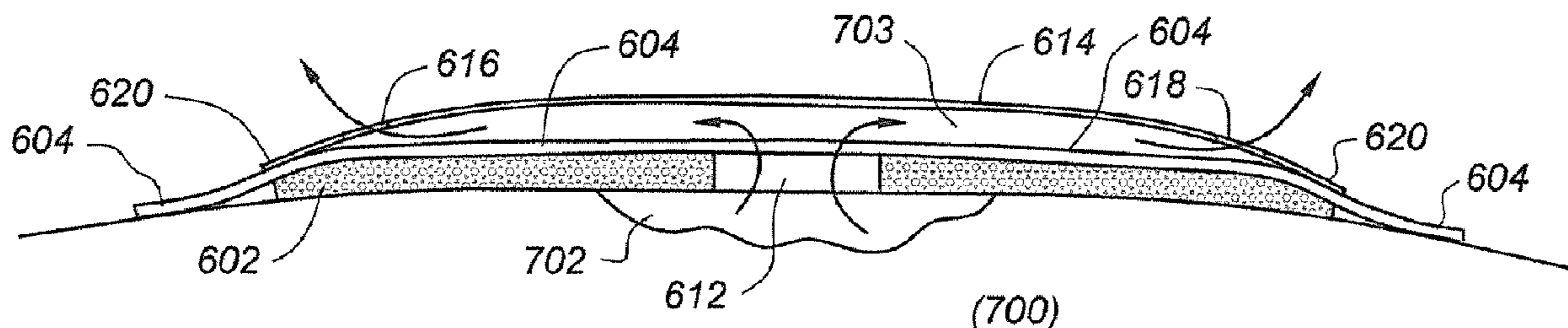
A wound dressing provides a tenacious occlusive seal against the skin of a wearer, even in the presence of excessive blood or heavy perspiration. The preferred embodiment combines an adhesive backing layer with a hydrogel island providing superior hydrophilic gel adhesion. The product performs under extreme temperatures (i.e., 32-140° F.), and may be used to hold other dressings in place. The preferred embodiments are entirely translucent, and include a large pull-tab for easy removal. Two dressings may be packaged in a pliable re-sealable protective pouch, thereby forming a portable "kit." Different "vented" embodiments are disclosed. A preferred structure includes a cover layer peripherally bonded to backing and hydrogel layers having a central aperture therethrough. The cover layer has one or more vent holes, and pressure is released through the central aperture and out the vent hole(s).

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(2013.01)

(58) **Field of Classification Search**
CPC A61F 13/023; A61F 13/0266

17 Claims, 8 Drawing Sheets



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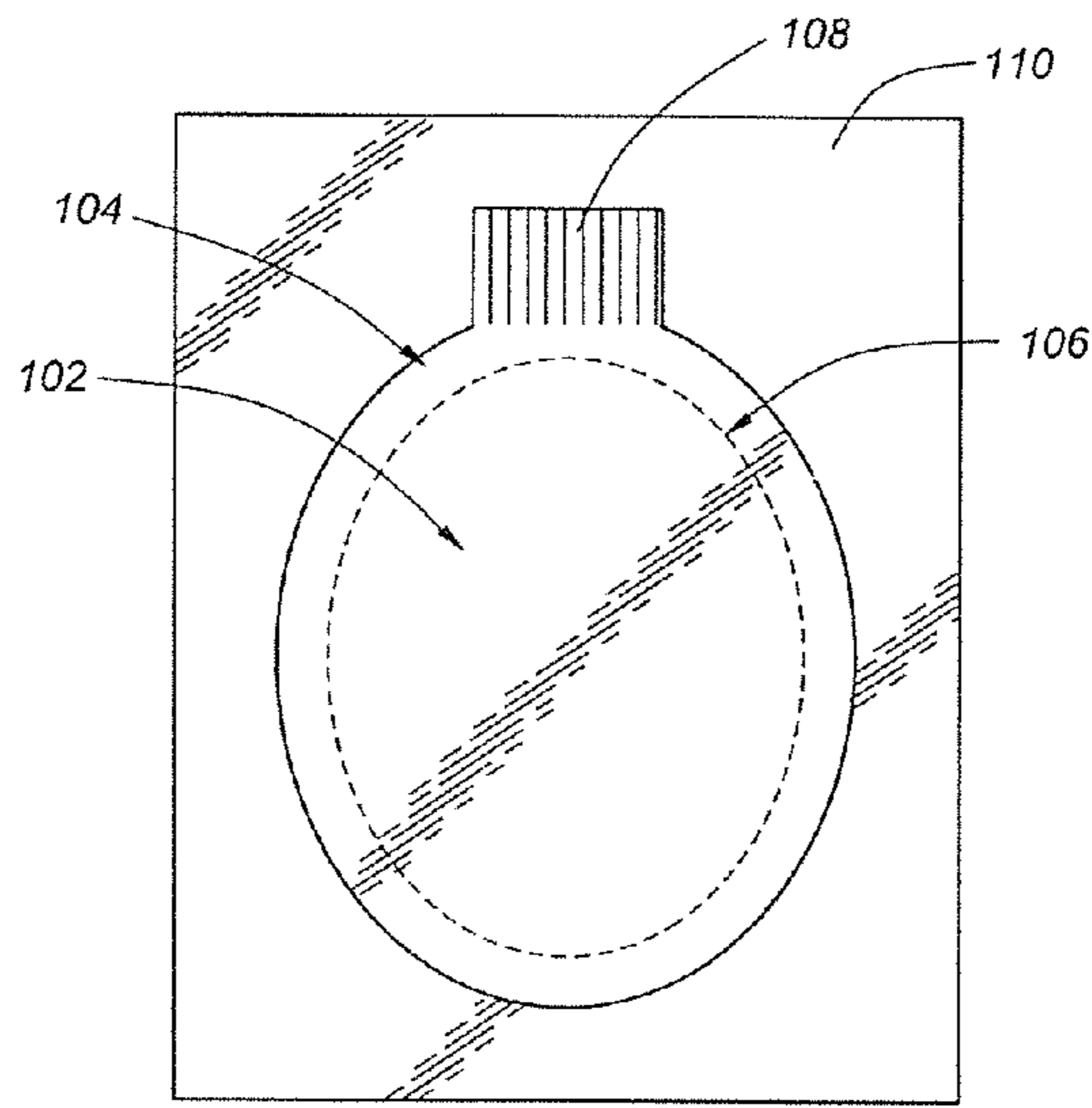


Fig - 1

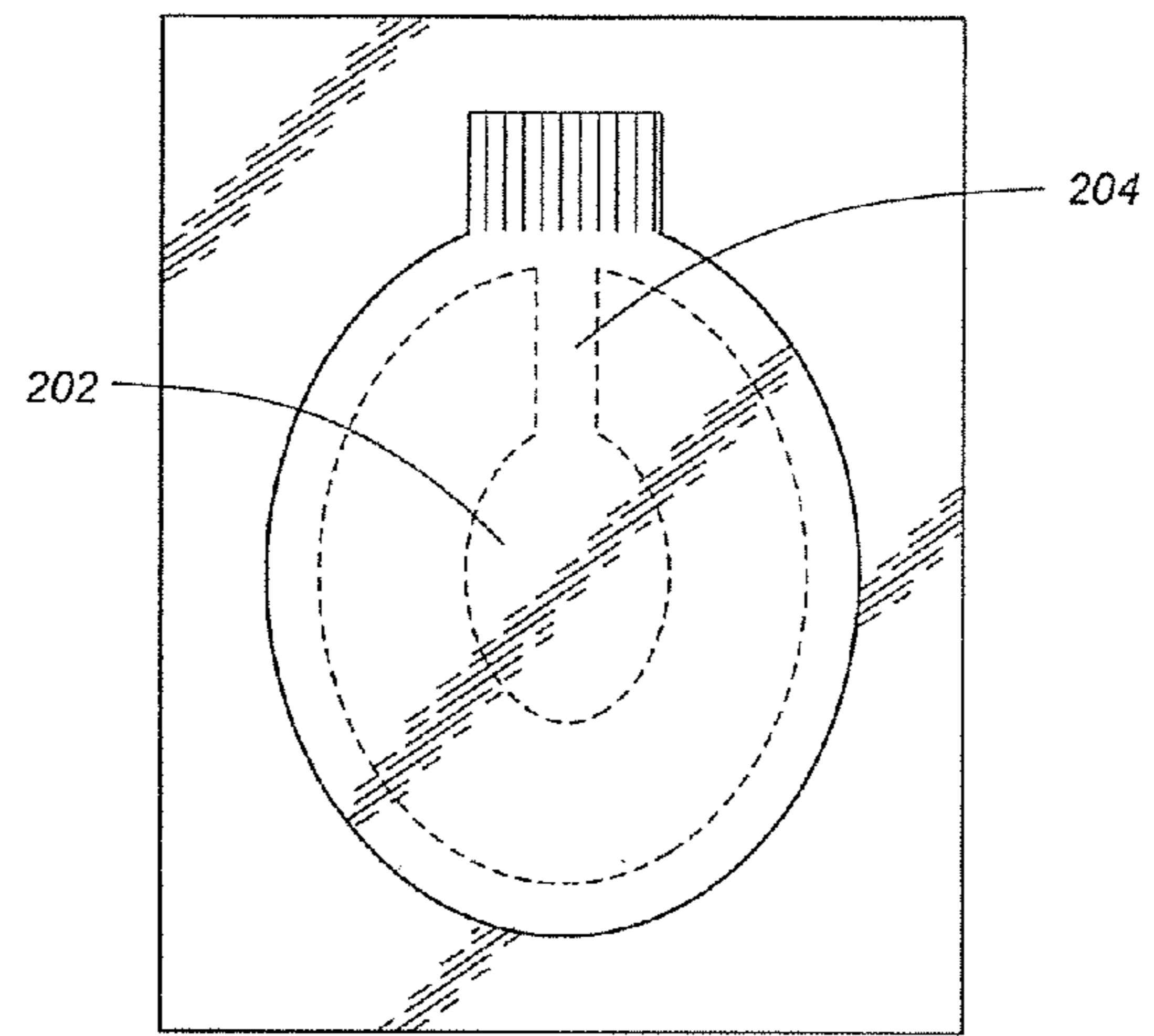


Fig - 2

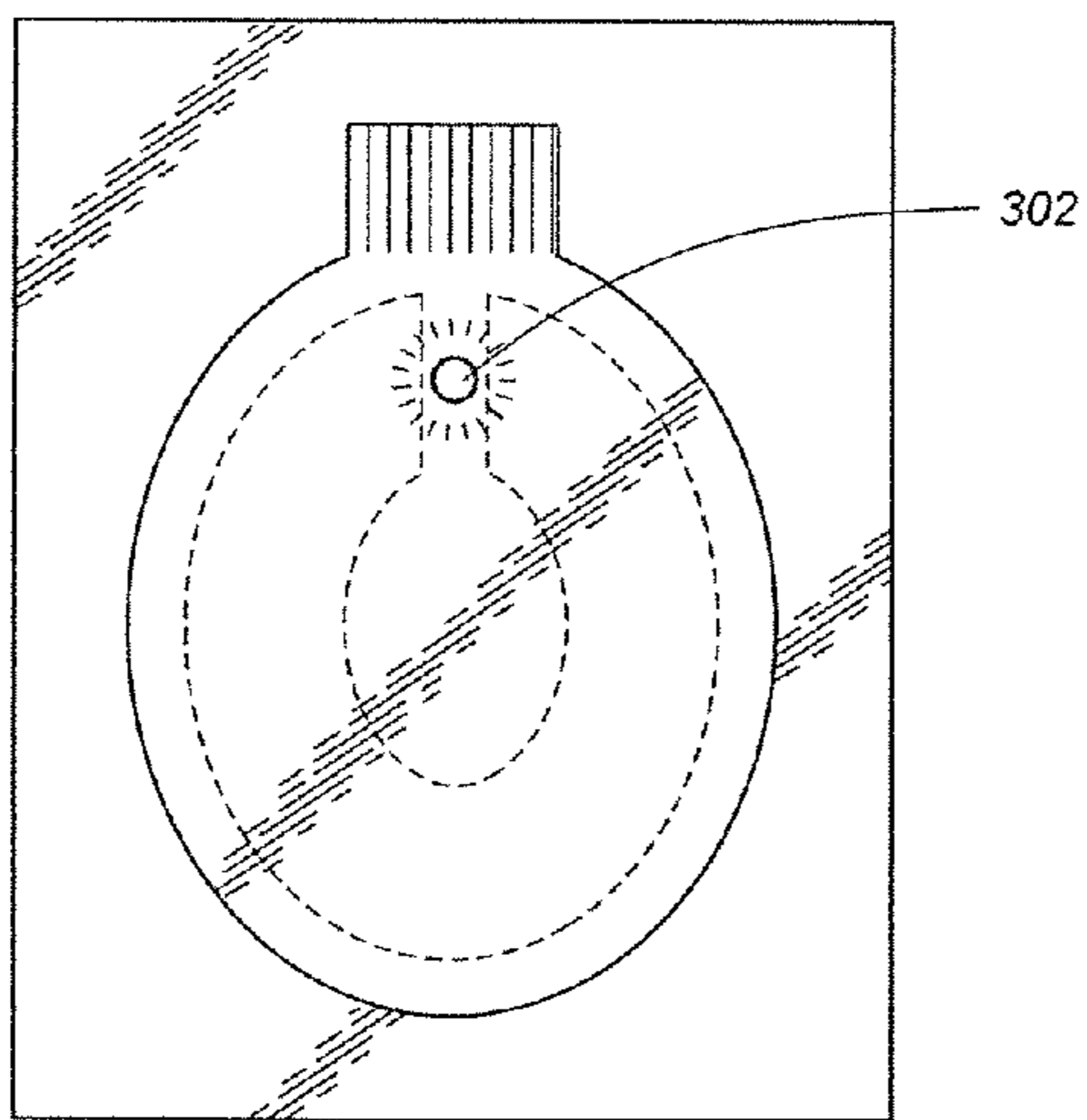
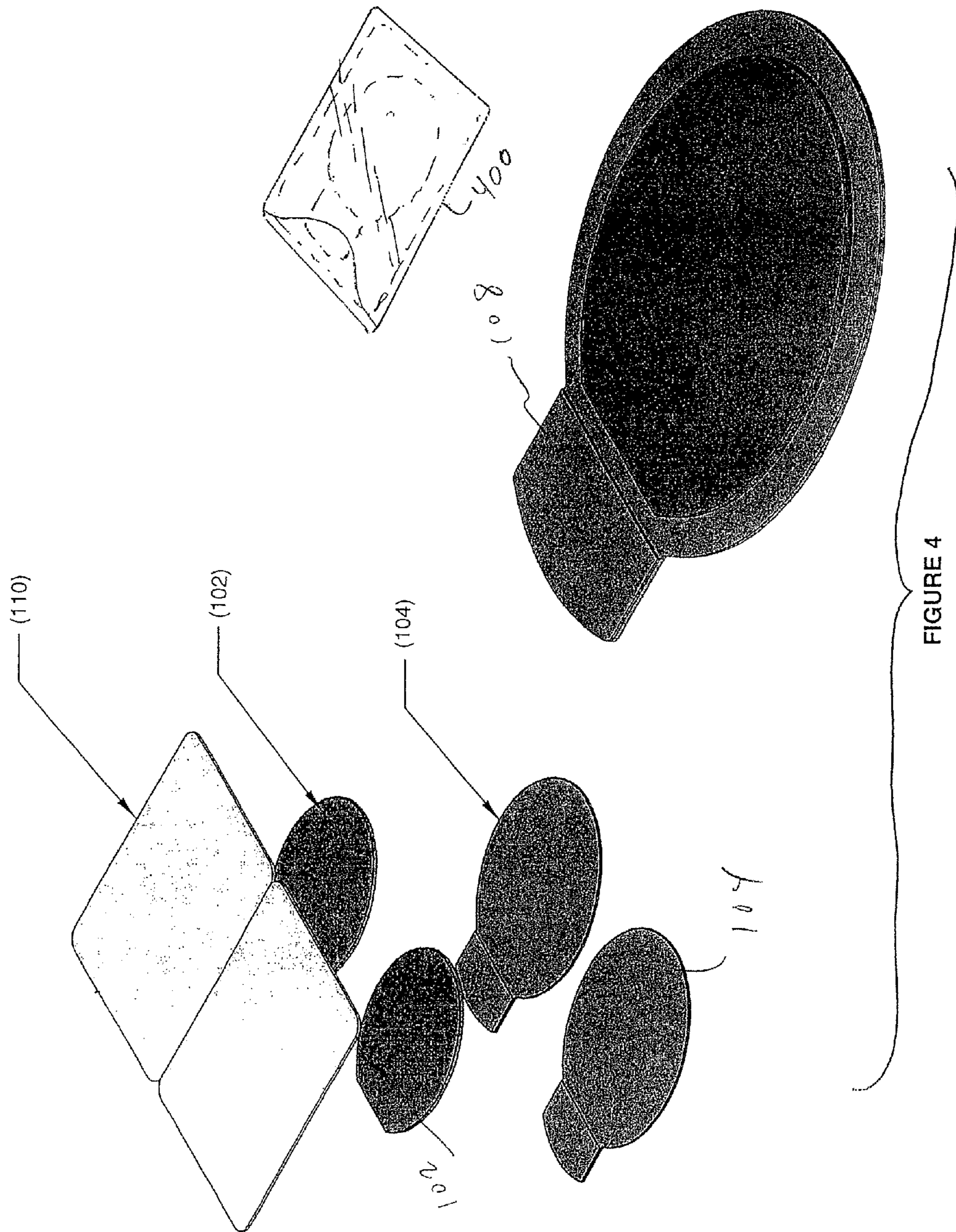


Fig - 3



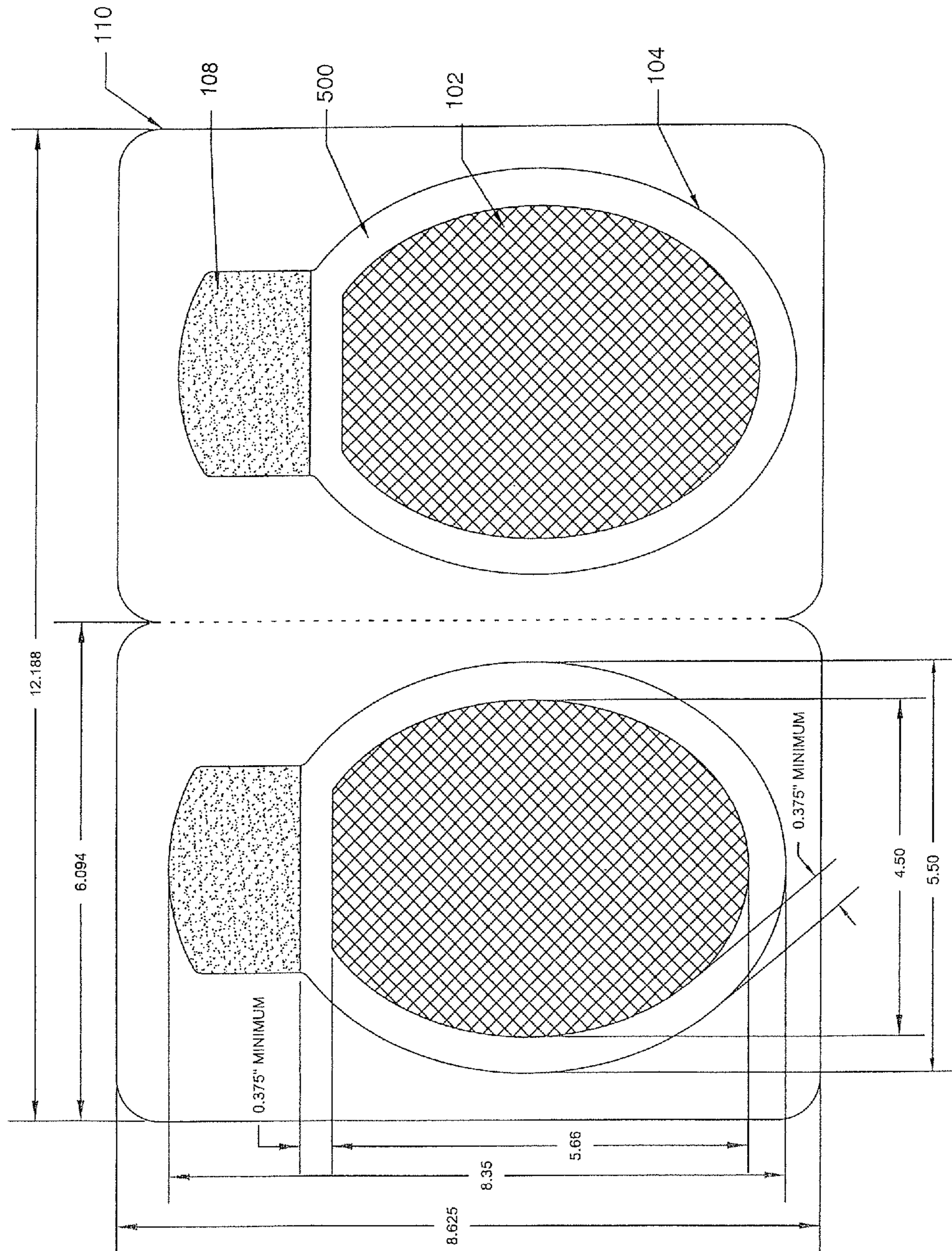


FIGURE 5

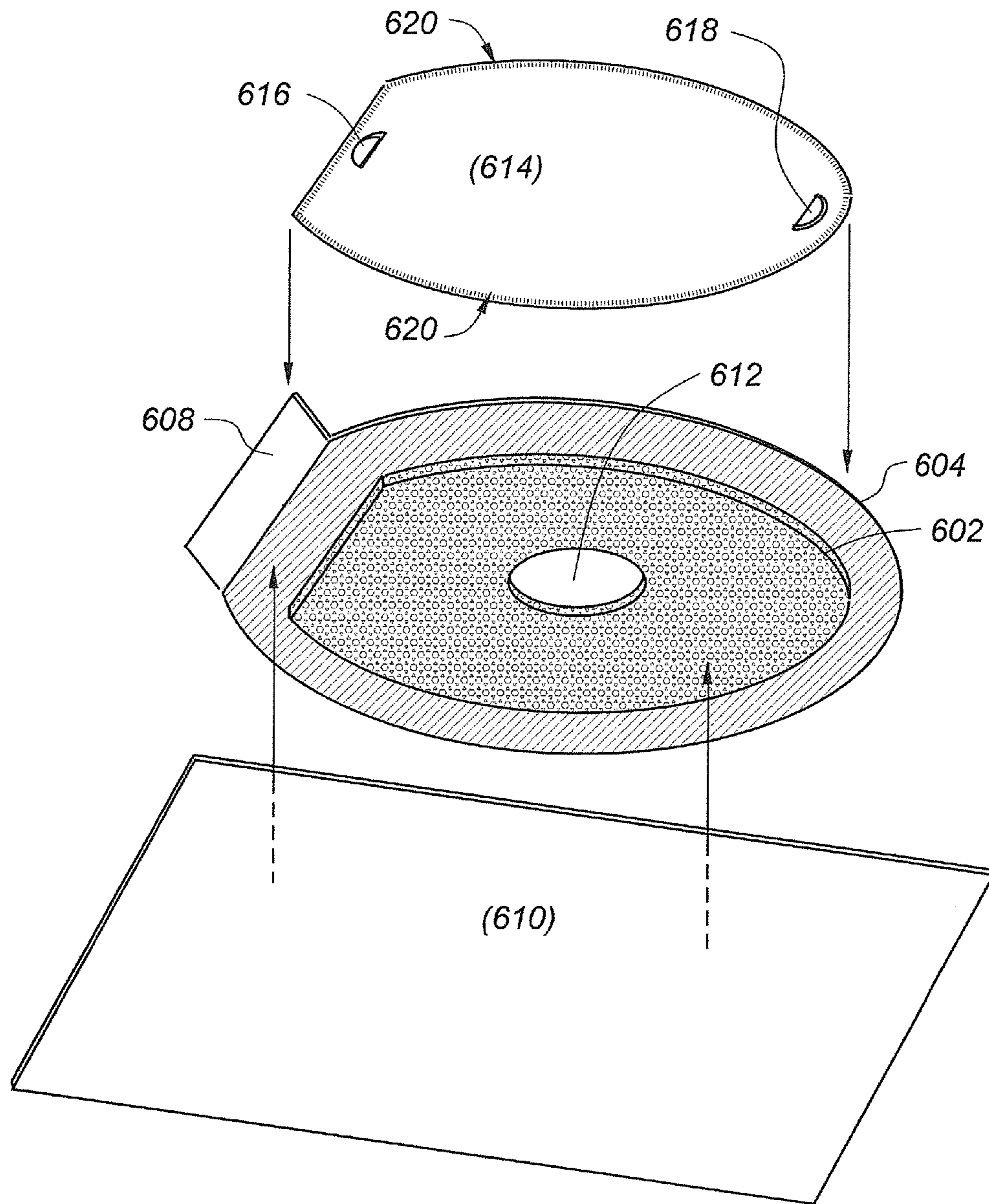


Fig - 6

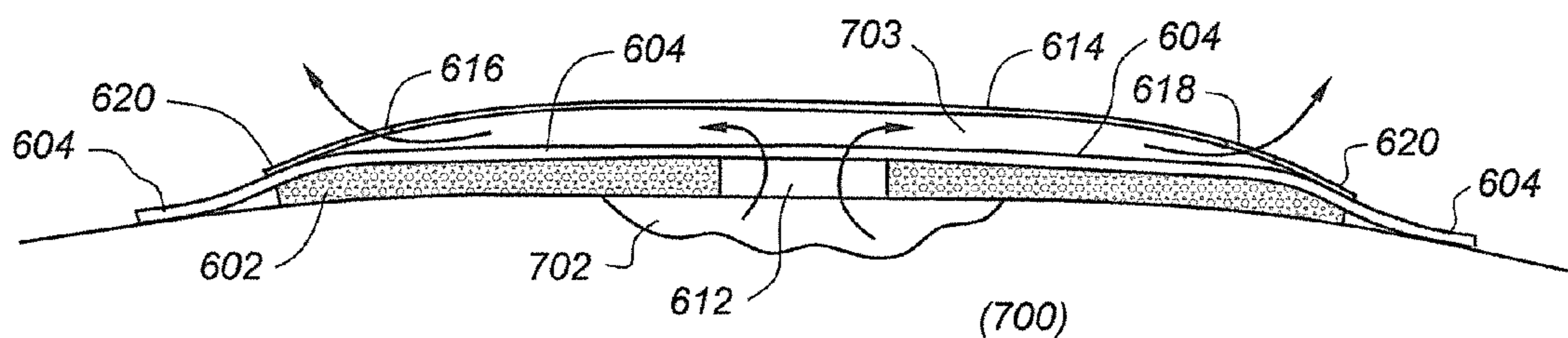


Fig - 7

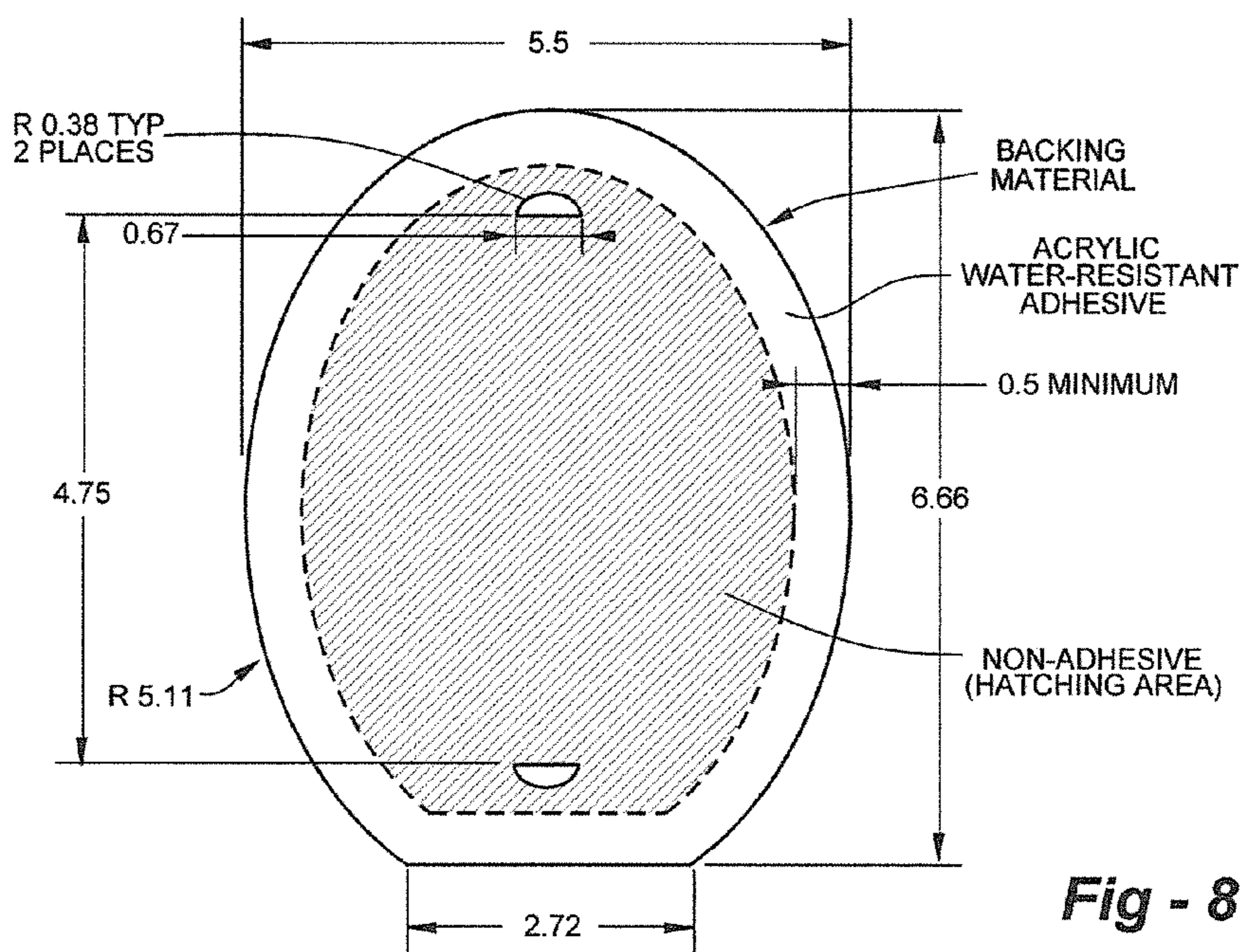


Fig - 8

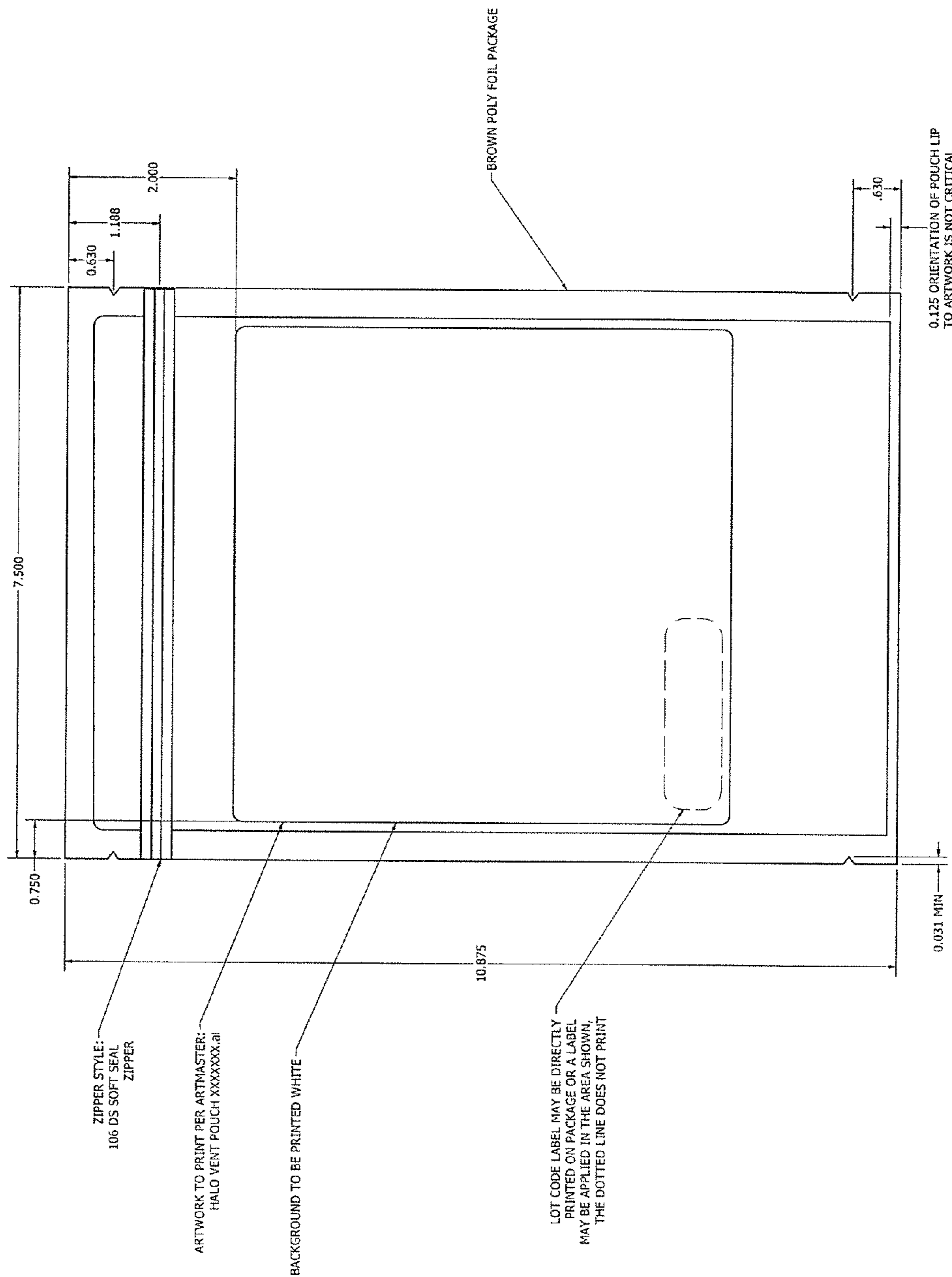


Fig. 9

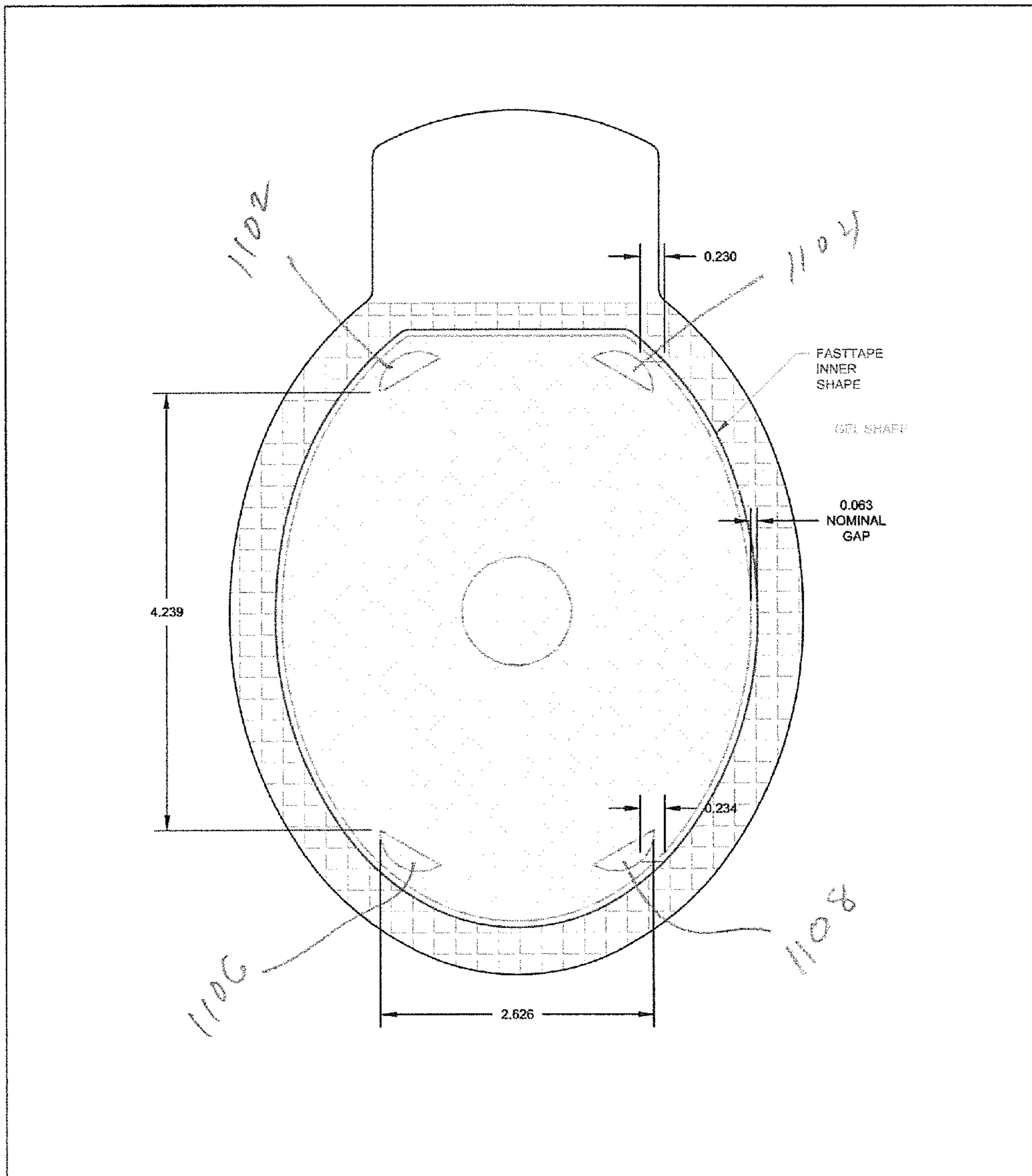


Fig - 10

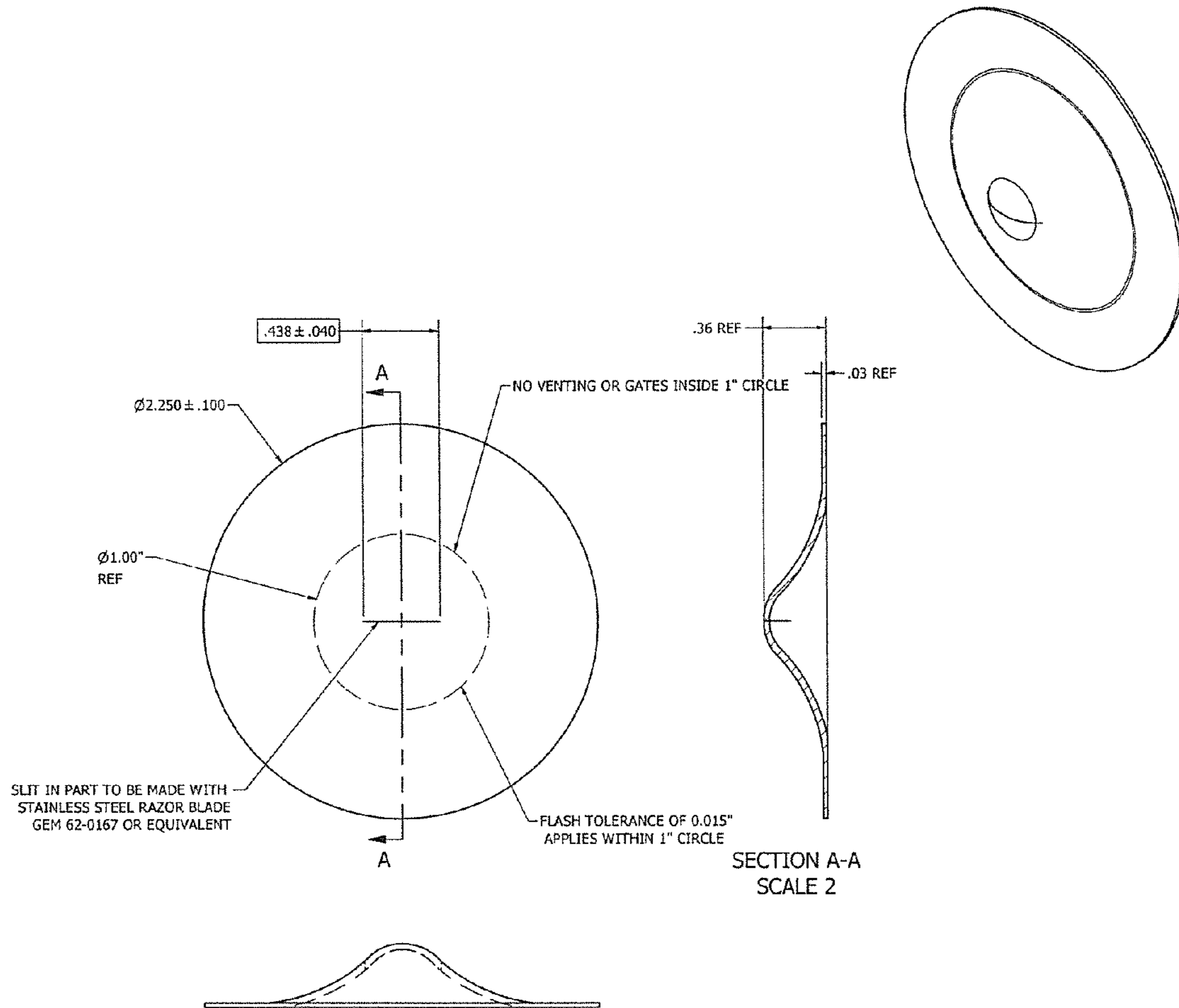


Fig 11

VENTED EMERGENCY WOUND DRESSINGS

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

REFERENCE TO RELATED APPLICATIONS

This application claims priority from U.S. Provisional Patent Application Ser. No. 61/915,198, filed Dec. 12, 2013, and is also a continuation-in-part of U.S. patent application Ser. No. 12/748,008, filed Mar. 26, 2010, which claims priority from U.S. Provisional Patent Application Ser. No. 61/163,613, filed Mar. 26, 2009, the entire content of all of which is incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates generally to wound dressings and, in particular, to a wound dressing that provides a unique combination of a flexible backing material and hydrogel to provide a safe and effective patch for emergency situations, including battlefield applications.

BACKGROUND OF THE INVENTION

There are instances when an emergency wound dressing may be required not only to stop bleeding, but also to block the transfer of gasses to or from the lungs. Bullet wounds in battlefield situations represent one such need. Until now, however, there are few if any bandages that will remain affixed to a recipient given heat and moisture from weather, sweating, and so forth.

SUMMARY OF THE INVENTION

This invention is a wound dressing that uses a novel combination of materials to provide a tenacious occlusive seal, even in the presence of excessive blood or heavy perspiration. The preferred embodiment combines an adhesive backing layer with a hydrogel island providing superior hydrophilic gel adhesion. The product performs under extreme temperatures (i.e., 32-140° F.), and may be used to hold other dressings in place. The preferred embodiments are entirely translucent, and include a large pull-tab for easy removal. One or two dressings may be packaged in a pliable re-sealable protective pouch.

Different "vented" embodiments are disclosed. A preferred structure includes a cover layer peripherally bonded to backing and hydrogel layers having a central aperture therethrough. The cover layer has one or more vent holes, and pressure is released through the central aperture and out the vent hole(s).

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view drawing that illustrates a preferred embodiment of the invention;

FIG. 2 is a drawing that depicts a vented structure;

FIG. 3 is a drawing that depicts a vented structure with an active status indicator;

FIG. 4 is a partially exploded view of a wound dressing assembly according to the invention;

FIG. 5 is a plan view drawing that shows one set of dimensions.

FIG. 6 is an exploded view drawing that illustrates a vented embodiment of the invention seen from a bottom perspective;

FIG. 7 is a not-to-scale cross section depicting the way in which the venting structure operates;

FIG. 8 is a detail drawing with applicable dimensions;

FIG. 9 shows details of a pouch structure;

FIG. 10 depicts an embodiment of the invention utilizing four vent holes; and

FIG. 11 illustrates an optional valve structure.

DETAILED DESCRIPTION OF THE INVENTION

This invention is a wound dressing that uses a novel combination of materials to provide a tenacious occlusive seal, even in the presence of excessive blood or heavy perspiration. FIG. 1 is a plan view drawing that illustrates a preferred embodiment of the invention, including a backing layer **104** and a pre-formed hydrogel pad **102**. The backing layer **104** is preferably a flexible polyethylene "tape" (i.e., 3.0 mil) having a hypoallergenic pressure-sensitive water-resistant adhesive such as an acrylic adhesive **500**. The hydrogel pad **102** may be obtained from Katecho, Inc. of Des Moines, Iowa (product code KM-10). The hydrogel material may be obtained from Katecho, Inc. of Des Moines, Iowa (product code KM-10). The backing material may be obtained from 3M Corp. of St. Paul, Minn. Other vendors are possible.

The hydrogel pad **102** preferably has a periphery **106** spaced apart from the periphery of the backing layer **104** in all dimensions to expose the adhesive layer. An adhesive-free tab **108**, which may be embossed, is used to release the pad from a release liner **110**. The release liner **110** extends beyond all sides of the backing layer **104**, as shown in FIGS. 1-5. The release liner may be a 3.0 mil PET layer. In terms of dimensions, the dressing has a preferred width on the order of 3 to 6 inches and a preferred length on the order of 4 to 8 inches. Other forms besides ovals may be used, including circles, squares and rectangles. Materials other than polyethylene may be used for the backing layer **104** so long as the adhesive and combined system is sufficiently tenacious in terms of adherence to the skin.

FIG. 4 is a partially exploded view of a wound dressing assembly according to the invention, and FIG. 5 is a plan view drawing that shows one set of dimensions. Two systems are shown, enabling the dressings to be folded against one another and placed in a pouch **400** which may be re-sealable, thereby forming a dressing/carrier "kit."

On occasion, the wound dressing may need to vent pressure built up from a chest cavity, for example. To address this, one or more vents such as **204** may be provided as shown in FIG. 2. As pressure builds around a wound in region **202**, it will be released through vent **204**. As a further alternative, a passive or active status sensor may be used to indicate a user condition or to show that pressure release has occurred. As shown in FIG. 3, such a monitor **302** may be passive, using dyes or other materials which change color in the presence of oxygen or other gasses, for example. The detector may be active, for example, using an electronic pressure sensor, an acoustic sensor (to detect lung sound) or resistive sensor (to detect perspiration or breathing) and a visual indicator such as an LED. The light may have different colors to convey status (i.e., green =OK; yellow =concern; red =emergency).

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In all embodiments, beneficial or therapeutic substances may be added to the hydrogel layer. For example, a clotting agent such as calcium carbonate may be added to aid in clotting, and/or an antimicrobial such as chlorhexidine digluconate may be used. Such substances may be in the range of 1-5% or thereabout.

FIG. 6 is an exploded view drawing that illustrates an alternative vented embodiment of the invention seen from a bottom perspective. The article comprises a backing layer shown at 604 and the hydrogel pad is shown at 602. As with other embodiments disclosed herein, the backing layer is preferably a flexible polyethylene "tape" (i.e., 3.0 mil) having a hypoallergenic pressure-sensitive adhesive. The hydrogel material may be obtained from Katecho, Inc. of Des Moines, Iowa (product code KM-10). The backing material may be obtained from 3M Corp. of St. Paul, Minn. as Part No. 1526. Other material and different vendors are possible.

In the embodiment of FIG. 6, the entire bottom surface of the backing layer 604 is coated with an adhesive shown by the hatching, and the hydrogel pad 602, which is preformed into the shape depicted, is adhered to the backing layer using the adhesive layer, the hydrogel itself, or both. Once adhered, the hydrogel forms an island having a periphery spaced apart from the periphery of the backing layer 104 in all dimensions to expose the adhesive layer. An adhesive-free tab 608 may be provided to release the dressing from a release liner 610. The release liner may be a 3.0 mil PET layer.

In terms of dimensions, the dressing of FIGS. 6, 8 has a preferred width on the order of 3 to 6 inches and a preferred length on the order of 4 to 8 inches. Other shapes besides ovals may be used, including circles, squares and rectangles. Materials other than polyethylene may be used for the backing layer 604 so long as the adhesive and combined system is sufficiently tenacious. A set of applicable dimensions are provided in FIG. 8. Two dressings may be folded against one another and placed in a pouch shown in FIG. 9 which may be re-sealable, thereby forming a dressing/carrier "kit"

Returning to FIG. 6, both the hydrogel layer 602 and backing layer 604 include a central aperture 612 which may be round with a preferred diameter in the range of 0.5 to 1.5 inches. Other dimensions and shapes including oval may be used. On the outer side of the backing layer, facing away from the recipient, there is attached a cover 614 having vent holes 616, 618. The cover 614 is peripherally bonded to the outer surface of the backing layer along line 620. The cover 614 may be the same material as the backing material, 3M No. 1526, and may have roughly the same outer dimensions as the hydrogel pad. The cover 614 may be attached to the backing layer with or without an adhesive, using thermal welding, for example. The Any appropriate peripheral adhesive may be used, including UV-cured products.

FIG. 7 is a not-to-scale cross section depicting the way in which the venting structure operates. As can be seen, if pressure builds up from wound 701 on patient 700, the gasses (or liquids) can flow through aperture 612 and out to atmosphere through vent holes 616, 618. When this happens, the entire cover 614 may pull slightly away from the backing material 604, temporarily creating a pocket 703 that is depressurized through the vent holes. After the pressure is relieved or with negative pressure, the cover 614 will typically fall back onto backing layer 604, thereby maintaining a seal around the wound.

FIG. 10 illustrates a preferred embodiment of the invention using four vent holes 1102, 1104, 1106, 1108 and

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dimensions. As a further embodiment, as opposed to an open central aperture through the hydrogel and backing layers leading to a pocket formed with the cover layer, a one-way bicuspid or tricuspid valve of the type shown in FIG. 11. The apex of the valve would be oriented away from the recipient, which would open when pressurized and close following pressurization to maintain cleanliness.

We claim:

1. A wound dressing, comprising:

a backing layer having a periphery, a front surface [with an adhesive layer adapted for patient contact] and a back surface [facing away from the patient];

a [preformed] hydrogel pad having a periphery, *the hydrogel pad being attached to the front surface of the backing layer, the hydrogel pad and backing layer both further including aligned central apertures;*

[the periphery of the hydrogel pad being less than that of the backing layer such that a ring of the adhesive layer remains exposed around the hydrogel pad;]

a cover [peripherally] bonded directly to the back surface of the backing layer so as to create an expandable pocket between the cover and the back surface of the backing layer;

wherein the cover includes at least one vent [hole through the cover] *passage* such that pressure from the wound temporarily expands the pocket, enabling liquids or gasses from the wound to be vented through the apertures, through the pocket, and out the at least one vent [hole] *passage* to atmosphere; and

after the pressure is relieved or with negative pressure, the cover falls back onto the backing layer, thereby eliminating the pocket between the cover and the back surface of the backing layer and maintaining a seal around the wound.

2. The wound dressing of claim 1, wherein the backing layer with the hydrogel pad attached thereto are temporarily held against a [larger] release layer.

3. The wound dressing of claim 1, wherein the backing layer is a polyethylene tape.

4. The wound dressing of claim 1, further including [an adhesive-free tab] *a pull-tab on the backing layer to assist in removing the wound dressing from the release layer.*

5. The wound dressing of claim 1, further including a pouch to protect the dressing, thereby providing a portable kit.

6. *The wound dressing of claim 1, having a shape that is circular.*

7. *The wound dressing of claim 1, having a shape that is rectangular.*

8. *The wound dressing of claim 1, having a width in the range of 3 to 6 inches.*

9. *The wound dressing of claim 1, having a length in the range of 4 to 8 inches.*

10. A wound dressing, comprising:

a backing layer having a periphery, a front surface adapted for patient contact and a back surface facing away from the patient;

a hydrogel pad having a periphery attached to the front surface of the backing layer, the hydrogel pad and backing layer both further including aligned central apertures;

the periphery of the hydrogel pad being less than that of the backing layer;

a cover having an inner surface bonded directly to the back surface of the backing layer, with the periphery of the cover being larger than the aligned central apertures of the hydrogel pad and the backing layers,

thereby forming a pocket between the back surface of the backing layer and the inner surface of the cover; wherein the pocket formed between the back surface of the backing layer and the inner surface of the cover communicates with at least one passage enabling liquids or gasses from the wound to be vented through the apertures and the pocket to atmosphere; and wherein, after the pressure is relieved or with negative pressure, the cover falls back onto the backing layer, thereby eliminating the pocket between the cover and the back surface of the backing layer and maintaining a seal around the wound.

11. The wound dressing of claim 10, wherein the backing layer with the hydrogel pad attached thereto are temporarily held against a release layer.

12. The wound dressing of claim 11, further including a pull-tab on the backing layer to assist in removing the wound dressing from the release layer.

13. The wound dressing of claim 10, further including a pouch to protect the dressing, thereby providing a portable kit.

14. The wound dressing of claim 10, wherein the wound dressing is circular.

15. The wound dressing of claim 10, wherein the wound dressing is rectangular.

16. The wound dressing of claim 10, having a width in the range of 3 to 6 inches.

17. The wound dressing of claim 10, having a length in the range of 4 to 8 inches.

* * * * *

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