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(54) CONTACT LENS PACKAGE WITH REDUCED LENS-PACKAGE INTERACTIONS AND ANTICOUNTERFEITING MEASURE

(57) The packages described by this invention all have reduced "head space," that is, the distance from lid to lens. Packages contain dimples to achieve this reduced head space. Specifically, packages are designed with dimple sag equal to or less than 1.90-mm, or volume displaced equal to or less than 360μl. Combined with the existing primary packaging, it has been found that such conditions provide for reduction in folded lens rate during shipping and handling. As well, lenses stored or having an extended time in low head space packages in a "foil down" orientation now have characteristics closer lenses stored in a "foil up orientation." The packages finally include a foil 3D pattern at a smaller scale than the dimple, by embossing or other methods allowing reduce lens sticking to the foil as well as an added anti-counterfeiting measure.

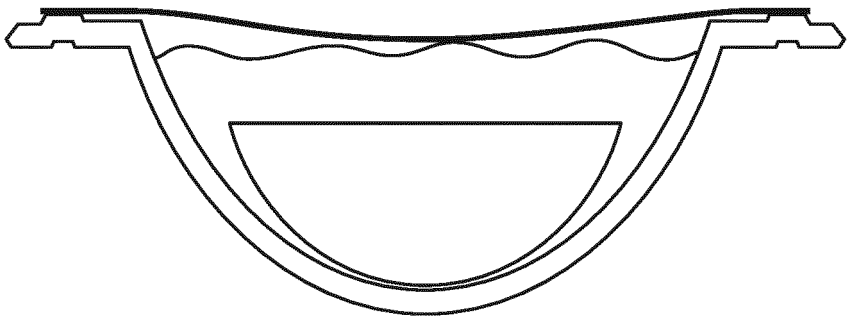


FIG. 3

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Description

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is continuation-in-part and claims benefit of US Serial No. 15/234,354, filed August 11, 2016. Serial No 15/234,354 is a continuation and claims benefit of Serial No. 14/185,207, filed February 20, 2014, and is now US Patent No. 9,439,487. In turn US Serial No. 14/185,207 is a non-provisional application of U.S. Serial No. 61/788,952, filed March 15, 2013. The complete disclosures of the aforementioned related U.S. patent applications are hereby incorporated herein by reference for all purposes.

FIELD OF THE INVENTION

[0002] This invention relates to ways to improve the capability of contact lenses with respect to user experience, after the lens package is opened, post-shipment and storage.

BACKGROUND

[0003] After manufacturing, a contact lens can interact with its packaging during storage or shipment. Efforts have been made by various entities to reduce the effects of these interactions. In general, the minimization of lens-to-package interaction should be optimized.

[0004] In some situations, it is suspected that there may be instances where the lens becomes folded (or at least slightly folded) during storage, even if unfolded when placed on the eye. Depending on the type of lens material, the effect of such folding could range from a handling inconvenience to an effect on the lens optical properties. Under other conditions, the lens can be "suction-cupped" to the foil or otherwise stuck between the foil and the package. Each of these are lens-package interactions to be avoided.

[0005] After reviewing these interactions, the inventors have successfully created a "low head space" condition for the lens in the package, while retaining high manufacturing efficiency in areas related to yield, throughput and capital employed. In other words, it is felt that providing for minimal space (i.e., "low" "head space") between the lens and the cover of the package would be beneficial to reduce the possibility of lens folding or inverting (that is, the lens flipping over. The inventors also have created a low-foil sticking condition that is beneficial for lens properties but also provides a unique visible pattern to the lens package that can be keyed into a verification scheme for added anti-counterfeiting measure.

[0006] The parameters involved in the project to provide "low head space" are:

- Conservation of lens design - lens interaction with the packaging post-manufacturing should be minimized.
- Customer experience - any negative customer experience should be avoided.
- Sterility - the sterility barrier (namely the heat seal between the foil and package) should be considered, both on the manufacturing line and during shipment.

[0007] The following terms will be used:

Dimpled package. The term "dimpled package" refers to the action of putting a concave shape in the foil of the package so that the plane of the foil projects inwards (i.e., into the package bowl) from the plane of the heat seal ring which joins the foil to the package. This reduces the head space available in the package at a given solution dose volume.

Dimple. When a part in the middle of the heat seal die that pushed onto the foil as the die affixes the foil to the package, the resultant concavity is referred to as a "dimple".

Sag refers to the distance between the plane defined by the top of the heat seal ring and the apex of the dimple.

Displacement refers to the volume displaced due to the shape of the dimple, from the reference plane defined by the top of the heat seal ring.

Inside Diameter, or ID, or Diameter refers to the outside diameter of the dimple, where it meets the plane defined by the top of the heat seal ring.

Outside Diameter or OD refers to the outermost diameter of the dimple. It may be different from the ID when the dimple has a flange with a diameter greater that the ID.

Mounting features refers to the design feature that allows the dimple to be secured in the heat seal die.

Pattern or emboss refers to a shape on the foil which forms a shape at a scale smaller than the overall concavity provided by a package dimple, that does not alter the main concave form.

SUMMARY OF THE INVENTION

[0008] As a result of our efforts, lens package arrangements with reduced head space were generated, using two different techniques:

- By increasing the dose volume of solution in the bulb of the package, without other package change ("overfill;") or
- By creating a dimple of a specific shape on the package while maintaining current dose.
- By a carefully controlled combination of both options.

As will be seen, lens folding during storage and handling post-manufacturing can be reduced using either method. This improvement takes a small amount of time (optimally, less than 30 minutes) to physically implement in manufacturing, costs a very low amount to provide for, and will have practically no effect on manufacturing.

[0009] The packages described by this invention all have reduced head space. From input of general parameters provided by users of these type packages, it was chosen to have packages containing dimples that will be geometrically equivalent (or even less intrusive) to the dimples described therein. So, specifically, packages were designed with sag equal to or less than 1.90-mm, or volume displaced equal to or less than 360μl. Combined with the existing primary packaging, it has been found that such conditions provide for reduction in folded lens rate during shipping and handling. As well, lenses stored or having an extended time in low head space packages in a "foil down" orientation now have characteristics closer lenses stored in a "foil up orientation."

[0010] In addition, there is disclosed a process for providing anti-counterfeiting measures to the disclosed package, so that the package cannot be easily copied. This in turn gives better assurance to the users that the subject contact lens is the original sourced by a known manufacturer.

DETAILED DESCRIPTION OF THE DRAWINGS

[0011] A specific dimple die is provided herein, as seen in Figure 1;

Figures 2 and 3 both show the effect of a contact lens sitting in a bulb without low head space (Fig. 2) and with low head space (Fig. 3);

Figure 4 displays a die used with the cover of a lens package to form a 20-mm diameter dimple with a pattern embossed thereon;

Figure 5 describes the comparison of volume displaced in a smaller size lens package as compared to a larger size package;

Figures 6 and 7 are views of other type dimple dies useful to create this invention;

Figure 8 is a graph of fold rate versus fill volume as seen in this invention;

Figure 9 is a chart outlining dimple size versus fold rate;

Figure 10 is a scatter plot of lens diameter obtained with two configurations of the present invention;

Figure 11 is a plot of rate success of the present invention;

Figure 12 is a depiction of a tool used for embossing the foil package cover;

Figures 13a, 13b and 13c describe examples of the type of embossed foil useful as an anti-counterfeiting measure when used to provide low head space for the lens, as described in the current invention; and

Figures 14a, 14b and 14c are packages containing the dimpled lids of Figures 13a, 13b and 13c.

DETAILED DESCRIPTION OF THE INVENTION

[0012] The packages described by this invention all have reduced head space. The reduced head space is obtained by either a saline solution adjustment, a concave on the foil above the bowl of the primary package, or a combination thereof. It is important to understand that, in particular, managing the proportional size of folded lenses during shipping and handling is linked to the head space and shape of a particular package, regardless of the method used to achieve the low head space. The headspace (expressed as a percentage of the total cavity volume desirable to achieve low folding) is dependent upon the cavity shape itself. Thus, the examples included in the present specification are not intended to limit to the scope of this invention, but rather to serve as relevant examples.

[0013] From general observations provided by users of these type packages, it was chosen to have packages containing dimples that will be geometrically equivalent (or even less intrusive) to the dimples described therein. It was determined that sag would be the most relevant quantity to define the foil deflection for the dimples of a diameter much smaller than the bulb opening (namely the 13-mm diameter size family in the case of subsequent examples). Sag has been found to be a better metric than displacement for a small diameter, because the foil increases the displacement well beyond the calculated geometric displacement of the dimple itself. Calculated displacement, on the other hand, should be the most relevant quantity to define foil deflection for dimples of diameter close in size to the bulb diameter (namely the 20-mm family).

Experiments

Evaluation of low head space by standard foil placement and increase in saline dose volume.

[0014] In a first set of experiments, contact lens manufacturing lines were used under experimental conditions to produce packages with varying amounts of head space, comprised between 34% of the total volume (950μl, or typical for lens packages) and 7% (1350μl, or fill of full bowl). During these experiments, the influence of head space versus fold was assessed.

[0015] The graph of Figure 8 shows the folded lenses after a "simulated shipping" test (replicating transit from manufacturing point to customer) for different levels of bowl fill (and therefore different head space.) From this graph, a reduction in folded lenses is observed at a dose volume above about 1150μl (or a head space of 21%.)

Evaluation of low head space by formation of dimple in the package.

[0016] In a second set of experiments, packages with low head space were created, using a dimple die in the foil above the lens bowl, one example of which is seen in Figure 1. This die created a dimple in the package, such as that seen in Figure 3. As seen in Figure 3, there is a sag S of the foil cover, which is not readily apparent in the earlier version of a contact lens package, as seen in figure 2.

[0017] During the first phase of the design, a variety of dimple shapes were evaluated using an offline heat seal unit. The packages were fed in the machine and a heat seal die modified to accommodate a center piece pushing the foil inward as the die approximated the foil. As well, the inventors also reduced head space by a combination of difference dimples and dose volumes. From handling a quantity of approximately 30 lenses for each design, it appeared that the lenses with any type of a chamber dome "bathtub" receptacle had been trialed (whether centered or not centered on the lidstock) had approximately 50% of the lenses stuck between the foil and the bowl (in other words, not free floating). It was decided that these options were not viable. As well, the packages made with tapered shape ("wedge") exhibited a large amount of creasing at the foil, which affects seal quality and the sterility. These shapes were also discarded as options.

[0018] After this first screening it was determined that a smoothly transitioned shape was best suited for the application. Examples of such shapes may be, but are not limited to: spherical, parabolic or elliptical shaped dimples.

[0019] The graph of Figure 9 displays the relation between head space and folded lenses for a dimple using a spherical section to indent the foil on the package. The dimple references correspond to slightly different dimple designs, all changing the head space by a similar volume. (By way of notation, the x-axis on the graph indicates "Outer Diameter/Inner Diameter/Sag.") It is very evident on the graph from Figure 8, that the dimple resulting in lower head space facilitated the reduction of the folded post simulated ship test.

[0020] In a third set of experiments, only continuous round dimple shapes were created. They were run on standard manufacturing equipment. The packages were focused on a combination of 13-mm and 20-mm dimples The 20 mm dimples have several types of patterns embossed to make sure the lens does not stick to the foil. The main take-away for this study was to focus on simple embossed patterns versus complex repetitive ones. Indeed, however, it was found that these patterns lift the lens edges away from the main foil surface, thereby eliminating the possibility of suction cupping onto the foil.

[0021] An added benefit for the user is that it becomes possible to make the patterns with aesthetically desirable shapes on the package:

1- By making the foil "matte" in the case of a small pattern.

2- By highlighting some inscription on the foil. A specific example is the ability to make one embossed line under the brand name ACUVUE® to underline it: ACUVUE®

3- Other aesthetically pleasing patterns are waves, stylized eye shape. These examples are meant to highlight the principle of the invention and are not limited to these specific patterns.

Dimples trialed:

[0022]

- Sphere section with a diameter of 20-mm.
- Sphere section with a diameter section of 13-mm.
- Embossed patterns of one, or a plurality of lines on the main dimple section - Can change head space and lens placement with respect to foil.
- Embossed microstructure changing the aspect of the foil (matte versus glossy) or changing the position of the lens with respect to the foil

[0023] Figure 4 displays a die used with the cover of a lens package to form a 20-mm dimple with a pattern embossed thereon (referred to as a "single line"). The packages with a pattern confirm the hypothesis that providing an irregular foil surface to the lens, even when the package is stored in a "foil down" position, avoids suction cupping that may alter slightly the effect of the lenses. The table of Figure 10 shows the effect of this invention on packages with similar head space; one set of packages has a 20-mm dimple with a pattern embossed, and the other set a 20-mm dimple without a pattern.

[0024] In addition to reducing the lens-to-package interactions, as a result of these tests, some basic functional design considerations were derived for the dimpled packaging. These design considerations highlight further refinements of the dimple process, and are not intended to be limiting the general scope of the invention.

- Mounting and centering: The dimple should preferably be back-mounted and centered in the heat seal die. Front mounted dimples were difficult to assemble. The back mounted dimple allows for a smooth dimple in the front and the centering system allows for the dimpling of the foil in the center of the bowl. Having an off-center dimple can create areas where the lens get pinched and interacts with the package, as described above.
- Material: the material of choice for the dimple die is stainless steel, for its slower heat transfer compared to the die material, as well as higher abrasion resistance compared to the die materials. Other dimple material that can also be considered, for such use would be, although would not be limited to: ceramics and high-heat resistance plastics like polyetherimide

or polyether ether ketone.

- Outside diameter: In the case of the 20-mm diameter dimple, the shaft below the dimple will have a reduced diameter so as to limit the heat transfer. A lower heat transfer between the dimple and the die is desirable to reduce the risk to melt the polymer layers of foil in areas outside of the heat seal contact zone. In the case of the 13-mm diameter dimple, the dimple will not have an extra flange so as to also provide more space between the dimple and the die, which is desirable to limit heat transfer and provides more space to ease access when cleaning. It should be noted that the diameters will be specific to the heat seal diameter and shape. Any optimized gap between the heat seal and the dimple to increase heat insulation and ease of mounting/cleaning is a corollary benefit.

[0025] The high sag/high displacement dimples are designed to reduce the head space in the package enough to provide a bubble size reduction to the desired range without changing the current qualified dose volume in the 900 to 1000μl. In order to achieve this, the two dimple die designs used are described in Figures 6 and 7.

Evaluation of dimple combined with a dose volume increase

[0026] Increasing the saline dose volume enough to remove any lens-to-package interaction has a drawback that under some opening techniques, some solution is pushed out of the package at opening. This is not optimal for customer experience. Deforming the foil enough to eliminate lens-package interactions at the same dose volumes also has a perceived drawback. The foil deformation is large enough to increase the risk of foil undulations occurring in the heat seal area. A solution using both techniques, each used to a lesser degree, was evaluated.

[0027] In a fourth set of experiments, dimples of lower sag and displacement were designed and paired with dose volumes slightly elevated. As already discussed, Figure 3 displays one such low sag/low displacement dimple. The chart of Figure 11 displays the folded rate of two low sag-low displacement dimples combined with dose volumes that result in a specific head space target. That head space is quantified by the bubble diameter. This is one example of quantification and this method is not intended to be limiting the scope of the invention. All dimples provide significant folded rate improvements.

[0028] As seen in Figure 12, a foil sheet is pressed at a pressing station along an assembly line. Of course, this foil sheet has already been sealed to the bulb of the package, into which has been placed a contact lens in its appropriate orientation, and a measure of saline. The foil sheet is embossed at this station into a shape such as those shapes described earlier in this specification, or any other shape that is aesthetically desired.

[0029] What has been found surprisingly is that the configuration with the embossing adds a certain amount of lens security to the package. That is, the embossing itself, in addition to being aesthetic, further prevents adhesion of the lens to the cover sheet by suction cupping. This improves lens presentation upon package opening. In addition, some lenses are affected in performance when the lenses are folded or as subject to optical artifacts when the lens is suction-cupped to the foil lidstock for long periods of time. Thus, there is an improvement in optical performance as well, when these lids are embossed.

[0030] Of course, this improvement in lens security directly translates into greater certainty for the user of finding a lens in its appropriate orientation upon opening the lens package just prior to placement on the eye. The designs result in the reduction of suction cupping, and could be different for varying package configurations. The examples stated above are not intended to limit the invention to specific patterns of lidstock.

[0031] In other embodiments, several embossing shapes could be available and "rotated" during manufacturing for use in a package. This could be done while similarly rotating lenses placed in the package (by code or SKU number) so that the embossing shape could serve as a "verification code" for the then-current lens design. As seen in Figures 6, 7 and more particularly in Figures 13a, 13b and 13c, there are various dies used for creating embosses on the foil sheet, which results in embossing in the foil while using these dies. These embosses are seen at Figures 14a (the cross-shaped emboss) 14b (the starfish-shaped emboss) and 14c (the three-pointed star-shaped emboss.)

[0032] It has become apparent that at the time of manufacture, it is relatively easy to copy an emboss. As a result, a particular emboss should be used for only a limited length of time before one attempts to counterfeit it. This allows the manufacturer to stay a step ahead of counterfeiters. Since contact lenses have a limited shelf life due to regulatory restrictions, by the time a counterfeiter is able to mimic the then-current emboss, the lenses themselves have passed their useful shelf-life, for instance as keyed off a particular lot number. Distributors can have available to them a listing a list of the then "current" embosses used on a foil sheet. As long as the emboss matches that on the package, there is greater assurance that in fact, the package is authentic. In this way, the emboss serves as a second validation of authenticity of the packaged contact lens.

[0033] Once an acceptably short time has lapsed, the manufacturer can then change the emboss, so that any particular emboss is used on the lid for only a very short time. In this way, the manufacturer helps give assurance to the user of authenticity in a low cost, yet efficient verification system during the manufacturing process. This process allows the manufacturer to stay "one step ahead" of the counterfeiter.

[0034] The foregoing is to be understood to be subject

to minor modifications, which will not depart from the spirit of the invention, which is to be understood from the attached claims and their equivalents.

Claims

1. A lens package with an anticounterfeiting measure contained therein, comprising:

   a bulb having a rim and comprising a volume;
   a generally thin cover placed over said bulb, said cover being generally flat;
   a contact lens contained in solution in said bulb; and
   such that said cover is sealed to said bulb at said rim, and said cover formed from a generally flexible material, such that when said cover is sealed to said bulb, a dimple is formed in said cover, said dimple having a concavity defining a sag depth, such that the concavity displaces volume from the volume of the bulb; and
   wherein the anticounterfeiting measure comprises a site on said cover for placing an emboss, such that said emboss can be varied at predetermined times.

2. The package of claim 1 wherein the dimple contains said emboss.

3. The package of claim 1 or 2 wherein the cover contains a dimple with an ornamental emboss.

4. The package of claim 1 or 2 wherein the emboss is cross-shaped.

5. The package of claim 1 or 2 wherein the emboss is starfish-shaped.

6. The package of claim 1 or 2 wherein the emboss is a three-pointed star shape.

7. The package of claim 1 or 3 wherein the emboss is cross-shaped.

8. The package of claim 1 or 3 wherein the emboss is starfish-shaped.

9. The package of claim 1 or 3 wherein the emboss is a three-pointed star shape.

10. A lens package with an anticounterfeiting measure contained therein, comprising:

    a bulb having a rim and comprising a volume;
    a generally thin cover placed over said bulb, said cover being generally flat;
    a contact lens contained in solution in said bulb; and
    such that said cover is sealed to said bulb at said rim, and said cover formed from a generally flexible material; and
    wherein the anticounterfeiting measure comprises a site on said cover for placing an emboss, such that said emboss can be varied at predetermined times.

11. The package of claim 10 further comprising a dimple on said cover, and wherein the dimple contains said emboss.

12. The package of claim 10 or 11 wherein the emboss is cross-shaped.

13. The package of claim 10 or 11 wherein the emboss is starfish-shaped.

14. The package of claim 10 or 11 wherein the emboss is a three-pointed star shape.

15. A lens package with an anticounterfeiting measure contained therein, wherein said anticounterfeiting measure comprises a cover for said package containing an area capable of embossing with an emboss, such that a manufacturer can vary said emboss over a predetermined period of time.

16. The package of claim 15 further comprising a dimple on said cover, and wherein the dimple contains said emboss.

17. The package of claim 15 or 16 wherein the emboss is cross-shaped.

18. The package of claim 15 or 16 wherein the emboss is starfish-shaped.

19. The package of claim 15 or 16 wherein the emboss is a three-pointed star shape.

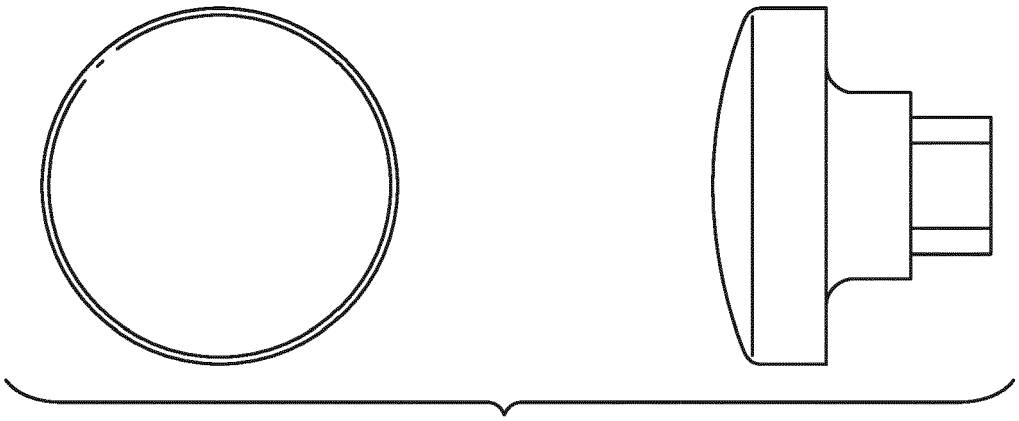


FIG. 1

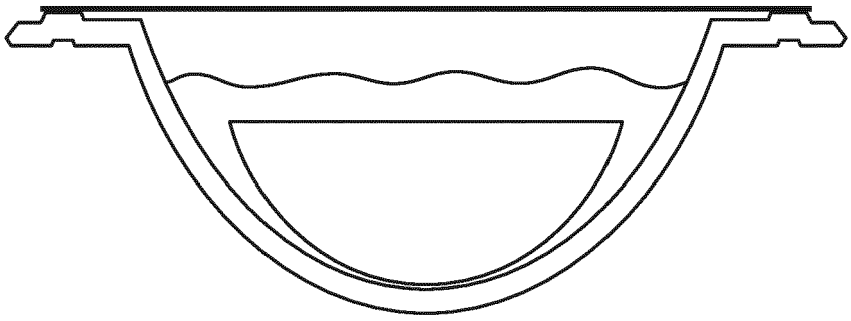


FIG. 2

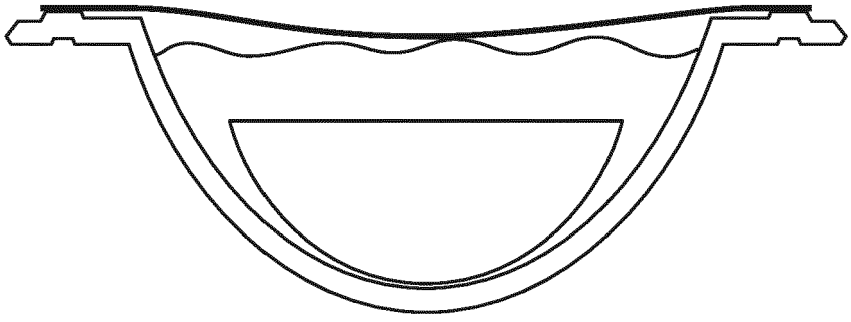


FIG. 3

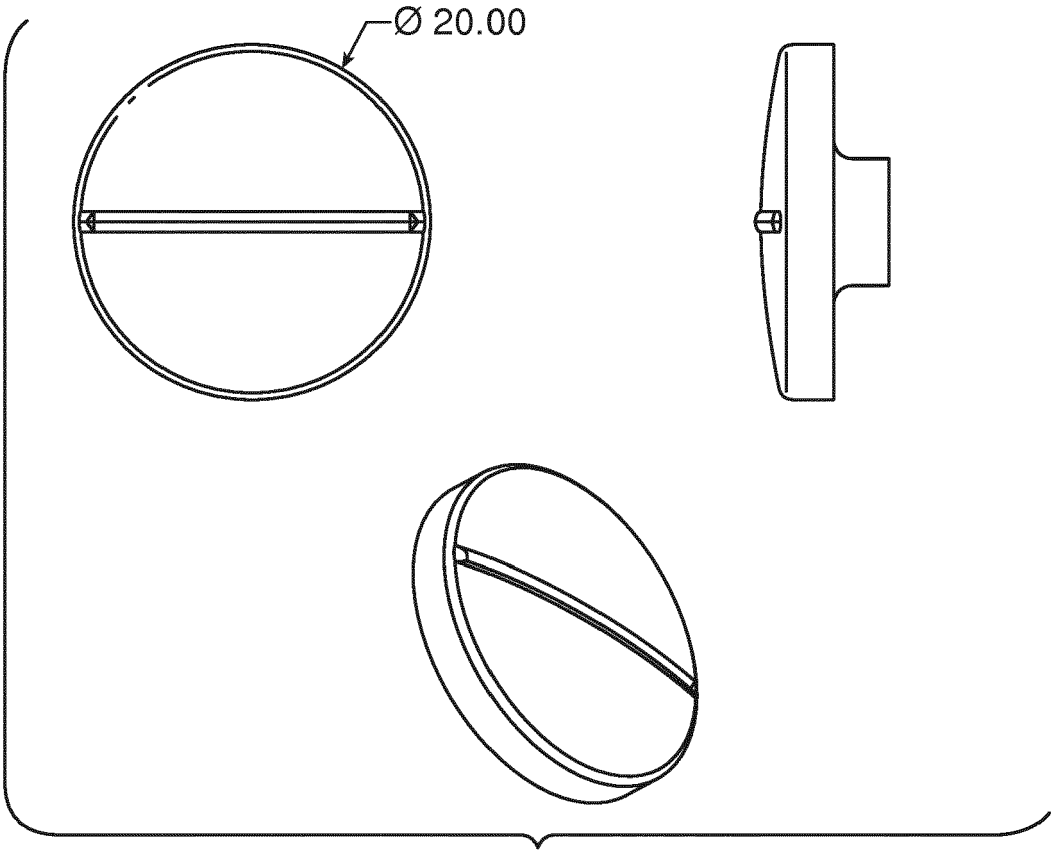

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FIG. 4

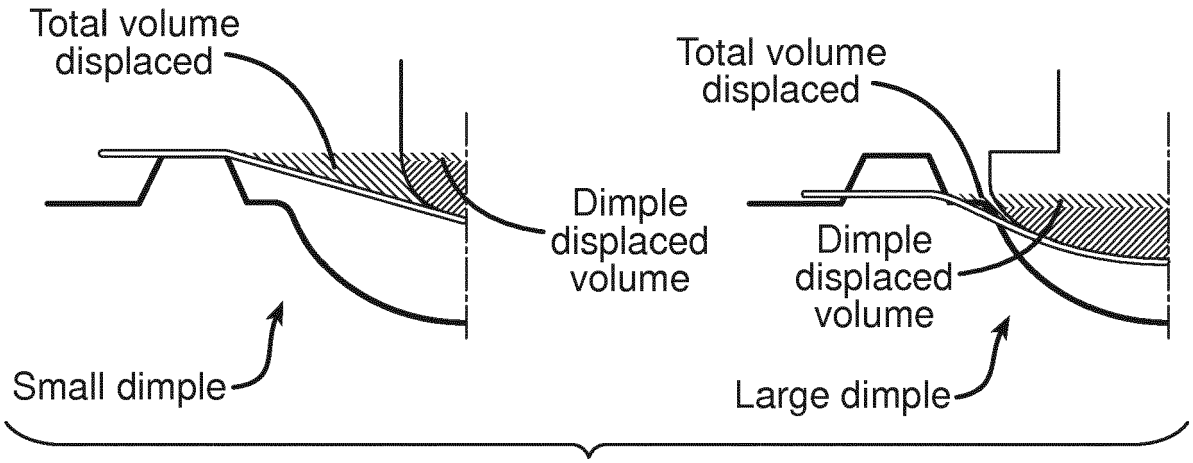

Total volume displaced
Dimple displaced volume
Small dimple
Total volume displaced
Dimple displaced volume
Large dimple

FIG. 5

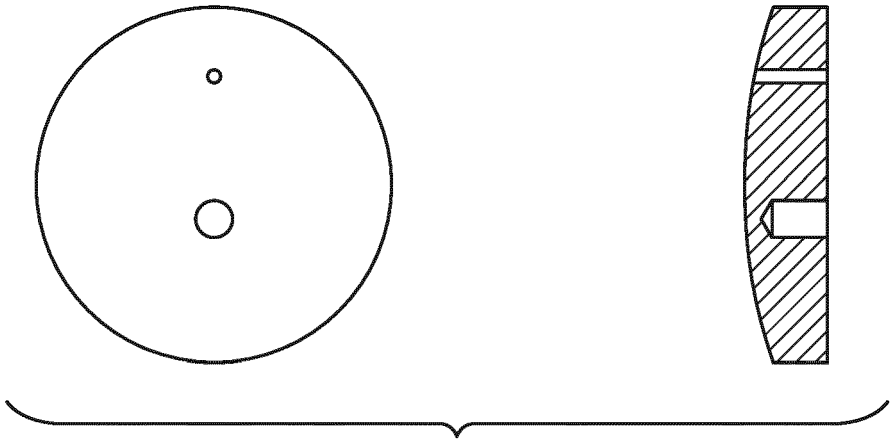


FIG. 6

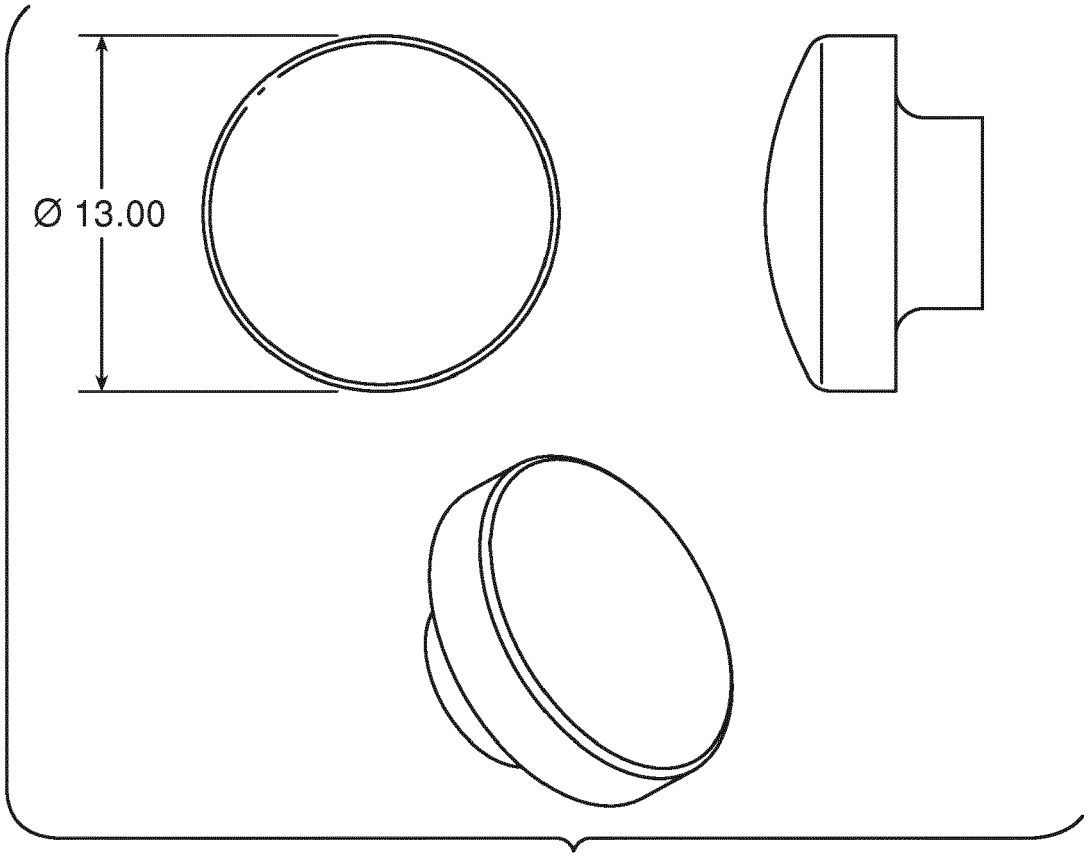


FIG. 7

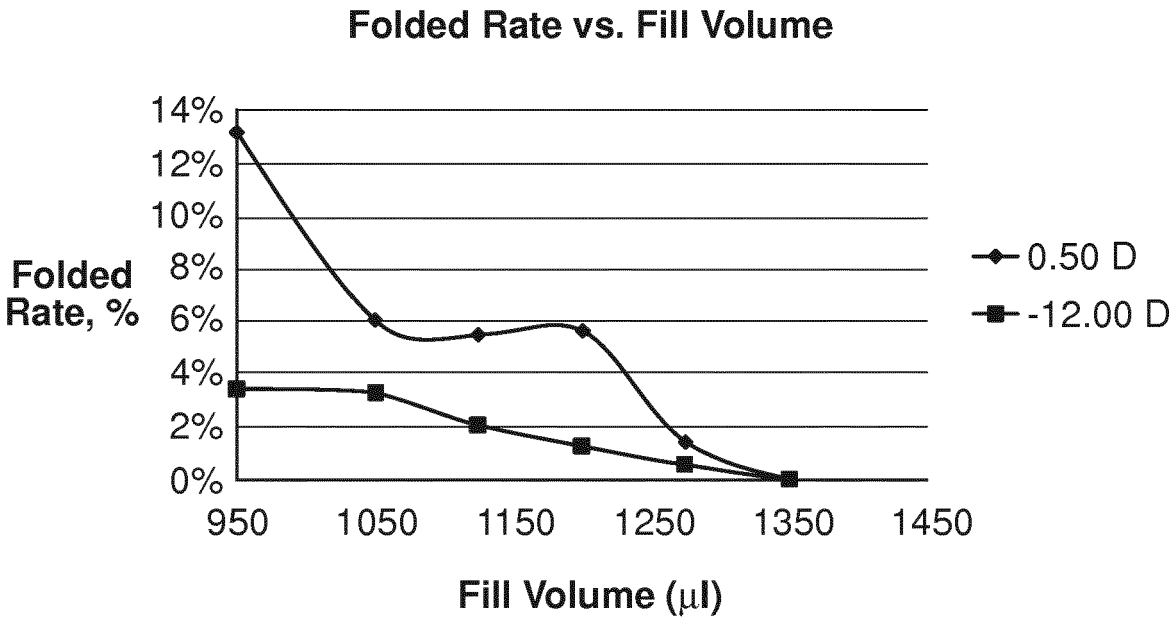

Folded Rate vs. Fill Volume
Folded Rate, %
14%
12%
10%
8%
6%
4%
2%
0%
950
1050
1150
1250
1350
1450
Fill Volume (μl)
0.50 D
-12.00 D

FIG. 8

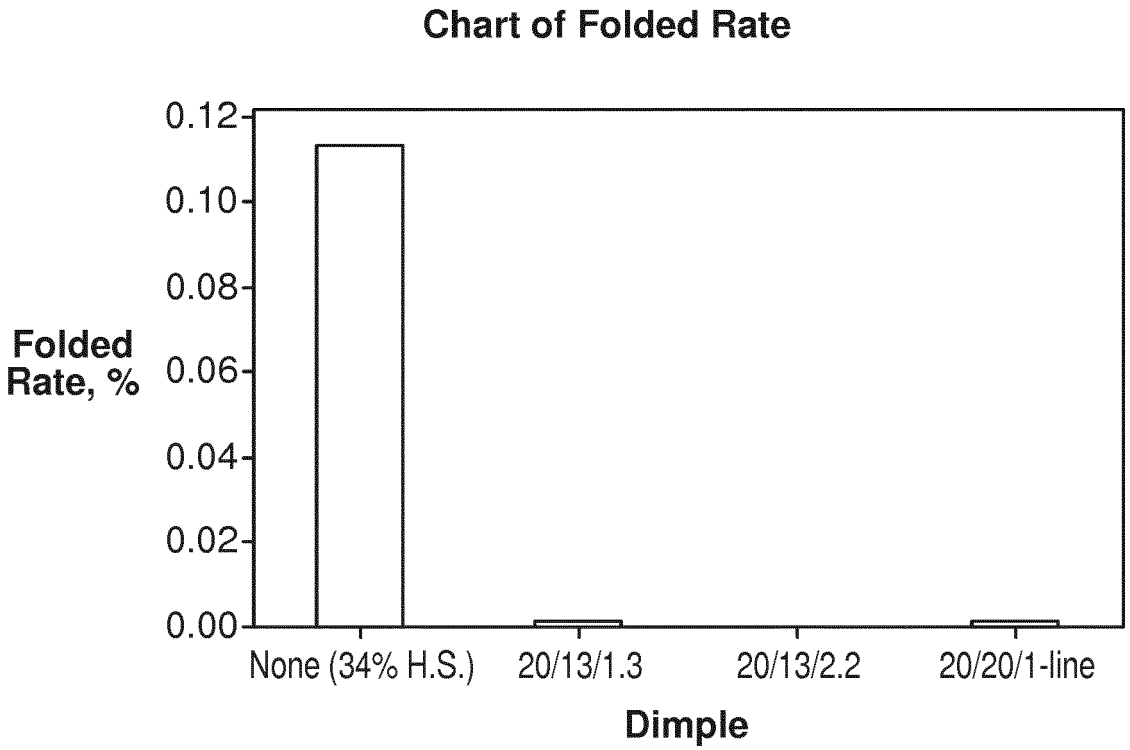

Chart of Folded Rate
Folded Rate, %
0.12
0.10
0.08
0.06
0.04
0.02
0.00
None (34% H.S.)
20/13/1.3
20/13/2.2
20/20/1-line
Dimple

FIG. 9

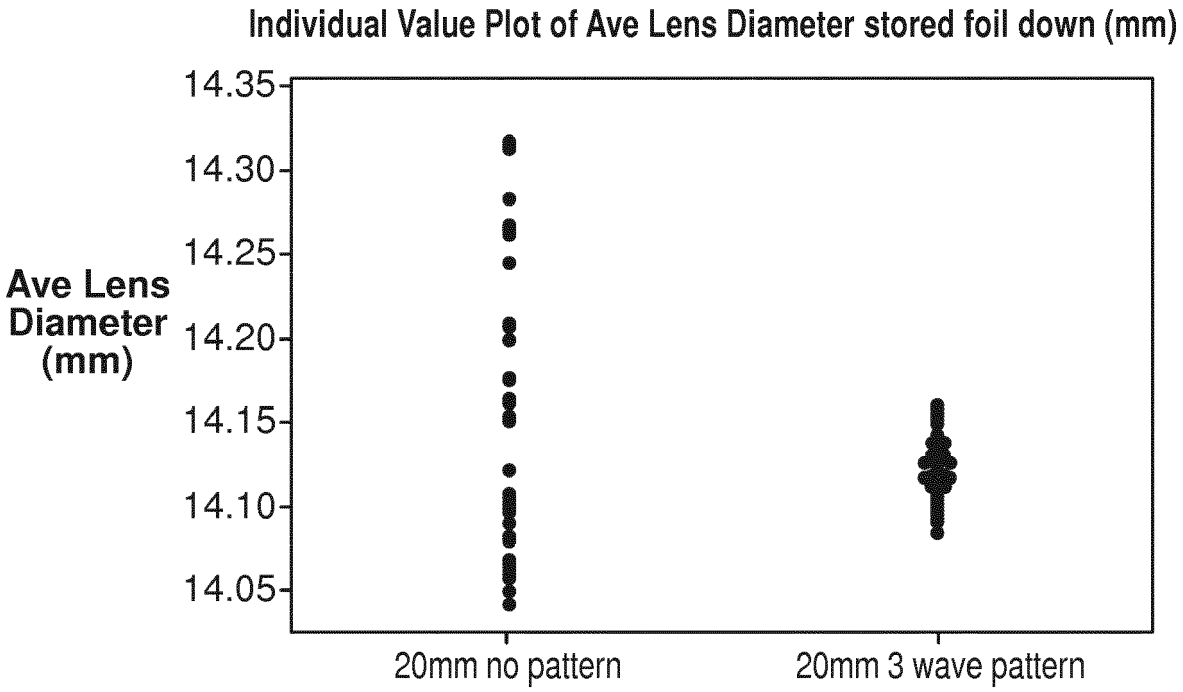

Individual Value Plot of Ave Lens Diameter stored foil down (mm)
Ave Lens Diameter (mm)
14.35
14.30
14.25
14.20
14.15
14.10
14.05
20mm no pattern
20mm 3 wave pattern

FIG. 10

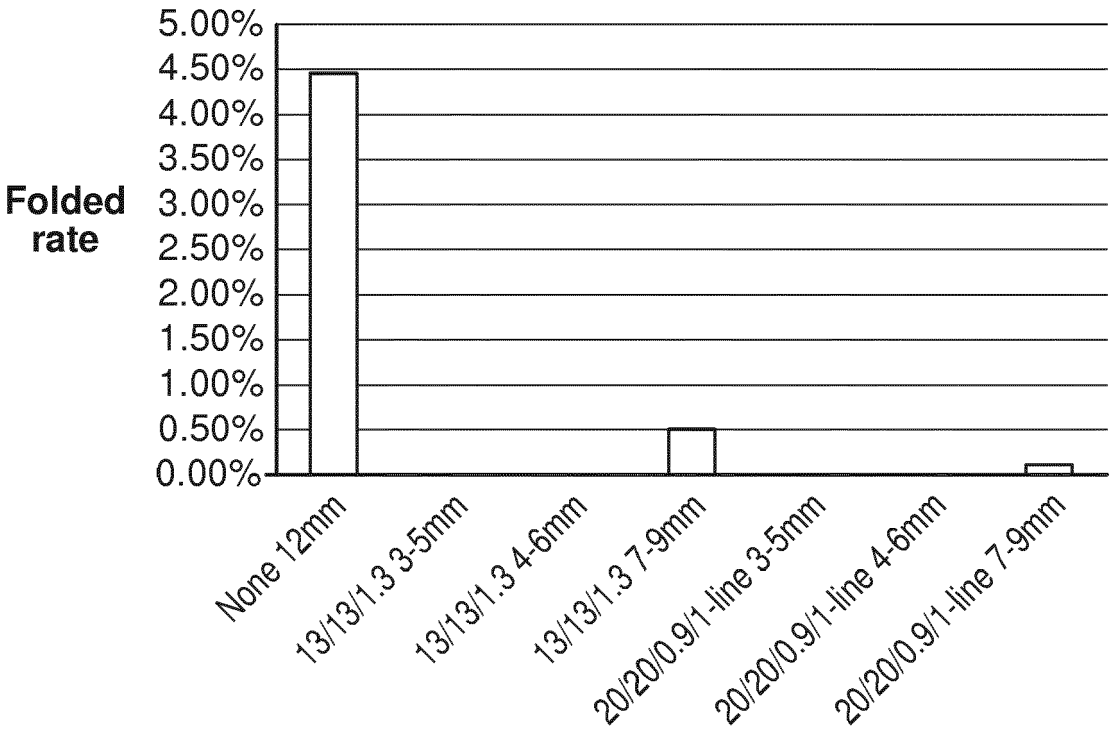

Folded rate
5.00%
4.50%
4.00%
3.50%
3.00%
2.50%
2.00%
1.50%
1.00%
0.50%
0.00%
None 12mm
13/13/1.3 3-5mm
13/13/1.3 4-6mm
13/13/1.3 7-9mm
20/20/0.9/1-line 3-5mm
20/20/0.9/1-line 4-6mm
20/20/0.9/1-line 7-9mm

FIG. 11

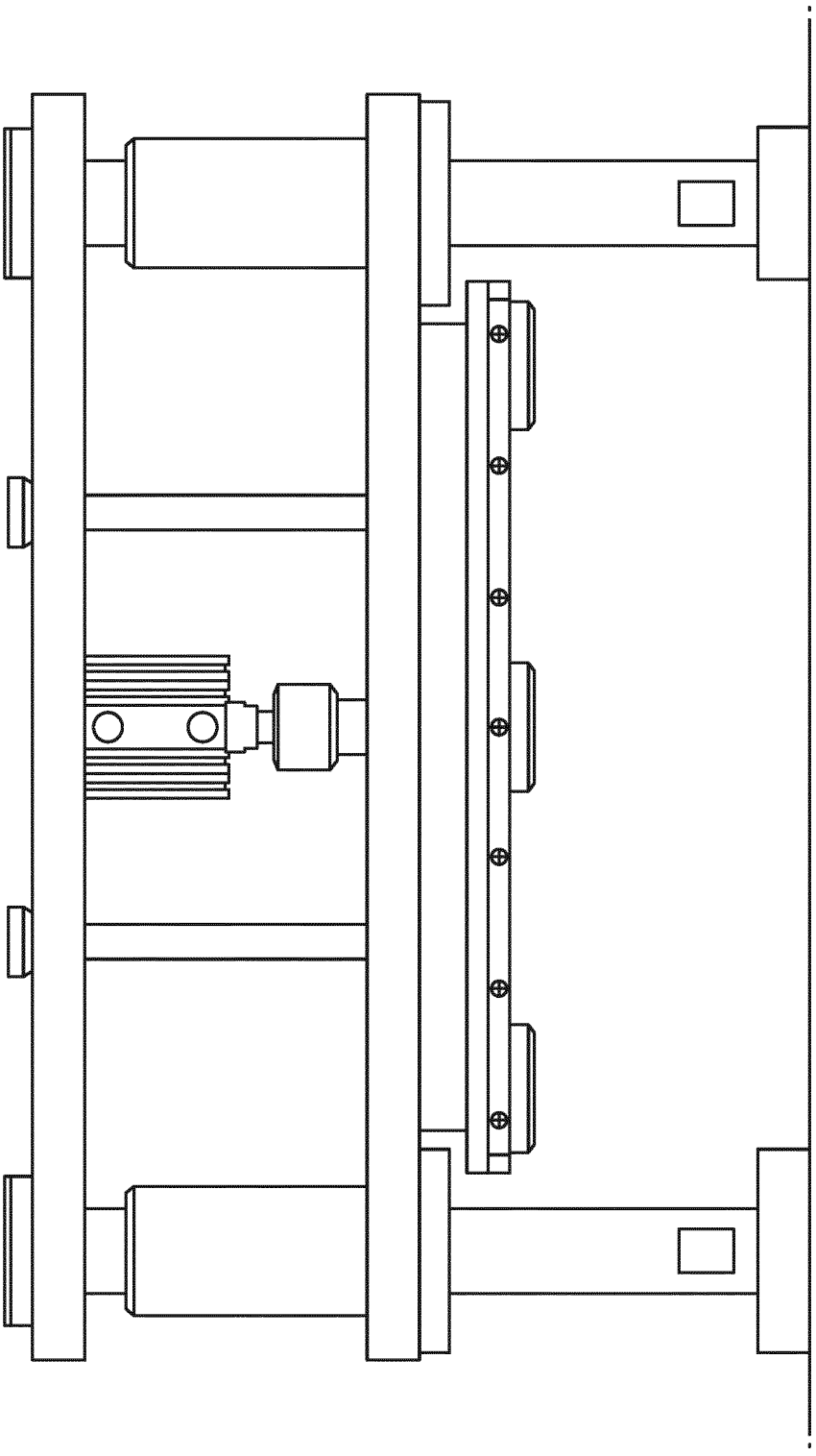


FIG. 12

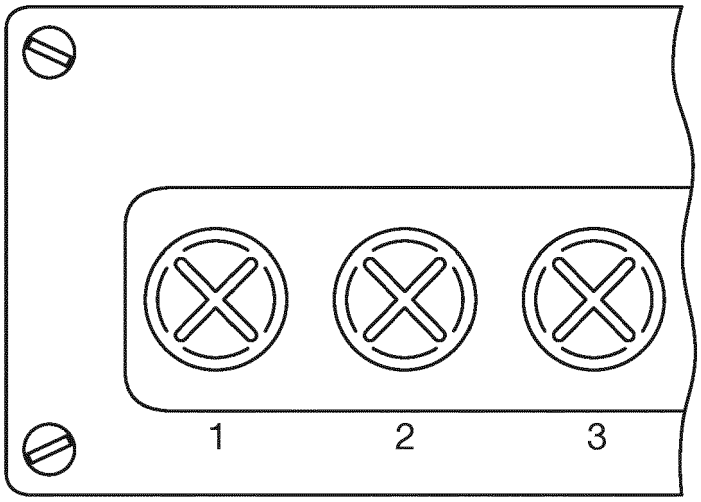


FIG. 13A

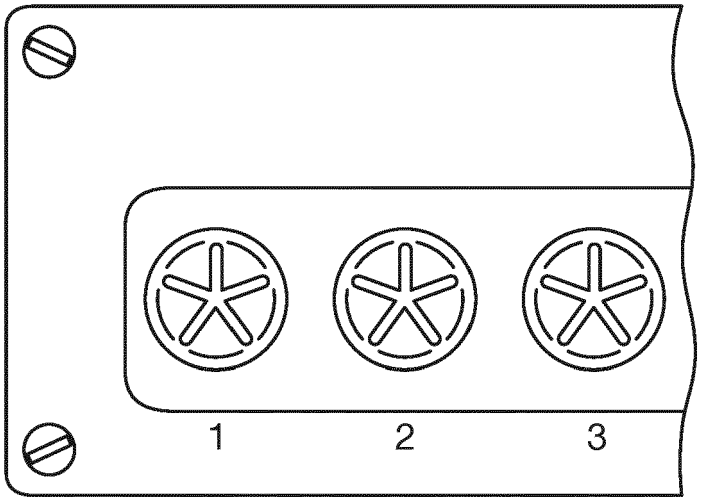


FIG. 13B

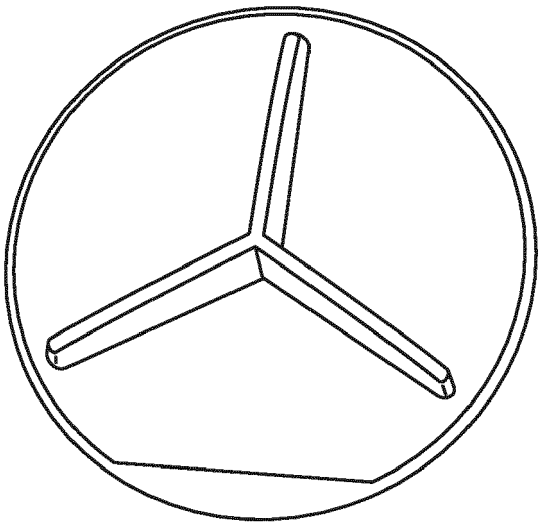


FIG. 13C

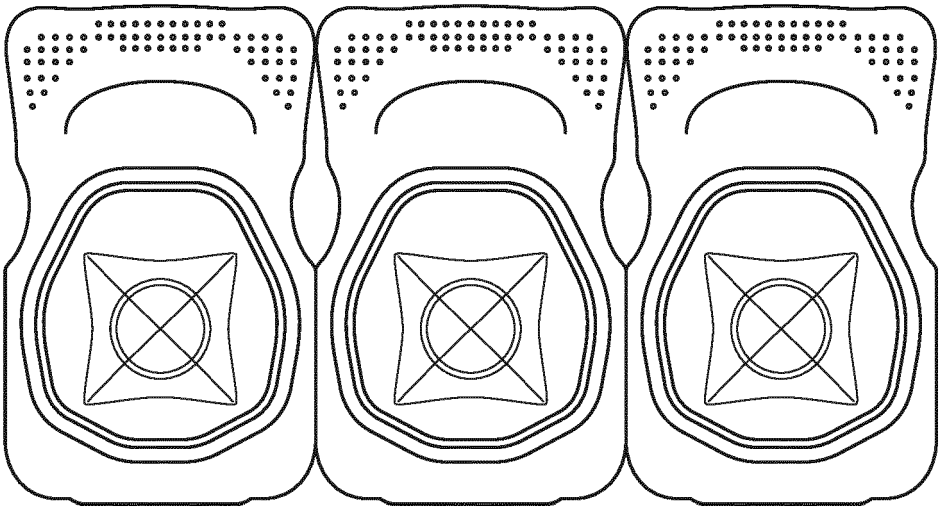


FIG. 14A

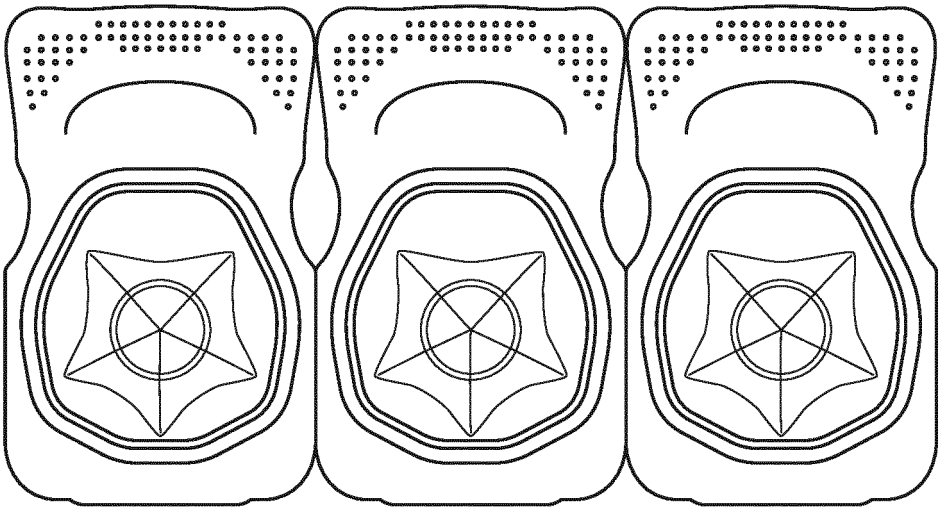


FIG. 14B

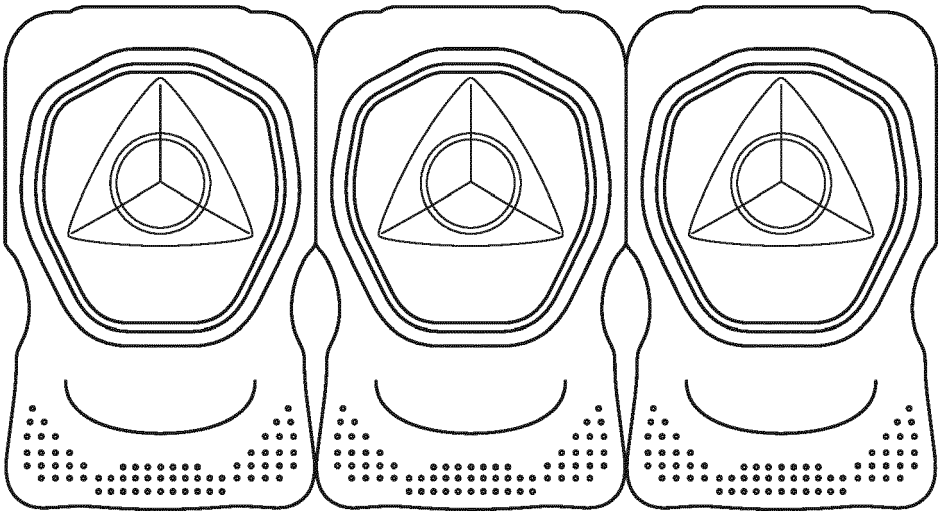


FIG. 14C

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EUROPEAN SEARCH REPORT

Application Number
EP 18 17 5590

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2014/262844 A1 (BARRE VINCENT [US] ET AL) 18 September 2014 (2014-09-18) * paragraph [0035] - paragraph [0045]; figures 1-7 * -----	1-19	INV. A45C11/00 B65D75/32

TECHNICAL FIELDS SEARCHED (IPC)

A45C
B65D

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	22 October 2018	Derrien, Yannick

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