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**US-A- 3 076 458**  
**US-A- 4 109 657**  
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# DESCRIPTION

## BACKGROUND

[0001] The present disclosure relates to a skin barrier for ostomy appliances, and more particularly to an oval shaped convex barrier ring according to the preamble of claim 1. A convex barrier ring of such kind is known from US 3,076,458.

[0002] Barrier rings are used with ostomy appliances to aid in sealing such appliances against peristomal skin surfaces and thereby protect those surfaces from exposure to stomal effluent as well as to prevent leakage of the effluent from about stoma-receiving openings of the pouches. However, the topography of stomas and peristomal surfaces surrounding stomas vary among patients, and sealing the ostomy appliances against such different peristomal surfaces and stomas remain as an area for further improvements.

[0003] For example, a stoma may protrude more or less, or may even be flush or recessed. Ostomy patients with flush or recessed stomas have found that if external pressure is applied in the peristomal region, sufficient protrusion of the stoma may occur to aid in the discharge of effluent directly into the collection pouch, thereby prolonging the effectiveness of the adhesive seal between the faceplate and the peristomal skin surface. Skin irritation and patient discomfort may also be greatly reduced. Thus, convex inserts and convex pressure rings, such as ADAPT® convex barrier rings available through the assignee of the present application, have been developed to apply pressure around such peristomal region.

[0004] Because of the inherent severe medical, social, economical and personal concerns related to the need for use of an ostomy appliance, improvements in barrier rings to provide better sealing function and/or comfort is an important factor in the quality of life of wearers and therefore in the consequent health and psychological aspects of the wearer. Any appreciable improvement of such ostomy appliances is therefore of great importance to the increasing number of such wearers. The present disclosure provides improved convex barrier rings according to various embodiments to enhance comfort and sealing between the peristomal skin surfaces and the ostomy appliances.

## BRIEF SUMMARY

[0005] Barrier rings according to various embodiments have a convex surface contour and a generally oval peripheral shape to provide improved sealing of ostomy appliances against peristomal surfaces. Further, the barrier rings can have an oval shaped stoma-receiving aperture to apply even pressure on the peristomal surfaces surrounding non-round stomas such as oval and loop stomas. Preferably, the convex oval barrier rings have tapered peripheral end portions, which can aid in sealing the ostomy appliances against folded or creased skin surfaces.

[0006] A barrier ring for attaching an ostomy appliance to a peristomal skin surrounding a stoma is described in claim 1. Preferred embodiments are described in the dependent claims.

[0007] A method of attaching an ostomy appliance to peristomal folded or creased skin surfaces surrounding a stoma of a wearer is described in claim 9.

[0008] 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

[0009] 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:

FIG. 1 is a perspective view of a convex barrier ring having a tapered oval shape according to an embodiment;

FIG. 2 is a top view of the convex barrier ring of FIG. 1;

FIG. 3 is a bottom view of the convex barrier ring of FIG. 1;

FIG. 4 is a front view of the convex barrier ring of FIG. 1;

FIG. 5 is a side view of the convex barrier ring of FIG. 1;

FIG. 6 is a partial cross-sectional view of the convex barrier ring of FIG. 1 taken along line B--B of FIG. 2;

FIG. 7 is a partial cross-sectional view of the convex barrier ring of FIG. 1 taken along line A--A of FIG. 2;

FIG. 8 is a top view of a convex barrier ring according to another embodiment; and

FIG. 9 is a top view of a convex barrier ring according to yet another embodiment.

## **DETAILED DESCRIPTION**

**[0010]** 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.

**[0011]** A barrier ring is used to fill in or caulk uneven skin contours near a stoma and to improve seal against the stoma. However, skin folds and creases formed from various postures, for example, sitting or bending, or from obesity, often reduce or break the seal around such areas and cause undesirable leakage. Similar seal problems also exist with patients with oval shape stomas, loop stomas, or other non-round stomas. For example, when patients with a loop stoma and/or skin folds due to obesity use a conventional round convex ring, leakage has been frequently observed around the 6 and 12 o'clock positions of the barrier ring due to reduced pressure against skin in those areas.

**[0012]** To overcome this problem, convex barrier rings having a generally oval shape body with tapered peripheral end portions are provided according to various embodiments. In FIGS. 1-7, a convex barrier ring 10 including an oval or elliptical stoma-receiving aperture 12 and a generally oval shaped body 11 with tapered peripheral end portions 14, 16 is illustrated according to an embodiment. The tapered, oval shaped body 11 that tapers at either side to terminate in the tapered peripheral end portions 14, 16 having a relatively small radius of curvature, such that the body 11 in plan view resembles a cat-eye (see e.g. FIGS. 2 and 3), thus the barrier rings having such a shape are also referred to herein as cat-eye barrier rings. The oval shaped stoma-receiving aperture 12 can improve the stoma fit, particularly for non-round stomas such as loop stomas and oval stomas. Further, the convexity of the body 11 and the elongated tapered peripheral end portions 14, 16 provide improved adhesion against uneven or folded or creased skin surfaces.

**[0013]** The barrier ring 10 has a top surface 18 having a convex contour 19 (FIGS. 1, 2, 4 and 5) and a flat bottom surface 20 (FIGS. 3, 4 and 5). In use, the flat bottom surface 20 of the barrier ring 10 is first applied on the adhesive side of an ostomy pouch faceplate (not shown), then the ostomy pouch, assembled with the barrier ring 10, is applied about the stoma in a usual manner such that the tapered peripheral end portions 14, 16 are positioned generally horizontally to fit in the folded or creased skin. Because the top surface 18 is the surface that contacts the skin, the top surface 18 is also referred to herein as a proximal bodyside surface.

**[0014]** The barrier ring 10 is formed of a suitable skin barrier material. The skin barrier material referred to herein may be any of the many skin barrier materials known in the art which is suitable for molding to form the barrier rings according to various embodiments. Preferably, the barrier ring 10 is formed of a flexible medical grade adhesive material, such that the barrier ring 10 can be stretched, cut and/or stacked together to improve the fit of the ostomy pouch system. For example, the barrier ring 10 can be formed of a pressure sensitive adhesive composition, such as that disclosed in US 5,492,943 assigned to the assignee of the present application. The barrier ring 10 formed of such flexible materials can apply soft pressure around the stoma to improve comfort, and reduce pressure sores, hernias, and other skin conditions, such as peristomal pyoderma gangrenosum, which can result from using firm convex barrier rings. Further, the flexibility of the material allows the user to stretch or manipulate the shape of the barrier ring 10 to better fit the stoma and peristomal skin surfaces.

**[0015]** The barrier ring 10 can be provided with protective coverings (not shown) on both top and bottom sides, which are removed by the user before using. The protective coverings can be formed of any suitable materials, such as paper or a polymeric film, and preferably coated with a release coating such as silicone.

**[0016]** Referring again to FIGS. 1-7, the illustrated convex barrier ring 10 has a generally oval shaped stoma-receiving aperture 12. The stoma-receiving aperture 12 is defined by an upper annular wall 26 and a lower annular wall 28. As shown in partial cross-sectional views of the barrier ring 10 (FIGS. 6 and 7), the upper annular wall 26 is slightly tapered. The annular wall 26 is sloped forming an angle 32 with a horizontal axis 30. In this embodiment the angle 32 is an obtuse angle, preferably about 95°, but may be a different angle, such as, for example, in the range of from about 85° to about 95°. In other embodiments, the angle 32 may be an acute angle or the stoma-receiving aperture 12 may be defined by a single annular wall (i.e. the angle 32 may be 90°). The oval aperture 12 has a major radius 22 along a major axis 21 and a minor radius 24 along a minor axis 23 (FIG. 2). The major radius 22 and the minor radius 23 are measured from the center 25 of the oval aperture to the lower annular wall 28. The major radius 22 is larger than the minor radius 24. In this embodiment, the major radius 22 is at least about 1.2 times the minor radius 24, preferably between about 1.4 and about 1.8 times the minor radius 24.

**[0017]** The convex top surface 18 of the barrier ring 10 includes a central portion 34 proximate the stoma-receiving aperture 12. The central portion 34 can have a generally flat surface having a cat-eye shaped perimeter 35 with a shape similar to the overall shape of the barrier ring body 11. The cat-eye shaped perimeter 35 terminates at tips 54, 56 at either end thereof, with end portions of the central portion 34 at 58, 60. The end portions 58, 60 of the central portion 34 terminate in tips. The central portion 34 is the thickest portion of the barrier ring 10 with a thickness 36 (FIGS. 6 and 7), and thus, defines the highest point of the barrier ring 10 that can apply the most pressure around the stoma (not shown.)

**[0018]** A first half 46 of the barrier ring 10 above the major axis 21 and a second half 48 below the major axis 21 are preferably symmetrical about the major axis 21. The top surface 18 slopes down with a curved contour 40 from the central portion 34 to a peripheral portion 38, which also has a generally flat surface. The curved contour 40 includes a convex portion 42 and a concave portion 44 as shown in FIGS. 1 and 7. FIG. 7 shows a partial cross-sectional view of the first half 46 of the barrier ring 10 along line A--A (FIG. 2). Since the barrier ring 10 is symmetrical about the major axis 21, a cross-sectional view of the bottom half 48 of the barrier ring 10 taken along the sectional line A--A will be the same as that shown in FIG. 2. Further, the convex top surface 18 of each of the first half 46 and the second half 48 of the barrier ring 10 has the same curved contour 40 including the convex portion 42 and the concave portion 44. The first half 46 and the second half 48 of the barrier ring 10 meet at the elongated tapered peripheral end portions 14, 16, wherein ridges 50, 52 are formed.

**[0019]** As shown in FIGS. 1 and 2, the ridges 50, 52 extend down from tips 54, 56 of the cat-eye shaped center portion 34 to the peripheral portion 38 of the tapered peripheral end portions 14, 16. FIG. 6 shows a partial cross-sectional view of the tapered peripheral end portion 16 taken along the ridge 52 at line B--B. As shown in FIG. 6, the ridges 50, 52 have a convex portion 62, and a concave portion 64. The barrier ring 10 is also symmetric about the minor axis 21, thus, a cross-sectional view of the tapered peripheral end portion 14 along the ridge 50 will be same as the cross-sectional view of the tapered peripheral end portion 16 shown in FIG. 6.

**[0020]** The convex barrier 10 can be made in various sizes to fit various stoma sizes and peristomal skin surfaces. In one embodiment, the convex barrier ring 10 has the oval stoma-receiving aperture 12 with a major radius 22 of between about 0.5 inches and about 1.5 inches, preferably between about 0.7 inches and about 1.2 inches. The convex barrier ring 10 has a width 66 at the elongated tapered peripheral end portions 16 as seen along line B--B (FIG. 6) of between about 0.5 inches and about 1.5 inches, preferably between about 0.8 inches and about 1.1 inches; and a width 68 as seen along line A--A (FIG. 7) of between about 0.3 inches and about 1.0 inches, and preferably between about 0.5 inches and about 0.8 inches. The center portion 34 of the convex barrier ring 10 has a width 70 at the elongated edge 60 as seen along line B--B (FIG. 6) of between about 0.15 inches and about 0.35 inches, preferably between about 0.20 inches and about 0.30 inches; and a width 72 as seen along line A--A (FIG. 7) of between about 0.03 inches and about 0.12 inches, preferably between about 0.05 inches and about 0.08 inches. The barrier ring 10 has the thickness 36 at the center portion 34 of between about 0.15 inches and about 0.5 inches, preferably between about 0.2 inches and about 0.3 inches.

**[0021]** Further, in the illustrated embodiment, the convex portion 42 of the curved contour 40 along line A--A (FIG. 7) has a radius 74 between about 0.15 inches and about 0.35 inches, preferably between about 0.20 inches and about 0.30 inches. The concave portion 44 has a radius 76 between about 0.30 inches and about 0.45 inches, preferably between about 0.35 inches and about 0.40 inches. The convex portion 62 of the ridge 52 along line B--B (FIG. 6) has a radius 78 between about 0.25 inches and about 0.40 inches, preferably between about 0.30 inches and about 0.35 inches. The concave portion 64 has a radius 80 between about 0.40 inches and about 1.10 inches, preferably between about 0.50 inches and about 0.75 inches. The flat peripheral portion 38 has a thickness 82 (FIG. 6) of between about 0.01 inches and about 0.04 inches, preferably between about 0.015 inches and about 0.025 inches. FIGS. 8 and 9 show a top view of convex barrier rings 90, 92 having different sizes and dimensions according to other embodiments.

## **Examples**

[0022] Dimensional details of three preferred embodiments of the convex barrier ring 10 are provided below in Table 1.

Table 1 Convex Oval Barrier Ring Examples

| Dimensions (Reference numbers correspond to FIGS. 1-7) | Example 1 (inches) | Example 2 (inches) | Example 3 (inches) |
|--------------------------------------------------------|--------------------|--------------------|--------------------|
| Major radius 22 - oval stoma-receiving aperture        | 0.945              | 0.748              | 1.102              |
| Minor radius 24 - oval stoma-receiving aperture        | 0.591              | 0.433              | 0.748              |
| Barrier width 66 along major axis                      | 1.034              | 0.981              | 0.894              |
| Barrier width 68 along minor axis                      | 0.670              | 0.670              | 0.670              |
| Center portion width 70 along major axis               | 0.272              | 0.219              | 0.230              |
| Center portion width 72 along minor axis               | 0.068              | 0.068              | 0.068              |
| Radius 78 of convex portion 62 along major axis        | 0.340              | 0.339              | 0.302              |
| Radius 80 of concave portion 64 along major axis       | 0.724              | 0.724              | 0.578              |
| Radius 74 of convex portion 42 along minor axis        | 0.250              | 0.250              | 0.250              |
| Radius 76 of concave portion 44 along minor axis       | 0.375              | 0.375              | 0.375              |
| Thickness 82 of barrier at peripheral portion          | 0.020              | 0.020              | 0.020              |
| Thickness 36 of barrier at center portion              | 0.250              | 0.250              | 0.250              |

[0023] 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.

## REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

### Patent documents cited in the description

- [US3076453A \[0001\]](#)
- [US5492943A \[0014\]](#)

**PATENTKRAV**

1. Konveks barrierering til fastgørelse af en stomiindretning til peristomal hud, som omgiver et stoma, hvilken konvekse barrierering omfatter:
- 5           en konveks proksimal overflade (18) på kropssiden;  
          en flad bundoverflade (20);  
          en oval stoma-modtagende åbning (12);  
          kendetegnet ved  
          et katteøjeformet element (11), som har aflange perifere endele (14, 16), hvor  
10       de aflange perifere endele omfatter kanter (50, 52);  
          hvor den konvekse proksimale overflade (18) på kropssiden omfatter en central  
          del nær ved den stoma-modtagende åbning (12), en perifer del og en overflade, som  
          strækker sig ned fra den centrale del til den perifere del med et buet omrids; og  
          hvor hver af kanterne (50, 52) strækker sig ned fra centerdelen til den perifere  
15       del, hvor kanterne (50, 52) er konfigureret til at passe i hudfolder eller rynker for at forbedre tætningen mellem barriereringen og den peristomale hud.
2. Barrierering ifølge krav 1, hvor den stoma-modtagende åbning (12) definerer en ovalformet periferi, hvor en hovedradius af den stoma-modtagende åbning er større  
20       end ca. 1,2 gange en mindre radius.
3. Konveks barrierering ifølge krav 1, hvor den ovale stoma-modtagende åbning (12) har en hovedradius og en mindre radius, og hvor hovedradiusen er mellem ca. 1,4 og ca. 1,8 gange den mindre radius.
- 25       4. Konveks barrierering ifølge krav 3, hvor det buede omrids omfatter en konveks del (42) og en konkav del (44).
5. Konveks barrierering ifølge krav 1, hvor det buede omrids af den konvekse proksimale overflade (18) på kropssiden er symmetrisk omkring en hovedakse og omkring en mindre akse.
- 30       6. Konveks barrierering ifølge et hvilket som helst af kravene 1-5, hvor den konvekse barrierering er udformet af et hudbarrieremateriale.

7. Konveks barrierering ifølge et hvilket som helst af kravene 1-6, hvor hudbarriere-materialet er et trykfølsomt adhæsivt præparat.

5 8. Barrierering ifølge et hvilket som helst af kravene 1-7, hvor et tværsnit, som tages langs med den mindre akse, definerer en konveks overflade, som går over i en konkav overflade fra den stoma-modtagende åbning (12) til en respektiv perifer del af barriereringen.

10 9. Fremgangsmåde til fastgørelse af en stomiindretning til peristomale foldede eller rynkede hudoverflader, som omgiver et stoma hos en bærer, hvilken fremgangsmåde omfatter:

tilvejebringelse af en konveks barrierering, som omfatter:

en konveks proksimal overflade (18) på kropssiden;

en flad bundoverflade (20);

15 en oval stoma-modtagende åbning (12); og

et katteøjeformet element (11), som har aflange perifere endedele (14, 16),

hvor de aflange perifere endedele omfatter kanter (50, 52);

20 hvor den konvekse proksimale overflade (18) på kropssiden omfatter en centerdel nær ved den stoma-modtagende åbning (12), en perifer del og en overflade, som strækker sig ned fra centerdelen til den perifere del med et buet omrids; og

hvor hver af kanterne (50, 52) strækker sig ned fra centerdelen til den perifere del, hvor kanterne (50, 52) er konfigureret til at passe i hudfolder eller rynker for at forbedre tætningen mellem barriereringen og den peristomale hud,

25 anbringelse af den flade bundoverflade (20) på en adhæsiv side af en frontplade af stomiindretningen;

anbringelse af stomiindretningen, som er samlet med den konvekse barrierering, omkring stomaet, således at stomaet er anbragt i den ovale stoma-modtagende åbning (12);

30 tætning af den konvekse proksimale overflade (18) på kropssiden mod de peristomale hudoverflader, således at de aflange perifere endedele er på linje med hudfolderne eller rynkerne.

10. Fremgangsmåde ifølge krav 9, hvor tætning af den konvekse proksimale overflade (18) på kropssiden omfatter positionering af de aflange perifere endedele (14, 16), så-

ledes at kanterne (50, 52) er anbragt i hudfolderne eller rynkerne for at forbedre tætningen mellem barriereringen og de peristomale hudoverflader og reducere lækage.

DRAWINGS

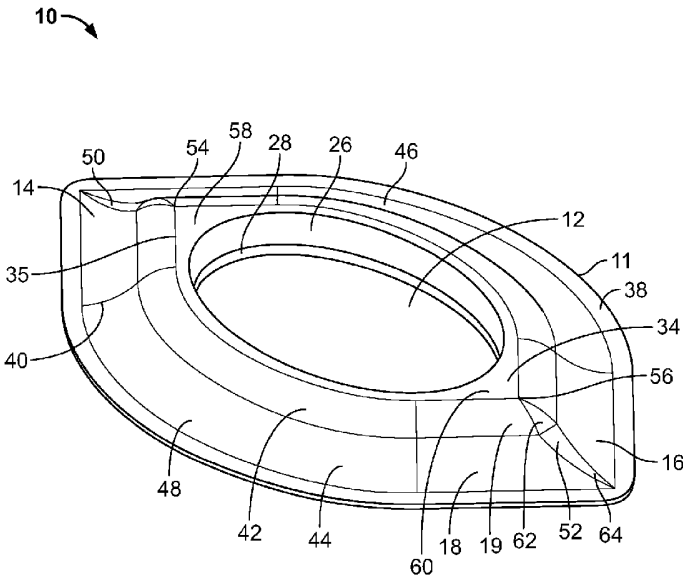


FIG. 1

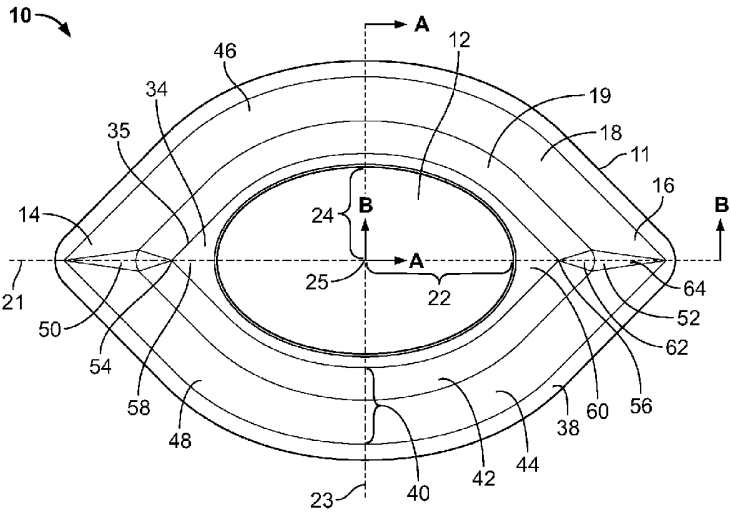


FIG. 2

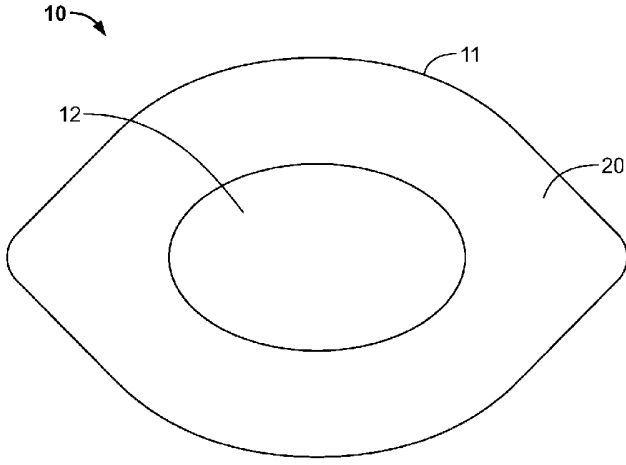


FIG. 3

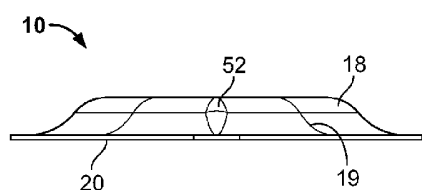


FIG. 4

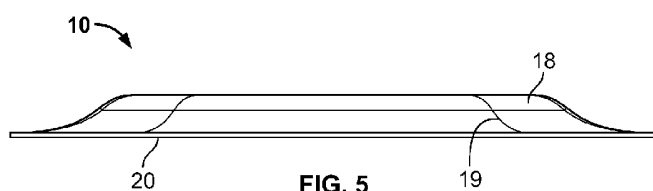


FIG. 5

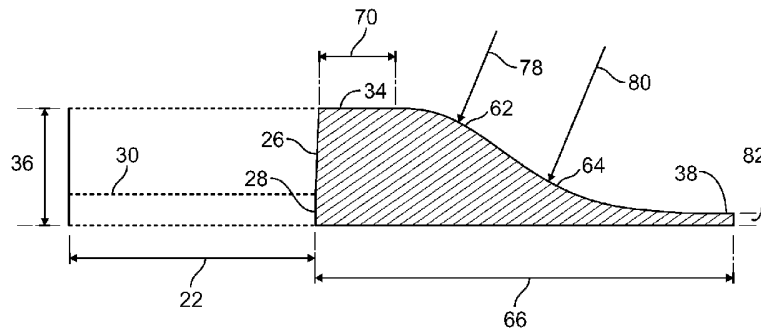


FIG. 6

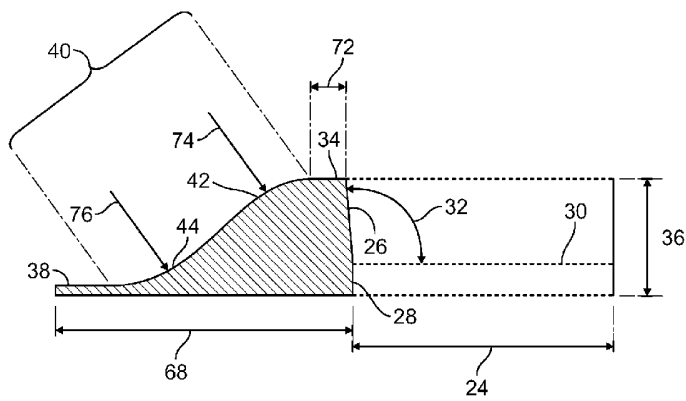


FIG. 7

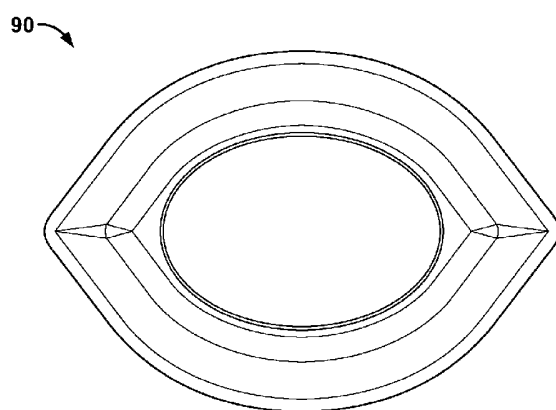


FIG. 8

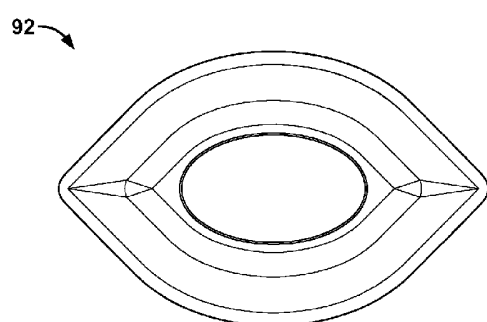


FIG. 9