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(54) **MASKED INTRAOCULAR IMPLANTS AND LENSES**

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(73) Assignee: **ACUFOCUS, INC.**, Irvine, CA (US)

(21) Appl. No.: **13/558,286**

(22) Filed: **Jul. 25, 2012**

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(63) Continuation of application No. 12/856,492, filed on Aug. 13, 2010.

(60) Provisional application No. 61/233,794, filed on Aug. 13, 2009, provisional application No. 61/233,804, filed on Aug. 13, 2009.

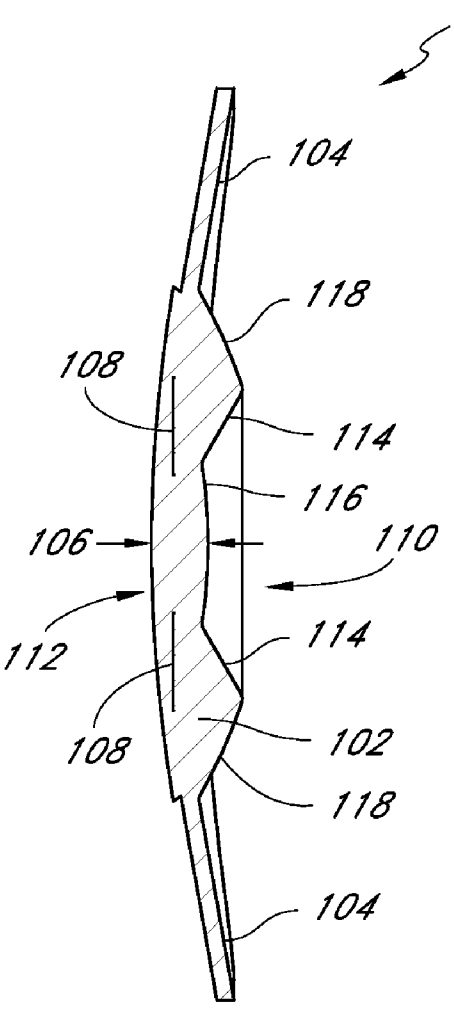
Publication Classification

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A61F 2/16 (2006.01)

(52) **U.S. Cl.** **623/6.17**

(57) **ABSTRACT**

Intraocular implants and methods of making intraocular implants are provided. The intraocular implants can improve the vision of a patient, such as by increasing the depth of focus of an eye of a patient. In particular, the intraocular implants can include a mask having an annular portion with a relatively low visible light transmission surrounding a relatively high transmission central portion such as a clear lens or aperture. This construct is adapted to provide an annular mask with a small aperture for light to pass through to the retina to increase depth of focus. The intraocular implant may have an optical power for refractive correction. The intraocular implant may be implanted in any location along the optical pathway in the eye, e.g., as an implant in the anterior or posterior chamber.



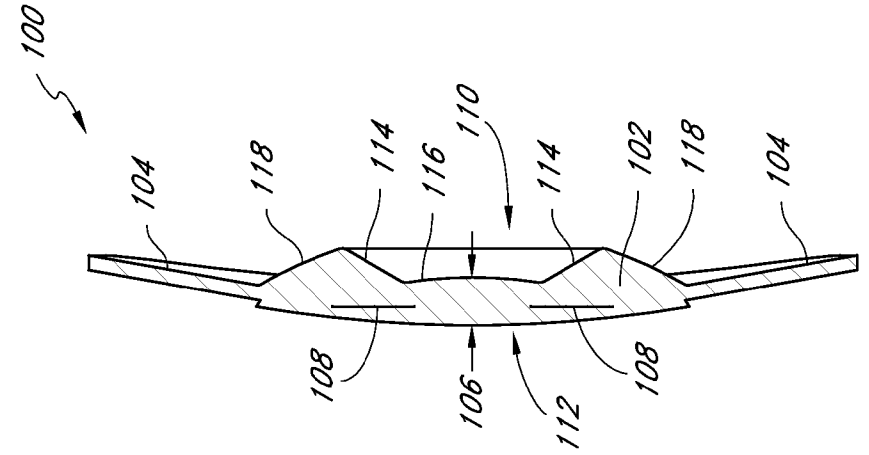

100
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FIG. 1B

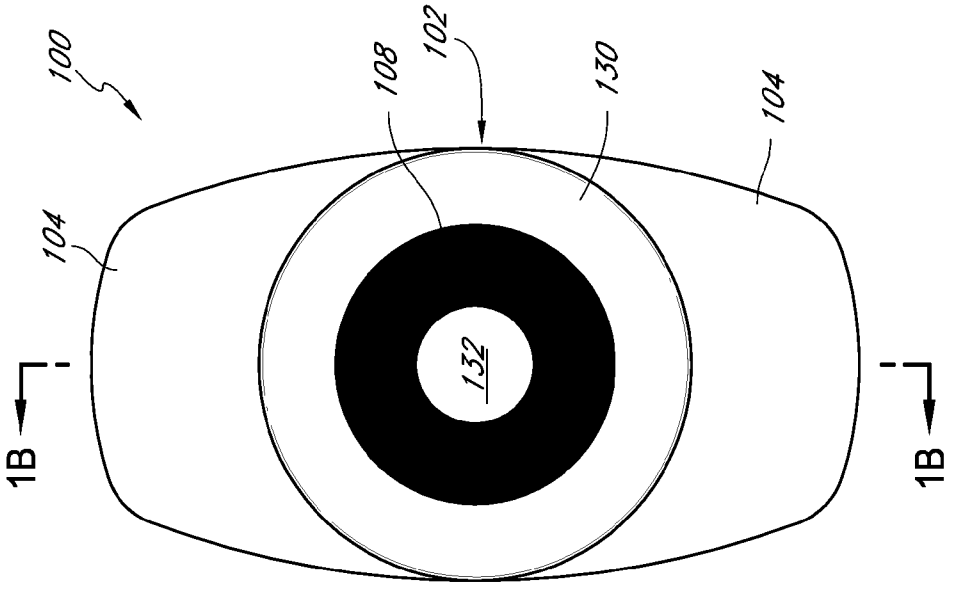

100
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132
1B
1B

FIG. 1A

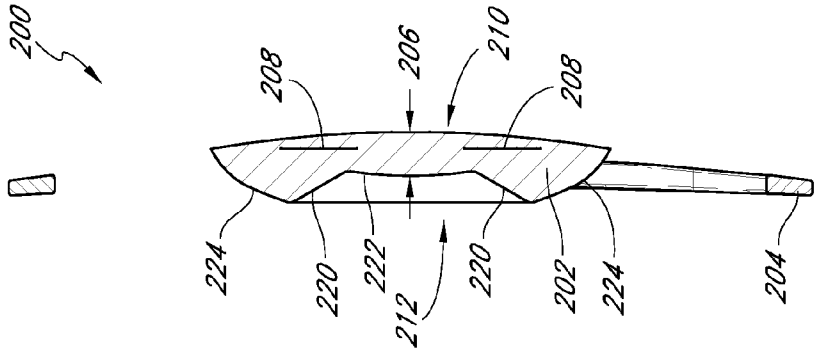

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FIG. 2B

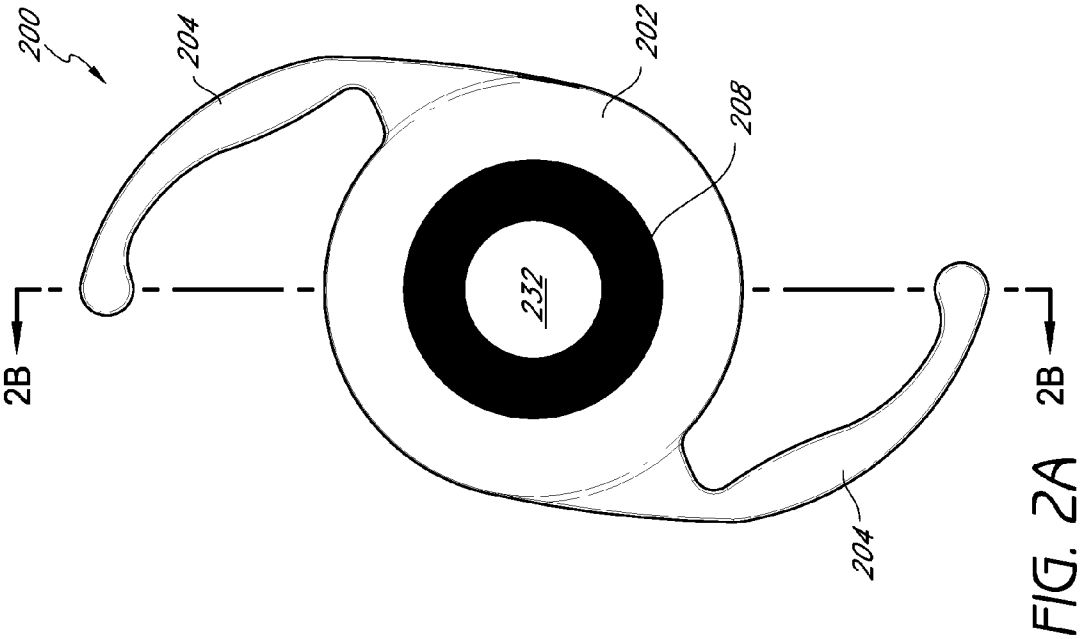

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202
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232
2B
2B
204

FIG. 2A

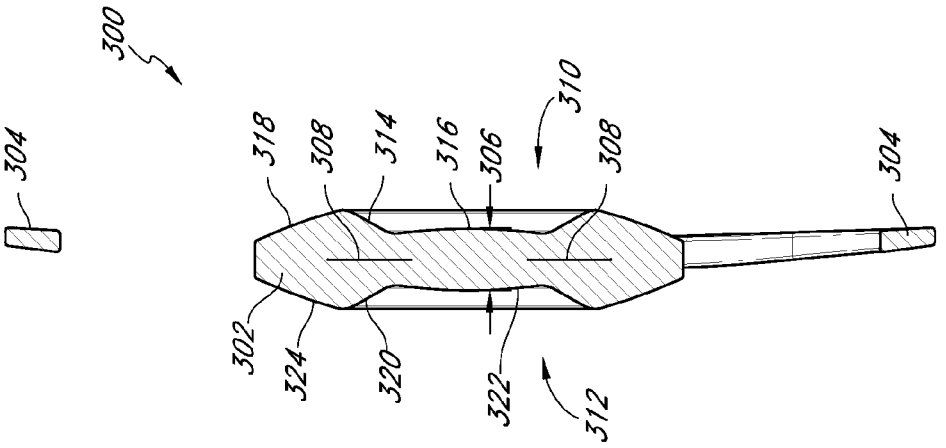

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312

FIG. 3B

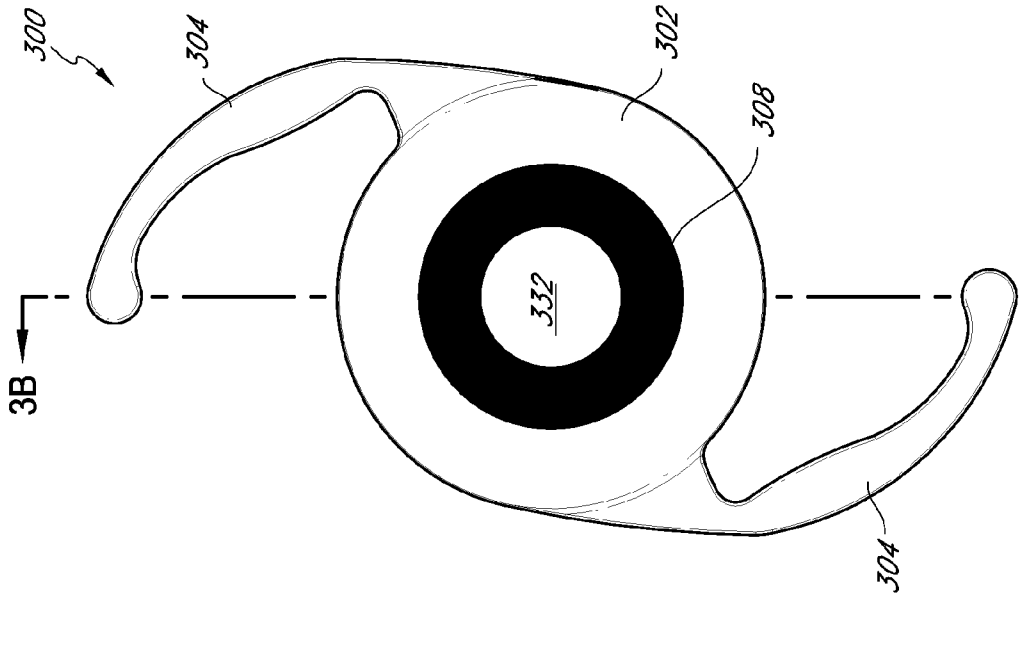

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302
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332
3B
3B
304

FIG. 3A

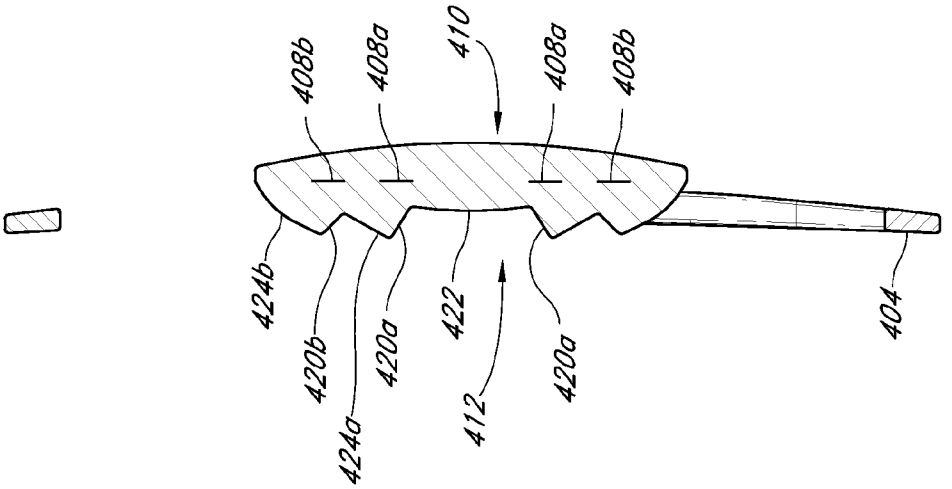

408b
408a
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408a
408b
424b
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424a
420a
422
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420a
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FIG. 4B

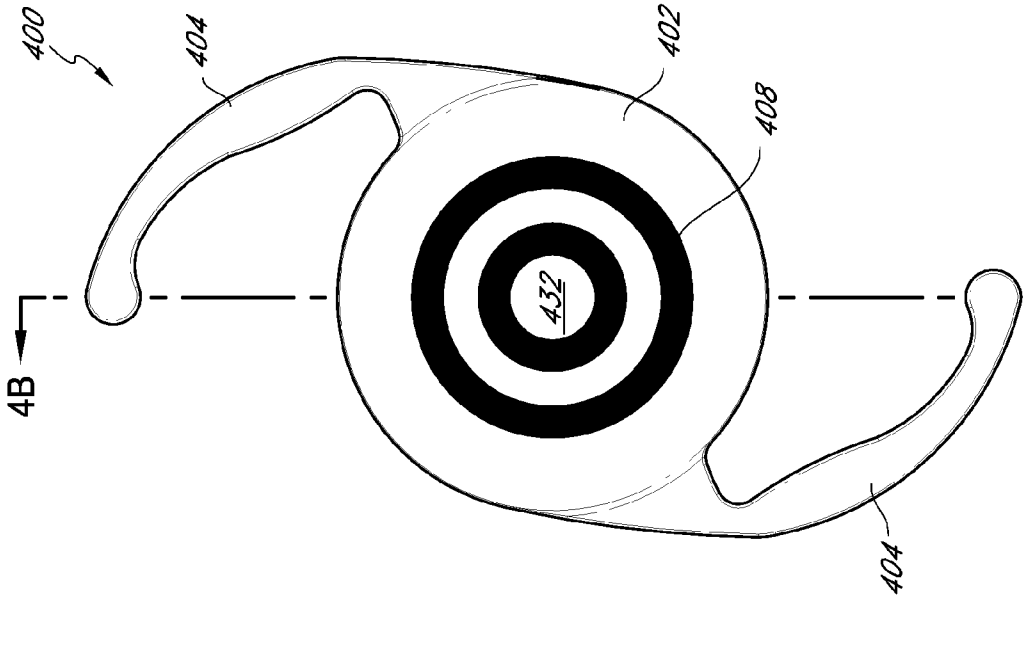

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FIG. 4A

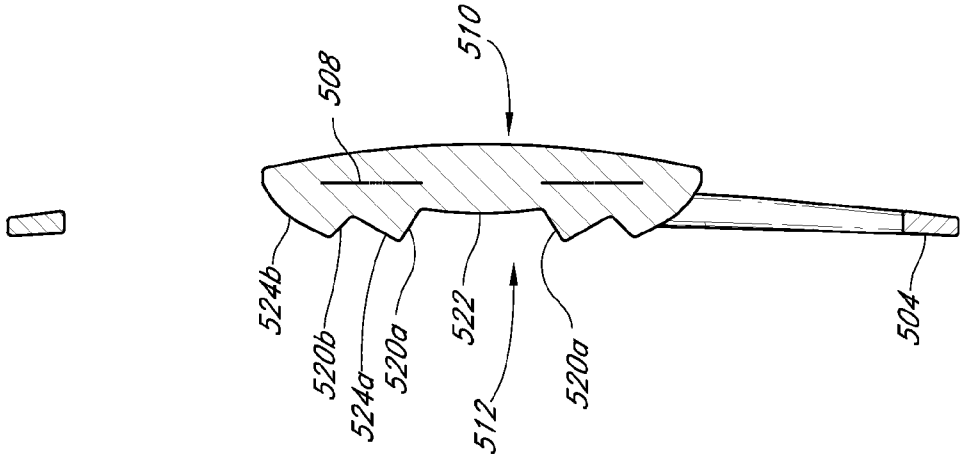

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FIG. 5B

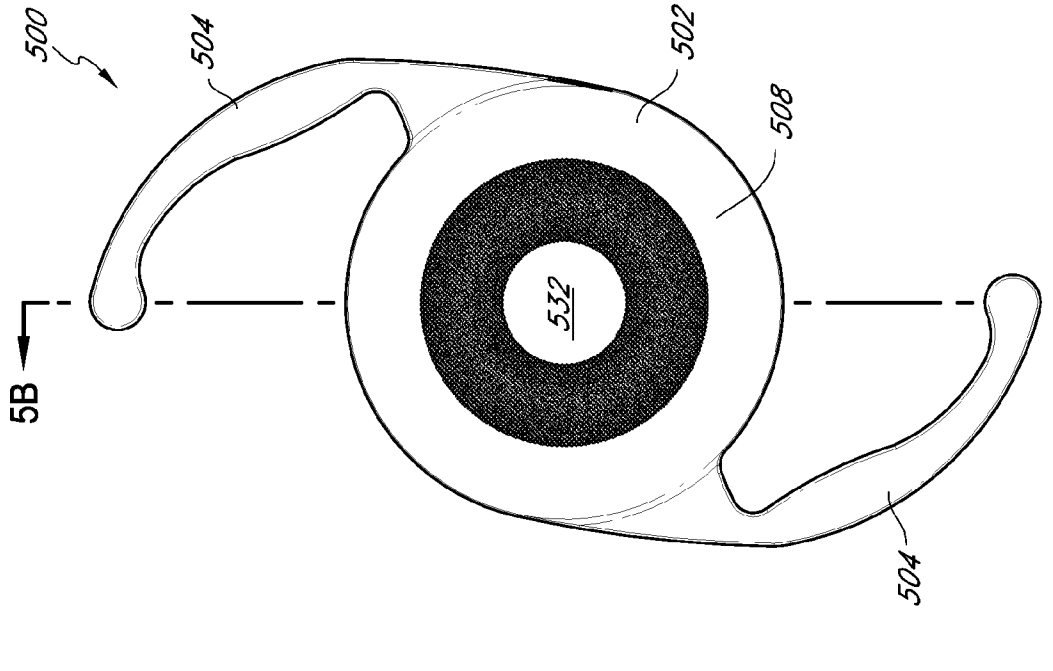

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5B
5B
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FIG. 5A

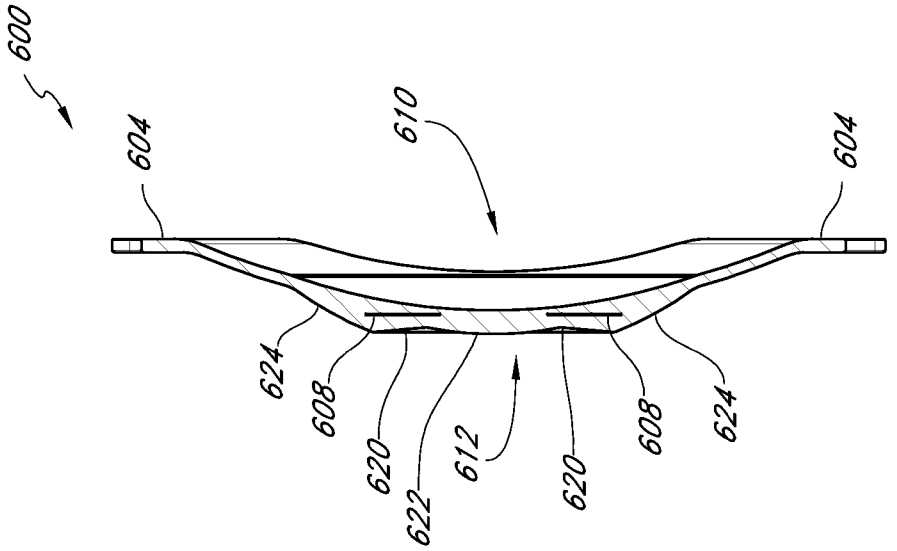

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FIG. 6B

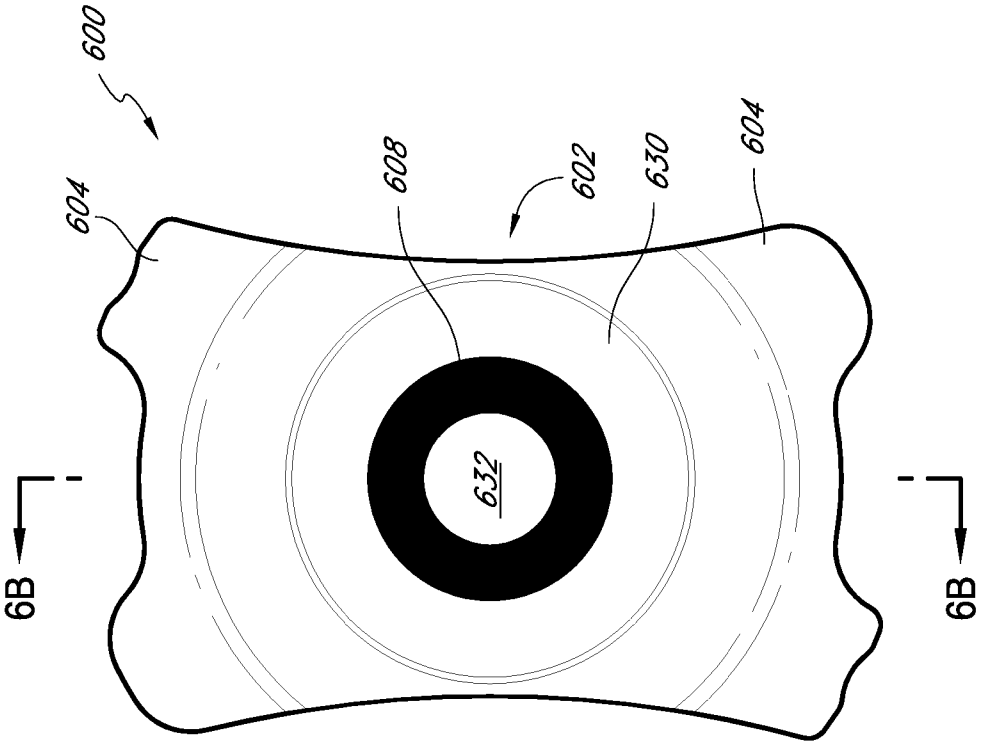

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6B

FIG. 6A

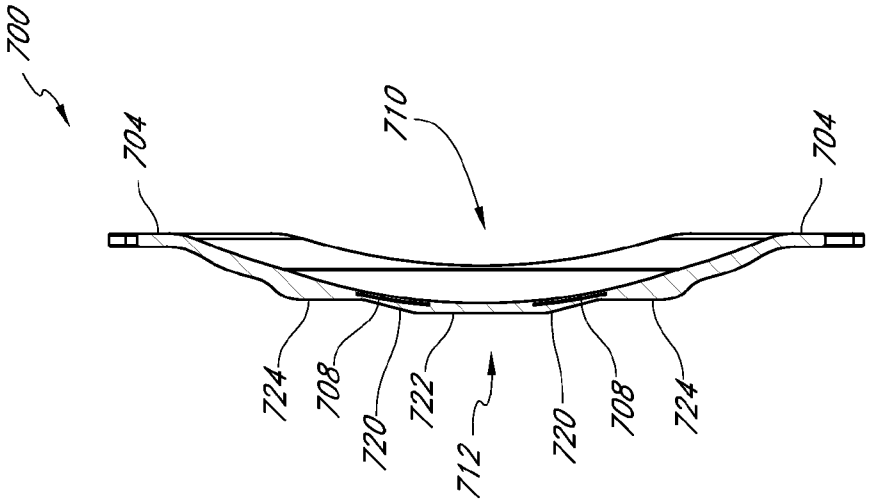

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FIG. 7B

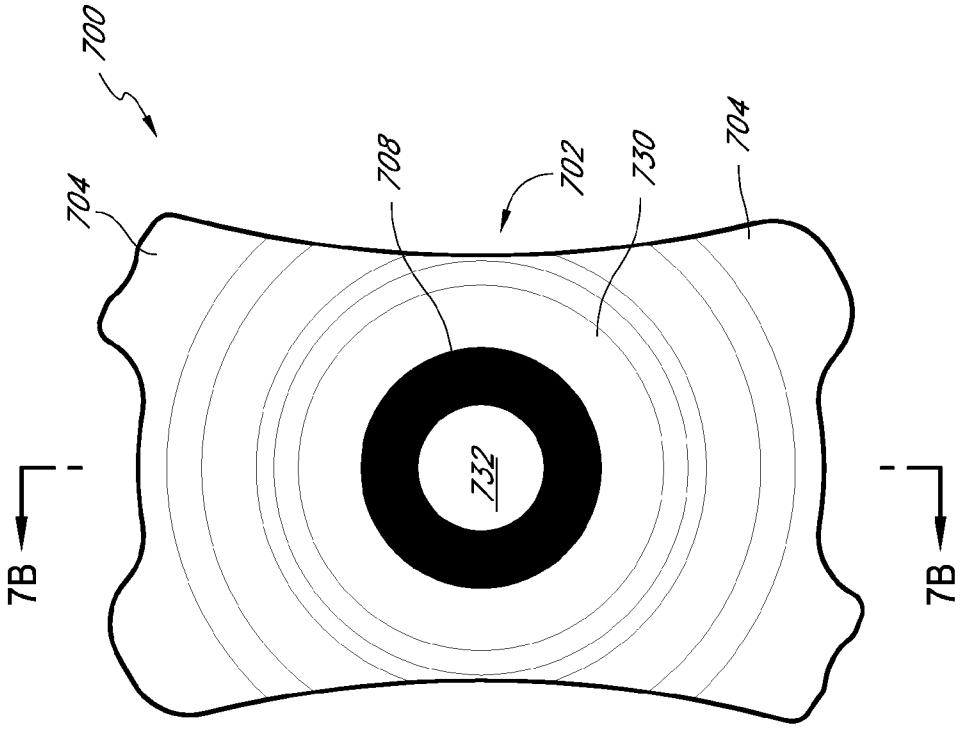

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7B

FIG. 7A

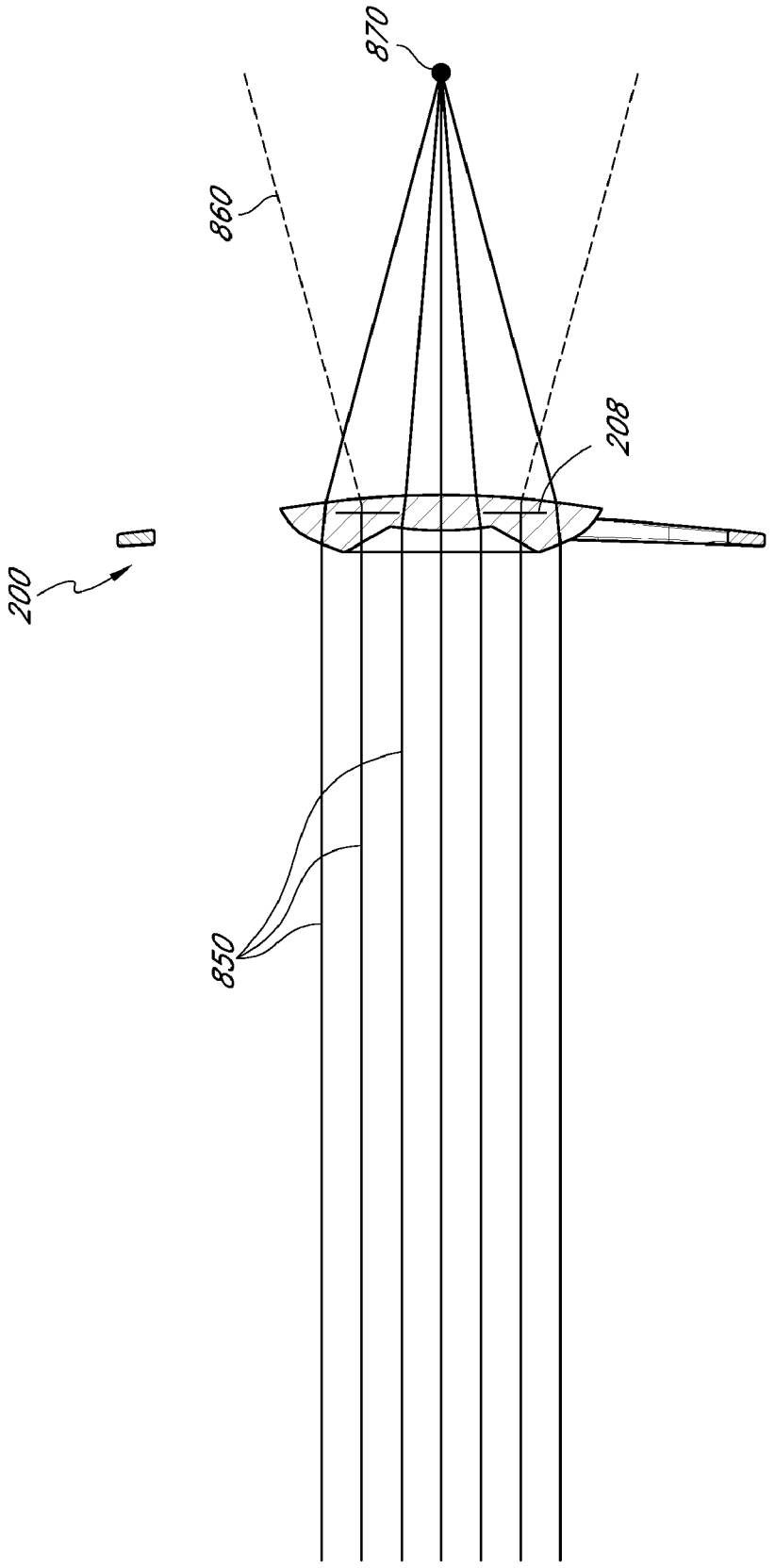


FIG. 8

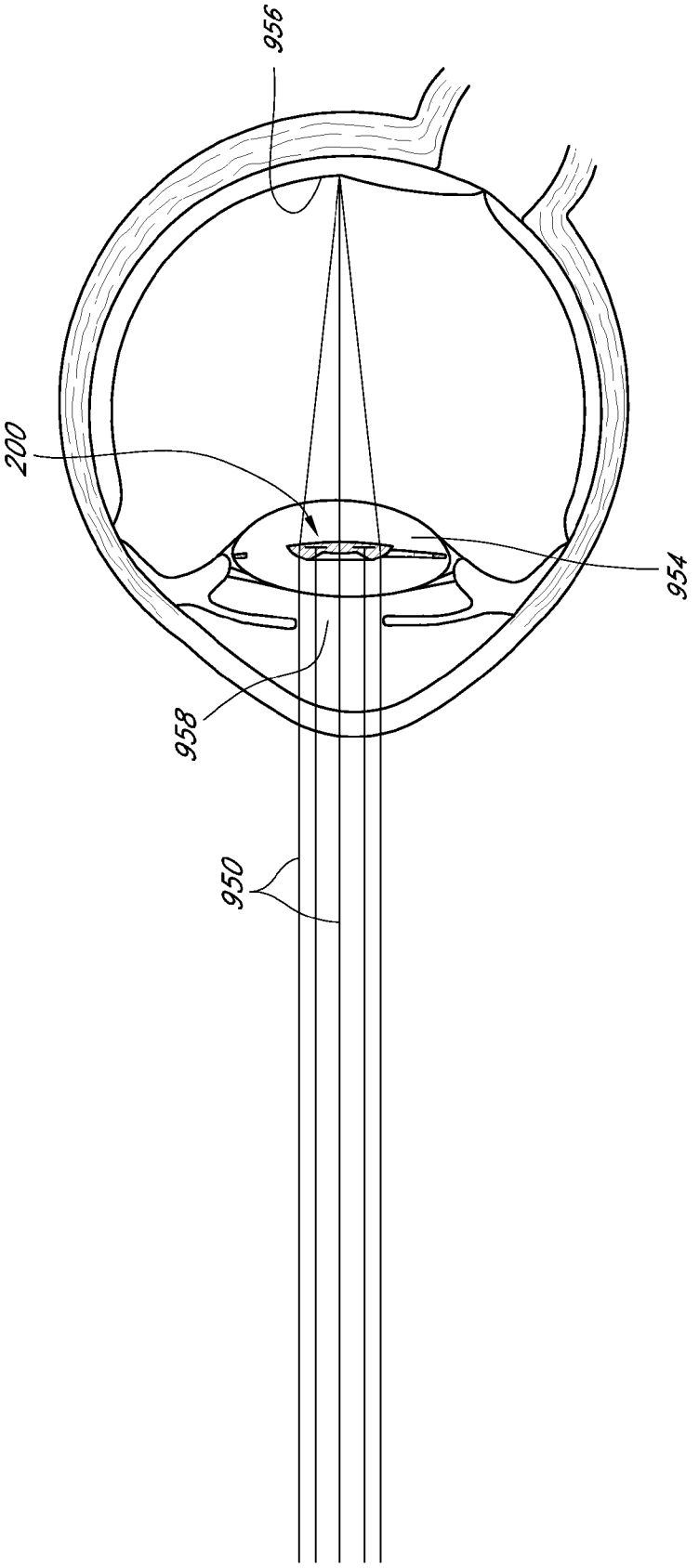


FIG. 9

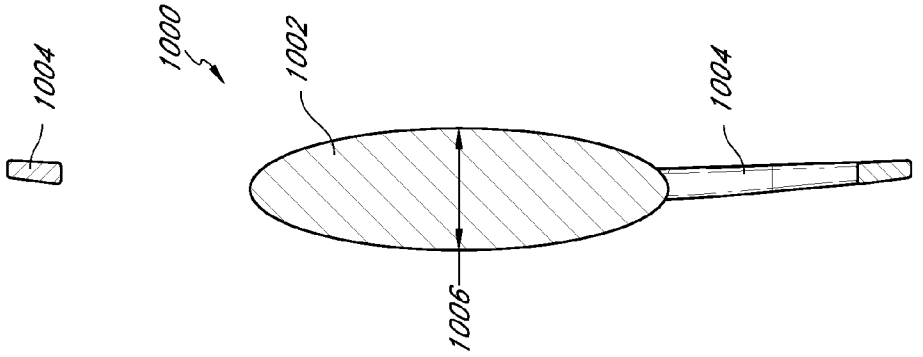


FIG. 10B

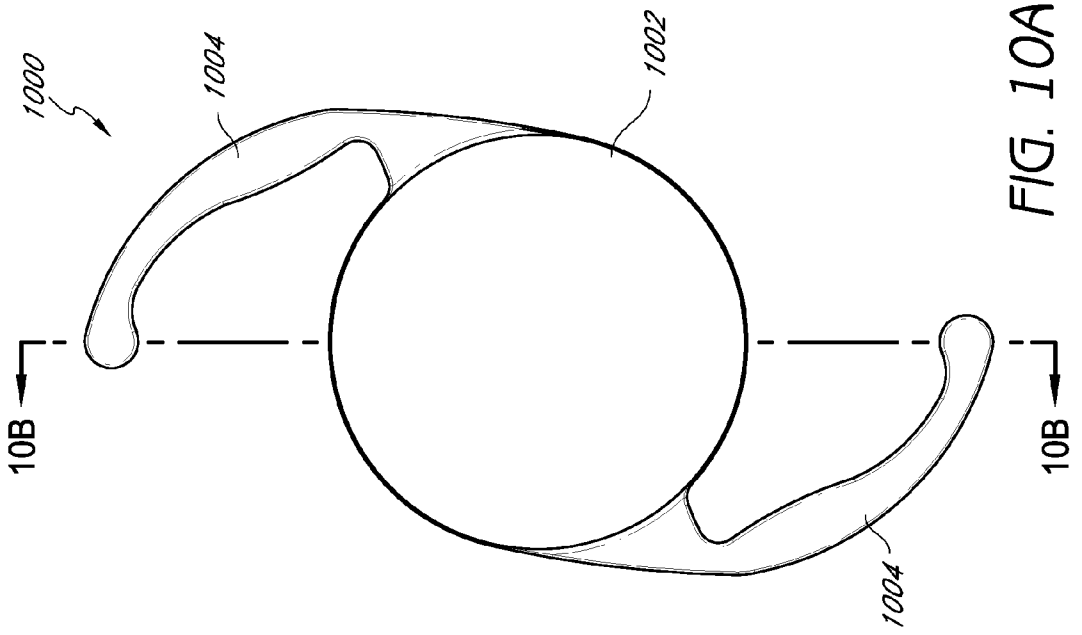


FIG. 10A

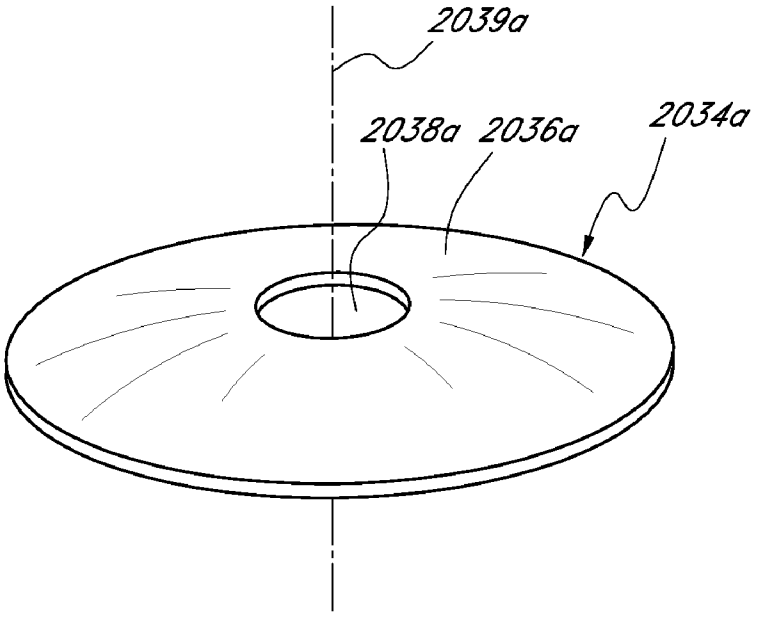


FIG. 11A

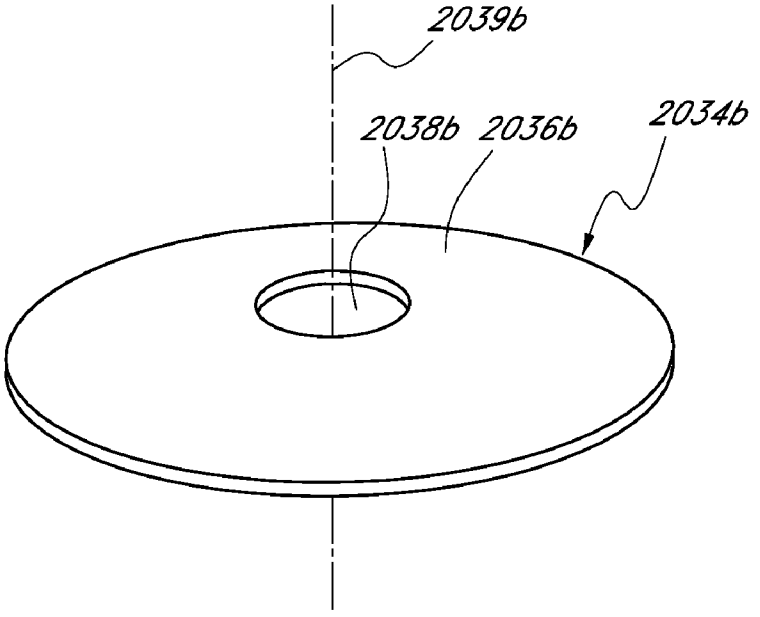


FIG. 11B

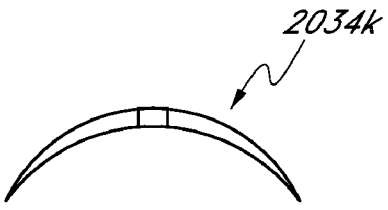


FIG. 12

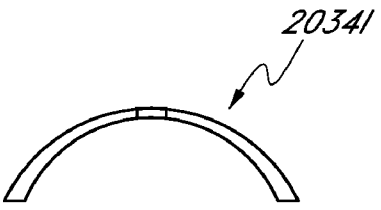


FIG. 13

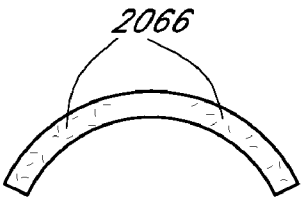


FIG. 14

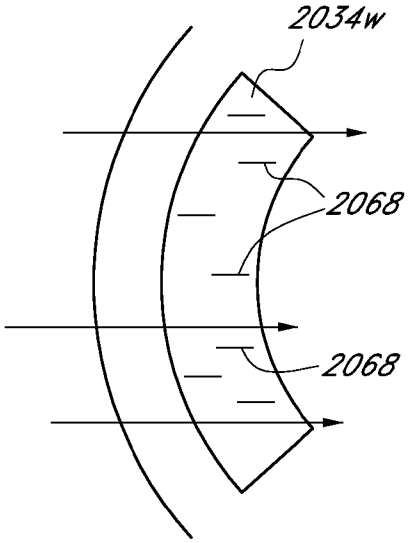


FIG. 15

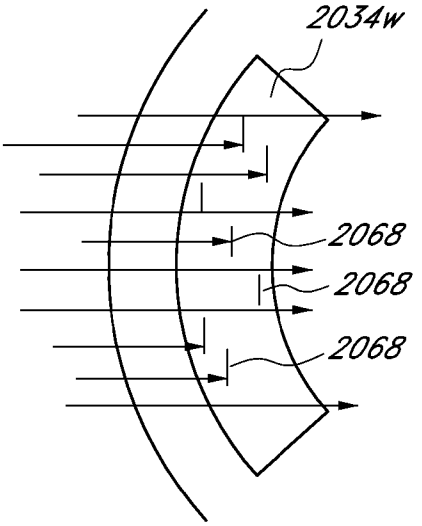


FIG. 16

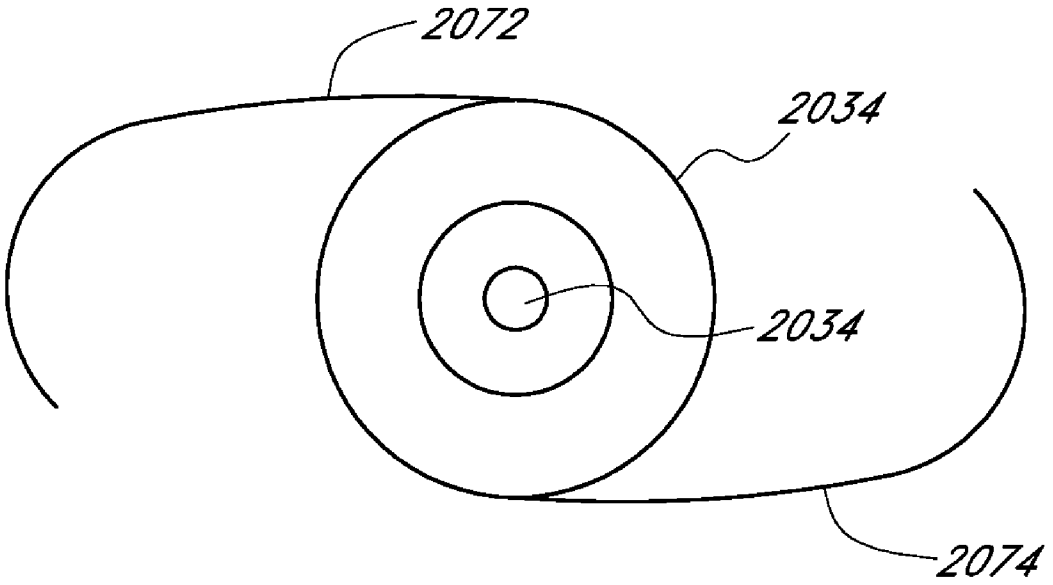


FIG. 17

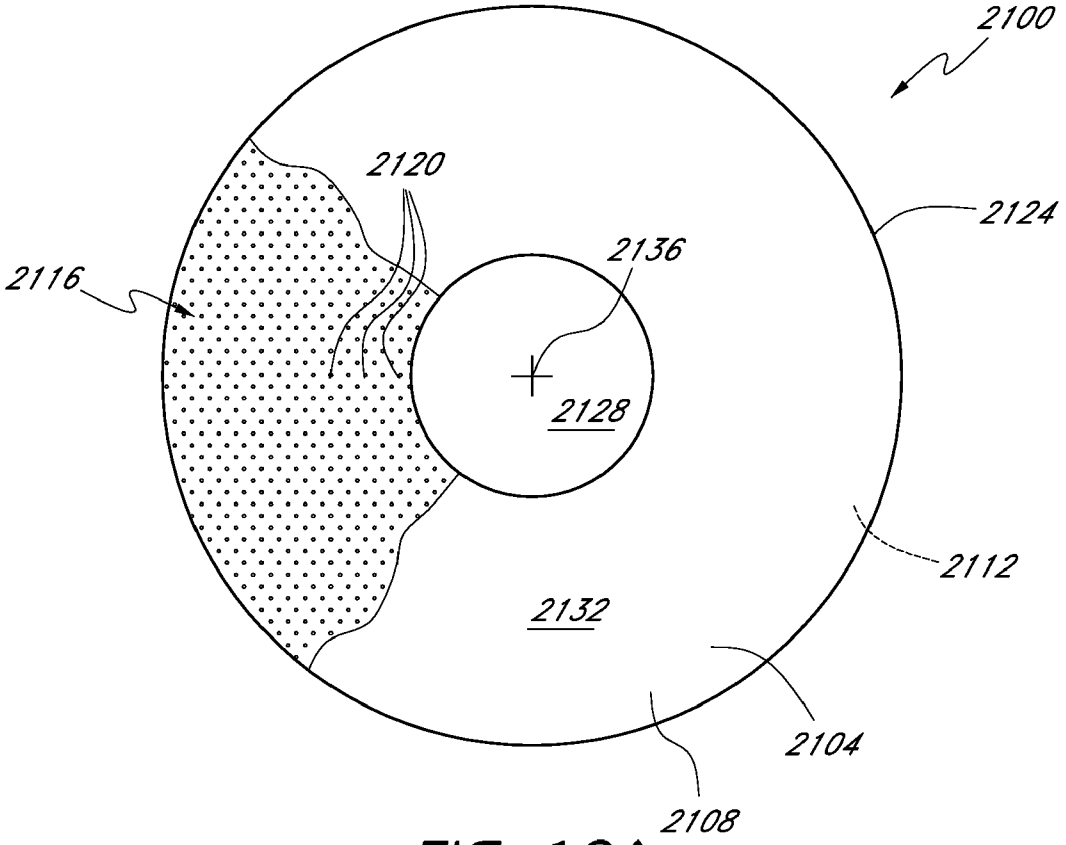


FIG. 18A

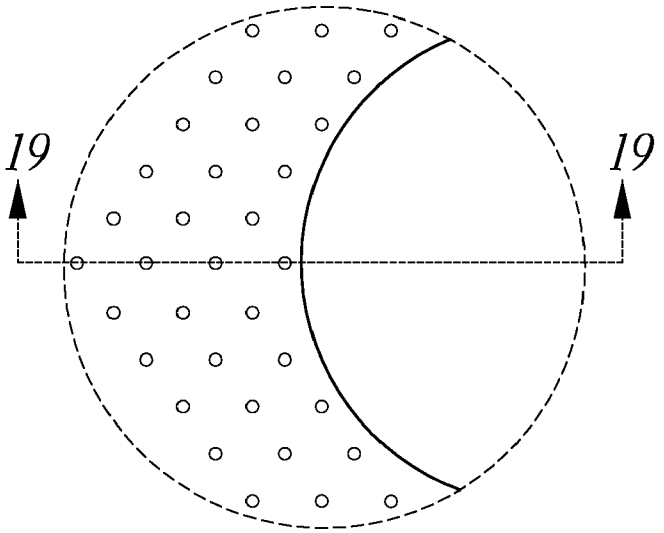


FIG. 18B

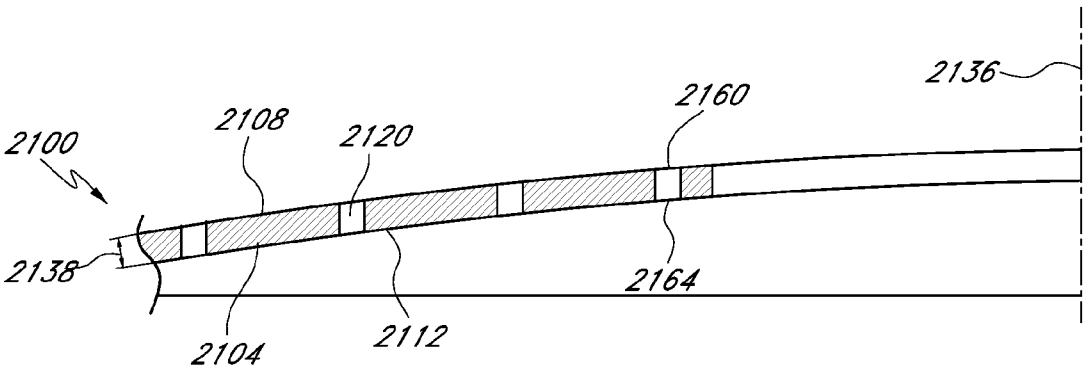


FIG. 19

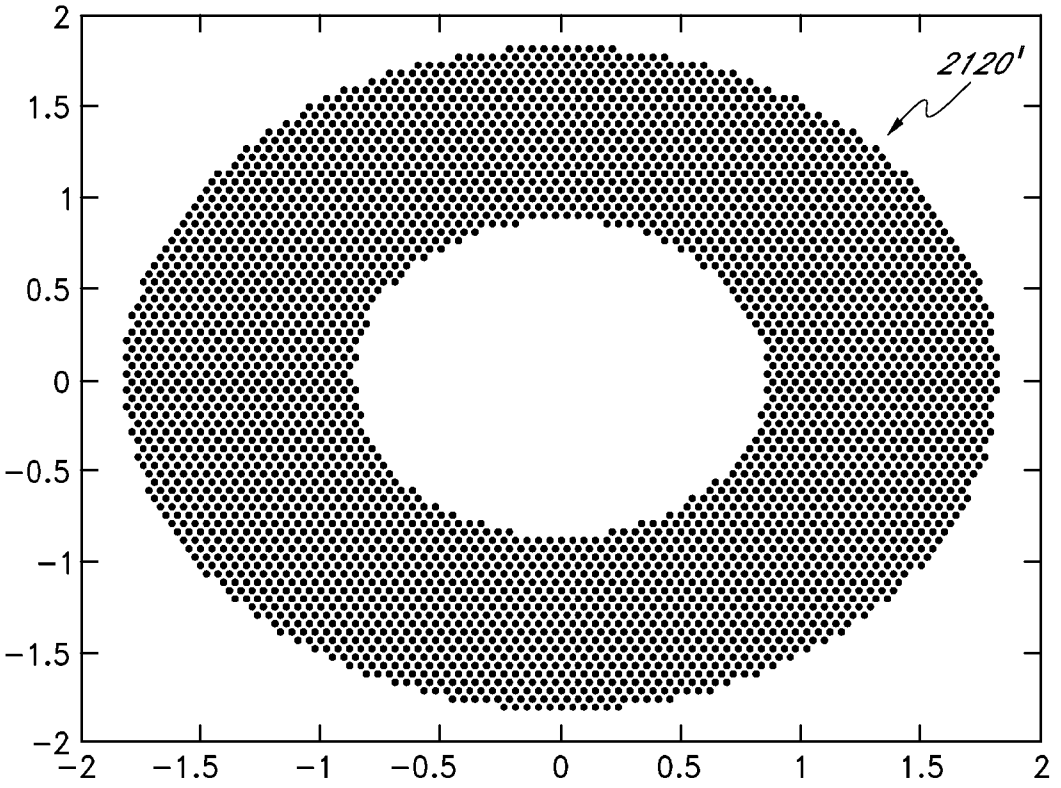


FIG. 20A

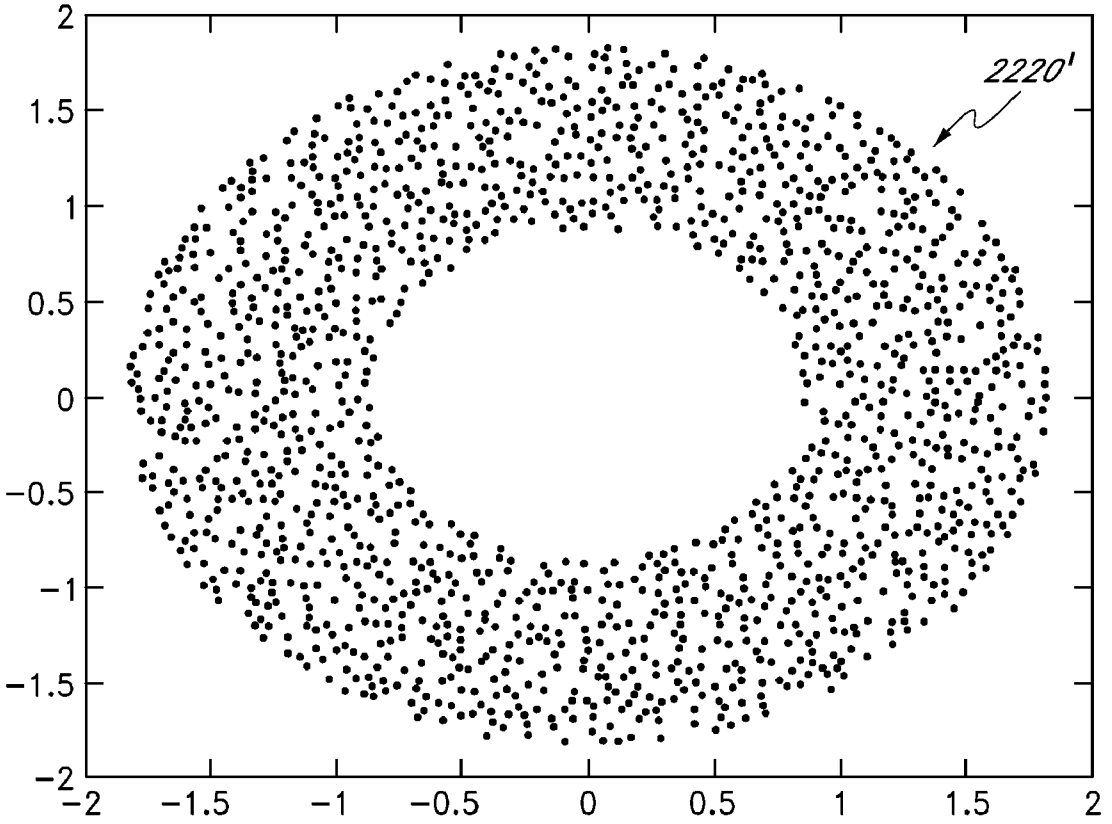


FIG. 20B

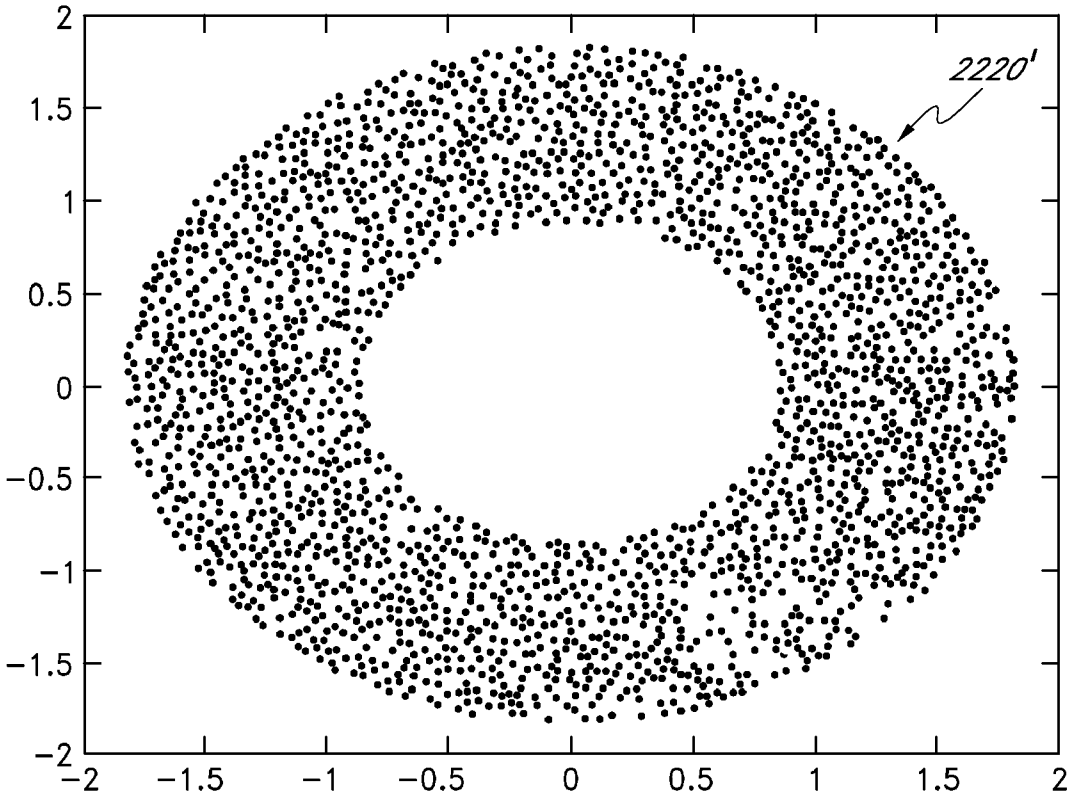


FIG. 20C

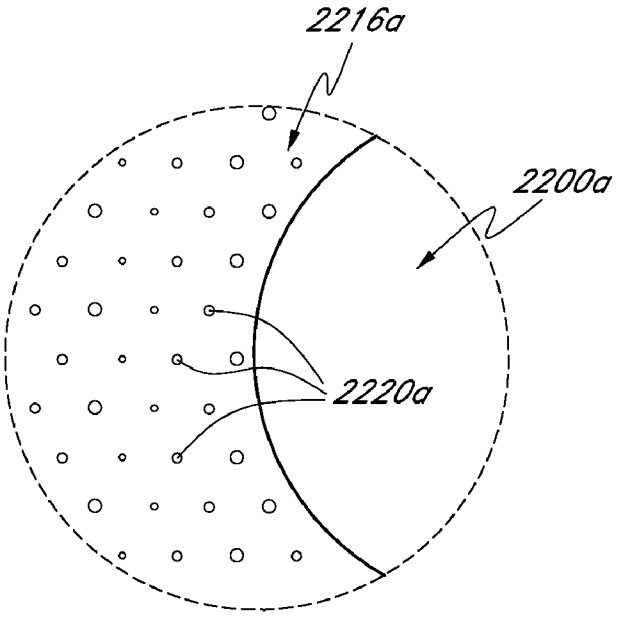


FIG. 21A

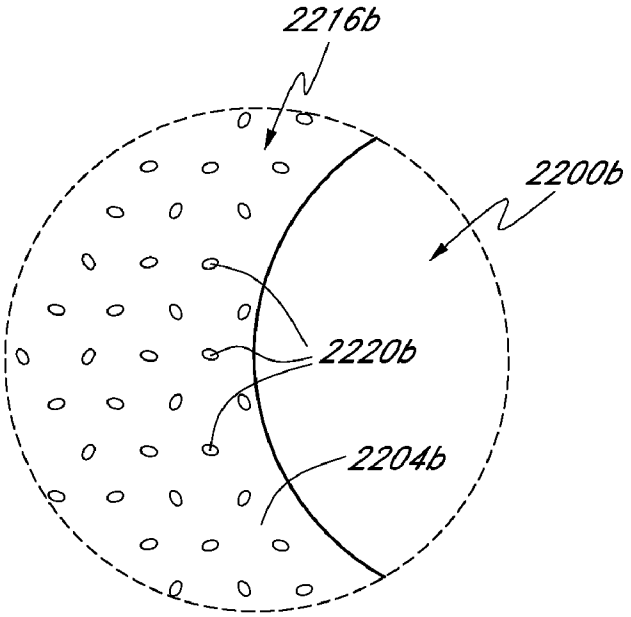


FIG. 21B

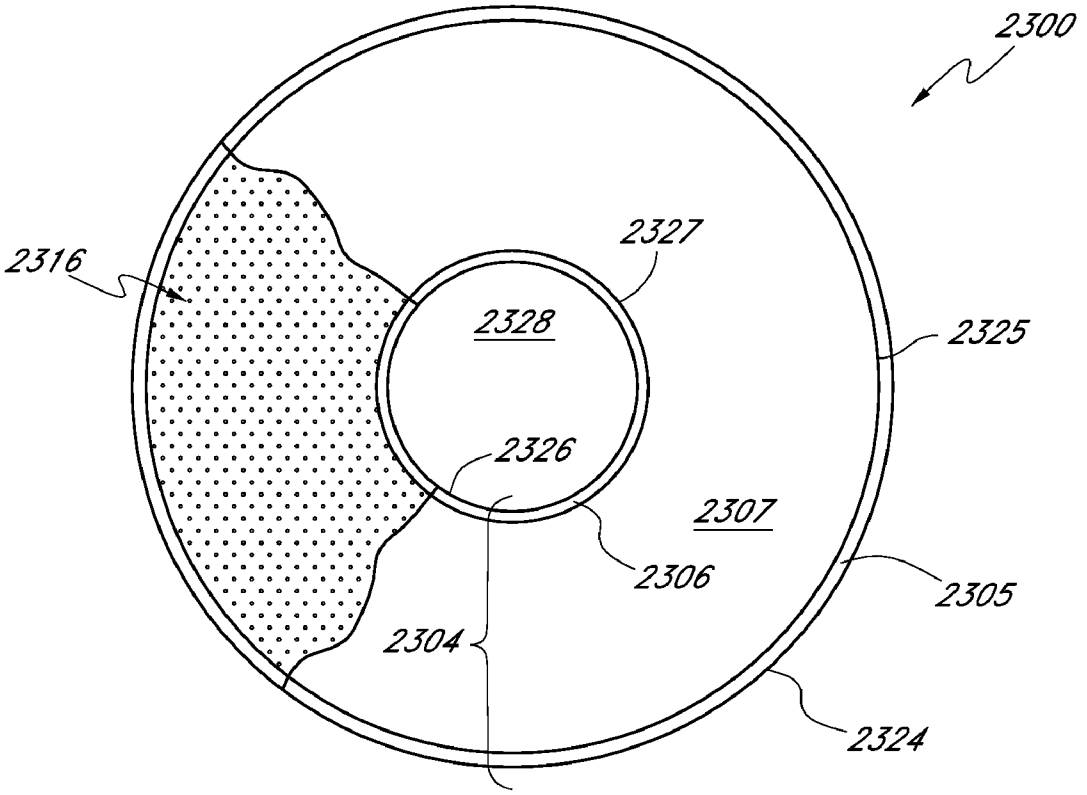


FIG. 22

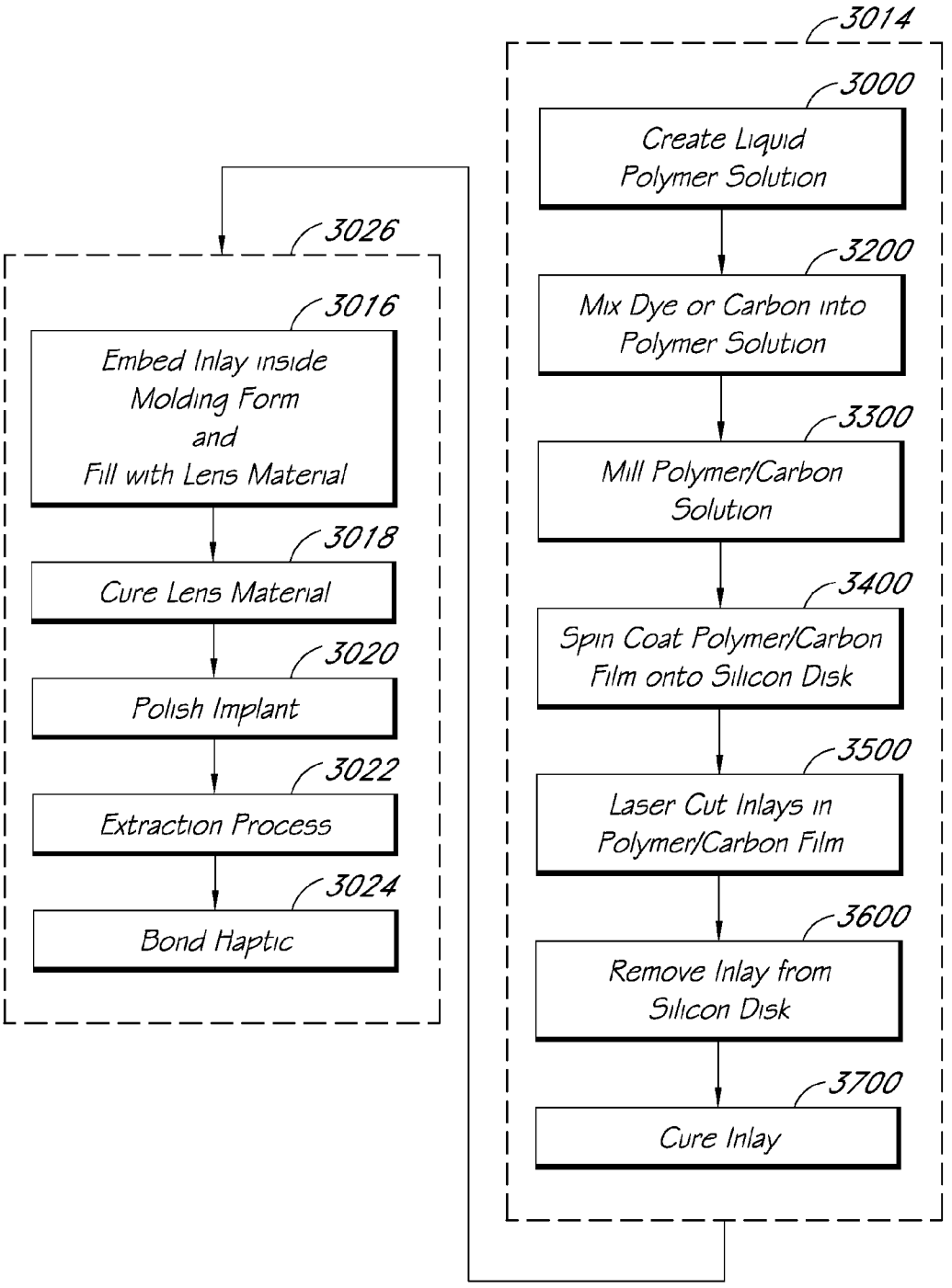

3014
3000
Create Liquid Polymer Solution
3200
Mix Dye or Carbon into Polymer Solution
3300
Mill Polymer/Carbon Solution
3400
Spin Coat Polymer/Carbon Film onto Silicon Disk
3500
Laser Cut Inlays in Polymer/Carbon Film
3600
Remove Inlay from Silicon Disk
3700
Cure Inlay
3026
3016
Embed Inlay inside Molding Form and Fill with Lens Material
3018
Cure Lens Material
3020
Polish Implant
3022
Extraction Process
3024
Bond Haptic

FIG. 23

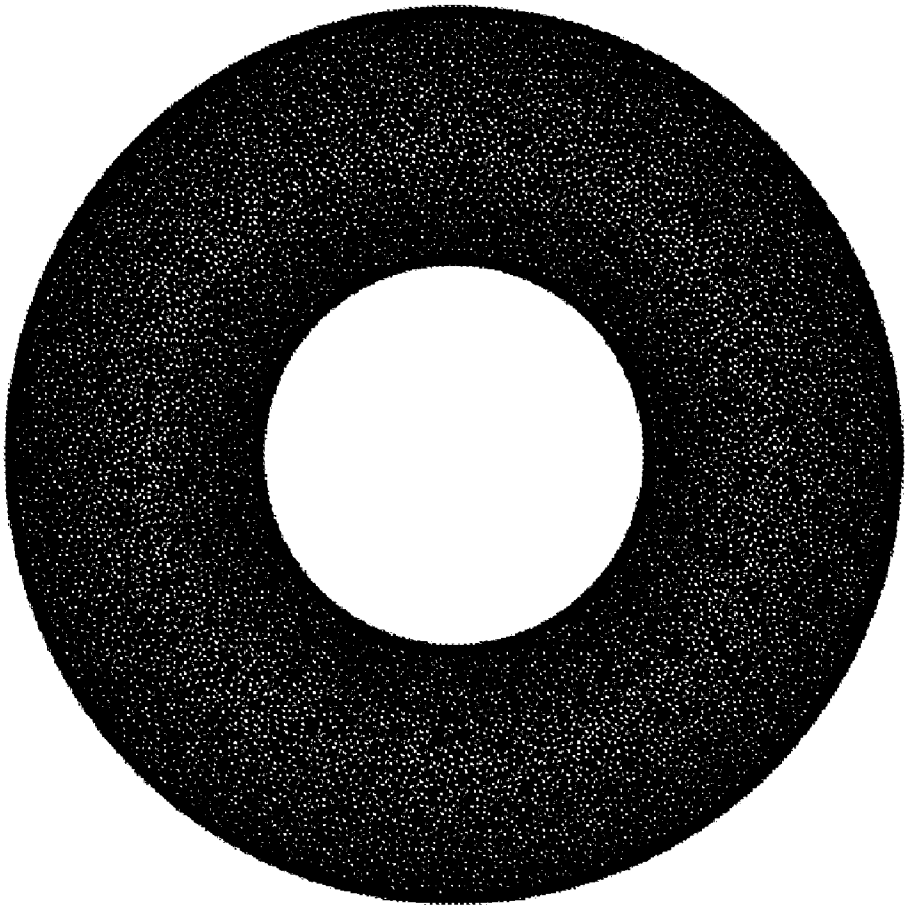


FIG. 24A

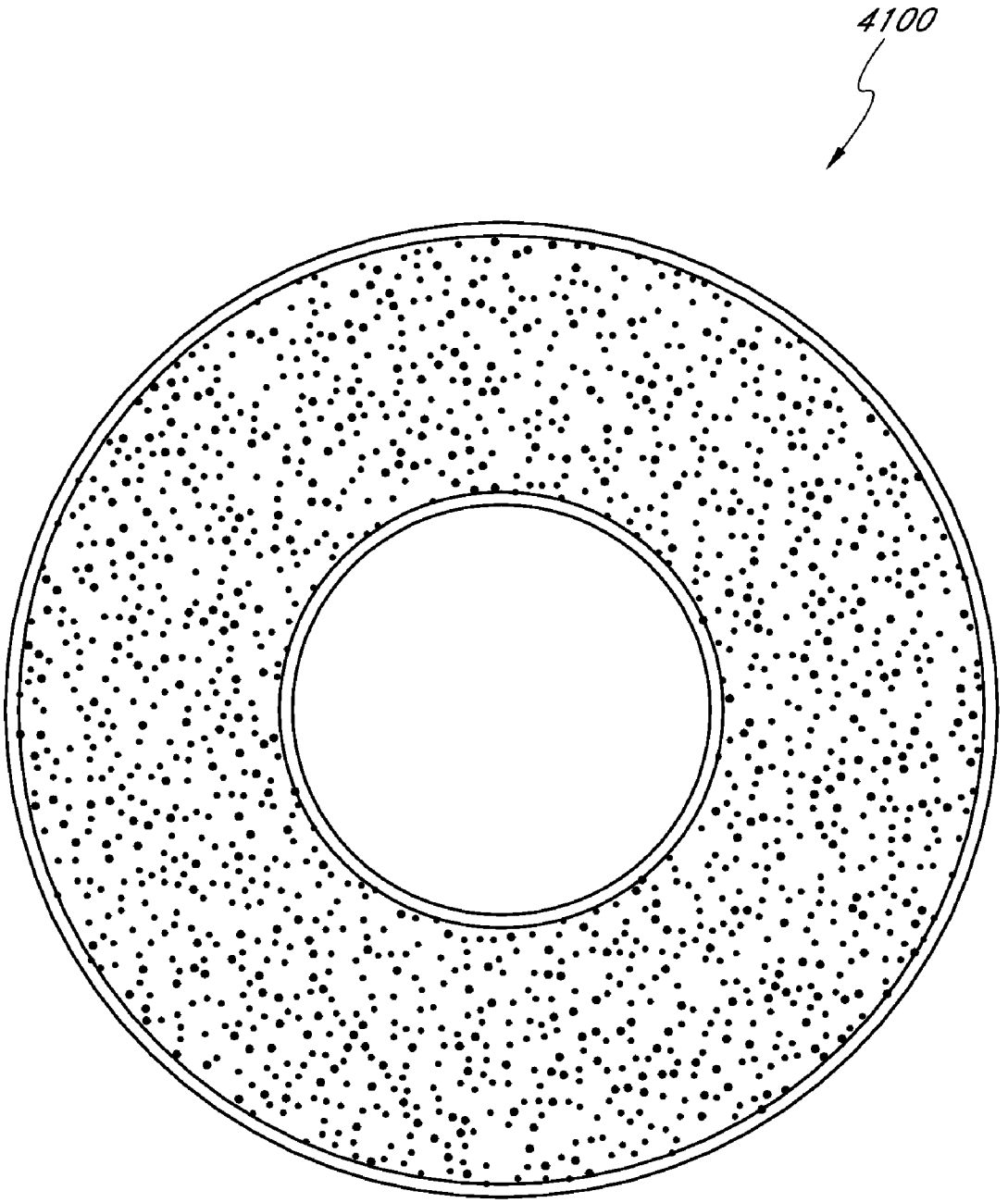


FIG. 24B

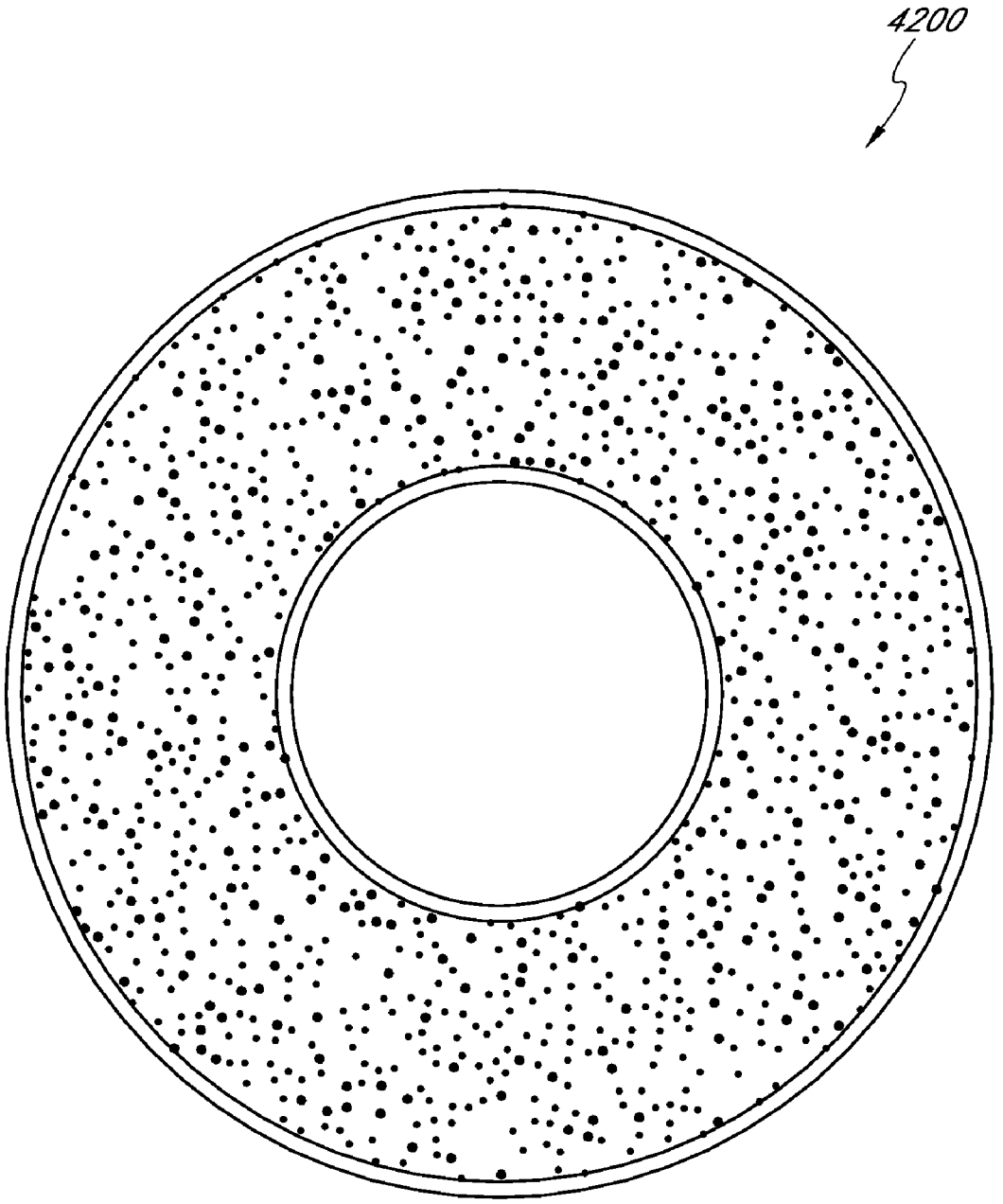


FIG. 24C

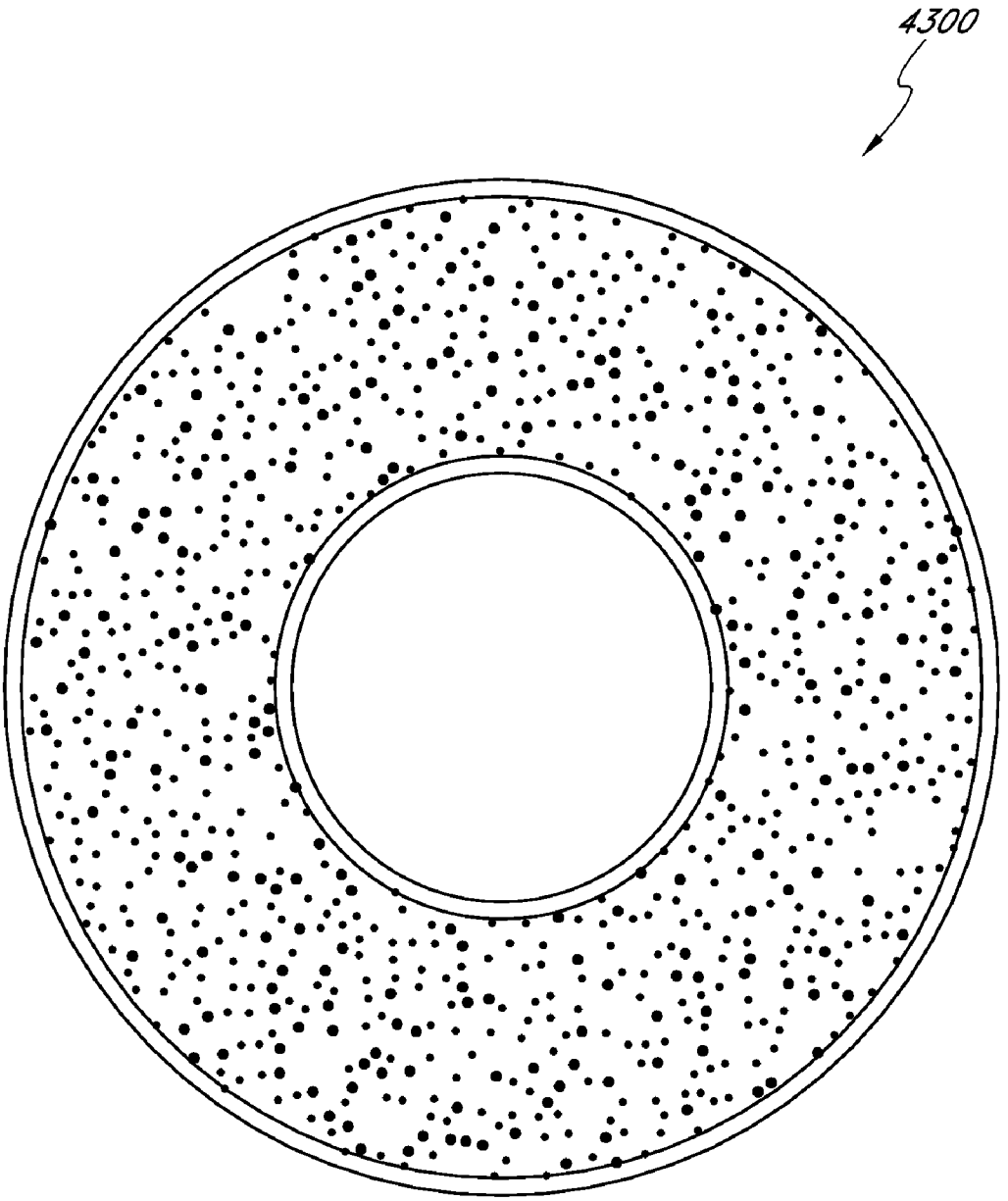


FIG. 24D

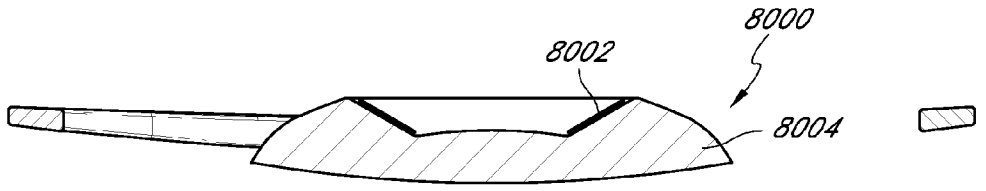


FIG. 25A

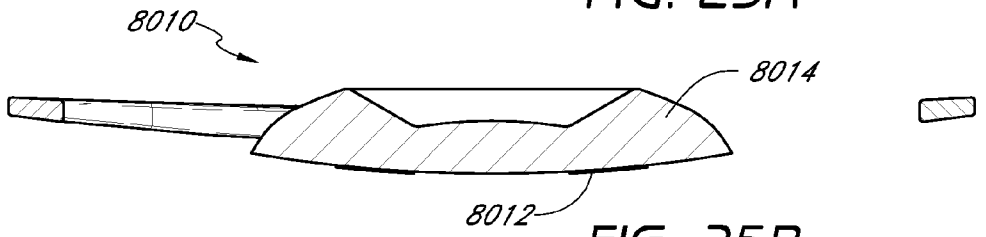


FIG. 25B

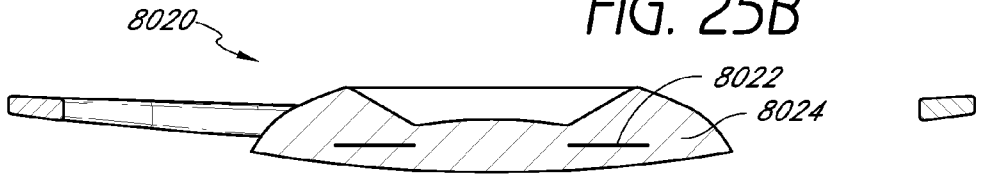


FIG. 25C

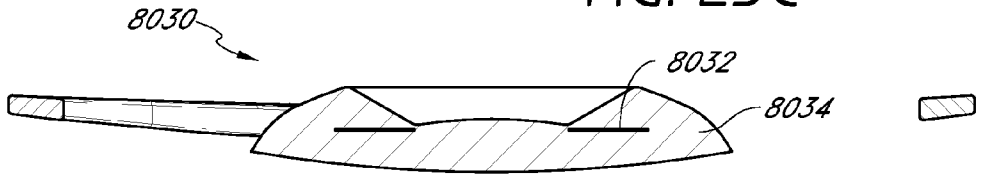


FIG. 25D

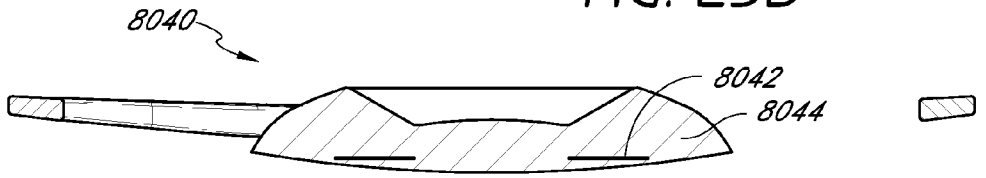


FIG. 25E

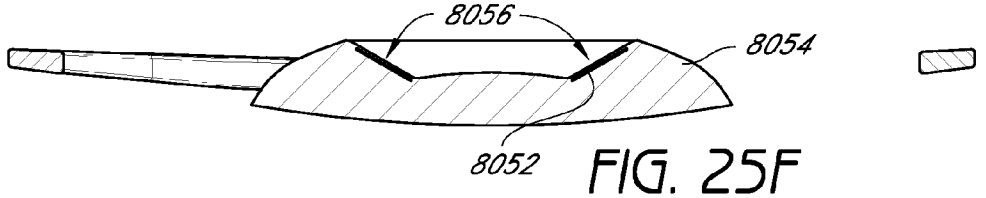


FIG. 25F

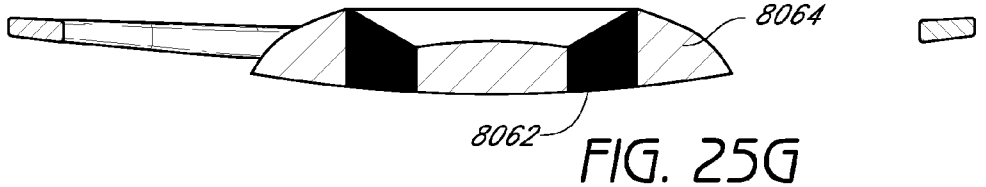


FIG. 25G

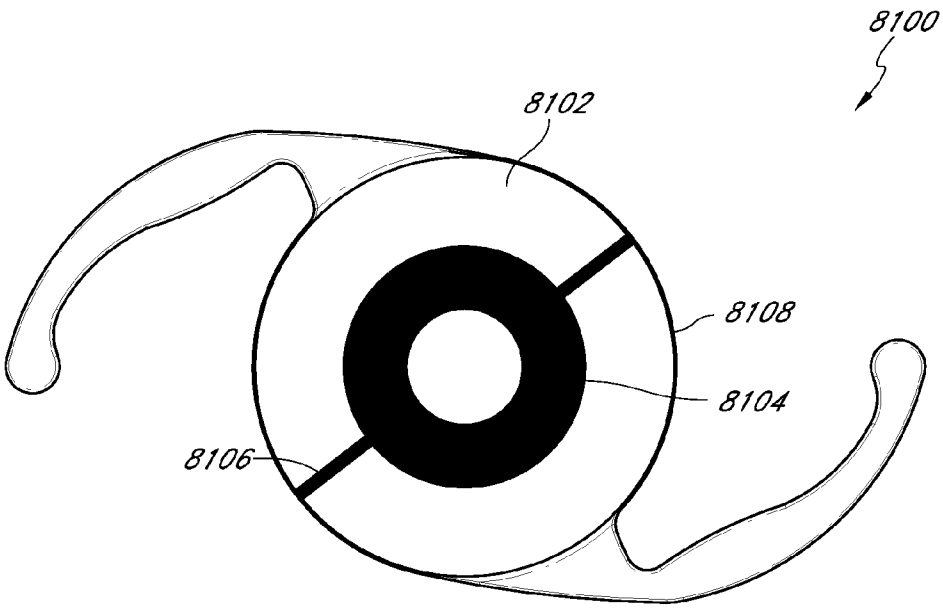


FIG. 26A

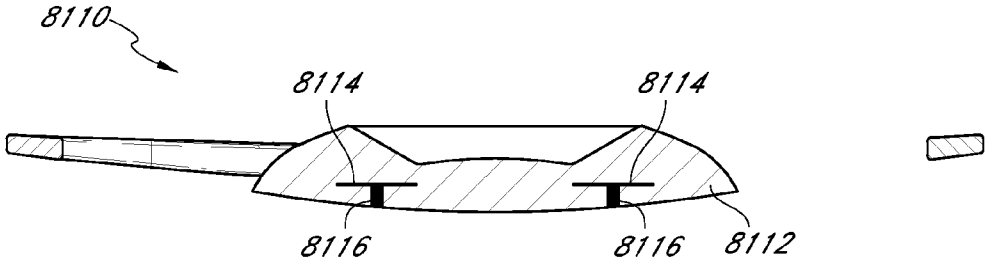


FIG. 26B

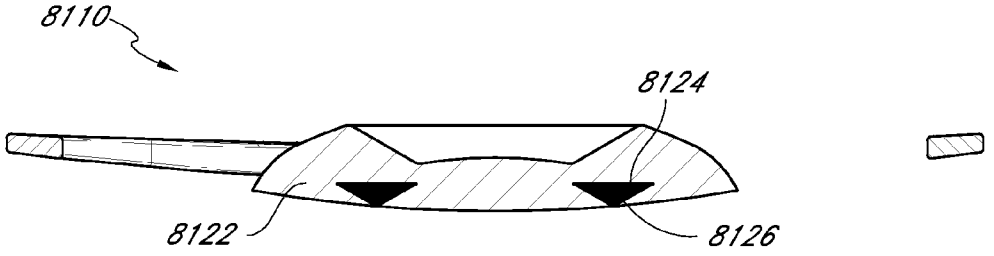


FIG. 26C

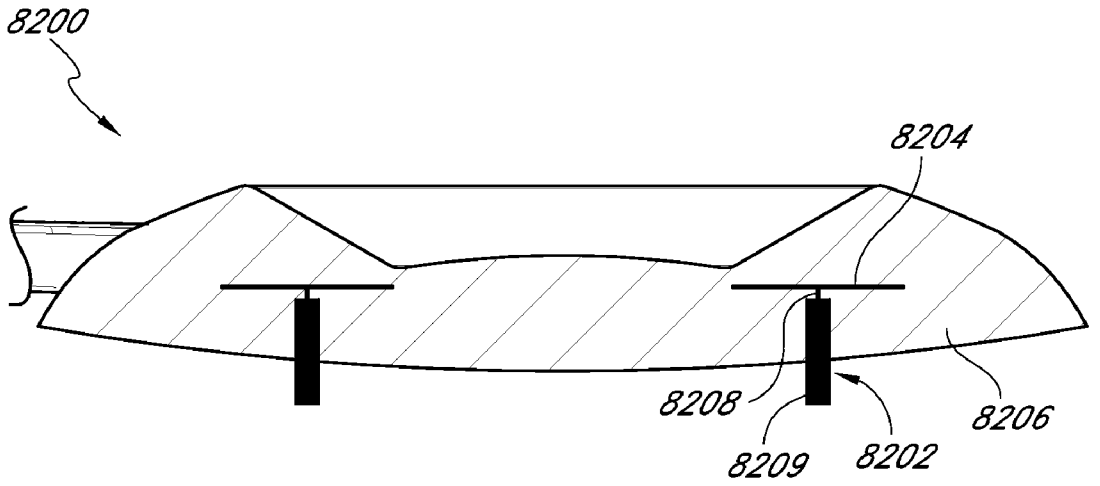


FIG. 27A

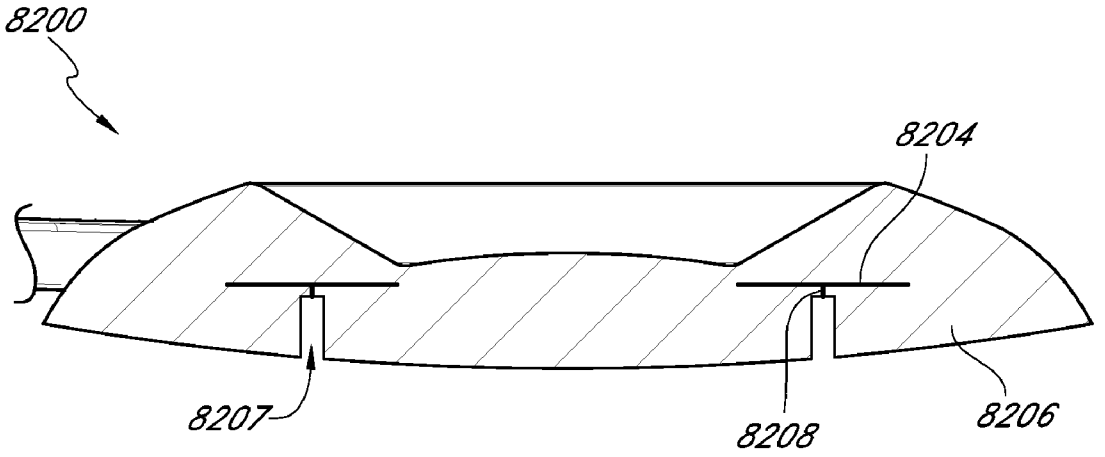


FIG. 27B

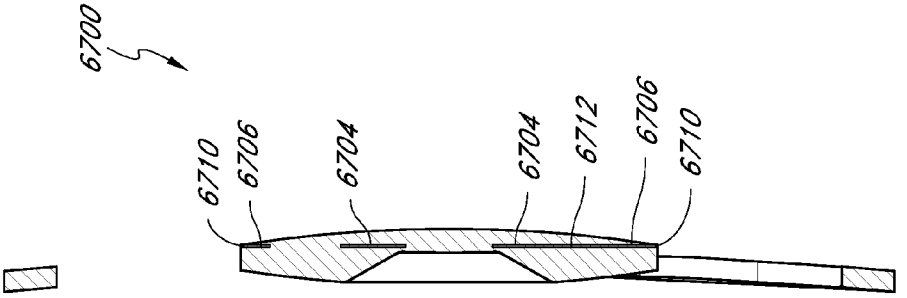


FIG. 28B

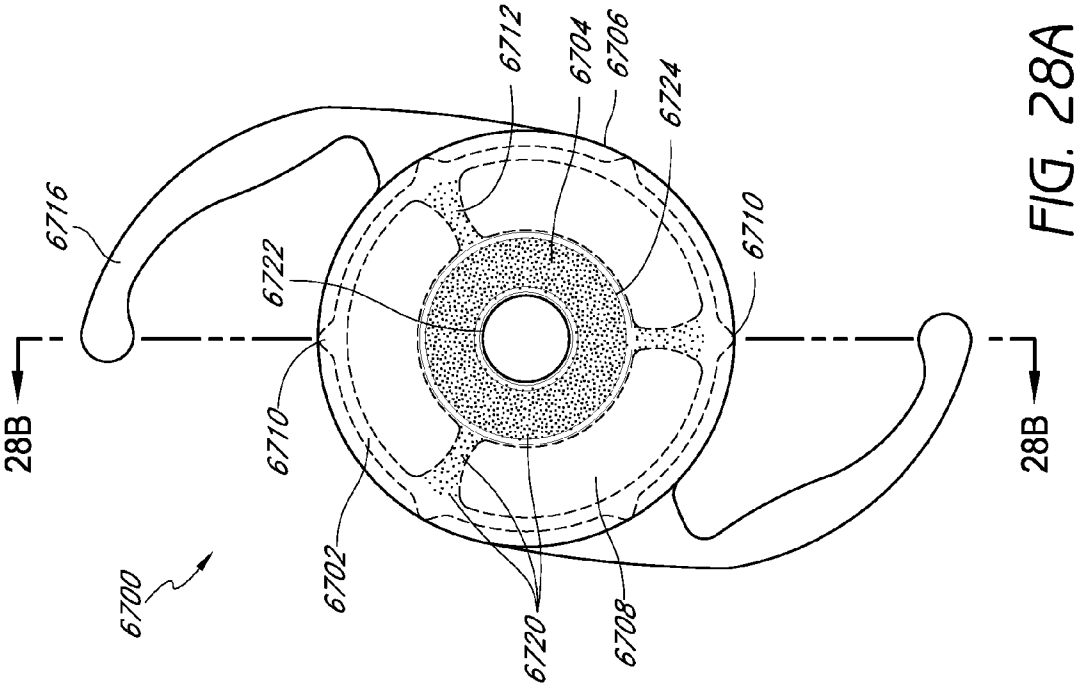


FIG. 28A

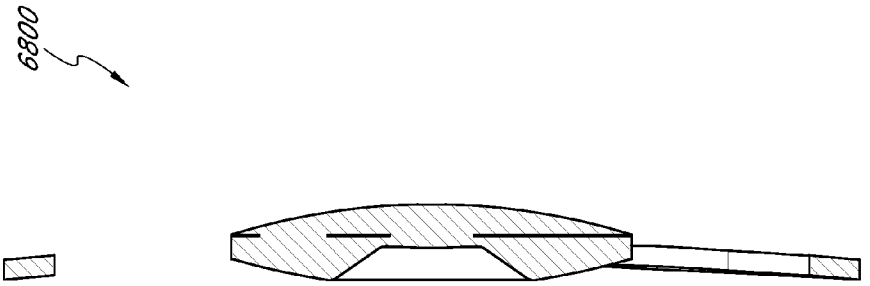


FIG. 29B

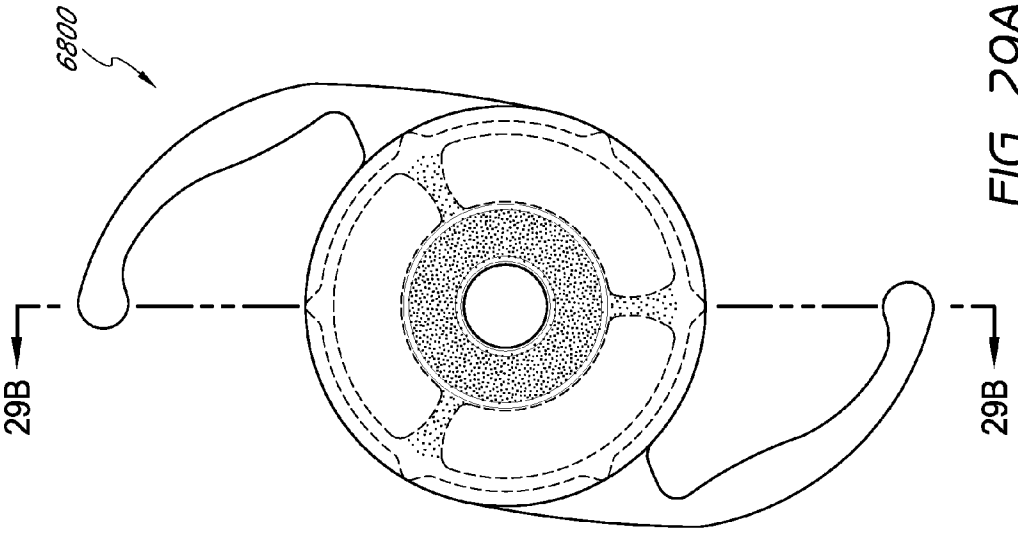


FIG. 29A

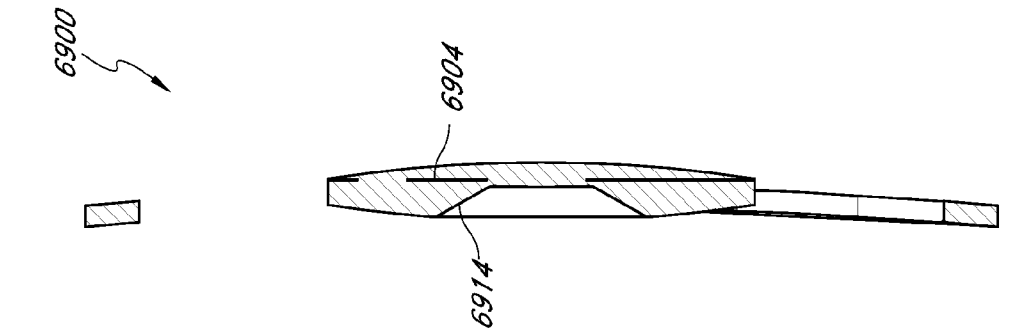


FIG. 30B

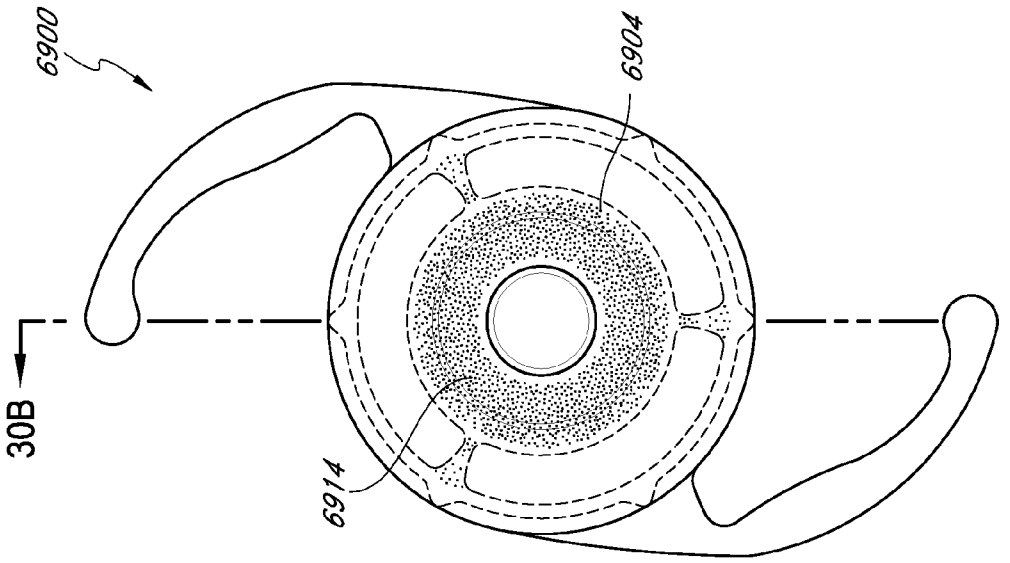


FIG. 30A

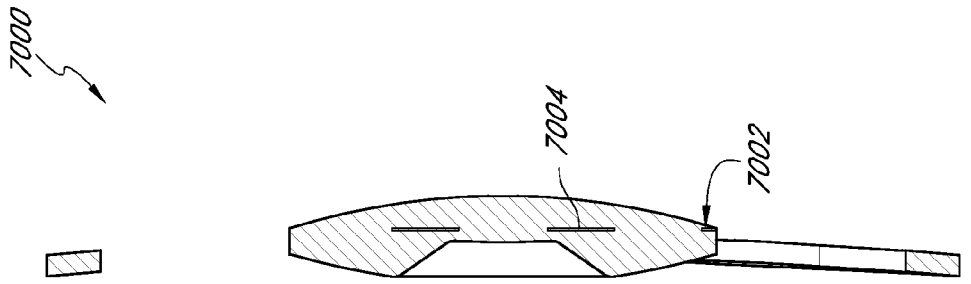


FIG. 31B

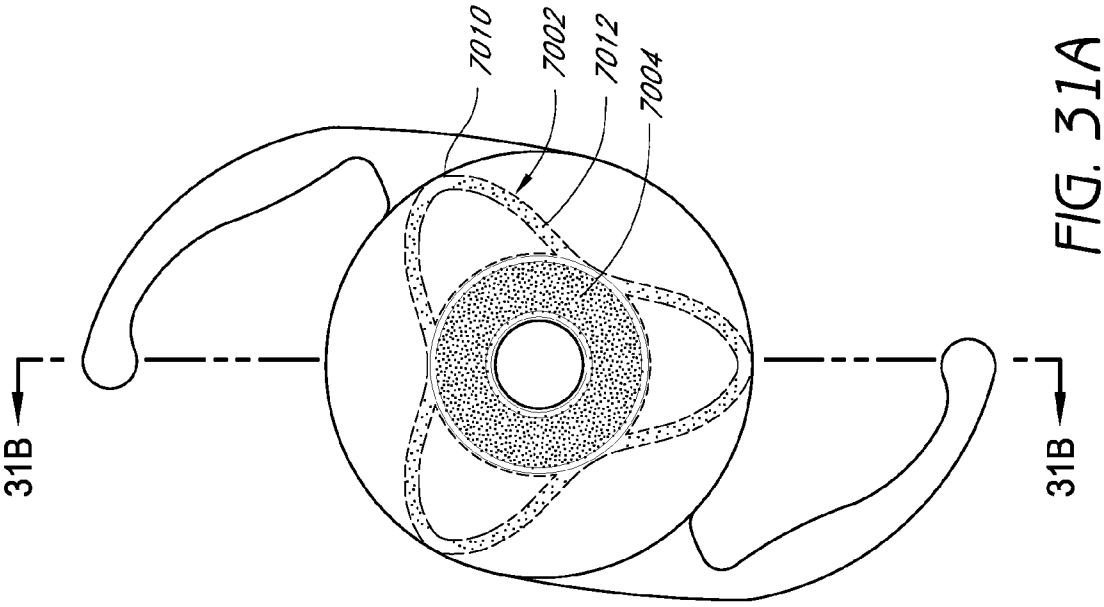


FIG. 31A

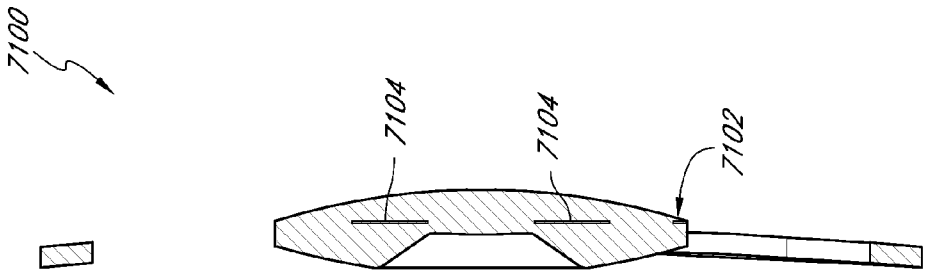


FIG. 32B

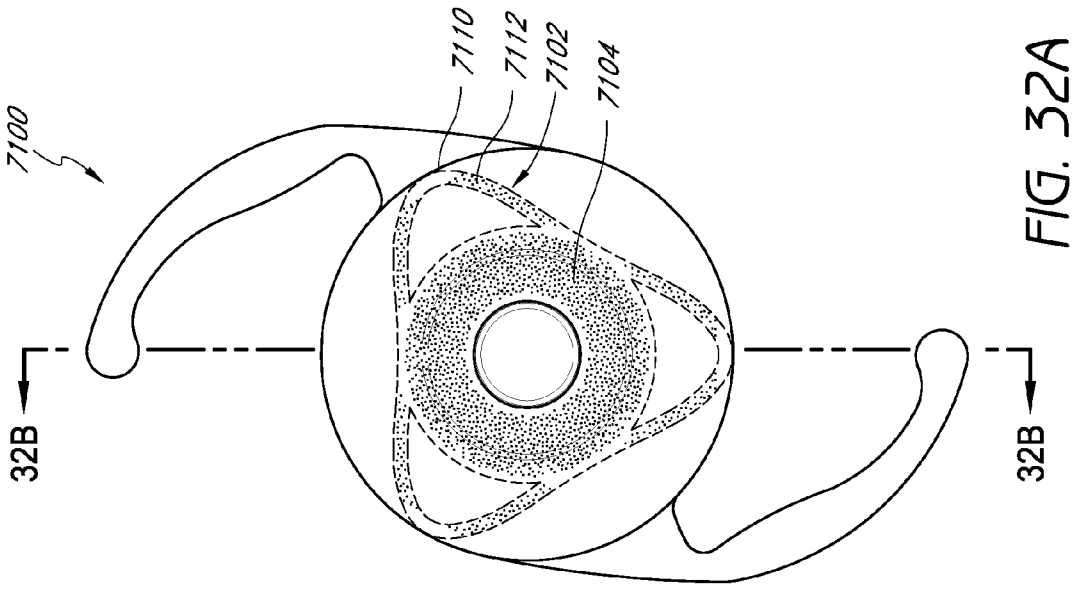


FIG. 32A

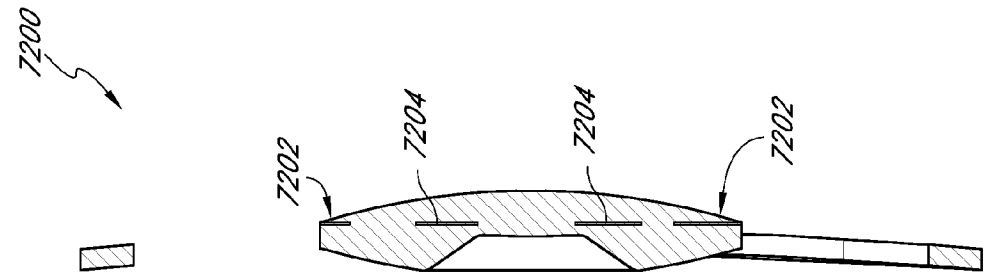


FIG. 33B

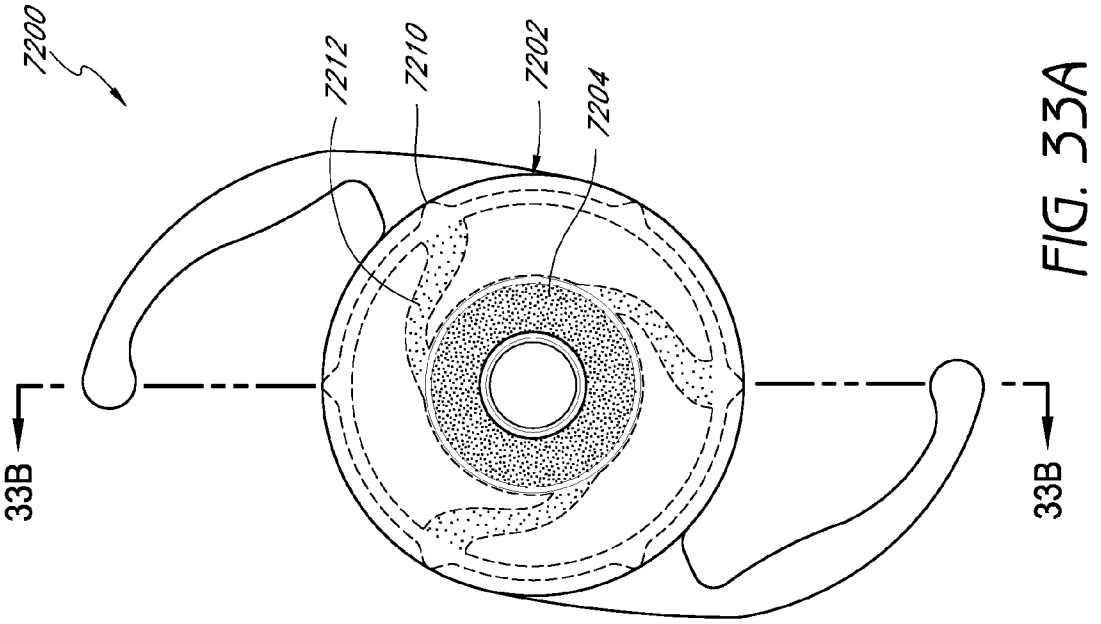


FIG. 33A

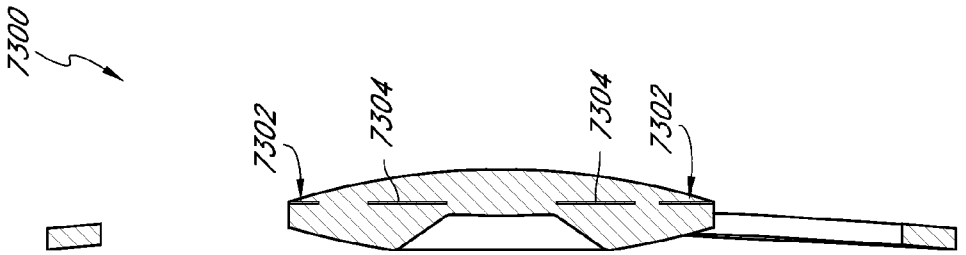


FIG. 34B

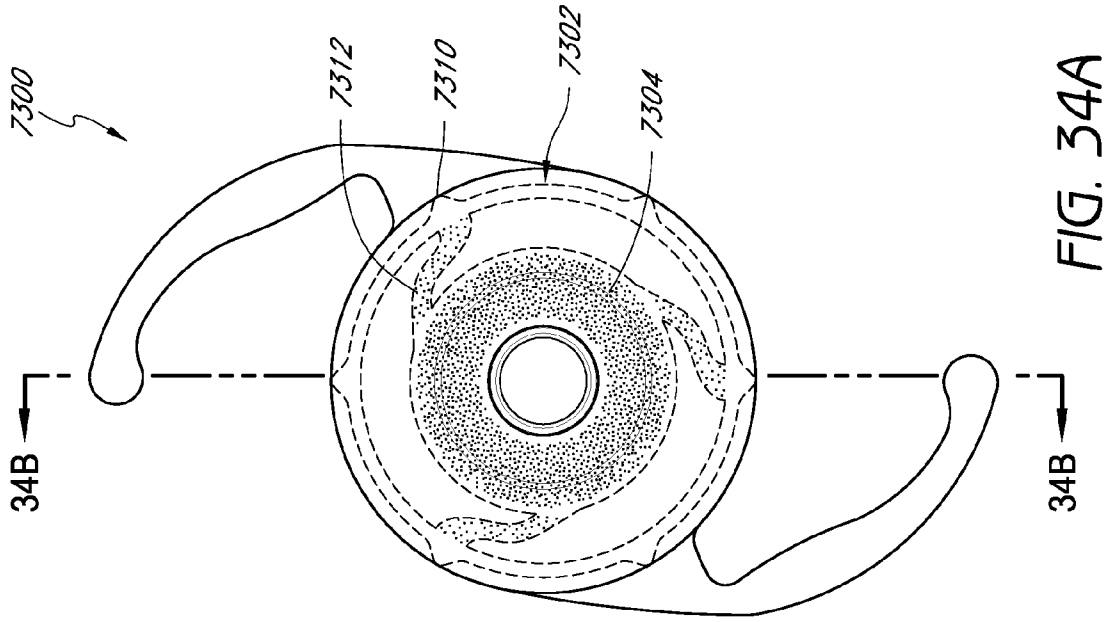


FIG. 34A

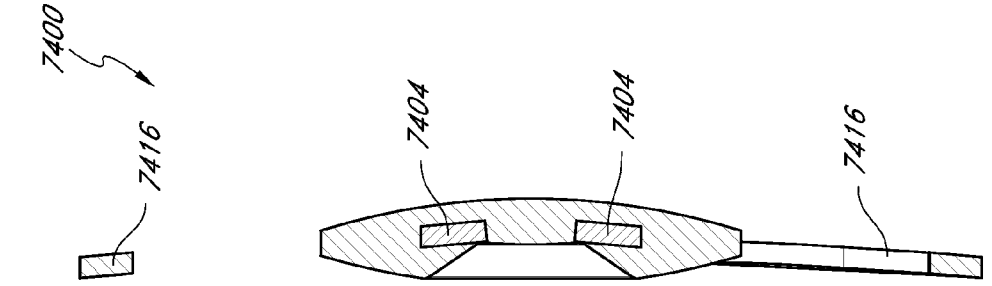


FIG. 35B

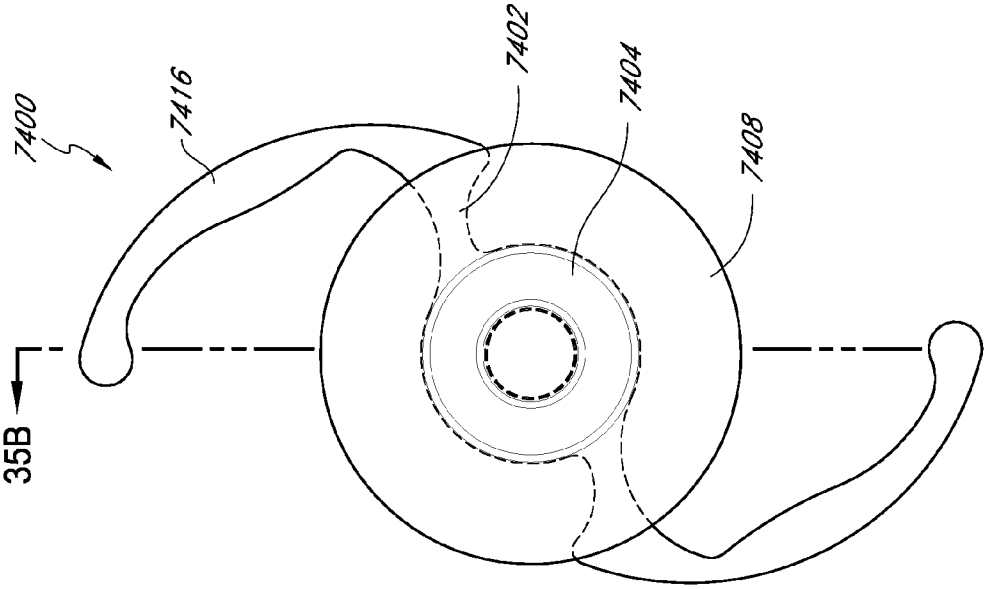


FIG. 35A

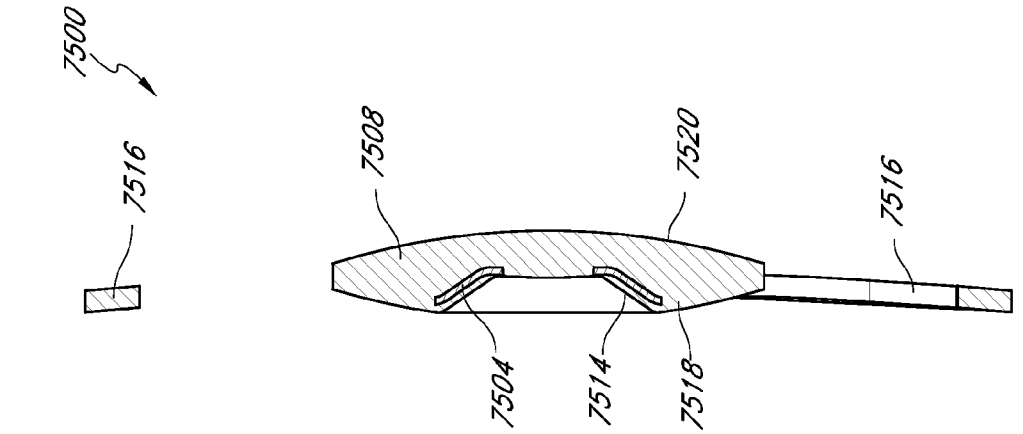


FIG. 36B

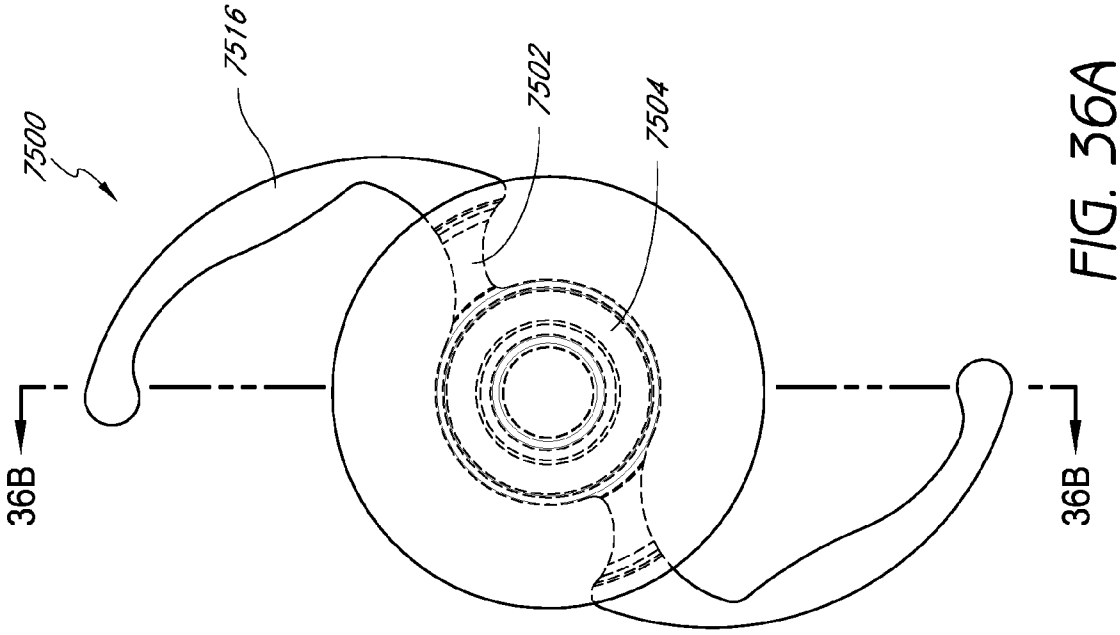


FIG. 36A

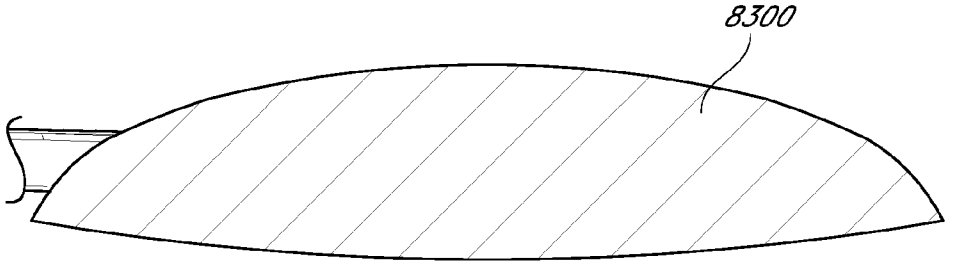


FIG. 37A

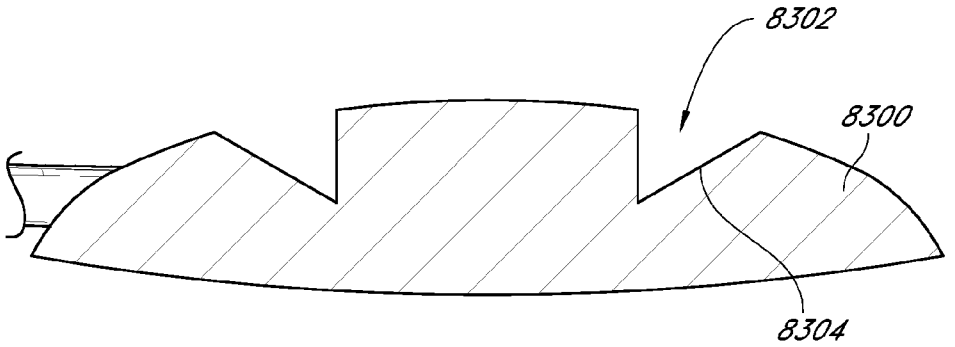


FIG. 37B

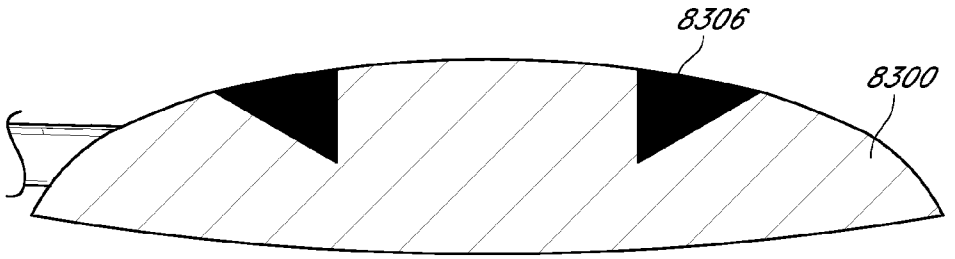


FIG. 37C

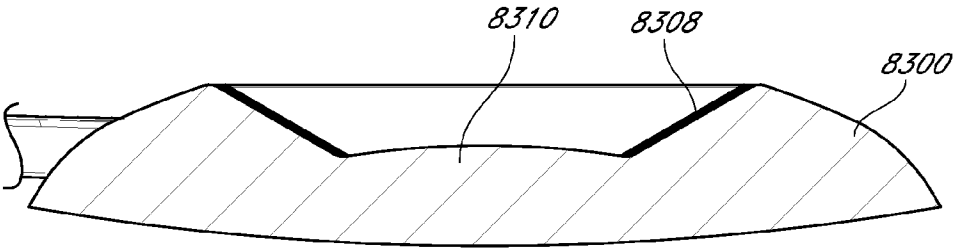


FIG. 37D

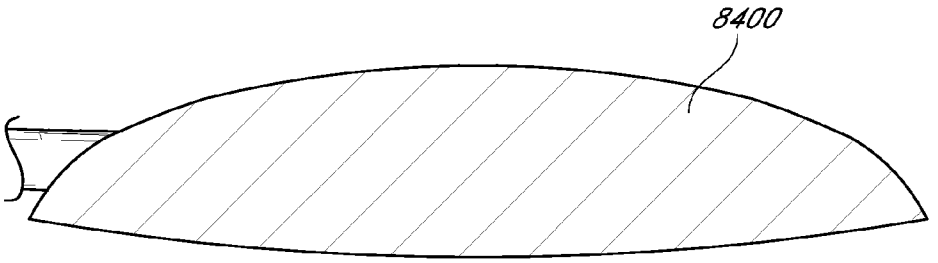


FIG. 38A

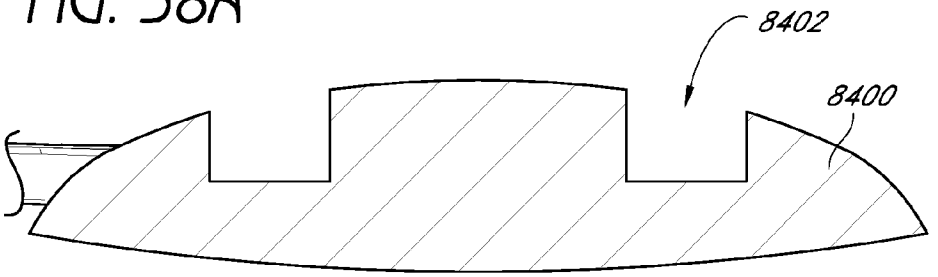


FIG. 38B

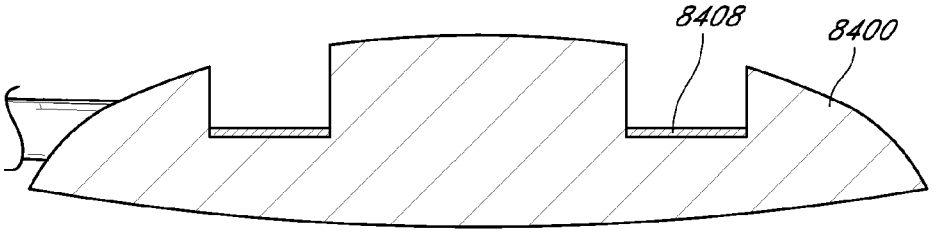


FIG. 38C

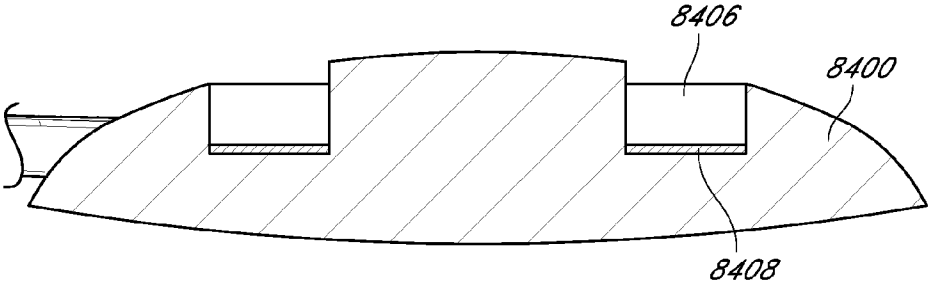


FIG. 38D

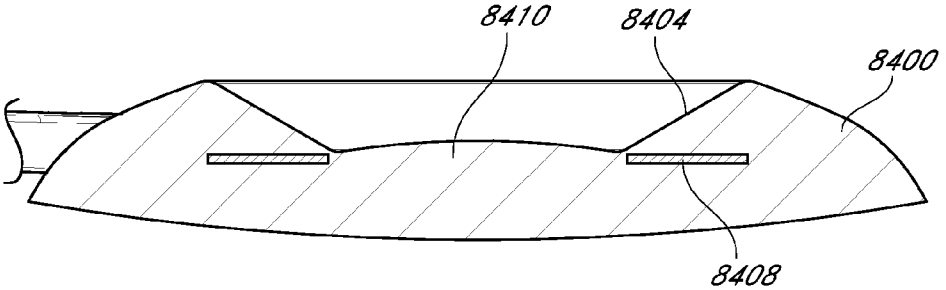


FIG. 38E

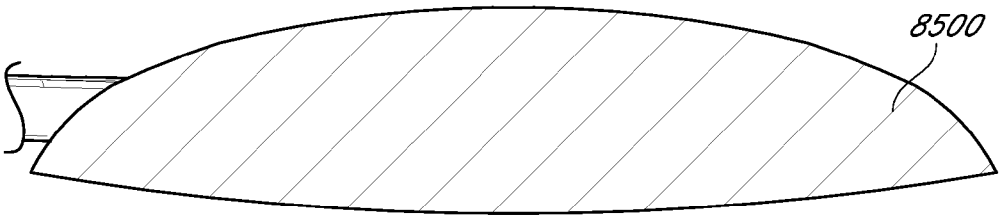


FIG. 39A

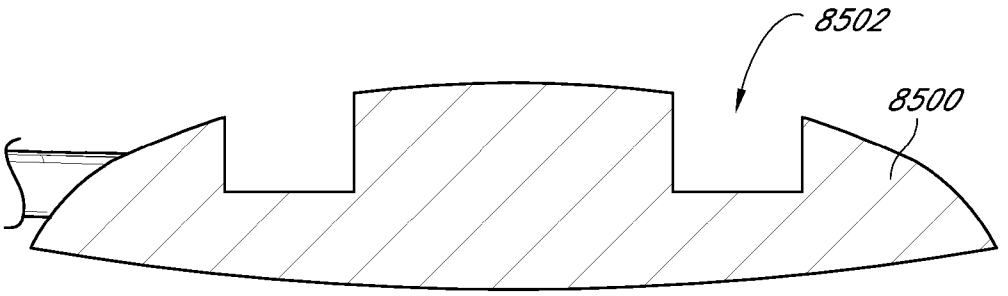


FIG. 39B

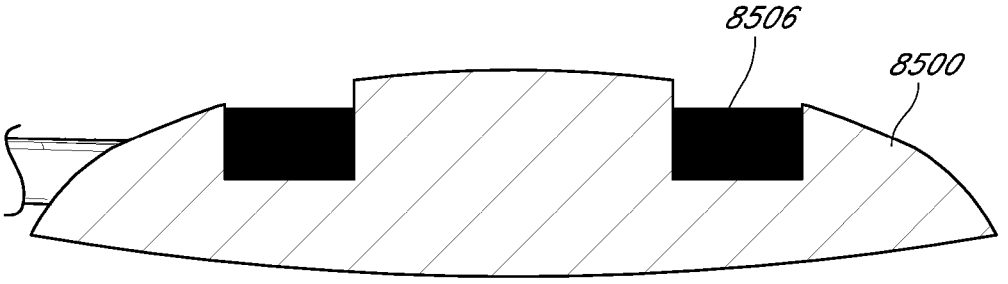


FIG. 39C

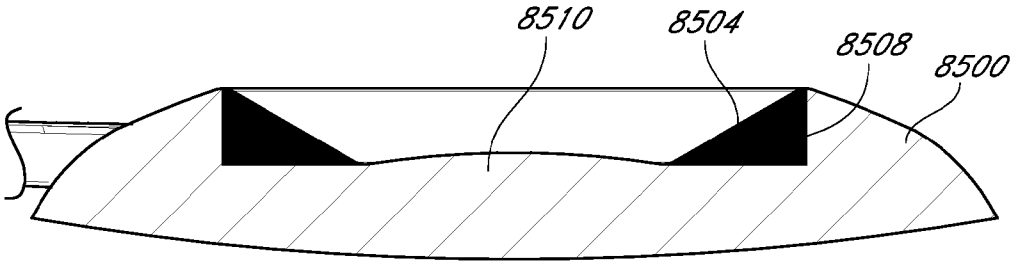


FIG. 39D

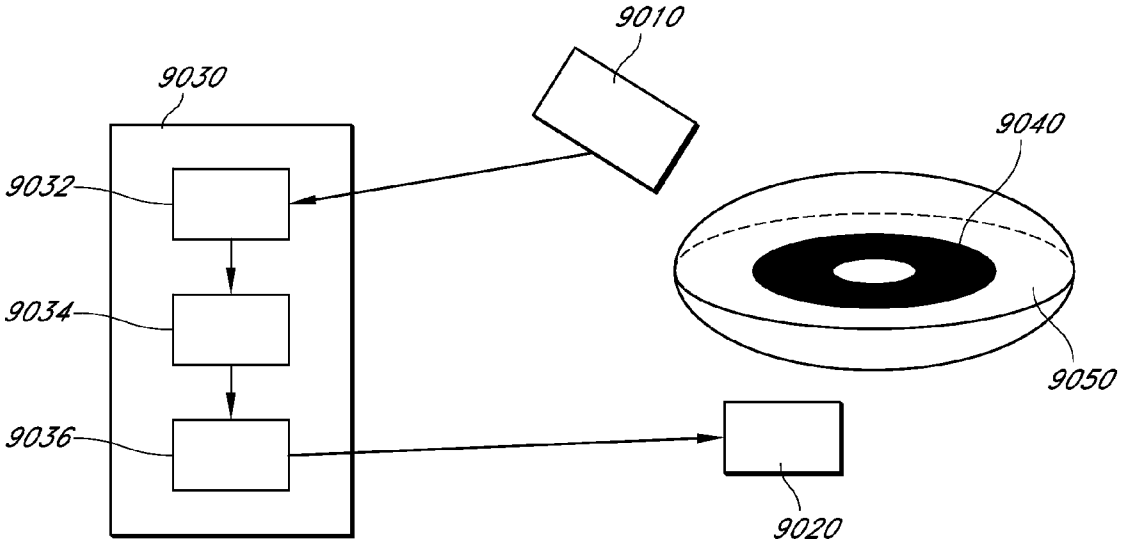

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FIG. 40

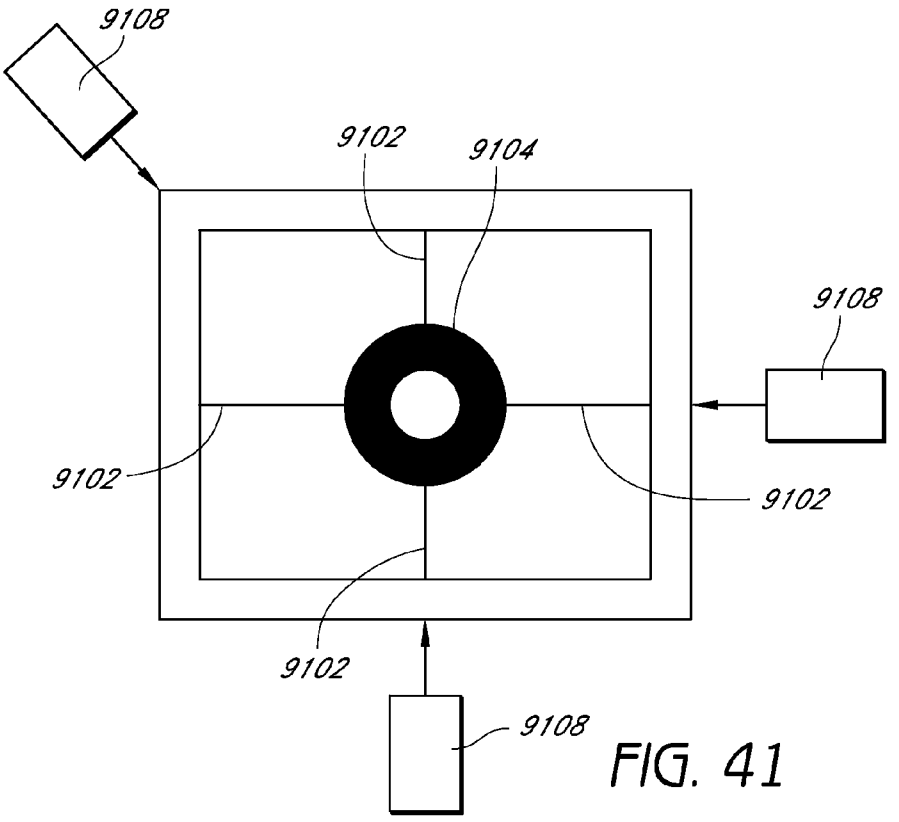

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9102
9102
9108

FIG. 41

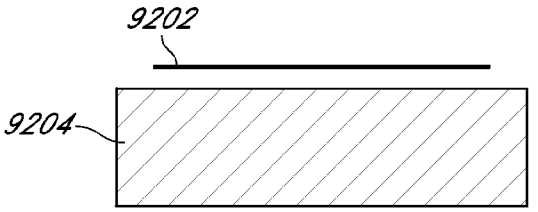


FIG. 42

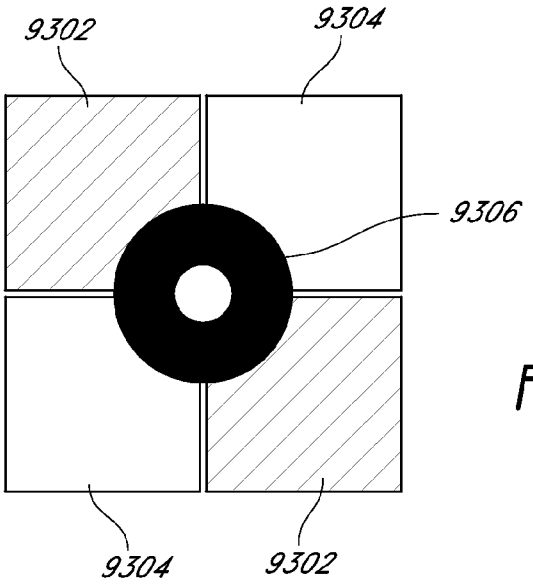


FIG. 43A

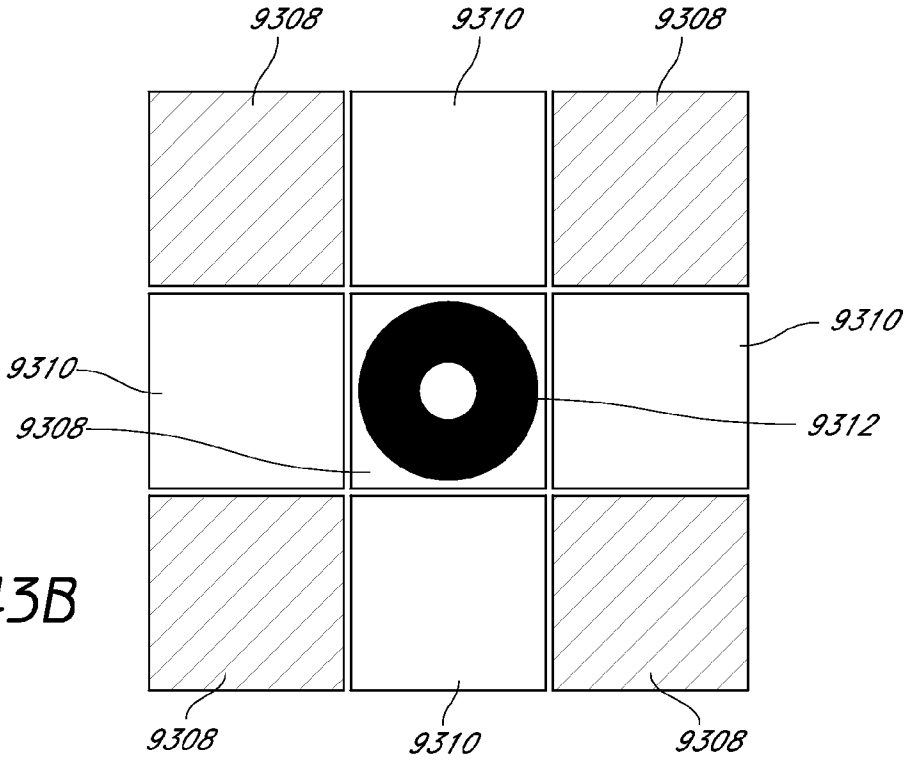


FIG. 43B

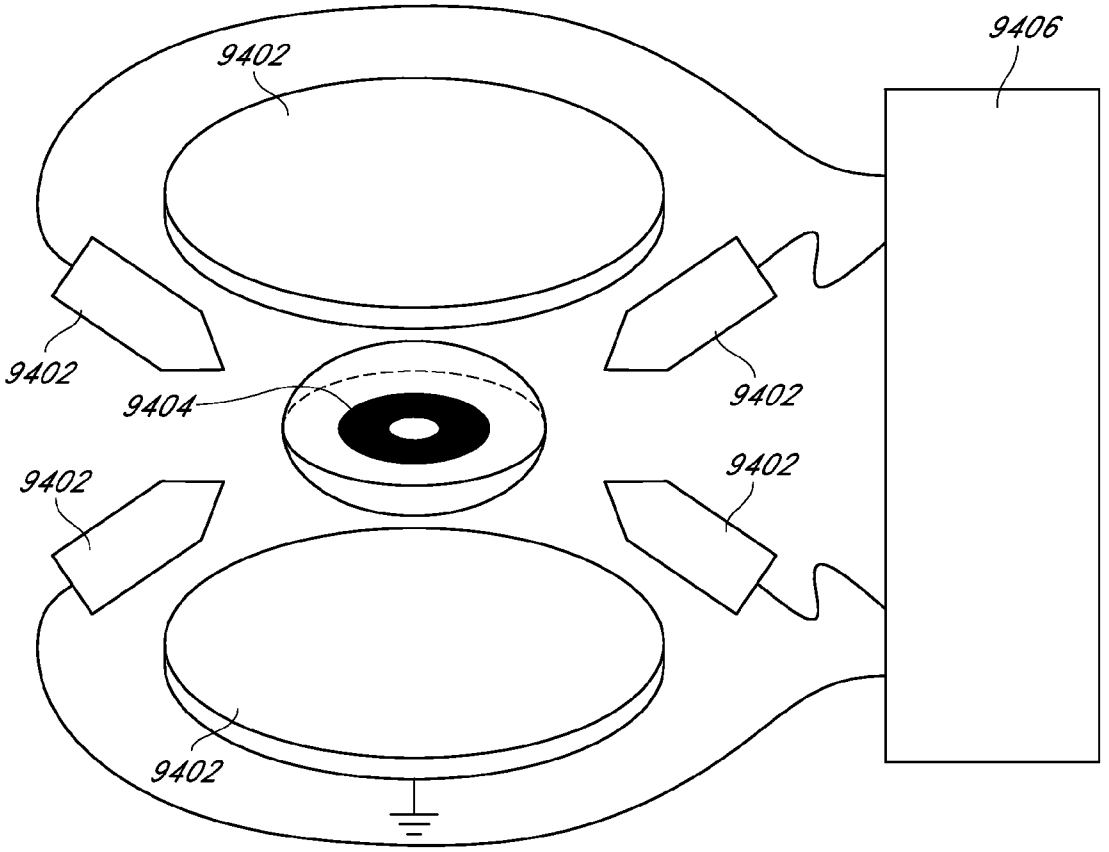


FIG. 44

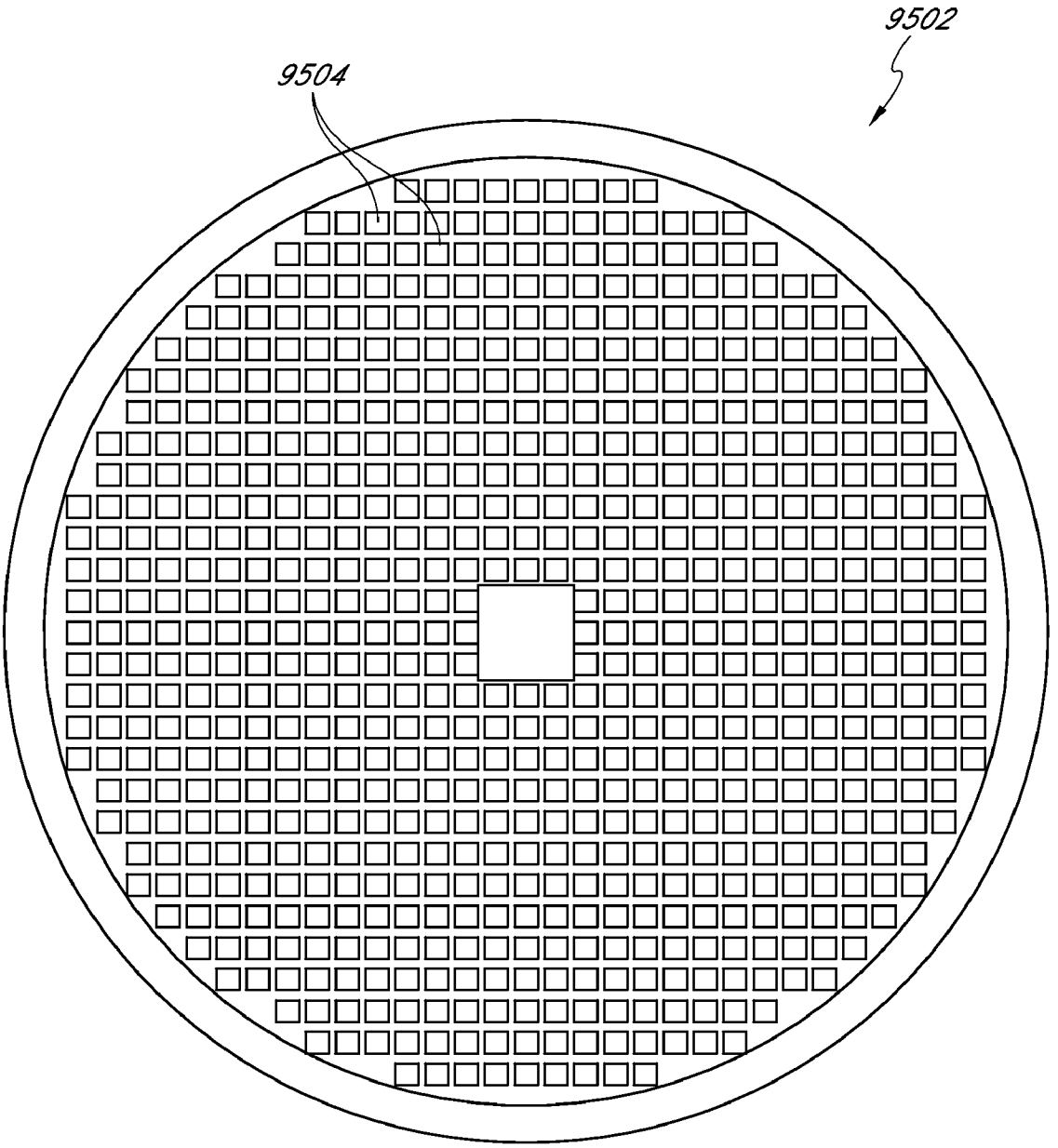


FIG. 45

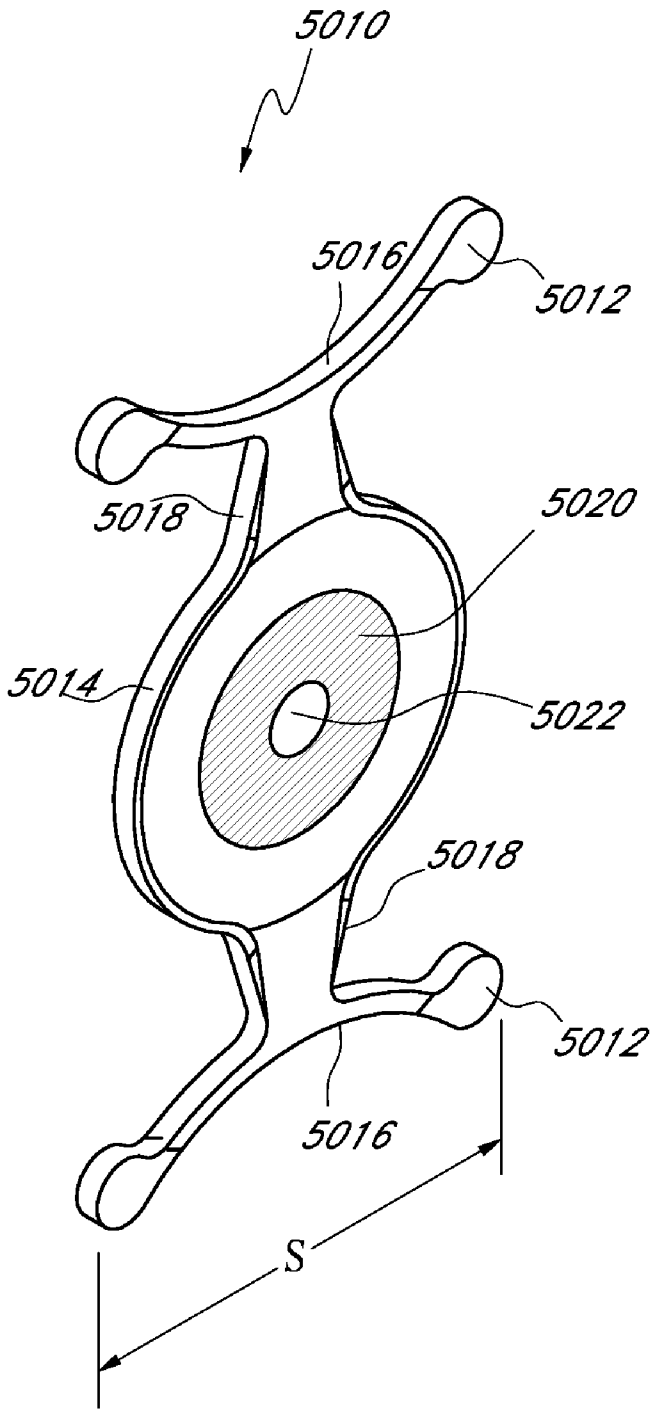


FIG. 46

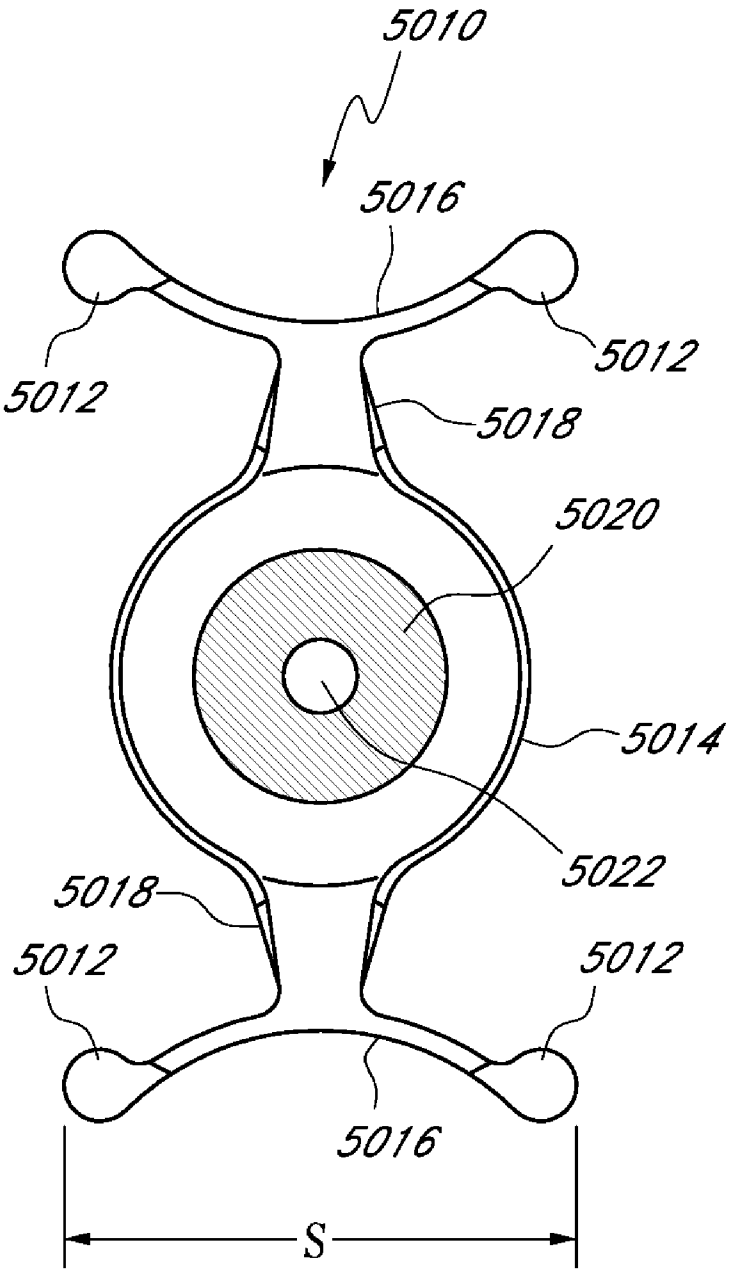


FIG. 47

FIG. 48A

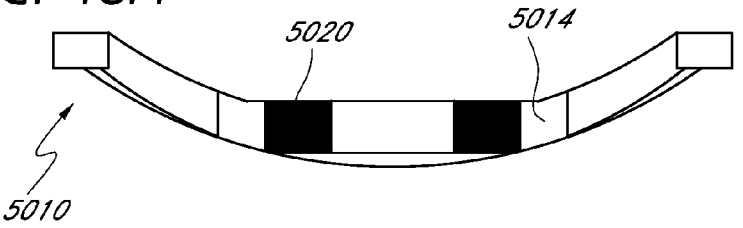


FIG. 48B

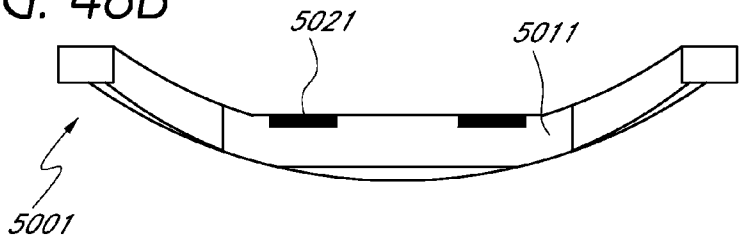


FIG. 48C

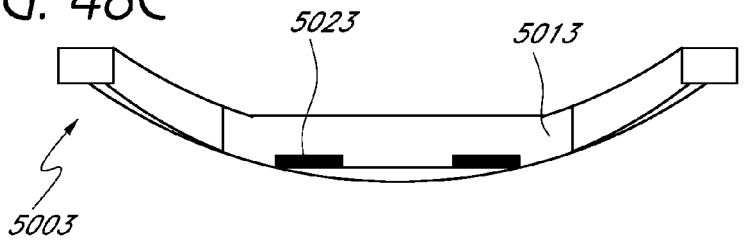


FIG. 48D

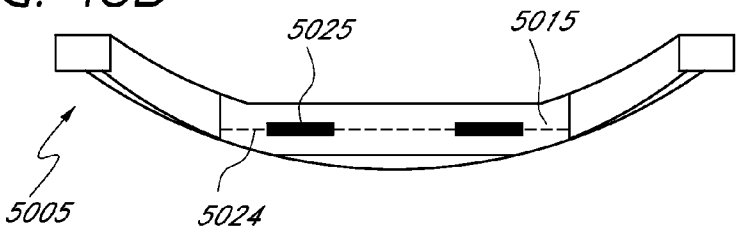


FIG. 48E

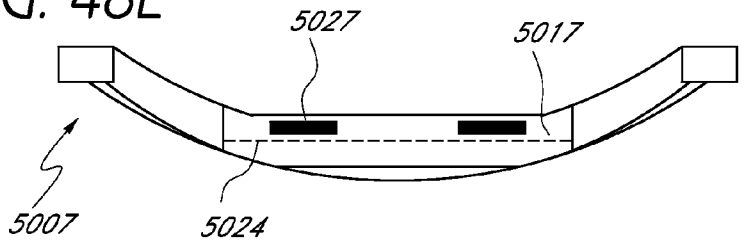
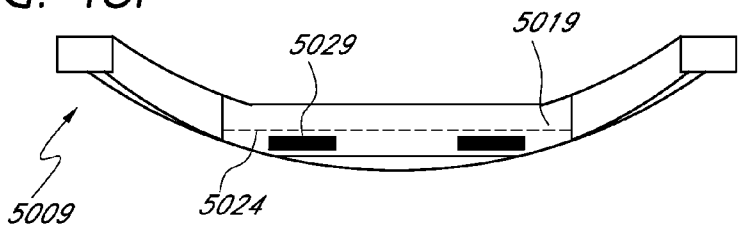


FIG. 48F



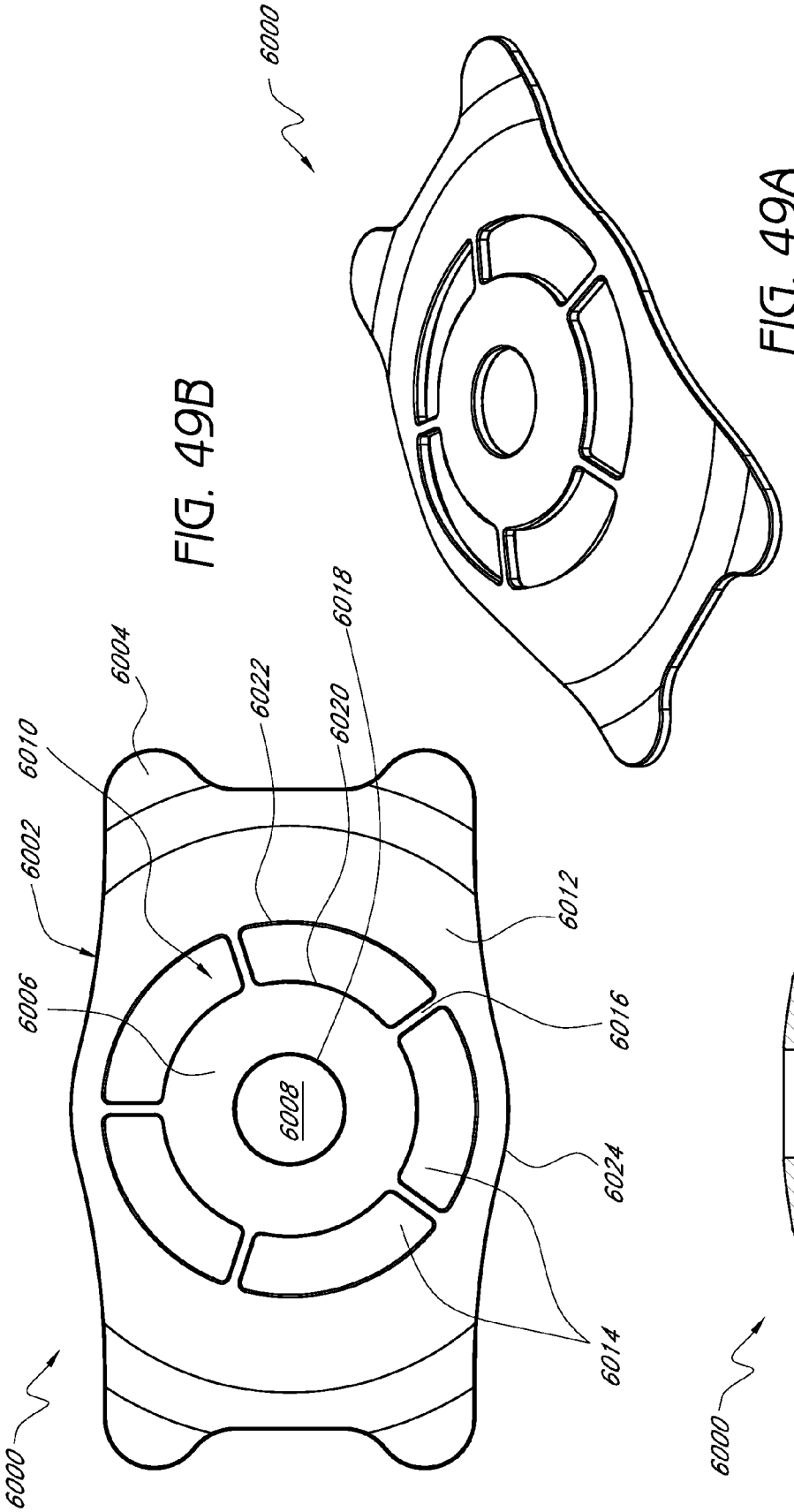


FIG. 49B

FIG. 49A

FIG. 49C

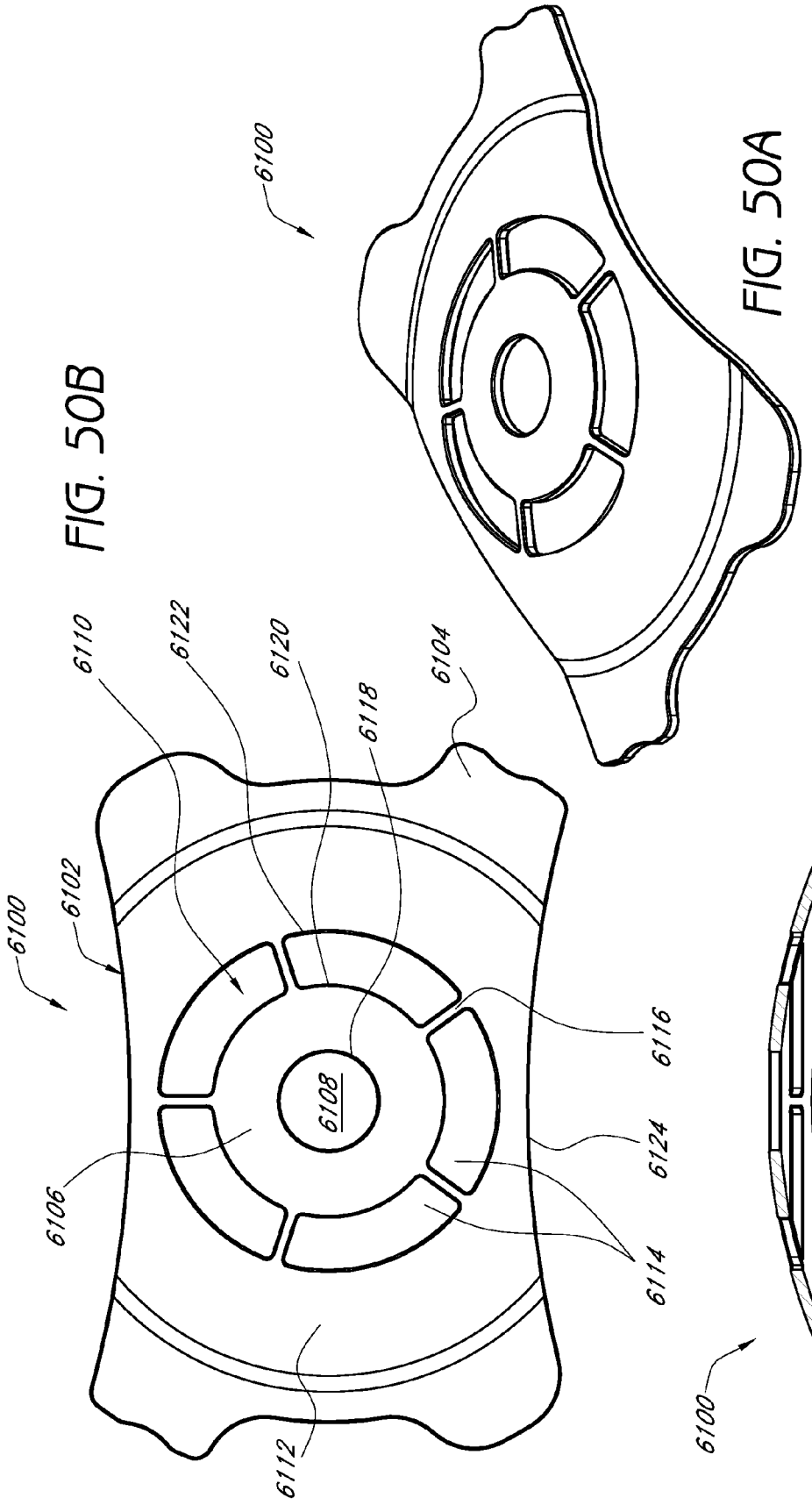


FIG. 50A

FIG. 50B

FIG. 50C

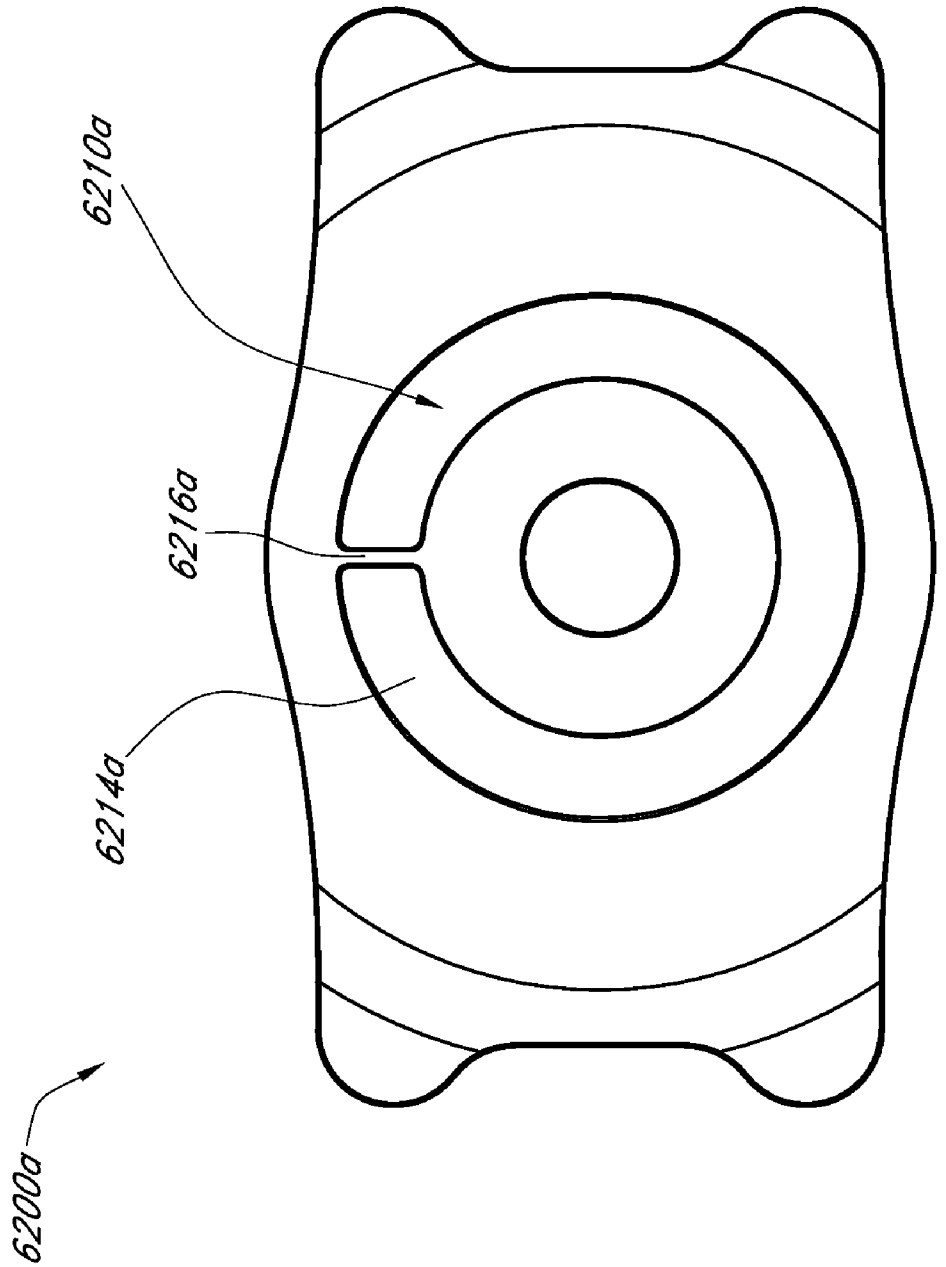


FIG. 51A

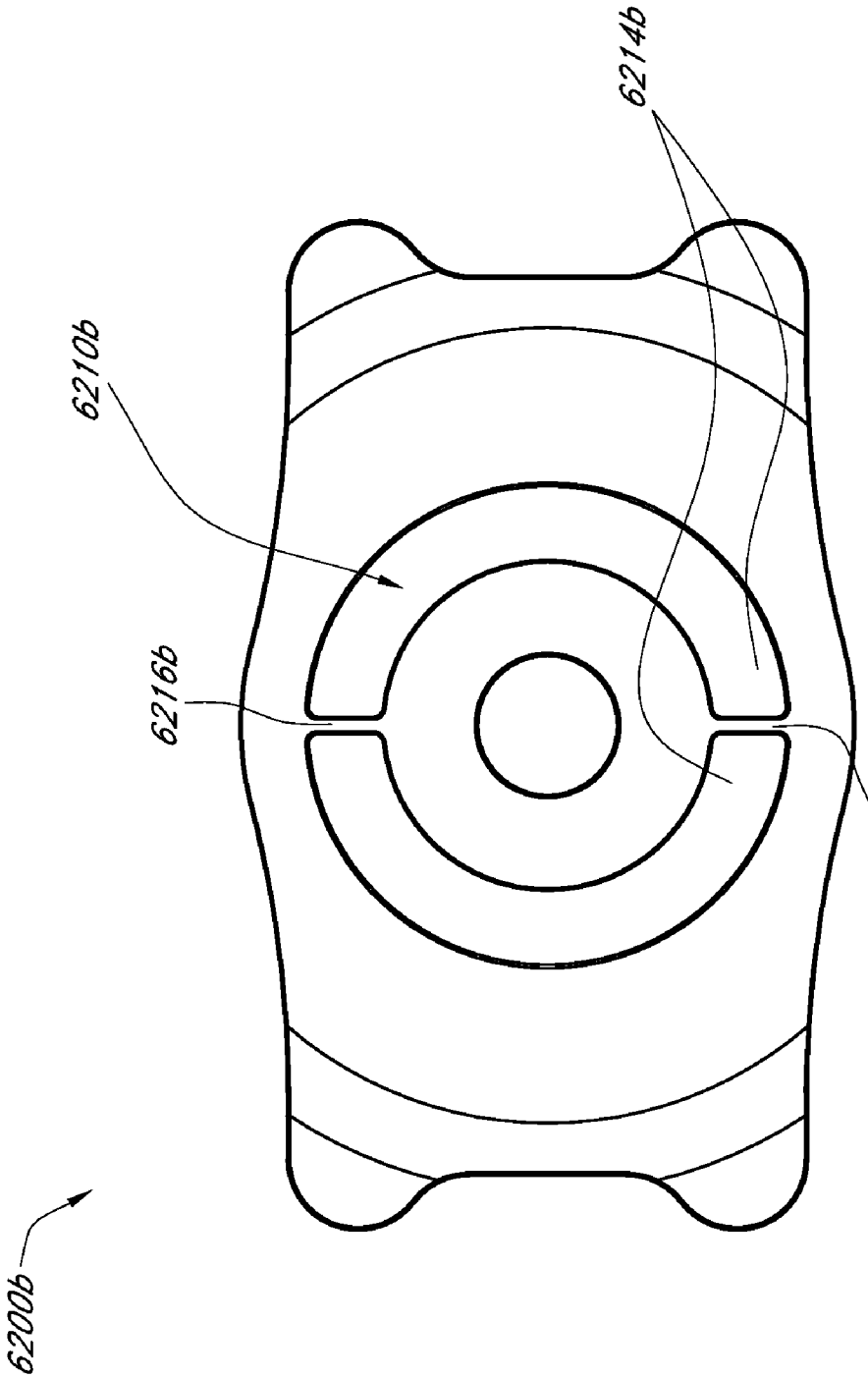


FIG. 51B

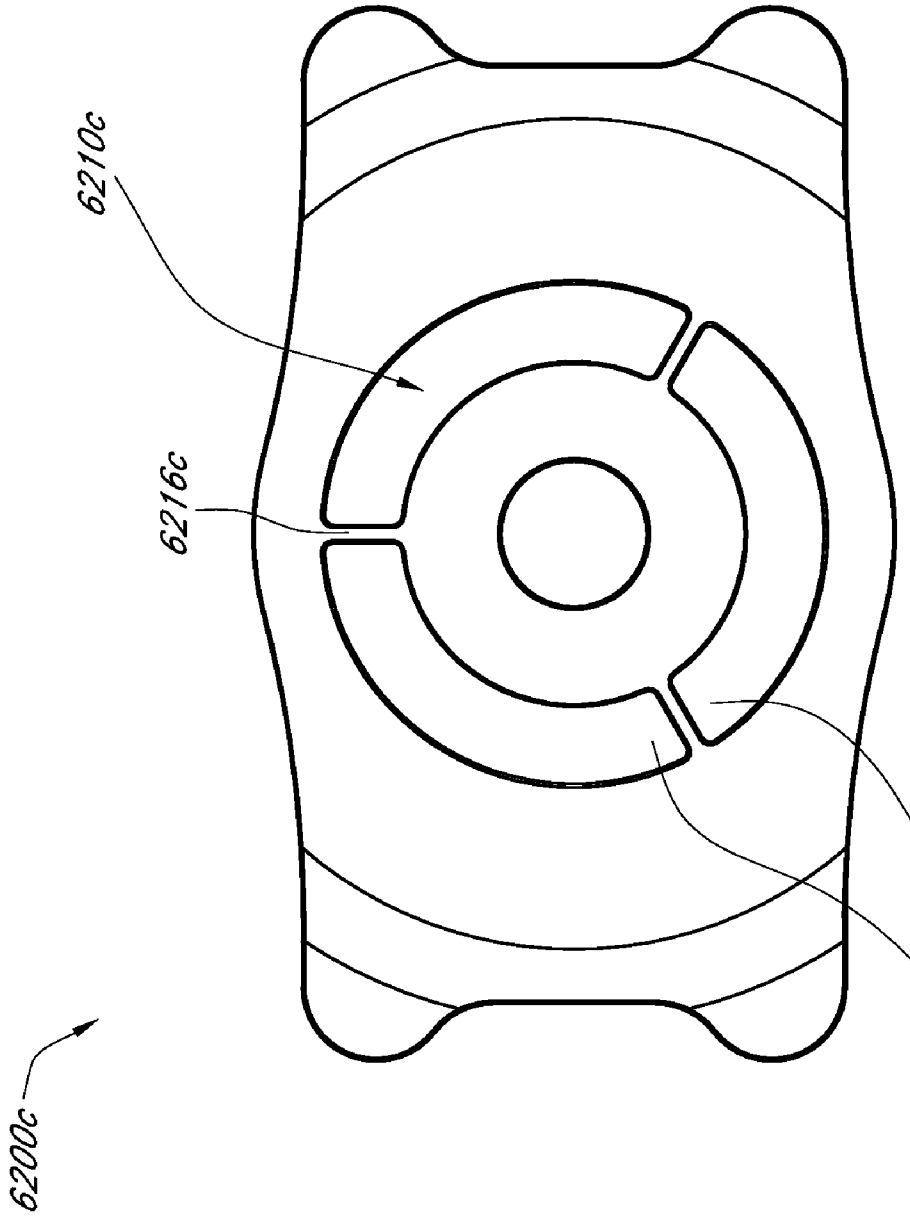


FIG. 51C

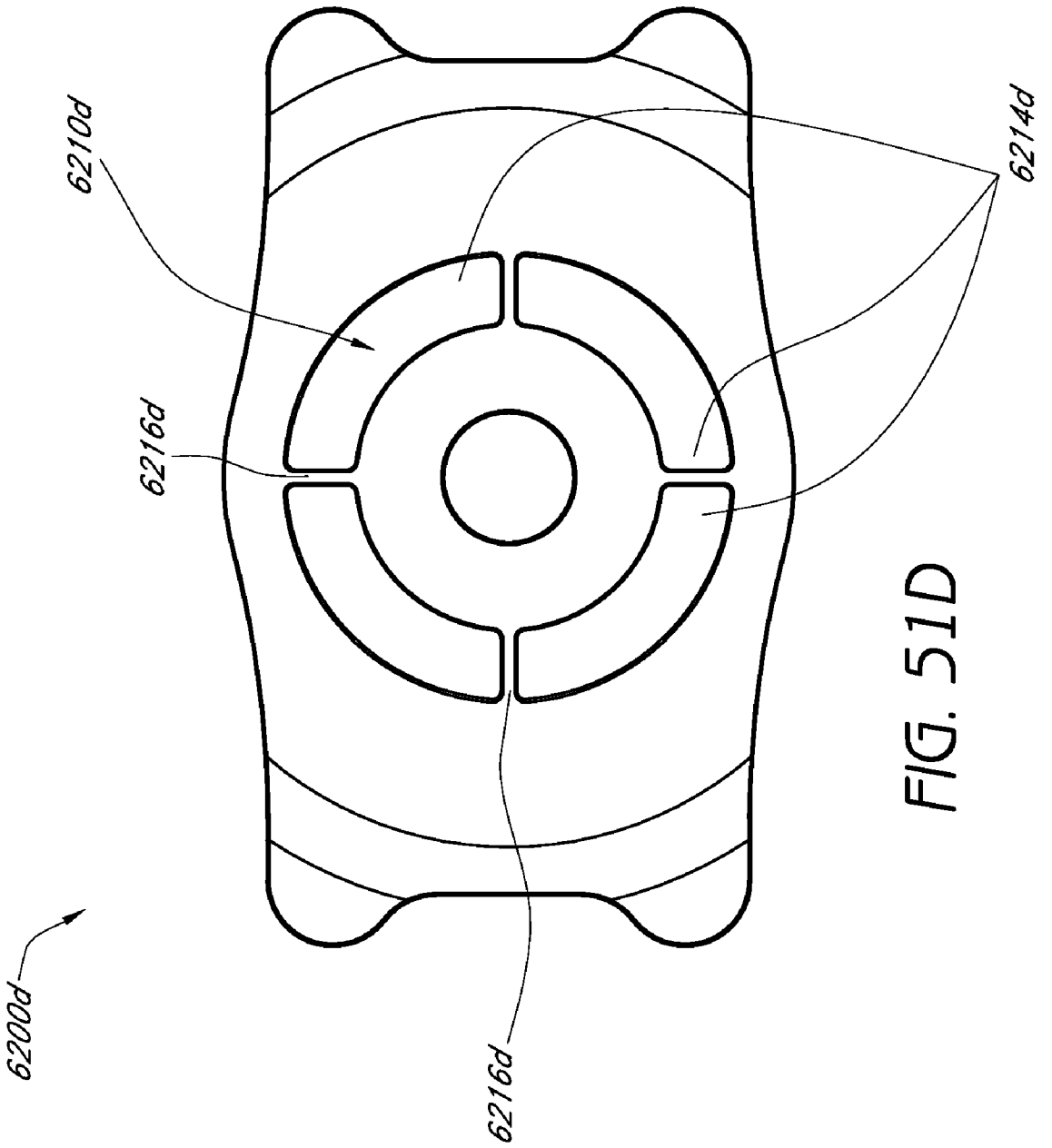


FIG. 51D

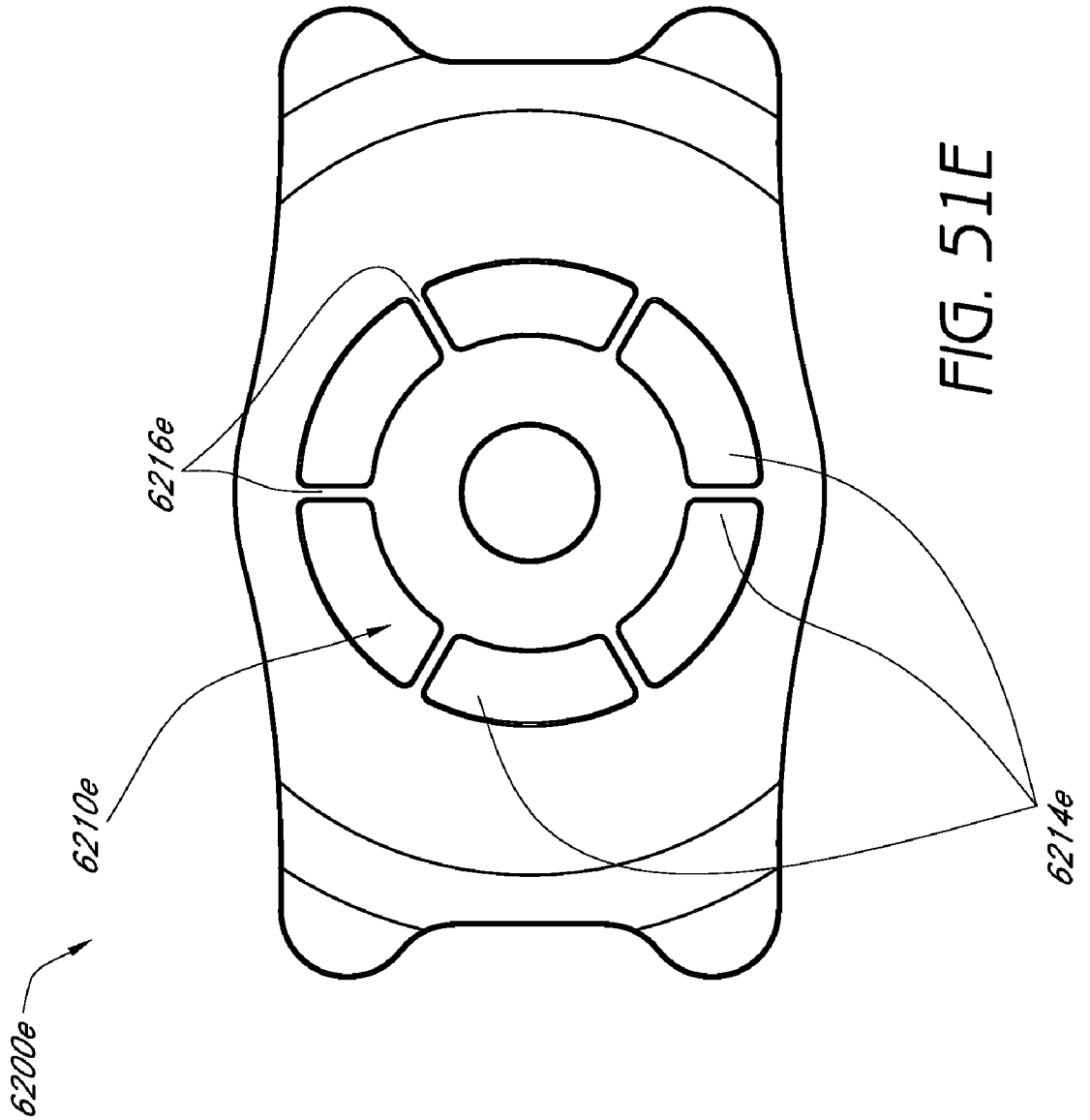


FIG. 51E

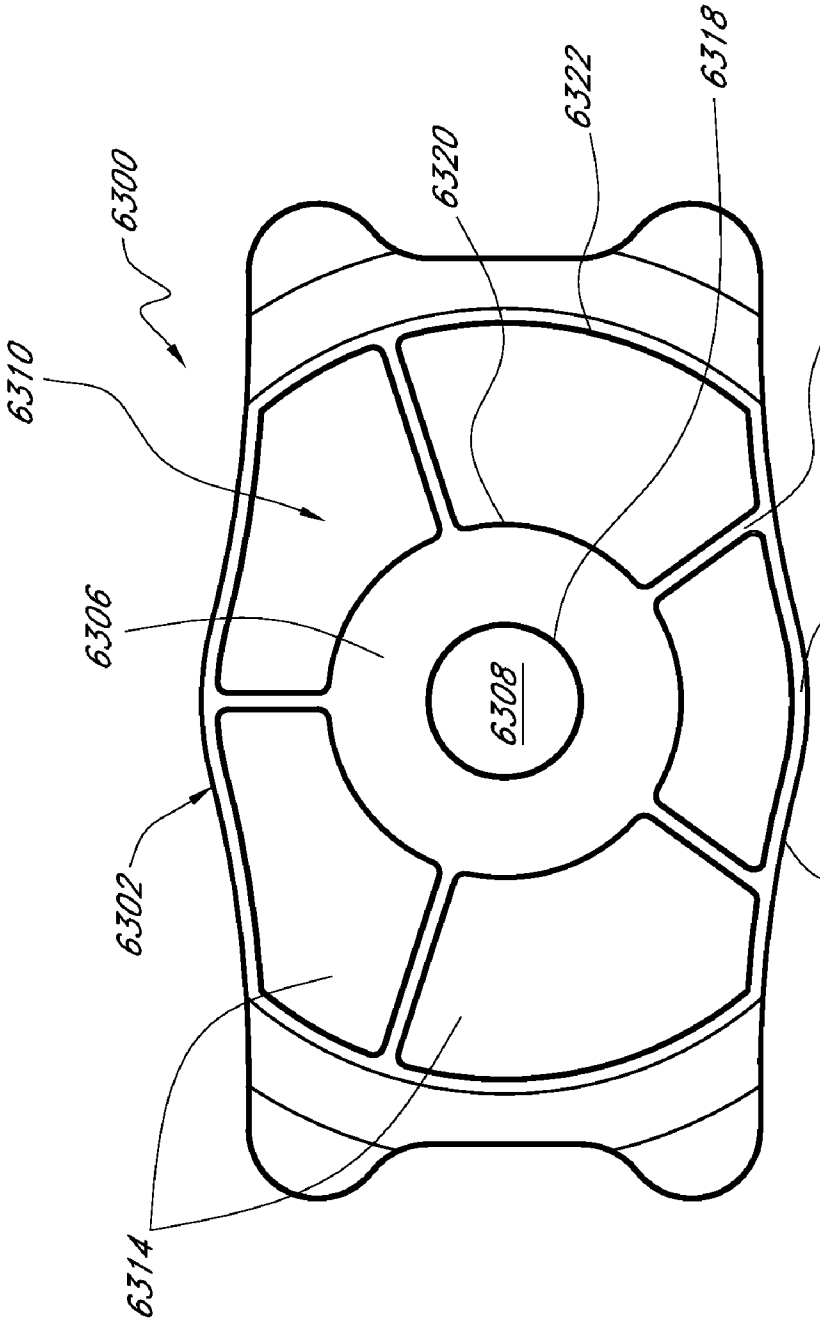


FIG. 52

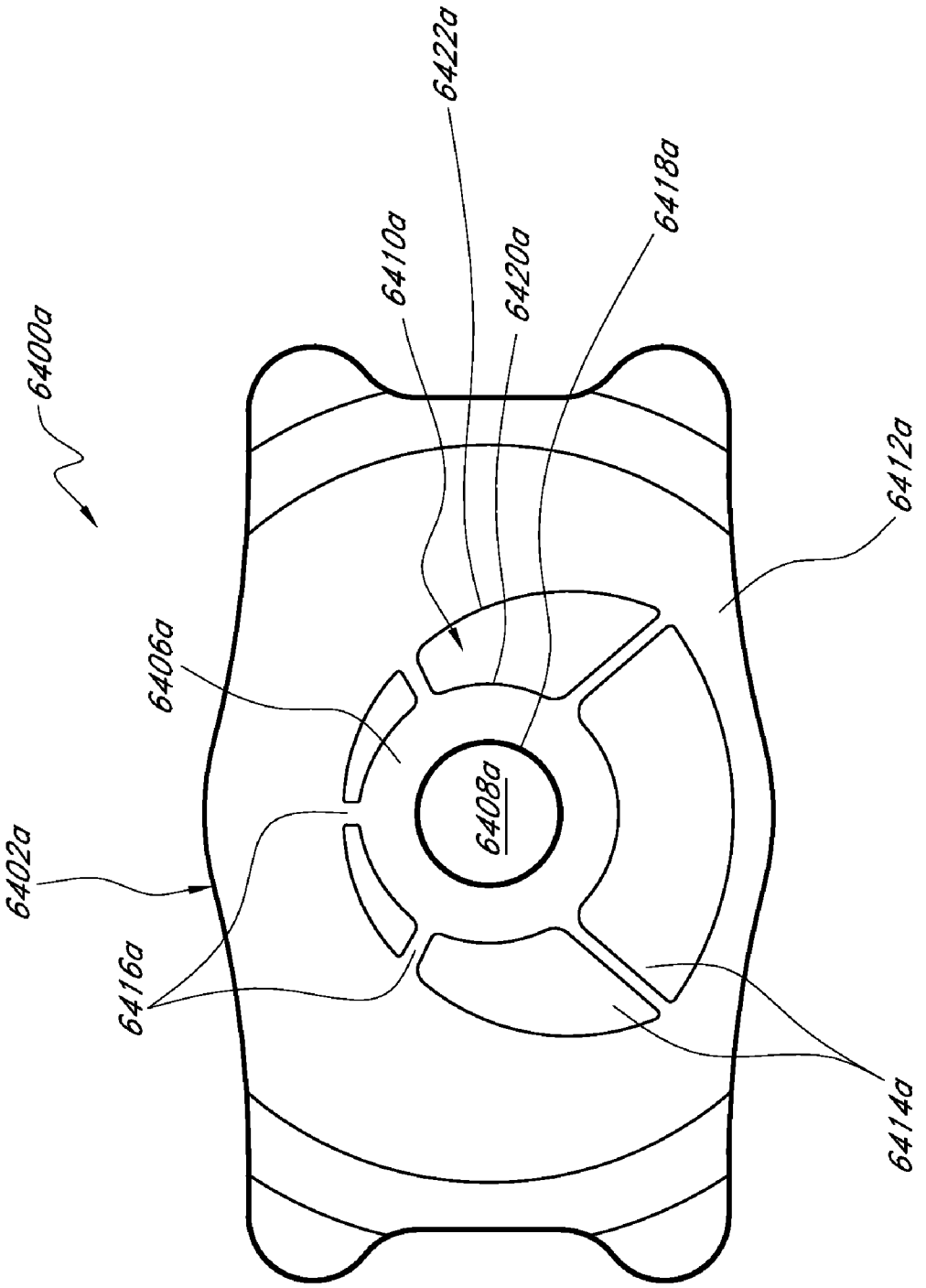

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6402a
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6414a

FIG. 53A

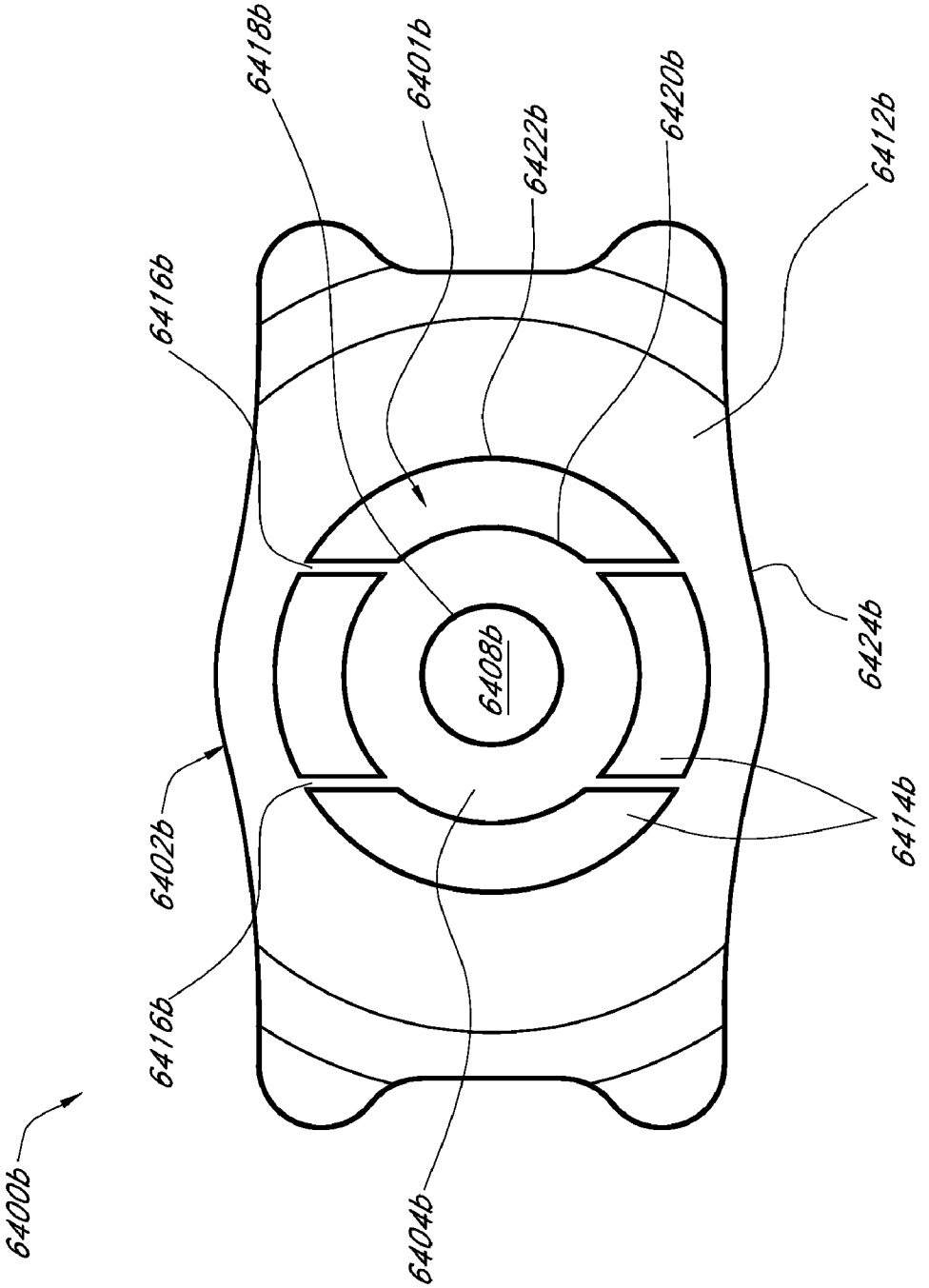

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6416b
6416b
6418b
6420b
6422b
6424b
6401b

FIG. 53B

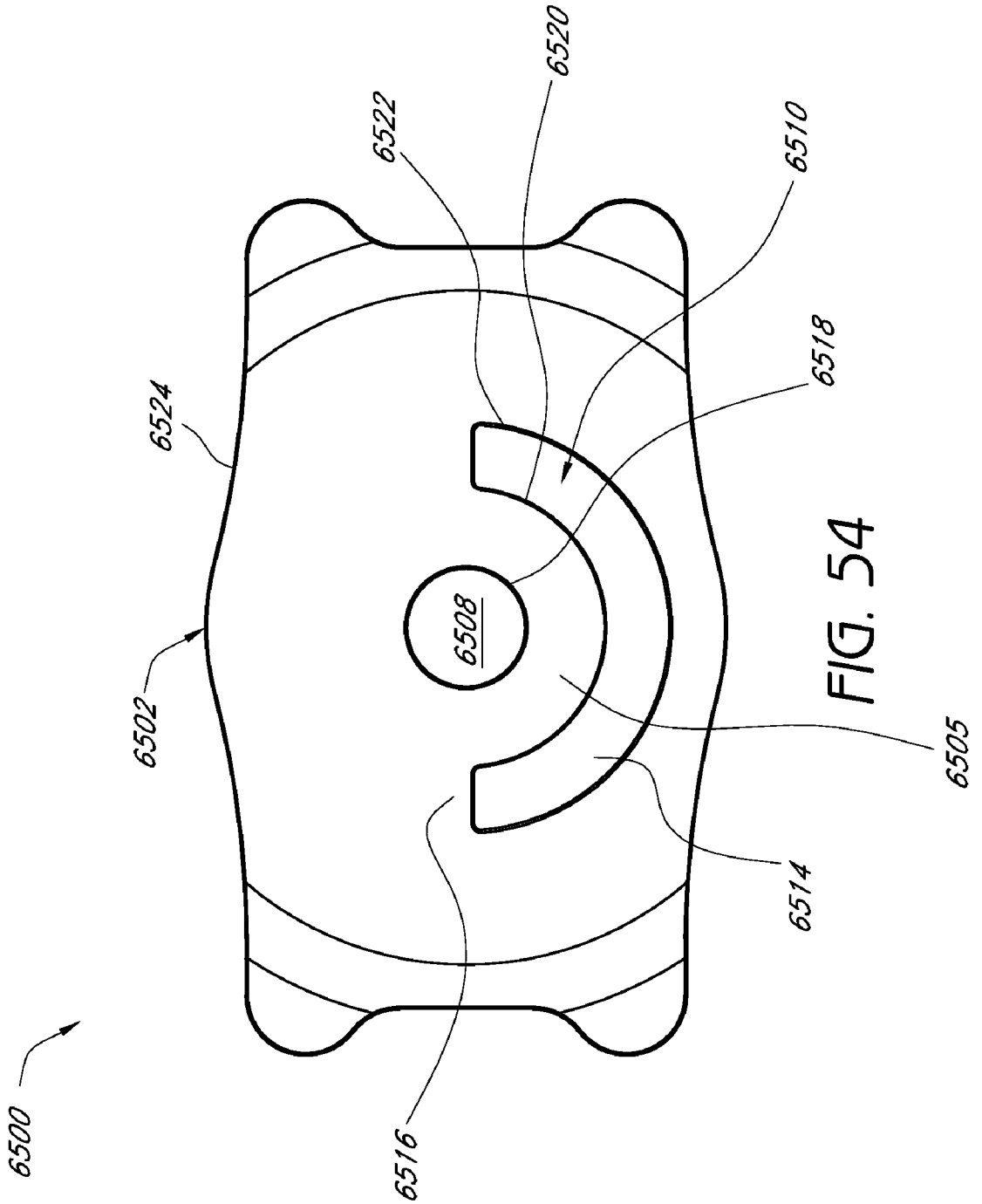


FIG. 54

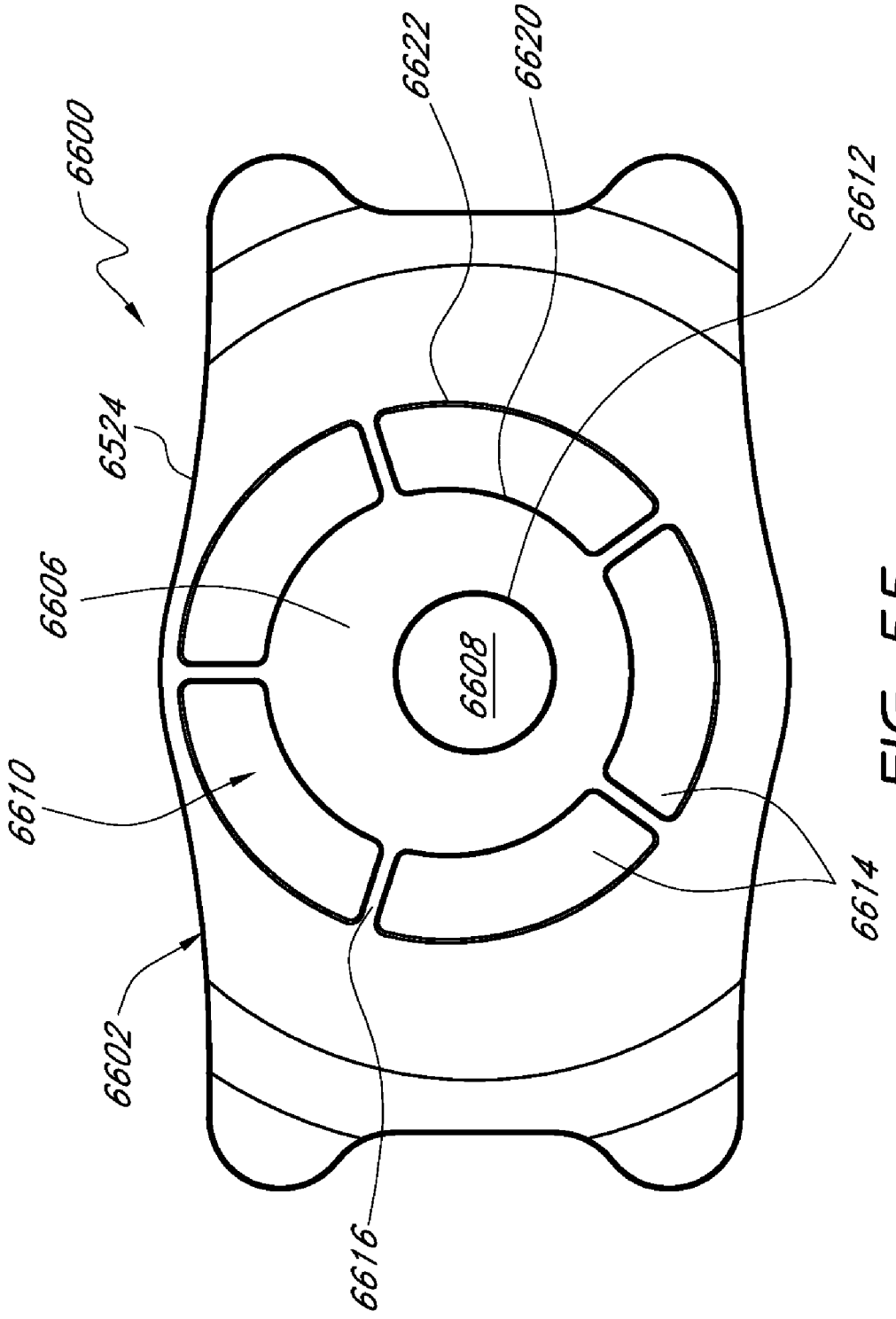


FIG. 55

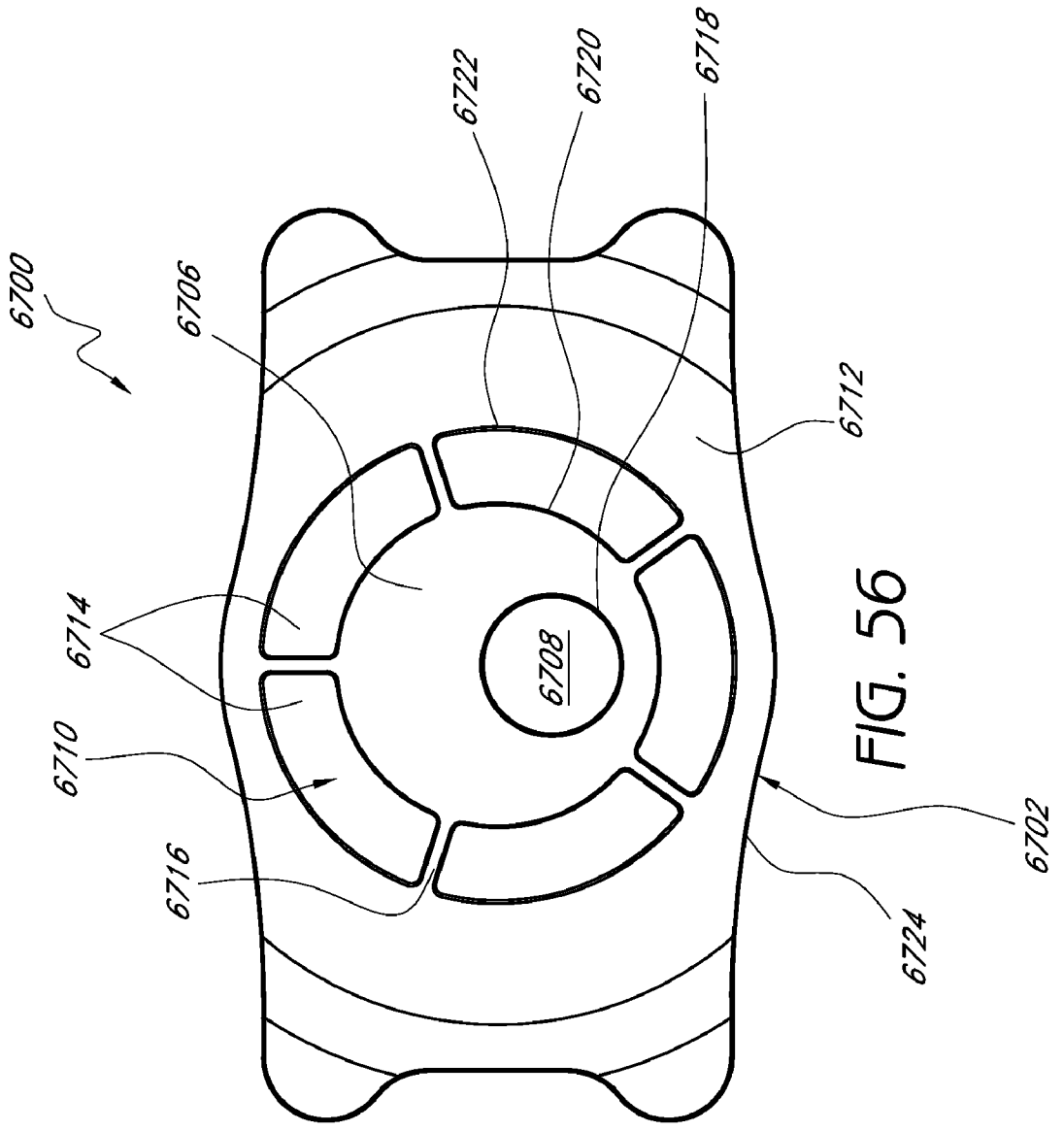


FIG. 56

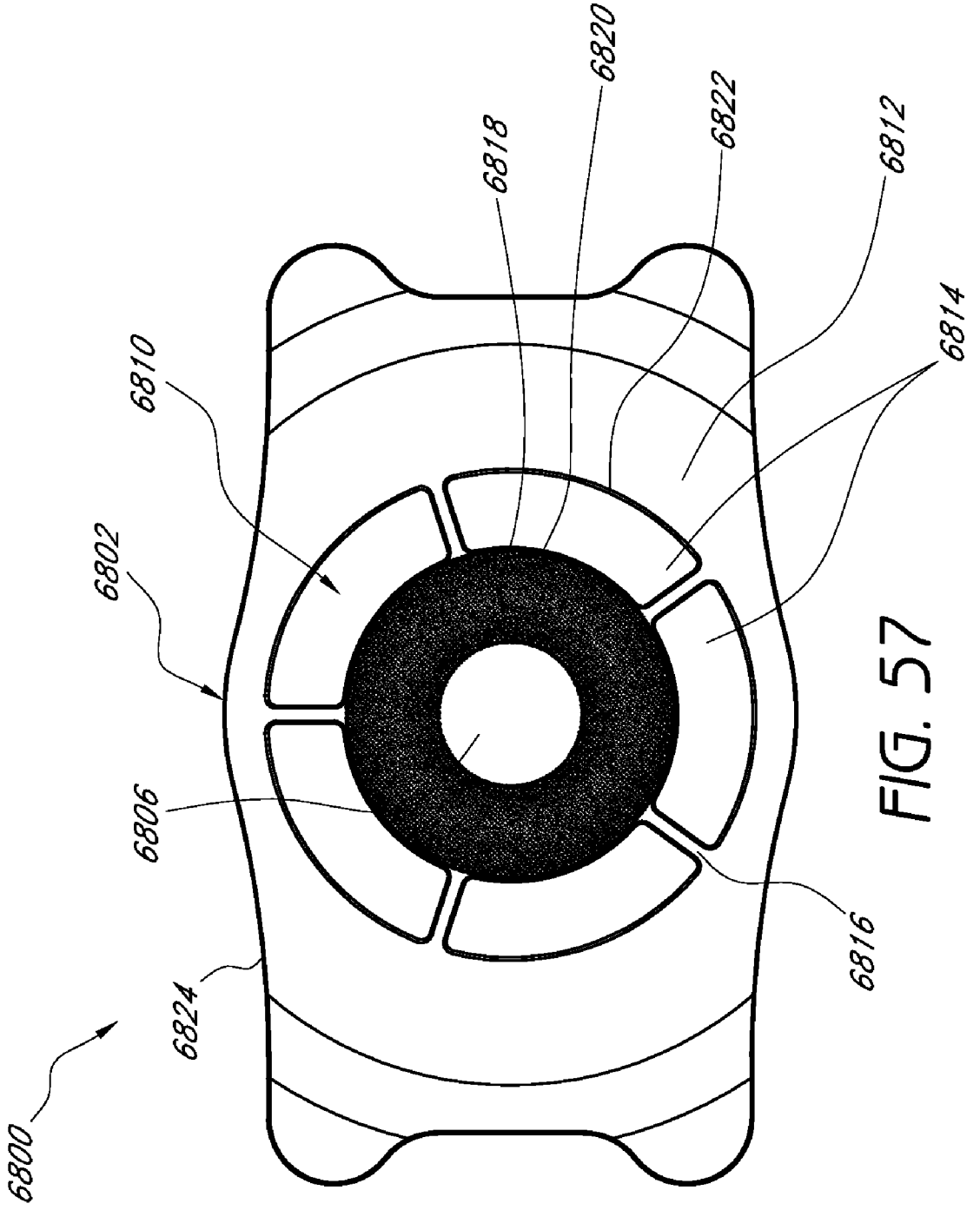


FIG. 57

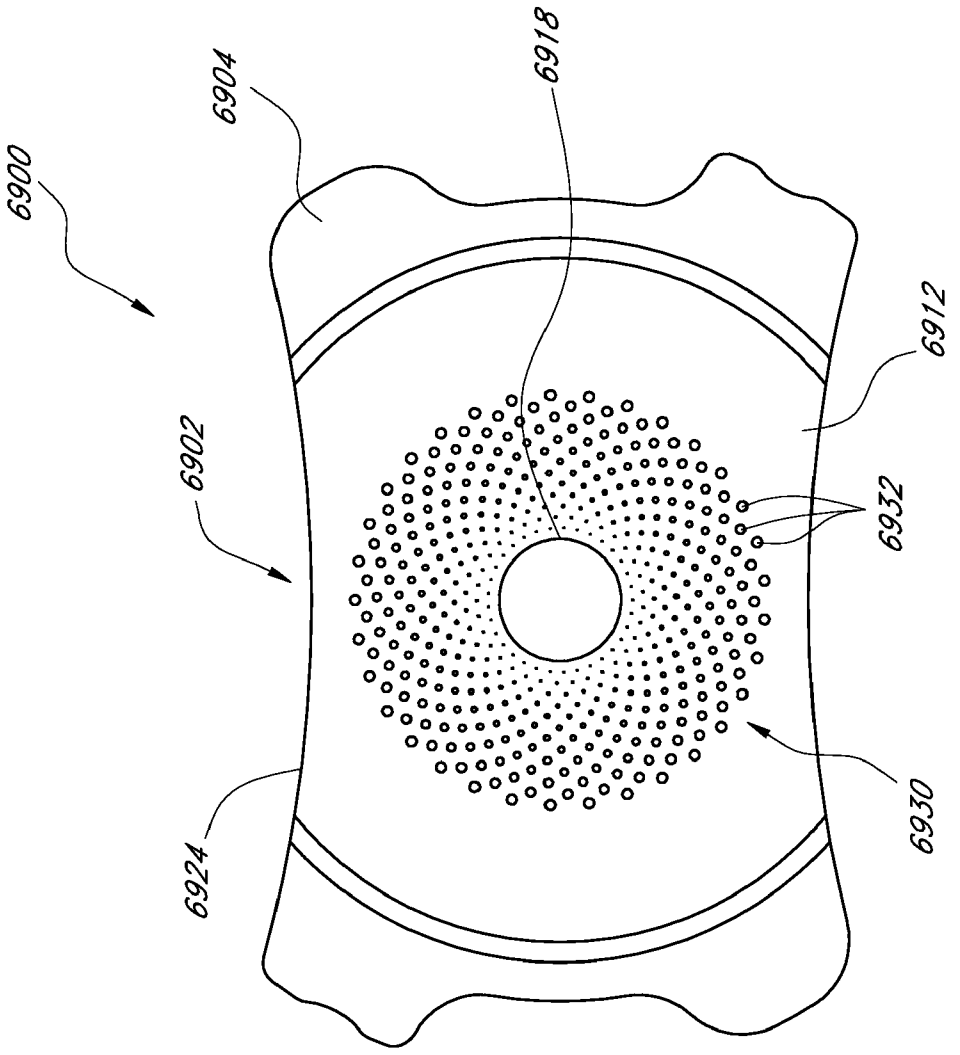


FIG. 58

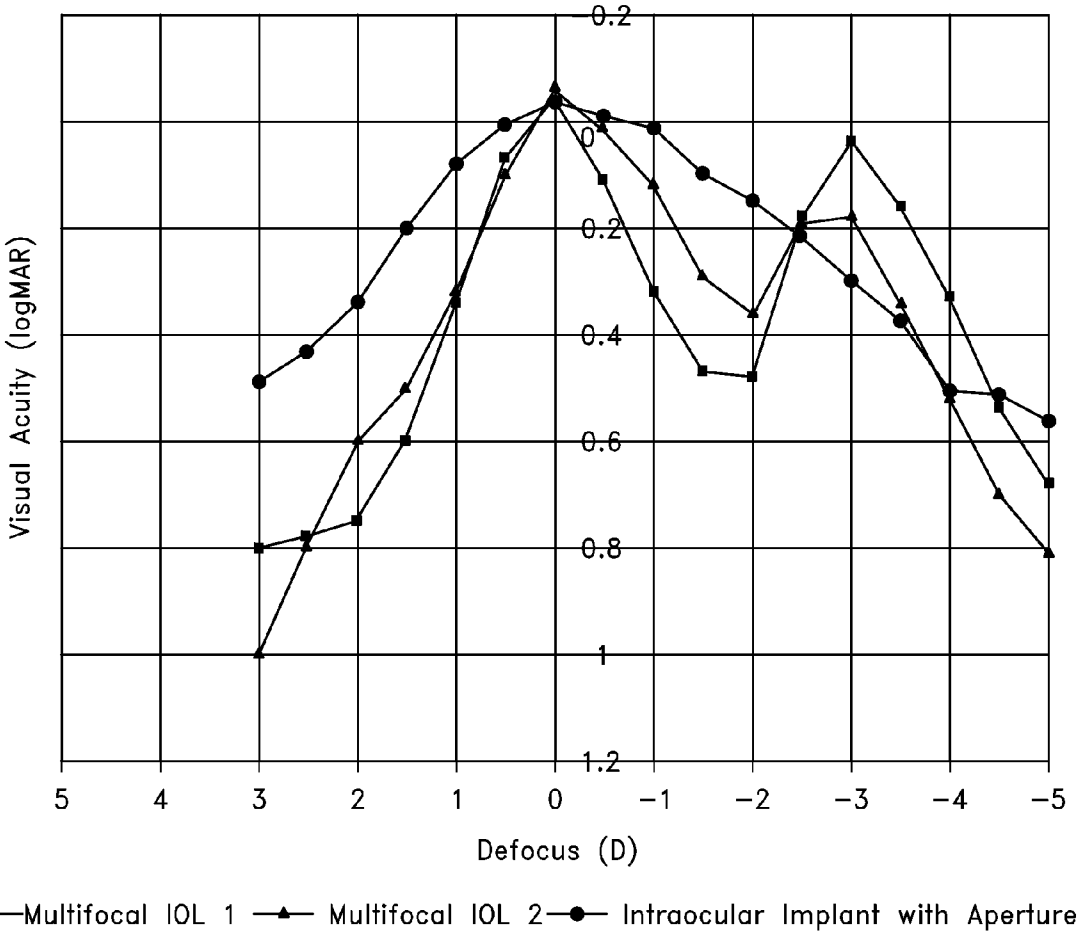

Visual Acuity (logMAR)
0.2
0
0.2
0.4
0.6
0.8
1
1.2
5
4
3
2
1
0
−1
−2
−3
−4
−5
Defocus (D)
Multifocal IOL 1
Multifocal IOL 2
Intraocular Implant with Aperture

FIG. 59

MASKED INTRAOCULAR IMPLANTS AND LENSES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 12/856,492, filed Aug. 13, 2010, entitled "MASKED INTRAOCULAR IMPLANTS AND LENSES," now pending, which claims the benefit of U.S. Provisional Application Nos. 61/233,794, filed Aug. 13, 2009, and 61/233,804, filed Aug. 13, 2009, the entirety of each of which is hereby incorporated by reference.

BACKGROUND

[0002] 1. Field

[0003] This application relates generally to the field of intraocular devices. More particularly, this application is directed to intraocular implants and lenses (IOLs), with an aperture to increase depth of focus (e.g. "masked" intraocular lenses) and methods of making.

[0004] 2. Description of the Related Art

[0005] The human eye functions to provide vision by transmitting and focusing light through a clear outer portion called the cornea, and further refining the focus of the image by way of a crystalline lens onto a retina. The quality of the focused image depends on many factors including the size and shape of the eye, and the transparency of the cornea and the lens.

[0006] The optical power of the eye is determined by the optical power of the cornea and the crystalline lens. In a normal, healthy eye, sharp images of distant objects are formed on the retina (emmetropia). In many eyes, images of distant objects are either formed in front of the retina because the eye is abnormally long or the cornea is abnormally steep (myopia), or formed in back of the retina because the eye is abnormally short or the cornea is abnormally flat (hyperopia). The cornea also may be asymmetric or toric, resulting in an uncompensated cylindrical refractive error referred to as corneal astigmatism.

[0007] A normally functioning human eye is capable of selectively focusing on either near or far objects through a process known as accommodation. Accommodation is achieved by inducing deformation in a lens located inside the eye, which is referred to as the crystalline lens. Such deformation is induced by muscles called ciliary muscles. In most individuals, the ability to accommodate diminishes with age and these individuals cannot see up close without vision correction. If far vision also is deficient, such individuals are usually prescribed bifocal lenses.

SUMMARY OF THE INVENTION

[0008] This application is directed to intraocular implants for improving the vision of a patient, such as by increasing the depth of focus of an eye of a patient. The intraocular implants can include a mask having an annular portion with a relatively low visible light transmission surrounding a relatively high transmission central portion such as a clear lens or aperture. This construct is adapted to provide an annular mask with a small aperture for light to pass through to the retina to increase depth of focus, sometimes referred to herein as pin-hole imaging or pin-hole vision correction. The intraocular implant may have an optical power for refractive correction. For example, the mask can be embodied in or combined with intraocular lenses (IOLs). The intraocular implant may be implanted in any location along the optical pathway in the eye, e.g., as an implant in the anterior or posterior chamber.

[0009] IOLs have been developed that provide a safe and effective surgical solution for cataracts. These lenses are surgically implanted after removal of a cataractous natural lens of the eye, restoring clarity and providing a replacement for the optical power that was removed. In a successful IOL implantation, the patient is typically emmetropic afterwards, meaning that their eye is focused for distance. However, conventional IOLs cannot accommodate to focus at different distances, so the patient typically needs additional correction (e.g., reading glasses) to see near objects clearly. Intraocular implants disclosed herein provide an improvement over presently available IOLs by incorporating a "mask" in the form of an aperture that improves depth of focus.

[0010] In certain embodiments, an intraocular device includes a lens body. The lens body includes an anterior and posterior surface. The posterior surface includes a first convex portion, a second concave portion and a third convex portion. The second concave portion is adjacent the first convex portion and the third convex portion. The third convex portion is annular and surrounds the second concave portion, and the second concave portion is annular and surrounds the first convex portion. An optical power between the first convex portion and the anterior surface is positive and an optical power between the third convex portion and the anterior surface is positive. The lens body further includes a mask positioned between the second concave portion and the anterior surface.

[0011] In certain embodiments, a lens body of an intraocular device includes a first surface and a second surface. A first portion of the first surface is convex, a second portion of the first surface is concave, and a third portion of the first surface is convex. The second portion is adjacent the first portion and the third portion. The lens body further includes a mask positioned to block a substantial portion of optical aberrations that would be created by the light passing through the second portion of the first surface.

[0012] In certain embodiments, an intraocular device includes a lens body with a positive optical power. The lens body includes an outer region and a recessed central region. At least a portion of the recessed central region includes a thickness less than at least a portion of the outer region. The lens body further includes a mask coupled with a curved transition between the outer region the recessed central region.

[0013] In certain embodiments, a method of making an intraocular device includes providing a lens body with a first surface and a second surface. The method further includes forming a convex surface on a first portion of the first surface, a concave surface on a second portion of the first surface and a convex surface on a third portion of the first surface. The second portion is adjacent the first portion and the third portion. The method also includes attaching a mask to the lens body that is positioned to block a substantial portion of the light passing through the second portion of the first surface.

[0014] In certain embodiments, a method of making an intraocular device includes forming a rod with an optically transparent inner region along a length of the rod, an optically transparent outer region along the length of the rod and a substantially optically non-transparent region along the length of the rod between the inner region and the outer region. The substantially non-transparent region can be a middle region, as discussed below. The method also can

include sectioning the rod along a plane substantially perpendicular to an axis parallel to the length of the rod to form a lens body with a first surface and a second surface. The method also can include forming a convex surface on a first portion of the first surface. The first portion can correspond to the inner region of the sectioned rod. The method can include forming a concave surface on a second portion of the first surface. The second portion can correspond to the non-transparent region. The method can include forming a convex surface on a third portion of the first surface. The third portion can correspond to the outer region. The second portion is adjacent the first portion and the third portion. In some embodiments, the non-transparent region is positioned such that, in use, the non-transparent region blocks a substantial portion of the light passing through the second portion of the first surface.

[0015] In certain embodiments, a method of making an intraocular device includes forming a lens body around a mask. The mask includes an aperture and an annular region, and the lens body comprising a first surface and a second surface. The method further includes forming a convex surface on a first portion of the first surface, a concave surface on a second portion of the first surface and a convex surface on a third portion of the first surface. The second portion is adjacent the first portion and the third portion. Forming the lens body around the mask includes locating the mask within the lens body such that, in use, the mask blocks a substantial portion of the light passing through the second portion of the first surface.

[0016] In certain embodiments, an intraocular implant includes an implant body. The implant body can include a pin-hole aperture in the implant body, and a mask substantially around the pin-hole aperture. The implant body can further include an outer hole region substantially outside an outer perimeter of the mask. The outer hole region can include at least one outer hole and at least one connection portion. An outer region of the implant body can be attached to the mask by the at least one connection portion.

[0017] In some embodiments, an intraocular device includes a lens body comprising a surface with a transition zone, the transition zone configured to reduce a thickness of the lens body along an optical axis of the lens body, and a mask configured to block a substantial portion of optical aberrations that would be created by light passing through the transition zone.

[0018] In further embodiments, an intraocular device includes a lens body comprising a first surface and a second surface. The first surface comprises a first portion, a second portion and a third portion. An optic axis of the lens body passes through the first portion, and the second portion is between the first portion and the third portion. The intraocular device can also include a mask positioned between the second surface and the second portion of the first surface. A distance from the first portion neighboring the second portion to a plane perpendicular to the optic axis and tangent to the second surface can comprise a first distance, and a distance from the third portion neighboring the second portion to the plane perpendicular to the optic axis and tangent to the second surface can comprise a second distance greater than the first distance.

[0019] In other embodiments, a method for improving the vision of a patient includes providing an intraocular device comprising a lens body comprising a surface with a transition zone. The transition zone can be configured to reduce a thickness of the lens body along an optic axis of the lens body, and the intraocular device can further include a mask configured to block a substantial portion of optical aberrations that would be created by light passing through the transition zone. The method can further include inserting the intraocular device into an intraocular space of an eye.

[0020] In certain embodiments, an intraocular implant includes an implant body comprising an outer surface that includes a posterior surface and an anterior surface, an opaque mask positioned between the posterior surface and the anterior surface of the implant body. The mask comprising an aperture. The intraocular implant can further include a support member coupled to the mask and extending from the mask to the outer surface of the implant body. The support member can extend from the mask to the posterior surface of the implant body. A first portion of the support member neighboring the mask can have a first cross-sectional area parallel the mask and a second portion of the support member neighboring the posterior surface can have a second cross-sectional area parallel the mask that is less than the first cross-sectional area. The support member may be configured to be removable from the intraocular implant. The support member may include a plurality of holes characterized in that at least one of the hole size, shape, orientation, and spacing of the plurality of holes is varied to reduce the tendency of the holes to produce visible diffraction patterns.

[0021] In certain embodiments, a method of making an intraocular implant includes providing an opaque mask comprising an aperture and at least one support member coupled to the mask, positioning the mask within a mold chamber such that the at least one support member is coupled to the mold chamber so that the mask resists movement, and flowing a lens material into the mold chamber so that at least a portion of the mask is encased within the lens material. The method may further include removing at least a portion of the at least one support member after injecting the lens material.

[0022] In other embodiments, a method of making an intraocular implant includes coupling an opaque mask comprising an aperture to a surface of a mold chamber, and flowing a lens material into the mold chamber to form an optic coupled to the mask.

[0023] In further embodiments, a method of making an intraocular implant includes removing a portion of a surface of an optic to form an annular cavity around an aperture region, at least partially filling the cavity with an opaque material, removing at least some of the aperture region and a central region of the optic to reduce a thickness of the aperture region of the optic. At least some of the opaque material may remain on the surface of the optic to form an opaque mask.

[0024] In another embodiment, a method of making an intraocular implant includes providing an optic with an annular cavity around an aperture region, at least partially filling the cavity with an opaque material, removing at least some of the aperture region and a central region of the optic to reduce a thickness of the aperture region of the optic. At least some of the opaque material can remain on the surface of the optic to form an opaque mask.

[0025] In even further embodiments, a method of making an intraocular implant includes positioning an opaque mask with an aperture within a mold cavity such that the mask is not in physical contact with the mold cavity, and injecting an implant body material into the mold cavity to form an implant body around the mask. For example, the mask can be positioned with magnetic fields or with wires extending from the mask to a frame outside of the mold cavity.

[0026] In certain embodiments, a intraocular implant includes an implant body comprising a body material and a mask with an aperture positioned within the implant body. The mask can include a plurality of holes that extend between a posterior surface and an anterior surface of the mask. The body material can extend through the plurality of holes of the mask, and the plurality of holes can be characterized in that at least one of the hole size, shape, orientation, and spacing of the plurality of holes is varied to reduce the tendency of the holes to produce visible diffraction patterns. The plurality of holes may be positioned at irregular locations. A first plurality of the holes may include first hole size, shape or spacing and at least another plurality of holes may include a second hole size, shape, or spacing different from the first holes size, shape, or spacing. A first plurality of the holes may include first hole size, a second plurality of the holes may include a second hole size different from the third hole size, and a third plurality of holes may include a third hole size different from the first holes size and the second hole size.

[0027] In certain embodiments, an intraocular implant includes an implant body configured to be implanted into a sulcus region of an eye of a patient. The implant body can include an aperture that is at least partially surrounded by an opaque region forming a mask and an outer hole region substantially outside an outer perimeter of the mask. The outer hole region can include at least one outer hole and at least one connection portion, and the outer hole region can have an incident visible light transmission of at least 90%. The implant body may also include an outer region attached to the mask by the at least one connection portion.

[0028] In other embodiments, a method of making an intraocular implant includes providing an implant body configured to be implanted into a sulcus region of an eye of a patient, forming an aperture in the implant body by removing a portion of the implant body, and forming at least one opening between the outer edge of the structure and a opaque mask region that neighbors the aperture.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIG. **1**A illustrates a front plan view of an embodiment of an intraocular lens with a recessed central region on the posterior surface as described herein.

[0030] FIG. **1**B illustrates a cross-sectional view of the intraocular lens of FIG. **1**A.

[0031] FIG. **2**A illustrates a front plan view of an embodiment of an intraocular lens with a recessed central region on the anterior surface as described herein.

[0032] FIG. **2**B illustrates a cross-sectional view of the intraocular lens of FIG. **2**A.

[0033] FIG. **3**A illustrates a front plan view of an embodiment of an intraocular lens with a recessed central region on the posterior surface and anterior surface as described herein.

[0034] FIG. **3**B illustrates a cross-sectional view of the intraocular lens of FIG. **3**A.

[0035] FIG. **4**A illustrates a front plan view of an embodiment of an intraocular lens with two transition zones and two masks as described herein.

[0036] FIG. **4**B illustrates a cross-sectional view of the intraocular lens of FIG. **4**A.

[0037] FIG. **5**A illustrates a front plan view of an embodiment of an intraocular lens with two transition zones and a single mask as described herein.

[0038] FIG. **5**B illustrates a cross-sectional view of the intraocular lens of FIG. **5**A.

[0039] FIG. **6**A illustrates a front plan view of an embodiment of an intraocular lens with a concave posterior surface and a positive optical power as described herein.

[0040] FIG. **6**B illustrates a cross-sectional view of the intraocular lens of FIG. **6**A.

[0041] FIG. **7**A illustrates a front plan view of an embodiment of an intraocular lens with a concave posterior surface and a negative optical power as described herein.

[0042] FIG. **7**B illustrates a cross-sectional view of the intraocular lens of FIG. **7**A.

[0043] FIG. **8** is a cross-sectional schematic representation of light passing through the intraocular lens of FIG. **2**B.

[0044] FIG. **9** is a schematic representation of light from a far object transmitted through an eye having an embodiment of an intraocular lens that is in the capsular bag.

[0045] FIG. **10**A illustrates a top view of a conventional intraocular lens.

[0046] FIG. **10**B illustrates a cross-sectional view of the conventional intraocular lens of FIG. **10**A.

[0047] FIG. **11**A is a perspective view of one embodiment of a mask.

[0048] FIG. **11**B is a perspective view of an embodiment of a substantially flat mask.

[0049] FIG. **12** is a side view of an embodiment of a mask having varying thickness.

[0050] FIG. **13** is a side view of another embodiment of a mask having varying thickness.

[0051] FIG. **14** is a side view of an embodiment of a mask with a material to provide opacity to the mask.

[0052] FIG. **15** is an enlarged, diagrammatic view of an embodiment of a mask that includes particulate structure adapted for selectively controlling light transmission through the mask in a low light environment.

[0053] FIG. **16** is a view of the mask of FIG. **15** in a bright light environment.

[0054] FIG. **17** is another embodiment of a mask that includes connectors for securing the mask within the eye.

[0055] FIG. **18**A is a top view of another embodiment of a mask configured to increase depth of focus.

[0056] FIG. **18**B is an enlarged view of a portion of the view of FIG. **18**A.

[0057] FIG. **19** is a cross-sectional view of the mask of FIG. **18**B taken along the section plane **19-19**.

[0058] FIG. **20**A is a graphical representation of one arrangement of holes of a plurality of holes that may be formed on the mask of FIG. **18**A.

[0059] FIG. **20**B is a graphical representation of another arrangement of holes of a plurality of holes that may be formed on the mask of FIG. **18**A.

[0060] FIG. **20**C is a graphical representation of another arrangement of holes of a plurality of holes that may be formed on the mask of FIG. **18**A.

[0061] FIG. **21**A is an enlarged view similar to that of FIG. **18**A showing a variation of a mask having non-uniform size.

[0062] FIG. **21**B is an enlarged view similar to that of FIG. **18**A showing a variation of a mask having a non-uniform facet orientation.

[0063] FIG. **22** is a top view of another embodiment of a mask having a hole region and a peripheral region.

[0064] FIG. **23** is a flow chart illustrating one method for making a masked intraocular implant from a mask comprising a highly fluorinated polymer and an opacification agent.

[0065] FIG. **24**A is a top plan view of an embodiment of a mask configured to increase depth of focus as described herein.

[0066] FIG. **24**B is a front plan view of an embodiment of a mask configured to increase depth of focus as described herein.

[0067] FIG. **24**C is a front plan view of an embodiment of a mask configured to increase depth of focus as described herein.

[0068] FIG. **24**D is a front plan view of an embodiment of a mask configured to increase depth of focus as described herein.

[0069] FIG. **25**A is a cross-sectional view of an embodiment of an intraocular implant with a mask coupled to the anterior surface of a transition zone as described herein.

[0070] FIG. **25**B is a cross-sectional view of an embodiment of an intraocular implant with a mask coupled to the posterior surface as described herein.

[0071] FIG. **25**C is a cross-sectional view of an embodiment of an intraocular implant with a mask embedded within the implant body about midway between the posterior and anterior surfaces as described herein.

[0072] FIG. **25**D is a cross-sectional view of an embodiment of an intraocular implant with a mask embedded within the implant body which is closer to the anterior surface than the posterior surface as described herein.

[0073] FIG. **25**E is a cross-sectional view of an embodiment of an intraocular implant with a mask embedded within the implant body which is closer to the posterior surface than the anterior surface as described herein.

[0074] FIG. **25**F is a cross-sectional view of an embodiment of an intraocular implant with a mask embedded within the implant body and within close proximity of the anterior surface of a transition zone as described herein.

[0075] FIG. **25**G is a cross-sectional view of an embodiment of an intraocular implant with a mask that extends between the anterior and posterior surfaces as described herein.

[0076] FIG. **26**A is a front plan view of an embodiment of an intraocular implant with support members extending from the mask to a peripheral surface of the implant body as described herein.

[0077] FIG. **26**B is a cross-sectional view of an embodiment of an intraocular implant with support members extending from the mask to the posterior surface of the implant body as described herein.

[0078] FIG. **26**C is a cross-sectional view of an embodiment of an intraocular implant with a mask integrated with the support members as described herein.

[0079] FIG. **27**A is a cross-sectional view of an embodiment of an intraocular implant with tabs extending from the mask to the posterior surface of the implant body as described herein.

[0080] FIG. **27**B is a cross-sectional view of the intraocular implant of FIG. **27**A wherein a portion of the tabs have been removed.

[0081] FIG. **28**A is a front plan view of an embodiment of an intraocular implant with a support member as described herein.

[0082] FIG. **28**B is a cross-sectional view of the intraocular implant of FIG. **28**A.

[0083] FIG. **29**A is a front plan view of an embodiment of an intraocular implant with a different optical power than the intraocular implant of FIG. **27**A.

[0084] FIG. **29**B is a cross-sectional view of the intraocular implant of FIG. **29**A.

[0085] FIG. **30**A is a front plan view of an embodiment of an intraocular lens with a mask that extends radially beyond the outer periphery of the transition zone as described herein.

[0086] FIG. **30**B is a cross-sectional view of the intraocular implant of FIG. **30**A.

[0087] FIG. **31**A is a front plan view of another embodiment of an intraocular implant with a support member as described herein.

[0088] FIG. **31**B is a cross-sectional view of the intraocular implant of FIG. **31** A.

[0089] FIG. **32**A is a front plan view of another embodiment of an intraocular implant with a mask that extends radially beyond the outer periphery of the transition zone as described herein.

[0090] FIG. **32**B is a cross-sectional view of the intraocular implant of FIG. **32**A.

[0091] FIG. **33**A is a front plan view of a further embodiment of an intraocular implant with a support member as described herein.

[0092] FIG. **33**B is a cross-sectional view of the intraocular implant of FIG. **33**A.

[0093] FIG. **34**A is a front plan view of a further embodiment of an intraocular implant with a mask that extends radially beyond the outer periphery of the transition zone as described herein.

[0094] FIG. **34**B is a cross-sectional view of the intraocular implant of FIG. **34**A.

[0095] FIG. **35**A is a front plan view of an embodiment of an intraocular implant with a support member coupled with a haptic as described herein.

[0096] FIG. **35**B is a cross-sectional view of the intraocular implant of FIG. **35**A.

[0097] FIG. **36**A is a front plan view of another embodiment of an intraocular implant with a support member coupled with a haptic as described herein.

[0098] FIG. **36**B is a cross-sectional view of the intraocular implant of FIG. **36**A.

[0099] FIG. **37**A is a cross-section view of an intraocular implant.

[0100] FIG. **37**B is a cross-section view of the intraocular implant of FIG. **37**A with a cavity formed into the implant body.

[0101] FIG. **37**C is a cross-section view of the intraocular implant of FIG. **37**B with the cavity at least partially filled with an opaque material.

[0102] FIG. **37**D is a cross-sectional view of the intraocular implant of FIG. **37**C with a portion of the opaque material and central region removed.

[0103] FIG. **38**A is a cross-section view of an intraocular implant.

[0104] FIG. **38**B is a cross-section view of the intraocular implant of FIG. **38**A with a cavity formed into the implant body.

[0105] FIG. **38**C is a cross-section view of the intraocular implant of FIG. **38**B with mask positioned within the cavity.

[0106] FIG. **38**D is a cross-section view of the intraocular implant of FIG. **38**C with the cavity at least partially filled with an implant body material.

[0107] FIG. **38**E is a cross-section view of the intraocular implant of FIG. **38**D with a portion of the implant body removed.

[0108] FIG. **39**A is a cross-section view of an intraocular implant.

[0109] FIG. **39**B is a cross-section view of the intraocular implant of FIG. **38**A with a cavity formed into the implant body.

[0110] FIG. **39**C is a cross-section view of the intraocular implant of FIG. **39**B with the cavity at least partially filled with an opaque material.

[0111] FIG. **39**D is a cross-sectional view of the intraocular implant of FIG. **39**C with a portion of the opaque material and central region removed.

[0112] FIG. **40** is a schematic of an embodiment of a mask positioning system for positioning a mask within a mold cavity as described herein.

[0113] FIG. **41** is an illustration of an embodiment of a mask positioning apparatus that includes wires coupled to a mask and a frame as described herein.

[0114] FIG. **42** is a side view of an embodiment of a mask levitated with a magnetic field as described herein.

[0115] FIG. **43**A is a top view of an embodiment of a mask levitated above of magnetic fields as described herein.

[0116] FIG. **43**B is a top view of another embodiment of a mask levitated above of magnetic fields as described herein.

[0117] FIG. **44** is a schematic of an embodiment of using electrostatic levitation to position a mask as described herein.

[0118] FIG. **45** is a top view of an embodiment of a bistable display that is capable of forming a mask as described herein.

[0119] FIG. **46** is a top perspective view of an embodiment of a masked intraocular implant configured to increase depth of focus described herein.

[0120] FIG. **47** is a top plan view of the intraocular implant of FIG. **46**.

[0121] FIG. **48**A is a side elevational view of an embodiment of an intraocular implant with a mask through the intraocular implant of FIG. **46**.

[0122] FIG. **48**B is a side elevational view of an embodiment of an intraocular implant with a mask on the posterior surface of the intraocular implant.

[0123] FIG. **48**C is a side elevational view of an embodiment of an intraocular implant with a mask on the anterior surface of the intraocular implant.

[0124] FIG. **48**D is a side elevational view of an embodiment of an intraocular implant with a mask positioned midway between the posterior and anterior surfaces of the intraocular implant.

[0125] FIG. **48**E is a side elevational view of an embodiment of an intraocular implant with a mask positioned between the posterior surface and a midway position between the posterior and anterior surfaces of the intraocular implant.

[0126] FIG. **48**F is a side elevational view of an embodiment of an intraocular implant with a mask positioned between the anterior surface and a midway position between the posterior and anterior surfaces of the intraocular implant.

[0127] FIG. **49**A is a top perspective view of an embodiment of an intraocular implant with five outer holes described herein.

[0128] FIG. **49**B is a top plan view of the intraocular implant of FIG. **56**A.

[0129] FIG. **49**C is a side elevational view of the intraocular implant of FIG. **56**A.

[0130] FIG. **50**A is a top perspective view of an embodiment of an intraocular implant with a different haptic than the intraocular implant of FIG. **56**A described herein.

[0131] FIG. **50**B is a top plan view of the intraocular implant of FIG. **57**A.

[0132] FIG. **50**C is a side elevational view of the intraocular implant of FIG. **57**A.

[0133] FIG. **51**A is a top plan view of an embodiment of an intraocular implant with a single outer hole described herein.

[0134] FIG. **51**B is a top plan view of an embodiment of an intraocular implant with two outer holes described herein.

[0135] FIG. **51**C is a top plan view of an embodiment of an intraocular implant with three outer holes described herein.

[0136] FIG. **51**D is a top plan view of an embodiment of an intraocular implant with four outer holes described herein.

[0137] FIG. **51**E is a top plan view of an embodiment of an intraocular implant with six outer holes described herein.

[0138] FIG. **52** is a top plan view of an embodiment of an intraocular implant with an outer hole region that extends out near the periphery of the implant body described herein.

[0139] FIG. **53**A is a top plan view of an embodiment of an intraocular implant with an outer hole region that extends out further away from the aperture in one direction than another described herein.

[0140] FIG. **53**B is a top plan view of an embodiment of an intraocular implant with non-uniform outer holes described herein.

[0141] FIG. **54** is a top plan view of an embodiment of an intraocular implant with an outer hole region that partially surrounds the aperture described herein.

[0142] FIG. **55** is a top plan view of an embodiment of an intraocular implant with a centrally located aperture and an off-center outer hole region described herein.

[0143] FIG. **56** is a top plan view of an embodiment of an intraocular implant with a centrally located outer hole region and an off-center aperture described herein.

[0144] FIG. **57** is a top plan view of an embodiment of an intraocular implant wherein the mask includes light transmission holes described herein.

[0145] FIG. **58** is a top plan view of an embodiment of an intraocular implant with light transmission holes gradually increasing in size radially out from the aperture.

[0146] FIG. **59** is a plot of visual acuity as a function of defocus comparing two typical multifocal IOLs and an embodiment of an ophthalmic device with an aperture described herein.

DETAILED DESCRIPTION

[0147] This application is directed to intraocular implants and methods of implanting intraocular implants. The natural lens of an eye is often replaced with an intraocular lens when the natural lens has been clouded over by a cataract. An intraocular lens may also be implanted into the eye to correct other refractive defects without removing the natural lens. The intraocular implants of the preferred embodiments include a mask adapted to provide a small aperture for light to pass through to the retina to increase depth of focus, sometimes referred to herein as pinhole imaging or pinhole vision correction. The intraocular implants may be implanted in the anterior chamber or the posterior chamber of the eye. In the posterior chamber, the implants may be fixated in the ciliary sulcus, in the capsular bag, or anywhere an intraocular implant is fixated. In some embodiments discussed below, the intraocular lenses have a reduced thickness in a central region compared to conventional intraocular lenses. The reduced thickness in the central region can help improve implantation of the intraocular lens. In further embodiments discussed

below, intraocular implants can have an outer hole region (e.g. perforated region) to improve a patient's low light vision.

I. Intraocular Implants with Reduced Thickness

[0148] Several alternatives to fixed-focus IOLs have been developed, including multifocal IOLs and accommodating IOLs that attempt to provide the ability to see clearly at both distance and near. Multifocal IOLs do provide good acuity at both distance and near, but these lenses typically do not perform well at intermediate distances and are associated with glare, halos, and night vision difficulties associated with the presence of unfocused light. Accommodating IOLs of several designs have also been developed, but none so far has been able to replicate the function of the natural crystalline lens. IOLs with apertures have been described by Vorosmarthy (U.S. Pat. No. 4,976,732). These devices, however, do not attempt to change focus from far to near, but merely attempt to reduce the blurry image from defocus to a level where a presbyopic emmetrope can read. Notably, Vorosmarthy did not address the issue of reducing thickness of a masked IOL for application in small-incision surgery.

[0149] Some embodiments of the present application provide a masked IOL with a thinner optic than has been known in the art. The advantage to a thinner optic is that the IOL can be inserted through a smaller incision into the eye. Since corneal incisions tend to distort the cornea and impair vision, reducing the size of the incision will improve the quality of vision. The optic is made thinner by means similar to a Fresnel lens, where alternating concentric zones provide focusing power and height steps. While the thickness reduction possible with a Fresnel lens is significant, the height steps are optically inappropriate for clinical application. They do not focus light to an image at the fovea, but instead scatter light, leading to dysphotopsias (streaks, shadows, halos, etc.) in the patient's vision. By combining Fresnel-type height steps with a mask that blocks light from passing through the steps and allows light to pass only through the focusing surfaces, one can eliminate the dysphotopsias associated with a common Fresnel lens, obtaining the benefit of reduced thickness without introducing unwanted optical effects.

[0150] Generally, intraocular implants are implanted into the eye by rolling up an intraocular implant and inserting the rolled up intraocular implant into a tube. The tube is inserted into an incision in the eye, and the intraocular implant is ejected out of the tube and deployed within the eye. Intraocular implants can be implanted within the lens capsule after removal of the natural lens, or in the anterior chamber, posterior chamber, and can be coupled with or attached to the ciliary sulcus (sometimes referred to herein as "sulcus-fixated"). Depending on the location of the intraocular implant within the eye, dimensions of the intraocular implant, including but not limited to the aperture of the mask, may be adjusted. By reducing the thickness of in the central region of the intraocular lens, the intraocular lens can be rolled up tighter and inserted into a smaller tube. A smaller incision can be made in the eye if a smaller tube is used. The result is a less invasive procedure with quicker recovery time for the patient. Also, compared with a conventional posterior chamber phakic intraocular lens, a reduced thickness lens that is fixated in the ciliary sulcus will allow more space between the intraocular lens posterior surface and the natural crystalline lens surface, thereby reducing the potential for contact between these surfaces.

[0151] In certain embodiments, an intraocular lens **100** includes a lens body **102** with an optical power to refract light and correct refractive errors of the eye. Certain embodiments are illustrated in FIGS. **1-10**. The intraocular lens **100** may include one or more haptics **104** to prevent the intraocular lens **100** from moving or rotating within the eye. As used herein the term "haptic" is intended to be a broad term encompassing struts and other mechanical structures that can be apposed against an inner surface of an eye and mounted to a lens structure to securely position a lens in an optical path of an eye. The haptics **104** can be a variety of shapes and sizes depending on the location the intraocular lens **100** is implanted in the eye. Haptics illustrated in FIGS. **1-10** can be interchanged with any variety of haptic. For example, the haptics illustrated in FIGS. **1-10** can be combined with the intraocular lens illustrated in FIGS. **1-10**. Haptics may be C-shaped, J-shaped, plate design, or any other design. An intraocular implant described herein may have two, three, four, or more haptics. The haptics may be of open or closed configuration and may be planar, angled, or step-vaulted. Examples of haptics are disclosed in U.S. Pat. Nos. 4,634,442; 5,192,319; 6,106,553; 6,228,115; Re. 34,251; 7,455,691; and U.S. Patent Application Publication 2003/0199978, which are incorporated in their entirety by reference.

[0152] In certain embodiments, the lens body **102** includes a posterior surface **110** and an anterior surface **112**, as illustrated in FIGS. **1**A-B. The lens body **102** includes a first portion **116** (e.g., inner portion or central region), a second portion **114** (e.g., transition zone) and a third portion **118** (e.g., outer portion or region) on the posterior surface **110**. The second portion **114** can be between and/or adjacent the first portion **116** and the third portion **118**. The second portion **114** can substantially surround the first portion **116**, and the third portion **118** can substantially surround the second portion **114**. In certain embodiments, the first portion **116** is substantially circular, and the second portion **114** and third portion **118** are substantially annular. The first portion **116** and third portion **118** can refract light or have an optical power to improve a patient's vision. The second portion **114** has one or more facets, grooves, crests, troughs, depressions, contours, surface curvatures, etc. to make the first portion **116** closer to the anterior surface **112** than if the posterior surface **110** did not have the second portion **114**. The second portion **114** can also be described as a "transition zone" between the first portion **116** and the third portion **118**. For example, the second portion **114** transition zone can slope toward the anterior surface **112** from the third portion **118** to the first portion **116**. In certain embodiments, the second portion **114** transition zone includes a surface substantially perpendicular to the anterior surface **112**. The transition zones are like those incorporated in a Fresnel lens. They enable the lens body to be made thinner than would be required in a conventional lens design. However, as with Fresnel lenses, the transition zones introduce optical aberrations that would not be clinically acceptable in intraocular lenses.

[0153] The intraocular lens **100** can include a mask **108** that can be positioned to block a substantial portion of light that would pass through the second portion **114** transition zone of the posterior surface **110**. "Blocked" as used in this context includes preventing at least a portion of light from passing through the mask, as well as preventing substantially all the light from passing through the mask. If the mask **108** did not block the light rays that would pass through the second portion **114**, aberrations would result since the refraction of light

(e.g. optical power, etc.) in the second portion **114** is typically different than in the first portion **116** and the third portion **118**.

[0154] In certain embodiments, the first portion **116** is convex, the second portion **114** is concave, and the third portion **118** is convex. In certain embodiments, the first portion **116** and the third portion **118** have a positive or converging optical power and the second portion **114** has a negative or diverging optical power. The second portion **114** may have curvature or no curvature in a direction extending radially from the first portion **116** to the third portion **118**. For example, the second portion **114** may have a positive or negative curvature (e.g., convex or concave) in a direction extending radially from the first portion **116** to the third portion **118**. Furthermore, the second portion **114** may form a closed loop and have surface similar to an outer surface of a frustoconical shape.

[0155] In certain embodiments, the first portion **116** is within a central region **132** of the lens body **102**. The central region **132** can be recessed within the lens body **102**. In certain embodiments, the third portion **118** is within an outer region **130** of the lens body **102**. In certain embodiments, an outer perimeter of the first portion **116** is surrounded and/or enclosed by an inner perimeter of the second portion **114**. In certain embodiments, an outer perimeter of the second portion **114** is surrounded and/or enclosed by an inner perimeter of the third portion **118**. In certain embodiments, the maximum thickness of the lens body **102** in the region of the first portion **116** is less than the maximum thickness of the lens body **102** in the region of the second portion **114**.

[0156] In certain embodiments, a lens body **202** includes a first portion **222**, a second portion **220** and a third portion **224** on the anterior surface **212**, as illustrated in FIGS. **2**A-B. The first portion **222**, the second portion **220** and the third portion **224** on the anterior surface **212** can have similar features as described above for the first portion **116**, the second portion **114** and the third portion **118** on the anterior surface **112**. The intraocular lens **200** can include a mask **208** that is positioned to block a substantial portion of light that passes through the second portion **220** of the anterior surface **212**.

[0157] In certain embodiments, both an anterior surface **312** and a posterior surface **310** have a first portion **316**, **322**, a second portion **314**, **320** and a third portion **318**, **324**, as illustrated in FIGS. **3**A-B. A mask **308** can be positioned so that a substantial portion of the light that passes through the second portion **320** of the anterior surface **312** and the light that would pass through the second portion **314** of the posterior surface **310** will be blocked by the mask **308**.

[0158] In certain embodiments, the mask is coupled with the second portion, which is concave. For example, the mask can be located adjacent the second portion. In certain embodiments, the mask is attached to the posterior surface, the anterior surface, or the posterior and the anterior surfaces. In certain embodiments, the mask is within the lens body or between the posterior surface and the anterior surface. The radial width or the area of the mask can be about the same as the radial width or the area of the second portion. In certain embodiments, the mask can extend at least partially into the area of the first portion and/or the third portion of the lens body. By extending the mask into the first portion and/or the third portion, the mask can block light that enters at large angles off the optical center axis of the lens body and that may then pass through the second portion.

[0159] Illustrated in FIGS. **4**A-B, an intraocular lens **400** can further include a fourth portion **420***b* and a fifth portion **424***b* on the anterior surface **412** and/or the posterior surface **410**. The fourth portion **420***b* is adjacent the third portion **424***a* and can substantially surround the third portion **424***a*. The fifth portion **424***b* is adjacent the fourth portion **420***b* and can substantially surround the fourth portion **420***b*. The fourth portion **420***b* can have similar features as described above for the second portion **420***a*, and the fifth portion **424***b* can have similar features as described above for the third portion **424***a*. The intraocular lens **400** can include a first mask **408***a* that is positioned to block a substantial portion of light that passes through the second portion **420***a* of the anterior surface **412**, and a second mask **408***b* that is positioned to block a substantial portion of light that passes through the fourth portion **420***b* of the anterior surface **412**. It should be understood that additional pairs of portions with a mask like the fourth portion **420***b*, the fifth portion **424***b* and the second mask **408***b* can be further included in an intraocular lens.

[0160] FIGS. **5**A-B illustrate an intraocular lens **500** similar to the intraocular lens **400** illustrated in FIGS. **4**A-B. Instead of the intraocular lens **400** having a first mask **408***a* and a second mask **408***b*, the intraocular lens **500** has a single mask **508** with a plurality of light transmission holes that allow at least partial light transmission through the mask **508**. The light transmission holes can be configured to allow substantially no light that passes through the second portion **520***a* and the fourth portion **520***b* to pass through the mask **508**, but allow at least some light that passes through the third portion **524***a* to pass through the mask **508**. For example, a middle annular region of the mask can have a plurality of holes to allow at least some light to pass through the mask, and an inner annular region and an outer annular region can have substantially no holes. Light transmission structures or holes are further discussed in sections below and can be applied to embodiments discussed herein.

[0161] The variety of intraocular lenses described herein are designed to suit the vision correction needs of particular patients. For example, for patients with relatively small pupils, dim light may present more of a vision issue than for patients with larger pupils. For smaller pupil patients, a mask with more light transmission and/or a smaller outer diameter will increase the amount of light that reaches the retina and may improve vision in dim light situations. Conversely, for larger pupil patients, less light transmission and/or a larger outer diameter mask may improve low-contrast near vision and block more unfocused light. The masked IOLs described herein give the surgeon flexibility to prescribe the appropriate combination of masked IOL features for particular patients.

[0162] FIGS. **6**-**7** illustrate additional embodiments of intraocular lenses **600**, **700**. The posterior surface and anterior surface of an intraocular lens can have a variety of curvatures. For example, the posterior surface and/or the anterior surface can be concave or convex. FIGS. **6**A-B illustrates an intraocular lens **600** with a concave posterior surface **610** with an anterior surface **612** to create a positive optical power lens. FIGS. **7**A-B illustrate an intraocular lens **700** with a concave posterior surface **710** with an anterior surface **712** to create a negative optical power lens. Both intraocular lenses **600**, **700** have a second portion **620**, **720** to reduce the overall thickness of the intraocular lenses **600**, **700**. Both intraocular lenses **600**, **700** also can include a mask **608**, **708** to block light that passes through the second portion **620**, **720**. For negative power intraocular lenses, such as the intraocular lens **700** of FIG. **7**, the thickness of the central region **732** of the lens body **702** may not be reduced by the second portion **720**. However, the thickness of the outer region **730** of the lens body **702** can

be reduced by the second portion **720** (e.g., transition zone). Advantageously, if an intraocular lens has a positive optical power or a negative optical power, the thickness of at least a portion of the lens body can be reduced by having the lens body include a second portion.

[0163] Tables I and II illustrate examples of intraocular lens with reduced lens body thicknesses. The column labeled "Reduced" corresponds to an intraocular lens with a second portion (e.g. transition zone), and the column labeled "Original" is corresponds to an intraocular lens without a second portion. The optic diameter is the diameter of the outer-most portion of the lens body with an optical power. The reduction percentage of the center region thickness indicated in Tables I and II can be about proportional to the reduction in the possible rolled up diameter of a reduced thickness IOL. Therefore, the reduction percentage of the center region thickness indicated in Tables I and II can also be about proportional to the reduction in the incision size that can be used during implantation of the IOL in a patient. An IOL is rolled up and inserted into a tube, and the tube is inserted into the incision. The IOL can then be deployed into the intraocular space of the eye. The IOL is often rolled up as tight as possible so that open space (e.g., voids) is minimized in a cross-section of the tube at a location where the implant body has the greatest cross-sectional area that is generally parallel with the optical axis of the implant body. Therefore, the cross-sectional area of the tube is greater than or equal to the greatest cross-sectional area of the implant body that is generally parallel with the optical axis of the implant body. For example, a 36% reduction in the cross sectional area of the implant body could reduce the cross sectional area of the tube by 36% or could reduce the diameter of the tube by about 20%. A minimum incision length is generally one-half of the circumference of the tube. Therefore, a 36% reduction in the cross sectional area of the implant body can result in about 20% reduction in incision length. For example, a 1.8 mm incision could be reduced to about 1.44 mm. A smaller incision is beneficial because it avoids post-operative astigmatism.

TABLE I

Examples of reduced thickness IOLs with positive optical power.

Optic	Material		Center region thickness [mm]			Cross section area of center region [mm^2]		
Diameter [mm]	[Ref. index]	Diopter	Original	Reduced	Reduction [%]	Original	Reduced	Reduction [%]
			Biconvex IOL					
5.5	1.4300	18.0	0.94	0.42	55	3.96	2.48	37
5.5	1.4300	24.0	1.20	0.56	53	4.93	3.13	37
5.5	1.4583	18.0	0.77	0.32	58	3.32	2.05	38
5.5	1.4583	24.0	0.96	0.42	56	4.02	2.51	38
6.0	1.4300	18.0	1.08	0.50	54	4.76	3.08	35
6.0	1.4300	24.0	1.40	0.62	56	6.04	3.85	36
6.0	1.4583	18.0	0.87	0.37	57	3.92	2.50	36
6.0	1.4583	24.0	1.10	0.50	55	4.88	3.13	36
			Sulcus-fixated IOL					
5.5	1.4583	5.0	0.34	0.15	56	1.75	1.22	30
5.5	1.4583	10.0	0.52	0.20	62	2.43	1.51	38
6.0	1.4583	5.0	0.37	0.17	54	1.95	1.36	30
6.0	1.4583	10.0	0.59	0.21	64	2.86	1.76	38

TABLE II

Examples of reduced thickness IOLs with negative optical power.

Optic	Material		Outer region thickness [mm]			Cross section area of outer region [mm 2]		
Diameter [mm]	[Ref. index]	Diopter	Original	Reduced	Reduction [%]	Original	Reduced	Reduction [%]
			Sulcus-fixated IOL					
5.5	1.4583	−5.0	0.26	0.17	35	1.09	0.77	29
5.5	1.4583	−10.0	0.41	0.25	39	1.52	0.97	36
6.0	1.4583	−5.0	0.29	0.20	31	1.12	0.77	31
6.0	1.4583	−10.0	0.48	0.32	33	1.57	0.99	37

[0164] FIG. **8** illustrates the operation of the intraocular lens **200** of FIGS. **2**A-B. In use, light enters the anterior surface **212**, passes through the lens body **202** and exits the posterior surface **210** of the intraocular lens **200**. The mask **208** is located such that the mask **208** blocks a substantial portion of the light rays **850** that pass through the second portion **220** of the anterior surface **212**, as illustrated in FIG. **8**. If the mask **208** did not block the light rays **850** that pass through the second portion **220**, aberrations would result. For example, if the curvature of the second portion **220** is configured to provide a negative or divergent optical power, light rays **860** passing through this region would diverge and not focus, as illustrated in FIG. **8**. The light rays **850** that pass through the first portion **222** and/or the third portion **224** would have a positive or convergent optical power. If the first portion **222** and the third portion **224** have a similar curvature or optical power, light rays **450** entering the anterior surface **212** and passing through the first portion **222** and/or the third portion **224** would converge at a common point **870** after passing through the posterior surface **210**, as illustrated in FIG. **8**. FIG. **9**A illustrates an intraocular lens **200** implanted within the capsular bag **954** of an eye **952**. Parallel light rays **950** that pass through the intraocular lens **200** converge on the retina **956**.

[0165] The lens body **202** can include one or more materials. In certain embodiments, the lens body **202** includes two or more materials. For example, the first portion **222** and the third portion **224** can include different materials. If the materials selected for the first portion **222** and the third portion **224** have different refractive indexes, the curvature of the first portion **222** and the third portion **224** can be different to obtain a similar optical power (e.g. dioptric power) for both portions.

[0166] Generally, the optical power of an intraocular lens is selected for focusing on far objects. A natural lens can deform to change the focal distance for far and near viewing. Conventional artificial intraocular lenses are generally unable to change the focal distance. For example, an eye that is presbyopic or where an artificial intraocular lens has an optical power for farther distance, light rays that enter the eye and pass through the cornea and the natural lens or artificial intraocular lens converge at a point behind or in front of the retina and do not converge at a point on the retina. The light rays strike the retina over a larger area than if the light rays converged at a point on the retina. The patient experiences this as blurred vision, particularly for up-close objects such as when reading. For such conditions, the mask **208** of the intraocular lens **200** can be configured with an aperture such that only a subset of light rays, e.g. a central portion, are transmitted to the retina. The mask **208** with an aperture can improve the depth of focus of a human eye. For example, the aperture can be a pin-hole aperture. The mask **208** blocks a portion of the outer light rays resulting in more focused light rays. The mask **208** can include an annular region surrounding an aperture. The aperture can be substantially centrally located on the mask. For example, the aperture can be located around a central axis of the mask, also referred to as the optical axis of the mask. The aperture of the mask can be circular or any other shape.

[0167] The mask **208** can be positioned in a variety of locations in or on the intraocular lens **200**. The mask **208** can be through the lens body **202**. The mask **208** can be positioned on the anterior or posterior surface of the lens body **202**. In certain embodiments, the mask **208** is embedded within the lens body. For example, the mask **208** can be positioned substantially at the midway line between the posterior and anterior surfaces of the lens body **202**. In certain embodiments, the mask **208** is positioned between the midway line and the posterior surface of the lens body **202**. Certain embodiments include the mask **208** being positioned midway, one-third or two-thirds between the midway line and the posterior surface of the lens body **202**. In certain other embodiments, the mask **208** is positioned between the midway line and the anterior surface of the lens body **202**. Certain embodiments include the mask **208** being positioned midway, one-third or two-thirds between the midway line and the anterior surface of the lens body **202**. If the transition zone is on the anterior surface of the implant body and the mask is positioned to be on or near the surface of the transition zone on the anterior surface, the mask may not extend beyond the transition zone since light even at large angles from the optical axis that hits or passes through the transition zone surface would be blocked by the mask.

[0168] In certain embodiments, the mask **208** of an intraocular lens **200** has an aperture wherein the mask blocks a portion of the light to improve viewing near objects, similar to a mask discussed above. Advantageously, the mask **208** can provide as an aperture and can block a portion light that may not converging on the retina **956** and also block light that passes through the second portion **220**, creating aberrations, as described above. In certain embodiments, the aperture of the mask **208** has a diameter of about 1 to 2 mm. In certain embodiments, the mask **208** has an outer perimeter with a diameter of about 3 to 5 mm.

[0169] In certain embodiments, the third portion **224** of intraocular lens **200** can improve low light vision. As the pupil of the eye enlarges, eventually light rays will enter and pass through the third portion **224** of the intraocular lens **200**. As illustrated in FIG. **9**, if the pupil **958** of the eye **952** is large enough so that light rays **950** pass through the third portion **224** of the intraocular lens **200**, additional light rays **950** will strike the retina. As discussed above, the intraocular lens **200** can have an optical power to correct for viewing far objects so that light rays from a far object are focused at one point on the retina. Near objects during low light conditions may result in an unfocused image if the intraocular lens **200** has an optical power to view far objects.

[0170] The mask **208** can have different degrees of opacity. For example, the mask **208** can block substantially all of visible light or may block a portion of visible light. The opacity of the mask **208** may also vary in different regions of the mask **208**. In certain embodiments, the opacity of the outer edge and/or the inner edge of the mask **208** is less than the central region of the mask **208**. The opacity in different regions may transition abruptly or have a gradient transition. Additional examples of opacity transitions can be found in U.S. Pat. Nos. 5,662,706, 5,905,561 and 5,965,330, which are incorporated in their entirety by reference.

[0171] A conventional intraocular lens **1000** is illustrated in FIGS. **10**A-B. By having a recessed portion on the posterior surface **310** (created by second portions **314**) and/or the anterior surface **312** (created by second portion **320**) of the lens body **302**, the maximum thickness of the intraocular lens **300** is reduced compared to a conventional lens body **1002** without such portions, as shown in FIG. **10**B. The cross-sectional thickness of the lens body **1002** is generally dependent on the optical power of the intraocular lens **1000** and the material of the lens body **1002**. In particular, the central region of the lens

body **1002** is generally the thickest section of the intraocular lens **1000** with a central region cross-sectional thickness **1006**. In certain embodiments disclosed herein, a lens body **202** of an intraocular lens **200** has a central region thickness **206** less than the central region thickness **1006** of other common lens bodies. In the embodiment of FIG. **3**B, the thickness **306** is further reduced compared to a conventional intraocular lens **1000**.

[0172] Generally, as discussed above, intraocular lenses are implanted into the eye by rolling up an intraocular lens and inserting the rolled up intraocular lens into a tube. One advantage to a thinner lens body is that it the intraocular lens can be more tightly rolled up resulting in being able to use a small tube and a small incision. Another advantage to a thinner lens body is that the intraocular lens can decrease risks associated with implanting in different locations within the eye. For example, an intraocular lens **200** can be implanted within the anterior chamber. An intraocular lens **200** can also be positioned within the posterior chamber so that the first portion **216** of the posterior surface **210** floats above the natural crystalline lens. The potential for contact between the posterior surface **210** of the intraocular lens **200** and the natural crystalline lens will be reduced because the reduced thickness of the intraocular lens **200**. For example, the intraocular lens **200** can be coupled with or attached to the ciliary sulcus (sometimes referred to herein as "sulcus-fixated"). An intraocular lens **200** can also be implanted in the capsular bag, as illustrated in FIG. **9**. Depending on the location of the intraocular lens within the eye, dimensions of the intraocular lens **200** including but not limited to the aperture of the mask **208** may be adjusted.

[0173] The intraocular lens **200** and/or the lens body **202** can be made from one or more materials. In certain embodiments, the intraocular lens **200** and/or the lens body **202** can comprise polymers (e.g. PMMA, PVDF, polypropylene, polycarbonate, PEEK, polyethylene, acrylic copolymers, polystyrene, PVC, polysulfone), hydrogels, and silicone.

II. Masks Providing Depth of Focus Correction

[0174] A variety of variations of masks that can be positioned on or within the implant body **2014** are discussed herein, and also described in U.S. Pat. No. 7,628,810, U.S. Patent Publication No. 2006/0113054, and U.S. Patent Publication No. 2006/0265058 which are hereby incorporated by reference in their entirety. FIG. **11**A illustrates one embodiment of a mask **2034***a*. The mask **2034***a* can include an annular region **2036***a* surrounding a pinhole opening or aperture **2038***a* substantially centrally located on the mask **2034***a*. The pinhole aperture **2038***a* can be generally located around a central axis **2039***a*, referred to herein as the optical axis of the mask **2034***a*. The pinhole aperture **2038***a* can be in the shape of a circle. FIG. **11**B illustrates another embodiment of a mask **2034***b* similar to the mask **2034***a* illustrated in FIG. **11**A. The annular region **2036***a* of the mask **2034***a* of FIG. **11**A has a curvature from the outer periphery to the inner periphery of the annular region **2036***a*; while the annular region **2036***b* of the mask **2034***b* of FIG. **11**B is substantially flat.

[0175] The mask can have dimensions configured to function with the implant body to improve a patient's vision. For example, the thickness of the mask can vary depending on the location of the mask relative to the implant body. For example, if the mask is embedded within the implant body, the mask can have a thickness greater than zero and less than the thickness of the implant body. Alternatively, if the mask is coupled to a surface of the implant body, the mask may preferably have a thickness no greater than necessary to have desired opacity so that the mask does not add additional thickness to the intraocular lens. In certain embodiments, the mask has a thickness of greater than zero and less than about 0.5 mm. In one embodiment, the mask has a thickness of about 0.25 mm. If the mask is on or near the surface of the transition zone, the mask can have a shape similar or the same as the transition zone.

[0176] The mask may have a constant thickness, as discussed below. However, in some embodiments, the thickness of the mask may vary between the inner periphery (near the aperture **2038**) and the outer periphery. FIG. **12** shows a mask **2034***k* that has a gradually decreasing thickness from the inner periphery to the outer periphery. FIG. **13** shows a mask **20341** that has a gradually increasing thickness from the inner periphery to the outer periphery. Other cross-sectional profiles are also possible.

[0177] The annular region **2036** can be at least partially opaque or can be completely opaque. The degree of opacity of the annular region **2036** prevents at least some or substantially all light from being transmitted through the mask **2032**. Opacity of the annular region **2036** may be achieved in any of several different ways.

[0178] For example, in one embodiment, the material used to make mask **2034** may be naturally opaque. Alternatively, the material used to make the mask **2034** may be substantially clear, but treated with a dye or other pigmentation agent to render region **2036** substantially or completely opaque. In still another example, the surface of the mask **2034** may be treated physically or chemically (such as by etching) to alter the refractive and transmissive properties of the mask **2034** and make it less transmissive to light.

[0179] In still another alternative, the surface of the mask **2034** may be treated with a particulate deposited thereon. For example, the surface of the mask **2034** may be deposited with particulate of titanium, gold or carbon to provide opacity to the surface of the mask **2034**. In another alternative, the particulate may be encapsulated within the interior of the mask **2034**, as generally shown in FIG. **14**. Finally, the mask **2034** may be patterned to provide areas of varying light transmissivity.

[0180] In another embodiment, the mask may be formed from co-extruded rods made of material having different light transmissive properties. The co-extruded rod may then be sliced to provide disks for a plurality of masks, such as those described herein.

[0181] Other embodiments employ different ways of controlling the light transmissivity through a mask. For example, the mask may be a gel-filled disk, as shown in FIG. **14**. The gel may be a hydrogel or collagen, or other suitable material that is biocompatible with the mask material and can be introduced into the interior of the mask. The gel within the mask may include particulate **2066** suspended within the gel. Examples of suitable particulate are gold, titanium, and carbon particulate, which, as discussed above, may alternatively be deposited on the surface of the mask.

[0182] The material of the mask **2034** may be any polymeric material. Where the mask **2034** is applied to the intraocular implant, the material of the mask **2034** should be biocompatible. Where a gel is used, the material is suitable for holding a gel. Examples of suitable materials for the mask **2034** include the preferred polymethylmethacrylate or other

suitable polymers or co-polymers, such as hydrogels, and the like. Of course, as indicated above, for non-gel-filled materials, a preferred material may be a fibrous material, such as a Dacron mesh.

[0183] FIGS. **15** and **16** illustrate one embodiment where a mask **2034***w* comprises a plurality of nanites **2068**. "Nanites" are small particulate structures that have been adapted to selectively transmit or block light entering the eye of the patient. The particles may be of a very small size typical of the particles used in nanotechnology applications. The nanites **2068** are suspended in the gel or otherwise inserted into the interior of the mask **2034***w*, as generally shown in FIGS. **15** and **16**. The nanites **2068** can be preprogrammed to respond to different light environments.

[0184] Thus, as shown in FIG. **15**, in a high light environment, the nanites **2068** turn and position themselves to substantially and selectively block some of the light from entering the eye. However, in a low light environment where it is desirable for more light to enter the eye, nanites may respond by turning or be otherwise positioned to allow more light to enter the eye, as shown in FIG. **16**.

[0185] Nano-devices or nanites are crystalline structures grown in laboratories. The nanites may be treated such that they are receptive to different stimuli such as light. In accordance with one aspect of certain embodiments, the nanites can be imparted with energy where, in response to a low light and high light environments, they rotate in the manner described above and generally shown in FIG. **16**.

[0186] Nanoscale devices and systems and their fabrication are described in Smith et al., "Nanofabrication," Physics Today, February 1990, pp. 24-30 and in Craighead, "Nanoelectromechanical Systems," Science, Nov. 24, 2000, Vol. 290, pp. 1502-1505, both of which are incorporated by reference herein in their entirety. Tailoring the properties of small-sized particles for optical applications is disclosed in Chen et al. "Diffractive Phase Elements Based on Two-Dimensional Artificial Dielectrics," Optics Letters, Jan. 15, 1995, Vol. 20, No. 2, pp. 121-123, also incorporated by reference herein in its entirety.

[0187] In additional embodiments, a photochromic material can be used as the mask or in addition to mask. Under bright light conditions, the photochromic material can darken thereby creating a mask and enhancing near vision. Under dim light conditions, the photochromic lightens, which allows more light to pass through to the retina. In certain embodiments, under dim light conditions, the photochromic lightens to expose an optic of the intraocular implant.

[0188] The mask can have different degrees of opacity. For example, the mask can block substantially all of visible light or may block a portion of visible light. The opacity of the mask may also vary in different regions of the mask. In certain embodiments, the opacity of the outer edge and/or the inner edge of the mask is less than the central region of the mask. The opacity in different regions may transition abruptly or have a gradient transition. Additional examples of opacity transitions can be found in U.S. Pat. Nos. 5,662,706, 5,905,561 and 5,965,330, which are incorporated in their entirety by reference.

[0189] In some embodiments, the mask **2034** is attached or fixed to the eye **2010** by support strands **2072** and **2074** shown in FIG. **17** and generally described in U.S. Pat. No. 4,976,732, incorporated by reference herein in its entirety.

[0190] Further mask details are disclosed in U.S. Pat. No. 4,976,732, issued Dec. 11, 1990 and in U.S. patent application Ser. No. 10/854,033, filed May 26, 2004, both of which are incorporated by reference herein in their entirety.

[0191] An advantage to embodiments that include a mask with an aperture (e.g., pin-hole aperture) described herein over multifocal IOLs, contact lenses, or treatments of the cornea is that all of these latter approaches divide the available light coming through the aperture into two or more foci while a mask approach has a single focus (monofocal). This limitation forces designers of multifocal optics to choose how much of the light is directed to each focal point, and to deal with the effects of the unfocused light that is always present in any image. In order to maximize acuity at the important distances of infinity (>6M) and 40 cm (normal reading distance), it is typical to provide little or no light focused at an intermediate distance, and as a result, visual acuity at these distances is poor.

[0192] With an aperture to increase depth-of-focus, however, the intermediate vision of presbyopic patient is improved significantly. Indeed, the defocus blur with the pinhole aperture is less at intermediate distances than at near. This can be seen in FIG. **59** which is a plot of visual acuity as a function of defocus comparing an embodiment of an ophthalmic device with an aperture and with two commercially available multifocal IOLs. While greater visual acuity is obtained with the multifocal IOLs at very close distances (33 cm, −3D), over the range of 1M (−1D) to 40 cm (−2.5D), the pin-hole aperture can outperform a multifocal optic in an intermediate range.

[0193] Visual acuity is measured in logMAR and is the log of the minimum angle of resolution or the smallest angular spacing that can be seen, and it is independent of viewing distance. A logMAR value of 0 means 20/20, 6/6, or a decimal acuity of 1 at distance, and equivalent to a near acuity of Jaeger 1 (J1). Defocus is measured in diopters, which are the reciprocal of the eye's focal length in meters. Thus, −1D of defocus means the eye is focused at 1/1=1 meter. The standard (US and Europe) reading distance is 40 cm, which is −2.5 D of defocus (1/0.4=2.5).

Iii. UV-Resistant Polymeric Mask Materials

[0194] Because the mask has a very high surface to volume ratio and is exposed to a great deal of sunlight following implantation, the mask preferably comprises a material which has good resistance to degradation, including from exposure to ultraviolet (UV) or other wavelengths of light. Polymers including a UV absorbing component, including those comprising UV absorbing additives or made with UV absorbing monomers (including co-monomers), may be used in forming masks as disclosed herein which are resistant to degradation by UV radiation. Examples of such polymers include, but are not limited to, those described in U.S. Pat. Nos. 4,985,559 and 4,528,311, the disclosures of which are hereby incorporated by reference in their entireties. In a preferred embodiment, the mask comprises a material which itself is resistant to degradation by UV radiation. In one embodiment, the mask comprises a polymeric material which is substantially reflective of or transparent to UV radiation. The lens body may include a UV absorbing component in addition to the mask being resistant to degradation by UV radiation or the mask may not be resistant to degradation by UV radiation since the UV absorbing component in the lens body may prevent degradation of the mask by UV radiation.

[0195] Alternatively, the mask may include a component which imparts a degradation resistive effect, or may be provided with a coating, preferably at least on the anterior sur-

face, which imparts degradation resistance. Such components may be included, for example, by blending one or more degradation resistant polymers with one or more other polymers. Such blends may also comprise additives which provide desirable properties, such as UV absorbing materials. In one embodiment, blends preferably comprise a total of about 1-20 wt. %, including about 1-10 wt. %, 5-15 wt. %, and 10-20 wt. % of one or more degradation resistant polymers. In another embodiment, blends preferably comprise a total of about 80-100 wt. %, including about 80-90 wt. %, 85-95 wt. %, and 90-100 wt. % of one or more degradation resistant polymers. In another embodiment, the blend has more equivalent proportions of materials, comprising a total of about 40-60 wt. %, including about 50-60 wt. %, and 40-50 wt. % of one or more degradation resistant polymers. Masks may also include blends of different types of degradation resistant polymers, including those blends comprising one or more generally UV transparent or reflective polymers with one or more polymers incorporating UV absorption additives or monomers. These blends include those having a total of about 1-20 wt. %, including about 1-10 wt. %, 5-15 wt. %, and 10-20 wt. % of one or more generally UV transparent polymers, a total of about 80-100 wt. %, including about 80-90 wt. %, 85-95 wt. %, and 90-100 wt. % of one or more generally UV transparent polymers, and a total of about 40-60 wt. %, including about 50-60 wt. %, and 40-50 wt. % of one or more generally UV transparent polymers. The polymer or polymer blend may be mixed with other materials as discussed below, including, but not limited to, opacification agents, polyanionic compounds and/or wound healing modulator compounds. When mixed with these other materials, the amount of polymer or polymer blend in the material which makes up the mask is preferably about 50%-99% by weight, including about 60%-90% by weight, about 65-85% by weight, about 70-80% by weight, and about 90-99% by weight.

[0196] Preferred degradation resistant polymers include halogenated polymers. Preferred halogenated polymers include fluorinated polymers, that is, polymers having at least one carbon-fluorine bond, including highly fluorinated polymers. The term "highly fluorinated" as it is used herein, is a broad term used in its ordinary sense, and includes polymers having at least one carbon-fluorine bond (C—F bond) where the number of C—F bonds equals or exceeds the number of carbon-hydrogen bonds (C—H bonds). Highly fluorinated materials also include perfluorinated or fully fluorinated materials, materials which include other halogen substituents such as chlorine, and materials which include oxygen- or nitrogen-containing functional groups. For polymeric materials, the number of bonds may be counted by referring to the monomer(s) or repeating units which form the polymer, and in the case of a copolymer, by the relative amounts of each monomer (on a molar basis).

[0197] Preferred highly fluorinated polymers include, but are not limited to, polytetrafluoroethylene (PFTE or Teflon®), polyvinylidene fluoride (PVDF or Kynar®), poly-1,1,2-trifluoroethylene, and perfluoroalkoxyethylene (PFA). Other highly fluorinated polymers include, but are not limited to, homopolymers and copolymers including one or more of the following monomer units: tetrafluoroethylene —(CF2-CF2)-; vinylidene fluoride —(CF2-CH2)-; 1,1,2-trifluoroethylene —(CF2-CHF)-; hexafluoropropene —(CF(CF3)-CF2)-; vinyl fluoride —(CH2-CHF)— (homopolymer is not "highly fluorinated"); oxygen-containing monomers such as —(O-CF2)-, —(O-CF2-CF2)-, —(O—CF(CF3)-CF2)-; chlorine-containing monomers such as —(CF2-CFCl)—. Other fluorinated polymers, such as fluorinated polyimide and fluorinated acrylates, having sufficient degrees of fluorination are also contemplated as highly fluorinated polymers for use in masks according to preferred embodiments. The homopolymers and copolymers described herein are available commercially and/or methods for their preparation from commercially available materials are widely published and known to those in the polymer arts.

[0198] Although highly fluorinated polymers are preferred, polymers having one or more carbon-fluorine bonds but not falling within the definition of "highly fluorinated" polymers as discussed above, may also be used. Such polymers include co-polymers formed from one or more of the monomers in the preceding paragraph with ethylene, vinyl fluoride or other monomer to form a polymeric material having a greater number of C—H bonds than C—F bonds. Other fluorinated polymers, such as fluorinated polyimide, may also be used. Other materials that could be used in some applications, alone or in combination with a fluorinated or a highly fluorinated polymer, are described in U.S. Pat. No. 4,985,559 and in U.S. Pat. No. 4,528,311, both of which are hereby incorporated by reference herein in their entirety.

[0199] The preceding definition of highly fluorinated is best illustrated by means of a few examples. One preferred UV-resistant polymeric material is polyvinylidene fluoride (PVDF), having a structure represented by the formula: —(CF2-CH2)n-. Each repeating unit has two C—H bonds, and two C—F bonds. Because the number of C—F bonds equals or exceeds the number of C—H bonds, PVDF homopolymer is a "highly fluorinated" polymer. Another material is a tetrafluoroethylene/vinyl fluoride copolymer formed from these two monomers in a 2:1 molar ratio. Regardless of whether the copolymer formed is block, random or any other arrangement, from the 2:1 tetrafluoroethylene:vinyl fluoride composition one can presume a "repeating unit" comprising two tetrafluoroethylene units, each having four C—F bonds, and one vinyl fluoride unit having three C—H bonds and one C—F bond. The total bonds for two tetrafluoroethylenes and one vinyl fluoride are nine C—F bonds, and three C—H bonds. Because the number of C—F bonds equals or exceeds the number of C—H bonds, this copolymer is considered highly fluorinated.

[0200] Certain highly fluorinated polymers, such as PVDF, have one or more desirable characteristics, such as being relatively chemically inert and having a relatively high UV transparency as compared to their non-fluorinated or less highly fluorinated counterpart polymers. Although the applicant does not intend to be bound by theory, it is postulated that the electronegativity of fluorine may be responsible for many of the desirable properties of the materials having relatively large numbers of C—F bonds.

[0201] In preferred embodiments, at least a portion of the highly fluorinated polymer material forming the mask comprises an opacification agent which imparts a desired degree of opacity. In one embodiment, the opacification agent provides sufficient opacity to produce the depth of field improvements described herein, e.g., in combination with a transmissive aperture. In one embodiment, the opacification agent renders the material opaque. In another embodiment, the opacification agent prevents transmission of about 90 percent or more of incident light. In another embodiment, the opacification agent renders the material opaque. In another embodiment, the opacification agent prevents transmission of

about 80 percent or more of incident light. Preferred opacification agents include, but are not limited to organic dyes and/or pigments, preferably black ones, such as azo dyes, hematoxylin black, and Sudan black; inorganic dyes and/or pigments, including metal oxides such as iron oxide black and ilminite, silicon carbide and carbon (e.g. carbon black, submicron powdered carbon). The foregoing materials may be used alone or in combination with one or more other materials. The opacification agent may be applied to one or more surfaces of the mask on all or some of the surface, or it may be mixed or combined with the polymeric material (e.g. blended during the polymer melt phase). Although any of the foregoing materials may be used, carbon has been found to be especially useful in that it does not fade over time as do many organic dyes, and that it also aids the UV stability of the material by absorbing UV radiation. In one embodiment, carbon may be mixed with polyvinylidene fluoride (PVDF) or other polymer composition comprising highly fluorinated polymer such that the carbon comprises about 2% to about 20% by weight of the resulting composition, including about 10% to about 15% by weight, including about 12%, about 13%, and about 14% by weight of the resulting composition.

[0202] Some opacification agents, such as pigments, which are added to blacken, darken or opacify portions of the mask may cause the mask to absorb incident radiation to a greater degree than mask material not including such agents. Because the matrix polymer that carries or includes the pigments may be subject to degradation from the absorbed radiation, it is preferred that the mask, which is thin and has a high surface area making it vulnerable to environmental degradation, be made of a material which is itself resistant to degradation such as from UV radiation, or that it be generally transparent to or non-absorbing of UV radiation. Use of a highly UV resistant and degradation resistant material, such as PVDF, which is highly transparent to UV radiation, allows for greater flexibility in choice of opacification agent because possible damage to the polymer caused by selection of a particular opacification agent is greatly reduced.

[0203] A number of variations of the foregoing embodiments of degradation resistant constructions are contemplated. In one variation, a mask is made almost exclusively of a material that is not subject to UV degradation. For example, the mask can be made of a metal, a highly fluorinated polymer, carbon (e.g., graphene, pure carbon), or another similar material. Construction of the mask with metal is discussed in more detail in U.S. application Ser. No. 11/000,562 filed Dec. 1, 2004 and entitled "Method of Making an Ocular Implant" and also in U.S. application Ser. No. 11/107,359 filed Apr. 14, 2005 with the title "Method of Making an Ocular Implant", both of which are incorporated herein in their entirety by reference. As used in this context, "exclusively" is a broad term that allows for the presence of some non-functional materials (e.g., impurities) and for an opacification agent, as discussed above. In other embodiments, the mask can include a combination of materials. For example, in one variation, the mask is formed primarily of any implantable material and is coated with a UV resistant material. In another variation, the mask includes one or more UV degradation inhibitors and/or one or more UV degradation resistant polymers in sufficient concentration such that the mask under normal use conditions will maintain sufficient functionality in terms of degradation to remain medically effective for at least about 5 years, preferably at least about 10 years, and in certain implementations at least about 20 years.

[0204] FIG. **23** is a flow chart illustrating methods for making a masked intraocular implant from a mask comprising a highly fluorinated polymer and an opacification agent. The method of FIG. **23** includes a first method **3014** of making a mask of highly fluorinated polymer and opacification agent and a second method **3026** of making an intraocular implant with the mask made from the first method **3014**.

[0205] At step **3000**, a liquid form of a polymer is created by dissolving polyvinylidene fluoride (PVDF) pellets into a solvent such as dimethyl acetamide (DMAC or DMA) using heat until the PVDF has completely dissolved. In one embodiment, the solution may be mixed for a minimum of 12 hours to ensure that the PVDF has completely dissolved. At step **3200**, the PVDF/DMAC solution is mixed with an opacification agent, such as a dye or carbon black, using a high speed shear mixer. In one embodiment, the carbon black comprises 13% by weight of the resulting composition while the PVDF comprises 87% by weight of the resulting composition. At step **3300**, the PVDF/carbon black solution is optionally milled in a high speed mill, for example an Eiger high speed mill, to break up any large carbon agglomerates in the solution. The PVDF/carbon black solution may be run through the mill a second time to further break up any carbon agglomerates. At step **3400**, the resulting solution is applied to a silicon wafer to create a polymer film on the silicon disk. Here, approximately 55 g of the PVDF/carbon black solution is poured into a dispensing barrel for application on a silicon wafer. The silicon disk is placed on the spinner of a spin casting machine and the dispensing barrel is used to apply a bead of PVDF/carbon black solution to the silicon wafer in a circular pattern, leaving the center 1" diameter of the disk empty. The spinner cycle is actuated to disperse the PVDF/carbon black solution over the disk, forming a uniform 10 micron thick film. A polymer film may also be deposited, spray coated, etc. to a silicon wafer. The coated silicon disk is then placed on a hot-plate to evaporate the DMAC. At step **3500**, the coated silicon wafer is placed under an excimer laser. A laser cutting mask is mounted in the laser and the laser is actuated. Using the laser cutting mask, approximately 150 mask patterns are laser machined into the PVDF/carbon black film. The mask patterns may also be formed using a punch technique, electron beam, etch, etc. The mask patterns are arranged such that the material extending approximately 5 mm from the edge of the silicon disk is not used. During the laser machining, the silicon disk may be bathed in nitrogen gas in order to cool the surface. At step **3600**, the laser machined masks are removed from the silicon disk using a razor blade. An optional step may include placing the laser-machined mask into a forming mold. The mold can be any shape desired, such as a flat mold, a convex mold, a concave mold, or a mold with a more complex shape. The mask may be placed in the bottom half of the forming mold in one technique. The top half of the forming mold can be placed on top of the mask and the molds can be placed in an oven at about 160° C. The molds are then heated and baked to form the masks. The molds are allowed to bake for approximately two hours at approximately 160° C. After two hours the oven temperature is reduced to about 30° C. and the masks are baked for approximately two hours or until the oven temperature has dropped to below around 40° C.

[0206] At step **3016**, the inlay (e.g. mask) made in the first method **3014** is placed in a mold form. In one embodiment, silicone or other lens material is injected into the mold form and around the inlay. At step **3018**, the silicone is cured to

form an implant body. At step **3020**, the intraocular implant is polished, and at step **3022**, the implant body is extracted from the mold form. At step **3024**, one or more haptics may be attached (e.g. bonded) to the implant body to form an intraocular implant. Step **3024** may be included for a three piece IOL design, but may not be needed for other designs. In certain embodiments, the one or more haptics are formed with the implant body during the injection process. For example, the implant body may be lathed and the haptics milled from a single piece. The intraocular implant can be subsequently inspected (e.g. cosmetic, diopter, resolution).

IV. Masks Configured to Reduce Visible Diffraction Patterns

[0207] Many of the foregoing masks can be used to improve the depth of focus of a patient. Various additional mask embodiments are discussed below. Some of the embodiments described below include light transmission holes through the mask annular region to change the amount of light blocked by the annular region. Light transmission holes through the mask can improve a patient's dim or low light vision. In certain arrangements of light transmission holes, the light transmission holes may generate diffraction patterns that interfere with the vision improving effect of the masks described herein. Accordingly, certain masks are described herein that include light transmission holes that do not generate diffraction patterns or otherwise interfere with the vision enhancing effects of the mask embodiments.

[0208] FIGS. **18-19** show one embodiment of a mask **2100** configured to increase depth of focus of an eye of a patient with presbyopia. The mask **2100** is similar to the masks hereinbefore described, except as described differently below. The mask **2100** can be made of the materials discussed herein, including those discussed above. Also, the mask **2100** can be formed by any suitable process. The mask **2100** is configured to be applied to an IOL.

[0209] In one embodiment, the mask **2100** includes a body **2104** that has an anterior surface **2108** and a posterior surface **2112**. The body **2104** may be formed of any suitable material, including at least one of an open cell foam material, an expanded solid material, and a substantially opaque material. In one embodiment, the material used to form the body **2104** has relatively high water content. In other embodiments, the materials that can be used to form the body **2104** include polymers (e.g. PMMA, PVDF, polypropylene, polycarbonate, PEEK, polyethylene, acrylic copolymers (e.g., hydrophobic or hydrophilic), polystyrene, PVC, polysulfone), hydrogels, silicone, metals, metal alloys, or carbon (e.g., graphene, pure carbon).

[0210] In one embodiment, the mask **2100** includes a light transmission hole arrangement **2116**. The light transmission hole arrangement **2116** may comprise a plurality of holes **2120**. The holes **2120** are shown on only a portion of the mask **2100**, but the holes **2120** preferably are located throughout the body **2104** in one embodiment. In one embodiment, the holes **2120** are arranged in a hex pattern, which is illustrated by a plurality of locations **2120'** in FIG. **20**A. As discussed below, a plurality of locations may be defined and later used in the later formation of a plurality of holes **2120** on the mask **2100**. The mask **2100** has an outer periphery **2124** that defines an outer edge of the body **2104**. In some embodiments, the mask **2100** includes an aperture **2128** at least partially surrounded by the outer periphery **2124** and a non-transmissive portion **2132** located between the outer periphery **2124** and the aperture **2128**.

[0211] Preferably the mask **2100** is symmetrical, e.g., symmetrical about a mask axis **2136**. In one embodiment, the outer periphery **2124** of the mask **2100** is circular. The mask in general has a diameter within the range of from about 3 mm to about 8 mm, often within the range of from about 3.5 mm to about 6 mm, and less than about 6 mm in one embodiment. In another embodiment, the mask is circular and has a diameter in the range of 4 to 6 mm. In another embodiment, the mask **2100** is circular and has a diameter of less than 4 mm. The outer periphery **2124** has a diameter of about 3.8 mm in another embodiment. In some embodiments, masks that are asymmetrical or that are not symmetrical about a mask axis provide benefits, such as enabling a mask to be located or maintained in a selected position with respect to the anatomy of the eye.

[0212] The body **2104** of the mask **2100** may be configured to be coupled with a particular intraocular lens design, either of reduced thickness design or of conventional design. For example, where the mask **2100** is to be coupled with a particular IOL that has curvature, the body **2104** may be provided with a corresponding amount of curvature along the mask axis **2136** that corresponds to the curvature. Likewise, the body **2104** may be provided with corresponding shape to accommodate IOL transition zones.

[0213] In some embodiments, the mask **2100** has a desired amount of optical power. Optical power may be provided by configuring the at least one of the anterior and posterior surfaces **2108**, **2112** with curvature. In one embodiment, the anterior and posterior surfaces **2108**, **2112** are provided with different amounts of curvature. In this embodiment, the mask **2100** has varying thickness from the outer periphery **2124** to the aperture **2128**.

[0214] In one embodiment, one of the anterior surface **2108** and the posterior surface **2112** of the body **2104** is substantially planar. In one planar embodiment, very little or no uniform curvature can be measured across the planar surface. In another embodiment, both of the anterior and posterior surfaces **2108**, **2112** are substantially planar. In general, the thickness of the body **2104** of the mask **2100** may be within the range of from greater than zero to about 0.5 mm. In another embodiment, the thickness **2138** of the mask **2100** is about 0.25 mm. [0201] A substantially planar mask has several advantages over a non-planar mask. For example, a substantially planar mask can be fabricated more easily than one that has to be formed to a particular curvature. In particular, the process steps involved in inducing curvature in the mask **2100** can be eliminated.

[0215] The aperture **2128** is configured to transmit substantially all incident light along the mask axis **2136**. The non-transmissive portion **2132** surrounds at least a portion of the aperture **2128** and substantially prevents transmission of incident light thereon. As discussed in connection with the above masks, the aperture **2128** may be a through-hole in the body **2104** or a substantially light transmissive (e.g., transparent) portion thereof. The aperture **2128** of the mask **2100** generally is defined within the outer periphery **2124** of the mask **2100**. The aperture **2128** may take any of suitable configurations, such as those described above.

[0216] In one embodiment, the aperture **2128** is substantially circular and is substantially centered in the mask **2100**. The size of the aperture **2128** may be any size that is effective to increase the depth of focus of an eye of a patient suffering from presbyopia. In particular, the size of the aperture **2128** is dependent on the location of the mask within the eye (e.g.,

distance from the retina). For example, in the intraocular space of the eye, the aperture **2128** can be circular, having a diameter of less than about 2 mm in one embodiment. In another embodiment, the diameter of the aperture is between about 1.1 mm and about 1.6 mm. In another embodiment, the aperture **2128** is circular and has a diameter of about 1.6 mm or less. In a further embodiment, the diameter of the aperture is about mm. Most apertures will have a diameter within the range of from about 0.85 mm to about 2.2 mm, and often within the range of from about 1.1 mm to about 1.7 mm.

[0217] In certain embodiments, the aperture **2128** includes an optical power and/or refractive properties. For example, the aperture **2128** can include an optic and can have an optical power (e.g. positive or negative optical power). In certain embodiments, the aperture **2128** can correct for refractive errors of an eye.

[0218] The non-transmissive portion **2132** is configured to prevent transmission of radiant energy through the mask **2100**. For example, in one embodiment, the non-transmissive portion **2132** prevents transmission of substantially all of at least a portion of the spectrum of the incident radiant energy. In one embodiment, the non-transmissive portion **2132** is configured to prevent transmission of substantially all visible light, e.g., radiant energy in the electromagnetic spectrum that is visible to the human eye. The non-transmissive portion **2132** may substantially prevent transmission of radiant energy outside the range visible to humans in some embodiments.

[0219] As discussed above, preventing transmission of light through the non-transmissive portion **2132** decreases the amount of light that reaches the retina and the fovea that would not converge at the retina and fovea to form a sharp image. As discussed above, the size of the aperture **2128** is such that the light transmitted therethrough generally converges at the retina or fovea. Accordingly, a much sharper image is presented to the eye than would otherwise be the case without the mask **2100**.

[0220] In one embodiment, the non-transmissive portion **2132** prevents transmission of at least about 90 percent of incident light. In another embodiment, the non-transmissive portion **2132** prevents transmission of at least about 95 percent of all incident light. The non-transmissive portion **2132** of the mask **2100** may be configured to be substantially opaque to prevent the transmission of light. As used herein the term "opaque" is intended to indicate a transmission of no more than about 2% of incident visible light. In one embodiment, at least a portion of the body **2104** is configured to be opaque to more than 99 percent of the light incident thereon.

[0221] As discussed above, the non-transmissive portion **2132** may be configured to prevent transmission of light without absorbing the incident light. For example, the mask **2100** could be made reflective or could be made to interact with the light in a more complex manner, as discussed in U.S. Pat. No. 6,554,424, issued Apr. 29, 2003, which is hereby incorporated by reference herein in its entirety.

[0222] As discussed above, the mask **2100** also has light transmission holes that in some embodiments comprises the plurality of holes **2120**. The presence of the plurality of holes **2120** (or other light transmission structures) may affect the transmission of light through the non-transmissive portion **2132** by potentially allowing more light to pass through the mask **2100**. In one embodiment, the non-transmissive portion **2132** is configured to absorb about 98 percent or more of the incident light from passing through the mask **2100** without holes **2120** being present. The presence of the plurality of holes **2120** allows more light to pass through the non-transmissive portion **2132** such that only about 95 percent of the light incident on the non-transmissive portion **2132** is prevented from passing through the non-transmissive portion **2132**. The holes **2120** may reduce the benefit of the aperture **2128** on the depth of focus of the eye by allowing more light to pass through the non-transmissive portion to the retina.

[0223] As discussed above, the holes **2120** of the mask **2100** shown in FIG. **18**A may be located anywhere on the mask **2100**. Other mask embodiments described herein below locate substantially all of the light transmission holes are in one or more regions of a mask.

[0224] The holes **2120** of FIG. **18**A extend at least partially between the anterior surface **2108** and the posterior surface **2112** of the mask **2100**. In one embodiment, each of the holes **2120** includes a hole entrance **2160** and a hole exit **2164**. The hole entrance **2160** is located adjacent to the anterior surface **2108** of the mask **2100**. The hole exit **2164** is located adjacent to the posterior surface **2112** of the mask **2100**. In one embodiment, each of the holes **2120** extends the entire distance between the anterior surface **2108** and the posterior surface **2112** of the mask **2100**.

[0225] In one embodiment, the holes **2120** have a diameter in the range of about 0.002 mm to about 0.050 mm. In certain embodiments, the holes **2120** have a diameter of about 0.005 mm or more. In another embodiment, the holes have a diameter of about 0.020 mm. In another embodiment, the holes have a diameter of about 0.025 mm. In another embodiment, the holes have a diameter of about 0.027 mm. In another embodiment, the holes **2120** have a diameter in the range of about 0.020 mm to about 0.029 mm. In one embodiment, the number of holes in the plurality of holes **2120** is selected such that the sum of the surface areas of the hole entrances **2140** of all the holes **2100** comprises about 5 percent or more of surface area of the anterior surface **2108** of the mask **2100**. In another embodiment, the number of holes **2120** is selected such that the sum of the surface areas of the hole exits **2164** of all the holes **2120** comprises about 5 percent or more of surface area of the posterior surface **2112** of the mask **2100**. In another embodiment, the number of holes **2120** is selected such that the sum of the surface areas of the hole exits **2164** of all the holes **2120** comprises about 5 percent or more of surface area of the posterior surface **2112** of the mask **2112** and the sum of the surface areas of the hole entrances **2140** of all the holes **2120** comprises about 5 percent or more of surface area of the anterior surface **2108** of the mask **2100**. In another embodiment, the plurality of holes **2120** may comprise about 1600 microperforations. In another embodiment, the plurality of holes **2120** comprises about 8400 microperforations.

[0226] Each of the holes **2120** may have a relatively constant cross-sectional area. In one embodiment, the cross-sectional shape of each of the holes **2120** is substantially circular. Each of the holes **2120** may comprise a cylinder extending between the anterior surface **2108** and the posterior surface **2112**.

[0227] The relative position of the holes **2120** is of interest in some embodiments. As discussed above, the holes **2120** of the mask **2100** are hex-packed, e.g., arranged in a hex pattern. In particular, in this embodiment, each of the holes **2120** is separated from the adjacent holes **2120** by a substantially constant distance, sometimes referred to herein as a hole pitch. In one embodiment, the hole pitch is about 0.045 mm.

[0228] In a hex pattern, the angles between lines of symmetry are approximately 43 degrees. The spacing between any two neighboring holes is generally within the range of from about 30 microns to about 100 microns, and, in one embodiment, is approximately 43 microns. The hole diameter is generally within the range of from about 2 microns to about 100 microns, and in one embodiment, is approximately 20 microns. The light transmission is a function of the sum of hole areas as will be understood by those of skill in the art in view of the disclosure herein.

[0229] Negative visual effects may arise due to the presence of the light transmission hole arrangement **2116**. For example, in some cases, a hex packed arrangement of the holes **2120** can generate diffraction patterns visible to the patient. For example, patients might observe a plurality of spots, e.g., six spots, surrounding a central light with holes **2120** having a hex patterned.

[0230] A variety of techniques are possible that produce advantageous arrangements of light transmission holes such that diffraction patterns and other deleterious visual effects do not substantially inhibit other visual benefits of a mask. In one embodiment, where diffraction effects would be observable, the light transmission holes are arranged to spread the diffracted light out uniformly across the image to eliminate observable spots. In another embodiment, the light transmission holes employ a pattern that substantially eliminates diffraction patterns or pushes the patterns to the periphery of the image.

[0231] FIGS. **20**B-**20**C show two embodiments of patterns of holes **2220'** that may be applied to a mask that is otherwise substantially similar to the mask **2100**. The holes **2220'** of the hole patterns of FIGS. **20**B-**20**C are spaced from each other by a random hole spacing or hole pitch. In other embodiments discussed below, holes are spaced from each other by a non-uniform amount, not a random amount. In one embodiment, the holes **2220'** have a substantially uniform shape (cylindrical shafts having a substantially constant cross-sectional area). FIG. **20**C illustrates a plurality of holes **2220'** separated by a random spacing, wherein the density of the holes is greater than that of FIG. **20**B. Generally, the higher the percentage of the mask body that has holes the more the mask will allow light to transmit through the mask. One way to provide a higher percentage of hole area is to increase the density of the holes. Increased hole density can also permit smaller holes to achieve the same light transmission as is achieved by less dense, larger holes.

[0232] FIG. **21**A shows a portion of another mask **2200***a* that is substantially similar to the mask **2100**, except described differently below. The mask **2200***a* can be made of the materials discussed herein, including those discussed above. The mask **2200***a* can be formed by any suitable process, such as those discussed herein and with variations of such processes. The mask **2200***a* has a light transmission hole arrangement **2216***a* that includes a plurality of holes **2220***a*. A substantial number of the holes **2220***a* have a non-uniform size. The holes **2220***a* may be uniform in cross-sectional shape. The cross-sectional shape of the holes **2220***a* is substantially circular in one embodiment. The holes **2220***a* may be circular in shape and have the same diameter from a hole entrance to a hole exit, but are otherwise non-uniform in at least one aspect, e.g., in size. It may be preferable to vary the size of a substantial number of the holes by a random amount. In another embodiment, the holes **2220***a* are non-uniform (e.g., random) in size and are separated by a non-uniform (e.g., a random) spacing.

[0233] FIG. **21**B illustrates another embodiment of a mask **2200***b* that is substantially similar to the mask **2100**, except as described differently below. The mask **2200***b* can be made of the materials discussed herein. Also, the mask **2200***b* can be formed by any suitable process, such as those discussed herein and with variations of such processes. The mask **2200***b* includes a body **2204***b*. The mask **2200***b* has a light transmission hole arrangement **2216***b* that includes a plurality of holes **2220***b* with a non-uniform facet orientation. In particular, each of the holes **2220***b* has a hole entrance that may be located at an anterior surface of the mask **2200***b*. A facet of the hole entrance is defined by a portion of the body **2204***b* of the mask **2200***b* surrounding the hole entrance. The facet is the shape of the hole entrance at the anterior surface. In one embodiment, most or all the facets have an elongate shape, e.g., an oblong shape, with a long axis and a short axis that is perpendicular to the long axis. The facets may be substantially uniform in shape. In one embodiment, the orientation of facets is not uniform. For example, a substantial number of the facets may have a non-uniform orientation. In one arrangement, a substantial number of the facets have a random orientation. In some embodiments, the facets are non-uniform (e.g., random) in shape and are non-uniform (e.g., random) in orientation.

[0234] Other embodiments may be provided that vary at least one aspect, including one or more of the foregoing aspects, of a plurality of holes to reduce the tendency of the holes to produce visible diffraction patterns or patterns that otherwise reduce the vision improvement that may be provided by a mask with an aperture, such as any of those described above. For example, in one embodiment, the hole size, shape, and orientation of at least a substantial number of the holes may be varied randomly or may be otherwise non-uniform. The mask may also be characterized in that at least one of the hole size, shape, orientation, and spacing of a plurality of holes is varied to reduce the tendency of the holes to produce visible diffraction patterns. In certain embodiments, the tendency of the holes to produce visible diffraction patterns is reduced by having a plurality of the holes having a first hole size, shape, or spacing and at least another plurality of the holes with a second hole size, shape, or spacing different from the first hole size, shape, or spacing. In other embodiments, the mask is characterized in that at least one of the hole size, shape, orientation, and spacing of a substantial number of the plurality of holes is different than at least one of the hole size, shape, orientation, and spacing of at least another substantial number of the plurality of holes to reduce the tendency of the holes to produce visible diffraction patterns. In further embodiments, the holes are positioned at irregular locations. For example, the holes are positioned at irregular locations to minimize the generation of visible artifacts due to the transmission of light through the holes.

[0235] FIG. **22** shows another embodiment of a mask **2300** that is substantially similar to any of the masks hereinbefore described, except as described differently below. The mask **2300** can be made of the materials discussed herein. Also, the mask **2300** can be formed by any suitable process, such as those discussed herein and with variations of such processes. The mask **2300** includes a body **2304**. The body **2304** has an outer peripheral region **2305**, an inner peripheral region **2306**, and a hole region **2307**. The hole region **2307** is located

between the outer peripheral region **2305** and the inner peripheral region **2306**. The body **2304** may also include an aperture region **2328**, where the aperture (discussed below) is not a through hole. The mask **2300** also includes a light transmission hole arrangement **2316**. In one embodiment, the light transmission hole arrangement includes a plurality of holes. At least a substantial portion of the holes (e.g., all of the holes) are located in the hole region **2307**. As above, only a portion of the light transmission hole arrangement **2316** is shown for simplicity. But it should be understood that the hole arrangement may be located throughout the hole region **2307**.

[0236] The outer peripheral region **2305** may extend from an outer periphery **2324** of the mask **2300** to a selected outer circumference **2325** of the mask **2300**. The selected outer circumference **2325** of the mask **2300** is located a selected radial distance from the outer periphery **2324** of the mask **2300**. In one embodiment, the selected outer circumference **2325** of the mask **2300** is located about 0.05 mm from the outer periphery **2324** of the mask **2300**.

[0237] The inner peripheral region **2306** may extend from an inner location, e.g., an inner periphery **2326** adjacent an aperture **2328** of the mask **2300** to a selected inner circumference **2327** of the mask **2300**. The selected inner circumference **2327** of the mask **2300** is located a selected radial distance from the inner periphery **2326** of the mask **2300**. In one embodiment, the selected inner circumference **2327** of the mask **2300** is located about 0.05 mm from the inner periphery **2326**.

[0238] The mask **2300** may be the product of a process that involves random selection of a plurality of locations and formation of holes on the mask **2300** corresponding to the locations. As discussed further below, the method can also involve determining whether the selected locations satisfy one or more criteria. For example, one criterion prohibits all, at least a majority, or at least a substantial portion of the holes from being formed at locations that correspond to the inner or outer peripheral regions **2305**, **2306**. Another criterion prohibits all, at least a majority, or at least a substantial portion of the holes from being formed too close to each other. For example, such a criterion could be used to assure that a wall thickness, e.g., the shortest distance between adjacent holes, is not less than a predetermined amount. In one embodiment, the wall thickness is prevented from being less than about 20 microns.

[0239] In a variation of the embodiment of FIG. **22**, the outer peripheral region **2305** is eliminated and the hole region **2307** extends from the inner peripheral region **2306** to an outer periphery **2324**. In another variation of the embodiment of FIG. **50**, the inner peripheral region **2306** is eliminated and the hole region **2307** extends from the outer peripheral region **2305** to an inner periphery **2326**.

[0240] In any of the foregoing mask embodiments, the body of the mask may be formed of a material selected to substantially prevent negative optic effects, such as diffraction, as discussed above. In various embodiments, the masks are formed of an open cell foam material, silicone, thermoset and thermoeleastic polymers such as PVDF, PMMA, metal, Teflon, or carbon. In another embodiment, the masks are formed of an expanded solid material.

[0241] As discussed above in connection with FIGS. **20**B and **20**C, various random patterns of holes may advantageously be provided. In some embodiments, it may be sufficient to provide regular patterns that are non-uniform in some aspect. Non-uniform aspects to the holes may be provided by any suitable technique.

[0242] In a first step of one technique, a plurality of locations **2220'** is generated. The locations **2220'** are a series of coordinates that may comprise a non-uniform pattern or a regular pattern. The locations **2220'** may be randomly generated or may be related by a mathematical relationship (e.g., separated by a fixed spacing or by an amount that can be mathematically defined). In one embodiment, the locations are selected to be separated by a constant pitch or spacing and may be hex packed.

[0243] In a second step, a subset of the locations among the plurality of locations **2220'** is modified to maintain a performance characteristic of the mask. The performance characteristic may be any performance characteristic of the mask. For example, the performance characteristic may relate to the structural integrity of the mask. Where the plurality of locations **2220'** is selected at random, the process of modifying the subset of locations may make the resulting pattern of holes in the mask a "pseudo-random" pattern.

[0244] Where a hex packed pattern of locations (such as the locations **2120'** of FIG. **20**A) is selected in the first step, the subset of locations may be moved with respect to their initial positions as selected in the first step. In one embodiment, each of the locations in the subset of locations is moved by an amount equal to a fraction of the hole spacing. For example, each of the locations in the subset of locations may be moved by an amount equal to one-quarter of the hole spacing. Where the subset of locations is moved by a constant amount, the locations that are moved preferably are randomly or pseudo-randomly selected. In another embodiment, the subset of location is moved by a random or a pseudo-random amount.

[0245] In certain embodiments, an outer peripheral region is defined that extends between the outer periphery of the mask and a selected radial distance of about 0.05 mm from the outer periphery. In another embodiment, an inner peripheral region is defined that extends between an aperture of the mask and a selected radial distance of about 0.05 mm from the aperture. In another embodiment, an outer peripheral region is defined that extends between the outer periphery of the mask and a selected radial distance and an inner peripheral region is defined that extends between the aperture of the mask and a selected radial distance from the aperture. In one technique, the subset of location is modified by excluding those locations that would correspond to holes formed in the inner peripheral region or the outer peripheral region. By excluding locations in at least one of the outer peripheral region and the inner peripheral region, the strength of the mask in these regions is increased. Several benefits are provided by stronger inner and outer peripheral regions. For example, the mask may be easier to handle during manufacturing or when being rolled without causing damage to the mask. In other embodiments, the mask does not include an outer peripheral region and/or inner peripheral region that do not have holes (e.g., holes may extend to the inner periphery and/or the outer periphery).

[0246] In another embodiment, the subset of locations is modified by comparing the separation of the holes with minimum and or maximum limits. For example, it may be desirable to assure that no two locations are closer than a minimum value. In some embodiments this is important to assure that the wall thickness, which corresponds to the separation between adjacent holes, is no less than a minimum amount.

As discussed above, the minimum value of separation is about 20 microns in one embodiment, thereby providing a wall thickness of no less than about 20 microns.

[0247] In another embodiment, the subset of locations is modified and/or the pattern of location is augmented to maintain an optical characteristic of the mask. For example, the optical characteristic may be opacity and the subset of locations may be modified to maintain the opacity of a non-transmissive portion of a mask. In another embodiment, the subset of locations may be modified by equalizing the density of holes in a first region of the body compared with the density of holes in a second region of the body. For example, the locations corresponding to the first and second regions of the non-transmissive portion of the mask may be identified. In one embodiment, the first region and the second region are arcuate regions (e.g., wedges) of substantially equal area. A first areal density of locations (e.g., locations per square inch) is calculated for the locations corresponding to the first region and a second areal density of locations is calculated for the locations corresponding to the second region. In one embodiment, at least one location is added to either the first or the second region based on the comparison of the first and second areal densities. In another embodiment, at least one location is removed based on the comparison of the first and second areal densities.

[0248] In a third step, a hole is formed in a body of a mask at locations corresponding to the pattern of locations as modified, augmented, or modified and augmented. The holes are configured to allow at least some light transmission through the mask without producing visible diffraction patterns.

V. Additional Mask Configurations

[0249] A mask can have a variety of other configurations including configurations that include features described above. For example, the density of light transmission holes (e.g. area of holes per area of mask) can be different in different areas of the mask. In certain embodiments, the density of holes increases radially out from the inner periphery to the outer periphery of the mask. In certain other embodiments, the density of holes decreases radially out from the inner periphery to the outer periphery of the mask. Other variations are also possible. For example, a center annular region of the mask **4000** can have a higher density of holes than an inner annular region and an outer annular region, as illustrated in FIG. **24**A. In another example, the center annular region of a mask has a lower density of holes than an inner annular region and an outer annular region. The density of holes is the percentage of surface area of the mask that has holes. A density of holes can be created by, for example, relatively few holes with relatively large area or relatively many holes with relatively small area. As described above, the holes can be arranged to reduce visible diffraction patterns.

[0250] The embodiment of the mask **4000** illustrated in FIG. **24**A has an irregular hole pattern as described in Section IV. The mask **4000** includes an inner peripheral region neighboring the inner periphery of the mask **4000**, an outer peripheral region neighboring the outer periphery of the mask **4000**, and ten annular bands between the inner periphery region and the outer periphery region. The first band of the ten annular bands neighbors the inner periphery region, the second band neighbors the first band, and so forth. The tenth band neighbors the outer periphery region. Each band includes 840 holes, and the inner periphery region and outer periphery region includes no holes and are 50 microns wide. Each of the bands has a band width, a percentage of light transmission through the band, and a hole diameter for the holes in the band, as illustrated in Table III. The holes in the ten bands provide an average light transmission of 5%. The number and the properties of the bands and the number and properties of the holes in each band can be varied. For example, the bands can be configured to create a light transmission profile as described above. In certain embodiments, the mask **4000** has no inner periphery region and/or outer periphery region.

TABLE III

Properties of the example mask illustrated in FIG. 24A.

Band No.	Hole Diameter (microns)	% Transmission	Band Width (microns)
1	5.45	2.3	146
2	7.45	4.3	127
3	9.45	6.9	114
4	11.45	10.2	105
5	10.45	8.5	97
6	9.45	6.9	91
7	8.45	5.6	86
8	7.45	4.3	81
9	6.45	3.2	78
10	5.45	2.3	74

[0251] The transition of the density of holes between the center annular region to the inner and/or outer annular regions can be a gradual radial transition or can be a transition with one or more steps. The change in the density of holes from one region to another can be done by having the number of holes remain constant while the hole size is varied, by having the hole size remain constant while the number of holes is varied, or a combination of varying the number of holes and the hole size. Additional details regarding transition of the density of holes between the center annular region to the inner and/or outer annular regions are described in the concurrently filed international patent application, the entirety of which is hereby incorporated by reference, titled "CORNEAL INLAY WITH NUTRIENT TRANSPORT STRUCTURES," International Patent Application No. TBD (Attorney Docket No. ACUFO.123VPC) filed the same day as the present application, which claims the benefit of U.S. Provisional Application No. 61/233,802, by Bruce Christie, Edward W. Peterson, and Corina van de Pol.

[0252] Advantageously, by having at least some light transmission through the mask, patient dim light vision can be improved over having substantially no light transmission through the mask. Embodiments include total area density of holes of the mask of greater than 1%, less than 10%, between 1% and 10%, between 2% and 5%. Embodiments include light transmittance through the mask of greater than 1%, less than 10%, between 1% and 10%, between 2% and 5%. In certain embodiments, the center annular region of the mask has an average light transmittance of between 2% and 5% and the inner annular region and the outer annular region have an average light transmittance of between 1 and 2%. In certain embodiments, the inner annular region is the annular region between the inner periphery of the mask to about one-third the radial distance from the inner periphery to the outer periphery of the mask. In certain embodiments, the outer annular region is the annular region between the outer periphery of the mask to about one-third the radial distance from the outer periphery to the inner periphery of the mask. In certain embodiments,

the center annular region is the annular region between the inner annular region and the outer annular region.

[0253] Advantageously, if the mask is in a position between the posterior and anterior surfaces of a lens body, the holes through the mask can help to prevent delamination of the interface between the mask and the lens body. Delamination can occur during manipulation of the intraocular implant such as when the intraocular implant is folded or rolled and placed into a tube to be implanted into the patient. The lens body can extend through the holes, thereby creating a bond (e.g. material "bridge") between the lens body on either side of the mask. Delamination can also be reduced by matching mechanical properties (e.g. elastic modulus) of the mask to the lens body. Another method to reduce delamination is to create a bond between the lens body and the mask. For example, the lens body and the mask can have cross-linking bonds or van der Waals forces between them.

[0254] The holes in the mask serve at least two purposes: the holes provide some light transmission and the holes create areas where the material of the implant body can extend through to create a material "bridge" that holds the mask in place. In certain embodiments, the mask includes holes greater than about 7 microns in diameter (e.g., greater than a cross-sectional area of about 35 μm^2), and preferably greater than about 10 microns in diameter (e.g., greater than a cross-sectional area of about 75 μm^2). In certain embodiments, the mask includes holes greater than about 7 microns in diameter (e.g., greater than a cross-sectional area of about 35 μm^2) and less than about 20 microns in diameter (e.g., less than a cross-sectional area of about 320 μm^2). In further embodiments, the mask includes holes less than about 50 microns in diameter (e.g., less than a cross-sectional area of about 2000 μm^2. Holes with diameters less than 7 microns may not be large enough for lens material such as silicone or acrylic to enter and migrate to form a bridge. Although, the viscosity of the lens material will affect whether the material will be able to migrate into the hole to form the bridge and a minimum cross-sectional area of the hole may be dependent on the material of the implant body. If the material of the implant body does not migrate into a hole, that hole may create a bubble that could interfere with the visual performance of the implant.

[0255] The total amount of light that passes through the mask can be desirable to be minimized to maximize near image contrast. Delamination can be prevented with a relatively small total area of the mask having holes for "bridges". For example, an area of about 3% of the mask can include holes which can balance maximizing mechanical strength and minimizing optical effects of the holes. In certain embodiments, the anterior surface of the mask has a mask surface area, and the light transmission structures (e.g., holes) in the mask have a total area on the anterior surface of the mask of about 1% to about 5% of the mask surface area. To limit the impact of diffraction of light passing through the holes of the mask, the holes can be made as small as possible. The Airy disc from each hole is larger the smaller the hole size, so the composite diffraction pattern produced by the pattern of holes becomes larger as well. The composite diffraction pattern spreads light over a larger portion of the retina, decreasing the local brightness of diffracted light and making diffraction artifacts less visible. Diffraction patterns produced by a pattern of holes also tends to have a chromatic component such that the diffraction halo tends to graduate in color radially. Varying the size of the holes produces this effect in multiple scales, which scrambles the color of the halo. This reduces color contrast in the halo, making it less noticeable.

[0256] In a certain embodiment, the mask includes randomly or pseudo-randomly placed holes across the mask. The mask **4100** illustrated in FIG. **24**B has a light transmission of about 3.02%. The mask of FIG. **24**B has holes with one of four hole diameters including 10 microns, 13 microns, 16 microns, and 19 microns. There is an equal number of holes with each hole diameter. An algorithm can be used to randomly or pseudo-randomly assign the variously sized holes to locations across the mask annulus. The rules for the randomization program can include (1) that there be no "collisions" of the holes (e.g., the holes have no contact with each other), (2) that no holes interfere with the inner and outer peripheral edges of the mask, and (3) that the holes are placed in such a way as to create substantial uniform density across the mask annulus. For example, the rules for the randomization program may include one or more of these rules. FIGS. **24**C and **24**D illustrate additional examples of hole positioning for masks **4200**, **4300** using similar parameters as that were used for the mask of FIG. **24**B.

[0257] The outer diameter of the outer periphery of the mask can be varied. In certain embodiments, the outer diameter is selected to selectively allow an amount of light to pass to the retina of the eye. The pupil of the eye changes size in different lighting condition. In low light situations, the pupil of the eye enlarges to let more light into the eye. The outer diameter can be selected so that light does not pass outside the outer periphery of the mask in relatively high light conditions, and so that at least some light can pass outside the outer periphery of the mask in relatively low light conditions. The pupil size of patients often can vary; therefore, the outer diameter of the mask can be selected for a specific patient pupil size. For example, for patients with relatively small pupils, dim light may present more of a vision issue than for patients with larger pupils. For smaller pupil patients, a mask with more light transmission and/or a smaller outer diameter will increase light reaching the retina and improve vision in dim light situations. Conversely, for larger pupil patients, less light transmission and/or a larger outer diameter mask may improve low-contrast near vision and block more unfocused light. The masked IOLs of the present application give the surgeon flexibility to prescribe the appropriate combination of masked IOL features for particular patients.

[0258] In certain embodiments, the center of the aperture of the mask is off-center to the center of the lens body. By having an aperture off-center to the optical center of the lens body, the intraocular lens can be rotated during the implantation procedure so that the optical center of the patient's eye can be aligned with the center of the aperture. The vision of the patient can be improved by aligning the optical center of the patient's eye with the aperture center.

VI. Methods of Making Ocular Implants

[0259] Intraocular implants (e.g., intraocular lenses) can be made or produced in a number of different ways. In certain embodiments, a rod can be formed with an optically transparent inner region along a length of the rod, an optically transparent outer region along the length of the rod and a substantially optically non-transparent middle region along the length of the rod between the inner region and the outer region. Cross-sectional sections along a plane substantially perpendicular to an axis parallel to the length of the rod can be

sectioned out to form an implant body (e.g., lens body) with a mask through the implant body. In certain embodiments, a rod can be formed by forming an optically transparent rod. An opaque cylinder can be formed around the optically transparent rod. An optically transparent cylinder can then be formed around the opaque cylinder. In certain embodiments, the cylinders are formed by casting or molding.

[0260] In alternative embodiments, an implant body can be formed and then a mask can be attached to the posterior surface and/or anterior surface of the implant body. For example, the mask can be adhered with adhesive (e.g. glued), mechanically attached, snapped on, welded (e.g. tack welding, area welding), taped, press fit, thermal or hydration swell fit, held by surface tension, electric charge, magnetic attraction, polymerization, in-situ cross-linking (e.g. cross-linked by radiation), chemical means, etc. FIG. **25**A illustrates an embodiment of an intraocular implant **8000** with a mask **8002** coupled to the anterior surface of the implant body **8004**, and FIG. **25**B illustrates another embodiment of an intraocular implant **8010** with a mask **8012** coupled to the posterior surface of the implant body **8014**.

[0261] In certain embodiments, the implant body includes a structure to allow a mask to securely attach thereto. For example, the implant body can include clips or other structures to physically attach the mask. The implant body can include a recessed portion on the posterior or anterior surface. A mask that substantially fills the recessed portion can be placed in the recessed portion of the implant body. The inner periphery and/or the outer periphery of the recessed portion can include one or more protrusions. The inner periphery and/or the outer periphery can include one or more recesses. The mask can be attached to the implant body by inserting the mask into the recessed portion and the one or more protrusions can enter the one or more recesses to prevent the mask from separating from the implant body. In certain embodiments, the mask is attached to the implant body after the intraocular implant has been inserted into the patient. In other embodiments, the mask is attached to the implant body before the implant body has been inserted into the patient. For example, the mask can be attached to the implant body in a factory or in an operating room.

[0262] In further embodiments, an implant body can be formed around a mask. For example, an implant body can be injected molded around a mask. FIG. **25**C illustrates one embodiment of an intraocular implant **8020** with a mask **8022** embedded within the implant body **8024**. The mask **8032**, **8042** can also be embedded near the anterior or posterior surface of the implant body **8034**, **8044** of the intraocular implant **8030**, **8040**, as illustrated in FIGS. **25**D and **25**E, respectively. As illustrated in FIG. **25**F, the mask **8052** can also be positioned near the transition zone **8056** of the implant body **8054**. When the masked is positioned on the transition zone surface or within close proximity of the transition zone surface, the mask does not necessarily need to extend beyond the transition zone **8056** since light even at large angles that hits or passes through the transition zone surface would be blocked by the mask. The mask **8062** may also extend from the anterior surface to the posterior surface of the implant body **8064**, as illustrated in FIG. **25**G. Any of the locations or positions of the masks of FIGS. **25**A-G can be applied to any of the implant bodies and intraocular implants described herein.

[0263] In certain embodiments, the intraocular implant includes one or more support members that extend from the mask to an outer surface of the implant body to aid in manufacturing intraocular implants with masks. The support members can suspend the mask in a mold cavity in desired alignment in relation to the mold cavity. A contact portion of the support member can physically contact a wall of the mold cavity to support the mask. For example, the support members can be removably coupled to mold to keep the mask stationary while the implant body is injected around the mask but can be removed after the implant body has been formed. The support member can be mechanically coupled to the mask, or the support member and mask can be a single piece (e.g., monolithic structure).

[0264] FIG. **26**A illustrates one embodiment of an intraocular implant **8100** with a mask **8104** that is within an implant body **8102**. The intraocular implant **8100** includes one or more support members **8106** that are coupled to the mask **8104** and extend to at least the outer periphery **8106** of the implant body **8102**. The support members **8106** may extend to the surface of the outer periphery **8106** or may extend beyond the surface of the outer periphery **8106**.

[0265] FIG. **26**B illustrates a second example of an intraocular implant **8110** that includes support members **8116**. The support members **8116** are coupled to the mask **8114** and extend from the mask **8814** to at least the posterior surface **8113** of the implant body **8112**. By positioning the support members **8116** between the mask **8114** and the posterior surface **8113**, the support members **8816** can be hidden from line of sight of a patient.

[0266] FIG. **26**C illustrates another example of support members **8126** that are hidden from a patient's line of sight. The mask **8124** and the support members **8126** are integrated into a toroid with a triangular or trapezoid cross-sectional shape. The portion of the toroid closer to the anterior surface of the implant body **8122** extends radially inwardly and outwardly further than the portion of the toroid closer to the posterior surface of the implant body **8122**. A cross-section of the mask **8124** and support members **8126** appear as a posteriorly-pointing triangle or as an inverted pyramid. Advantageously, this embodiment minimizes unintended light blockage.

[0267] The support structures may also include tabs that can be removed after the implant body has been formed around the mask. FIG. **27**A illustrates an embodiment of an intraocular implant **8200** with support structures **8202** that include tabs. The support structures **8202** have a first portion **8208** that extends from the mask **8204** to a position within the implant body **8206** with a first cross-sectional area. The support structures **8202** also have a second portion **8209** that extends from the first portion to the surface of the implant body **8206** with a second cross-sectional area that is greater than the first cross-sectional area. After the implant body **8206** is formed around the mask **8204**, the support structures **8202** can be broken off at or near the first portion **8208**, as illustrated in FIG. **27**B. Removal of the second portion **8209** can leave behind a cavity **8207** in the implant body **8206**. The cavity **8207** can be left open or can be filled. For example, if increasing the biocompatibility of the implant **8200** is desired, the cavities **8207** can be filled so that the mask **8204** is physically or biologically isolated from the eye within or by the implant body **8206**.

[0268] FIG. **28**A is a top view and FIG. **28**B is a cross-sectional view of an embodiment of an intraocular implant **6700** with a support member **6702**. The support member **6702** extends from the mask **6704** to the outer periphery **6706** of the

implant body **6708**. The support member **6702** can include one or more contact portions **6710** that can removably couple to the mold during injection of the implant body **6708** around the mask **6704**. In certain embodiments, the implant body **6708** is injected around both the mask **6704** and the support member **6702**. The support member **6702** can also include linking members **6712** that couple the contact portions **6710** and the mask **6704**. The linking members **6712** have an anterior and/or posterior surface area that is minimized so that the linking member **6712** substantially does not block light that passes through the implant body **6708** outside the outer periphery of the mask **6704**.

[0269] The support structure **6702** can include more mass near the outer periphery of the implant body **6708** where the support structure **6702** would less likely interfere with the patient's vision. For example, the support structure **6702** can have an annulus or ring near the outer periphery of the implant body **6708** that provides additional support and further restricts movement of the mask **6704** and portions of the support structure **6702** during molding process when material flows around the mask. The flow of material can produce forces on the mask **6704** and support structure **6702**. In certain embodiments, the implant body **6708** and the haptics **6716** are a single piece (e.g., monolithic structure).

[0270] As illustrated in FIG. **28**A, the mask **6704**, linking members **6712**, and/or support structure **6702** may include light transmission structures **6720** such as holes, as described herein. The mask **6704** may also include an inner peripheral region **6722** neighboring the inner diameter and an outer peripheral region **6724** neighboring the outer diameter that substantially does not have light transmission structures **6720**, as described above. The light transmission structures **6720** can be applied to any of the embodiments of described herein and the different configurations of light transmission structures described herein such as varying hole spacing, size, shape and/or orientation can be applied to this embodiment or any embodiment that includes a mask.

[0271] FIG. **29**A is a top view and FIG. **29**B is a cross-sectional view of an embodiment of an intraocular implant **6800** similar to the intraocular implant **6700** of FIGS. **28**A and **28**B with a different optical power. The intraocular implants features described herein can be combined with a variety of optical power implant bodies.

[0272] FIG. **30**A is a top view and FIG. **30**B is a cross-sectional view of another embodiment of an intraocular implant **6900** similar to the intraocular implant **6700** of FIGS. **28**A and **28**B. The outer periphery of the mask **6904** extends beyond the outer periphery of the transition zone (e.g., second portion) **6914** which can block light that pass through the transition zone **6914** at large incident angles (e.g., angle between the normal to the surface and the incident light) to the anterior surface of the implant body **6908**.

[0273] FIGS. **31**A-**34**B are additional embodiments of intraocular implants **7000**, **7100**, **7200**, **7300** with various configurations of support members **7002**, **7102**, **7202**, **7302**. For example, the intraocular implants **7000**, **7100** of FIGS. **31**A-**32**B have support members **7002**, **7102** that have linking members **7012**, **7112** that loop from a first portion of the mask **7004**, **7104** to a contact portion **7010**, **7110** and back to a second portion of the mask **7004**, **7104**. The intraocular implants **7200**, **7300** of FIGS. **33**A-**34**B are similar to the intraocular implant **6700** of FIGS. **28**A-B; however, the linking members **7212**, **7312** do not connect the mask **7204**, **7304** and the contact portions **7210**, **7310** through a straight path. The linking members **7212**, **7312** connect the mask **7204**, **7304** and the contact portions **7210**, **7310** through a curved or wavy path. The curved or wavy path can reduce visible effects of the linking members **7212**, **7312** that a patient may observe.

[0274] The support members may be integrated with the haptic of intraocular implant. The haptic and support member may be coupled together or can be a single piece (e.g., monolithic structure). In certain embodiments, the mask, support member, and haptic are all coupled together. For example, the mask, support member, and haptic can be a single piece (e.g., monolithic structure). The mask, support member, and/or haptic may comprise the same material. Furthermore, the mask, support member, and/or haptic may comprise the same material of the implant body; however, the mask, support member, and/or haptic may include or incorporate a dye or other pigment to create opacity. Alternatively, the mask, support member, and/or haptic may comprise different materials than the implant body, but be materials that are compatible with the material of the implant body. FIG. **35**A is a top view and FIG. **35**B is a cross-sectional view of an embodiment of an intraocular implant **7400** with a support structure **7402** coupled to a mask **7404** and haptics **7416**. The support structure **7402** extends away from the mask **7404** to an outer surface of the implant body **7408**. The haptics **7416** extend away from the support structure **7402** and implant body **7408**. The haptics **7416** can provide contact portions with the mold to retain the mask **7404** while the implant body **7408** is injected around the mask **7404**. The mask **7404**, support structure **7402**, and haptics **7416** can be a single piece or coupled together such that they are configured to resist forces applied to the mask during formation of the implant body **7408**. In certain embodiments, the haptic, support members, and mask may be substantially planar.

[0275] FIG. **36**A is a top view and FIG. **36**B is a cross-sectional view of an embodiment of an intraocular implant **7500** similar to the intraocular implant **7400** of FIGS. **35**A-B. However, the mask **7504** is configured to be near the anterior surface **7518** of the implant body **7508** and follows the contours of the anterior surface **7518** of the implant body **7508**. The closer the mask **7504** is to the anterior surface **7518** less light that pass through the transition zone **7914** on the anterior surface at large incident angles can pass through the posterior surface **7520** which can be observed as visible artifacts to a patient. For embodiments where the transition zone is on the posterior surface, the mask can be positioned to be near the posterior surface. The support member **7502** can also configured to be near the anterior surface **7518** of the implant body **7508**.

[0276] In certain embodiments, the mask is printed onto an implant body. The mask can be printed on the posterior and/or the anterior surface of the implant body. The printed mask can either be adjacent the surface of the implant body or can penetrate into the implant body (stain, tattoo, etc.). Printing options can include offset printing, block printing, jet printing, etc. The mask can also be applied to the implant body by thermal transfer or hot stamping. The mask may also be laser etched onto the surface or within the implant body such as with a sub-surface laser engraving. The printed mask can be bonded or adhered to the implant body. In certain embodiments, the mask is printed onto the implant body after the implant body has been inserted into the patient. In other embodiments, the mask is printed onto the implant body before the implant body has been inserted into the patient. For

example, the mask can be printed onto the implant body in a factory or in an operating room.

[0277] FIGS. **37**A-D illustrate another method of forming a mask **8308** on the anterior (or posterior) surface of an implant body **8300** with a transition zone **8304**. FIG. **37**A illustrates an implant body **8300** without a transition zone **8304** or mask **8308**. A cavity **8302** such as an annulus can be formed (mechanically, chemically, etc.) into the anterior surface of the implant body **8300**, as illustrated in FIG. **37**B. The cavity **8302** can form the transition zone **8304**. As illustrated in FIG. **37**C, the cavity **8302** can be at least partially filled with an opaque material **8306** so that the transition zone **8304** is substantially covered. The central region **8310** can be formed (mechanically, chemically, etc.), as illustrated in FIG. **37**D. Some of the opaque material **8306** can also be removed when the central region **8310** is formed while leaving a layer of opaque material **8306** substantially covering the transition zone **8304** to form a mask **8308**.

[0278] FIGS. **38**A-E illustrate method of forming a mask **8408** within the implant body **8400**. FIG. **38**A illustrates an implant body **8400**, and FIG. **38**B illustrates the implant body **8400** with a cavity **8402** formed into the anterior surface. A mask **8408** can be positioned within the cavity **8402**, as illustrated in FIG. **38**C, and the cavity **8402** can be at least partially filled with an implant body material **8406** to embed the mask **8408** into the implant body **8400**, as illustrated in FIG. **38**D. FIG. **38**E illustrates the implant body **8400** with a portion the implant body material removed to form the central region **8410** and the transition zone **8404**.

[0279] FIGS. **39**A-D illustrate another method of forming a mask **8508** on the anterior surface of an implant body **8500** with a transition zone **8504**. FIG. **39**A illustrates an implant body **8500** without a transition zone **8504** or mask **8508**. A cavity **8502** such as an annulus can be formed into the anterior surface of the implant body **8500**, as illustrated in FIG. **39**B. As illustrated in FIG. **39**C, the cavity **8502** can be at least partially filled with an opaque material **8506**. The central region **8510** can be formed, as illustrated in FIG. **39**D. Some of the opaque material **8506** can also be removed when the central region **8510** is formed, and the opaque material **8506** can form a transition zone **8504** and a mask **8508**.

[0280] In certain embodiments, a mask is formed in or on the implant body by selectively making the material of the implant body opaque or reflective. For example, materials such as black silicone, carbon-powdered Teflon, PVDF with carbon, etc. can be used. Additional examples of materials that the mask can include are described in U.S. Patent Publication No. 2006/0265058. The implant body can be a material that changes from transparent to opaque (e.g., a photochromic material) or reflective upon being exposed to certain conditions. The molecular structure of the implant body material can be changed optically, chemically, electrically, etc. For example, structure of the implant body can be changed to create voids, regions of altered index, surface facets, etc. In certain embodiments, a dye in or on the implant body can be activated with light or electricity to change from being transparent to opaque or reflective. In certain embodiments, the mask is formed after the implant body has been inserted into the patient. In other embodiments, the mask is formed before the implant body has been inserted into the patient. For example, the mask can be formed in a factory or in an operating room.

[0281] In certain embodiments, the implant body has posterior and/or anterior surfaces with contours to create an optical power. The contours of the surfaces of the implant body can also be formed by a number of methods. For example, the implant body can be molded into a shape. In another example, the surfaces of the implant body can be milled to form the contours.

[0282] Haptics can be formed with the implant body or can be subsequently attached to the implant body. For example, haptics can be cast or molded onto the implant body in a single-piece configuration. In addition, haptics can be mechanically attached to the implant body. For example, holes can be drilled into the implant body and haptics can be inserted. Haptics can also be attached by using an adhesive or glue. In certain embodiments, the intraocular implant does not have an implant body. If the intraocular implant does not have an implant body, the haptics can be attached to the mask.

[0283] There are also a number of methods of positioning and adjusting the mask within a mold cavity of a mold. For example, a single mold can be used while the position of a mask within the mold cavity can be adjusted to accurately position mask relative to the mold cavity and eventually the implant body. FIG. **40** illustrates an embodiment of a mask positioning system **9000** that includes positioning sensors **9010**, a mask positioning apparatus **9020**, and a control system **9030**. The control system **9030** can include sensor interface **9032** in electrical communication with a feedback control **9034** that is in electrical communication with a mask positioning interface **9036**. The mask positioning apparatus **9020** can position the mask **9040** within the implant body **9050**.

[0284] The positioning sensors **9010** can be used to measure the position of the mask within the mold cavity. For example, a Hal Effect sensor can detect magnetic fields, and the sensor's output voltage can vary in response to changes in a magnetic field. With a fixed magnetic field, the distance to the source of the field can be accurately calculated. Diamagnetic levitation and induction levitation are options that can be used with a magnetic mask. Cameras, ultrasonic detectors, capacitive proximity sensors, and laser interferometry can also be used to measure the position of the mask.

[0285] A number of types of mask positioning apparatuses **9020** and methods can be used to move and position the mask within the mold cavity. For example, wires, such as nanowires, can be coupled to the mask and a frame such as a frame that surrounds the mask. FIG. **41** illustrates an embodiment of a mask positioning apparatus **9100** that includes four nanowires **9102** that are coupled to four areas on the mask **9104** at 0, 90, 180, and 270 degree positions on the mask **9104** to a surrounding frame **9106**. The frame **9106** can then be moved to position the mask **9104** with, for example, mechanical actuators and/or servos **9108**. Nanowires can be formed by electrodeposition. In certain embodiments, the mask and nanowires are electrodeposited to form a monolithic structure. Since the mask can have a low mass, small wires such as nanowires could be sufficient to move the mask around within a liquid polymer, and could be easily broken or sheared off from the implant body after the polymer has solidified or cured. One advantage of nanowires is that they are small and would minimize optical performance of the intraocular implant. In certain embodiments, the wires can also themselves provide the movement of the mask thereby eliminating the use of external actuators. The wires could include a shape memory alloy such as nitinol which, when heated can deform to cause movement of the mask. Nitinol wires can be, for example, about 0.003 inches in diameter.

[0286] Diamagnetic levitation can also be used to position the mask. A diamagnetic substance is one whose atoms have no permanent magnetic dipole moment. When an external magnetic field is applied to a diamagnetic substance a weak magnetic dipole moment is induced in the direction opposite the applied field. Pyrolytic graphite is strongly diamagnetic, and pyrolytic graphite has a specific gravity around 2.1, so it is easily levitated. Diamagnetic levitation occurs by bringing a diamagnetic material in close proximity to material that produces a magnetic field. The diamagnetic material will repel the material producing the magnetic field. Most substances that are not magnetic are weakly diamagnetic. The repulsive force may not be strong enough to overcome the force of gravity. To cause diamagnetic levitation, both the diamagnetic material and magnetic material produce a combined repulsive force to overcome the force of gravity. The magnetic field can be from a permanent magnet or can be from an electromagnet. The mask **9202** can be a diamagnetic material that can be levitated with a magnetic field **9204**, as illustrated in FIG. **42**. The magnetic field can be manipulated to position the mask within a mold cavity. For example, the magnetic field can be configured to constrain the mask while also levitating it. Multiple magnetic field (e.g., magnets) can be used to control the properties and shape of the magnetic field. FIGS. **43**A and **43**B illustrate top views of examples of first magnetic fields **9302**, **9308** and second magnetic fields **9304**, **9310** that can constrain a mask **9306**, **9312**. The first magnetic fields **9302**, **9308** have an opposite magnetic field as the second magnetic fields **9304**, **9310**. In certain embodiments, the mask includes a permanent magnetic field. If the mask has a permanent magnetic field, more force between the mask and the magnetic fields may be able to be produced.

[0287] A mask may also be levitated by using sonic levitation. Acoustic radiation pressure can produce intense sound wave in the liquid polymer to move the mask. Electrostatic levitation can also be used by applying an electrostatic field to the mask to counterbalance gravity. High voltage electrodes **9402** can be oriented around the mask **9404**, as illustrated in FIG. **44**. For example, two electrodes **9402** can be oriented on opposite sides of the mask **9404** on each of three axes that are perpendicular to each other for a total of six electrodes. The electrodes can be in electrical communication with a high voltage generator and controller **9406**.

[0288] The mask may be formed by a bistable display (e.g., Cholesteric Liquid Crystal Display (ChLCD)) that is capable of maintaining a state (e.g., opaque or transparent) without electrical power. FIG. **45** illustrates a bistable display **9502**. Electrical power can be used to change the state of a pixel **9504** to either opaque or transparent. The pixels that are opaque can form the mask. Therefore, the inner diameter, outer diameter, and aperture of the mask can be adjusted.

VII. Intraocular Implants with Haptics

[0289] Anterior chamber intraocular lens have generally been made from polymethyl methacrylate (PMMA), which is a relatively hard thermoplastic. A certain amount of rigidity was believed necessary to maintain stability of the implant in the anterior chamber. For example, a stiffening element can be added to the haptic to achieve the desirable stability of the intraocular lens (see, e.g., U.S. Pat. No. 6,228,115 (Hoffmann, et al.)). However, the compressive forces of PMMA intraocular lenses is far in excess of what is required for stability. It is also possible to construct intraocular lenses from soft materials such as silicones, hydrogels and soft acrylics. With these softer materials, there is some question as to the stability of the implant in the anterior chamber; however, intraocular implants made from soft material are stable when certain compressive forces and contact areas are used.

[0290] For example, the commercially available Bausch & Lomb NuVita Model MA 20 exhibits a force response of approximately 2.7 mN at 1 mm of compression when measured according to the industry standard compression test, ISO/DIS 11979-3. The intraocular implant illustrated in FIGS. **46-47** can exhibit a force response of less than approximately 0.5 mN at 1 mm of compression when made from a soft acrylic material, which is similar to the commercially available Alcon Model SA30EL posterior chamber lens. The broad haptic contact areas found on posterior chamber IOLs such as the Alcon Model SA30EL are generally not suitable for implantation in the anterior chamber because such designs can cause translational movement of the haptic contact points relative to the anterior chamber tissue, resulting in chronic irritation and the formation of synechia. The formation of calluses around the haptics may also cause late-onset glaucoma. Advantageously, an intraocular implant having haptics that contact the anterior chamber angle at only four locations, and with a ratio of haptic spread to optic diameter of less than 1.5, and preferably around 1.3 for a 5.5 mm optic provides sufficient stability without excessive angle contact.

[0291] As illustrated in FIGS. **46** and **47**, an intraocular implant **5010** can include an intraocular body **5014** with a mask **5020** in or on the implant body **5014**. The implant body **5014** can include a lens body. For example, the lens body can include any lens body described herein. In addition, the intraocular implant **5010** can be implanted in phakic or aphakic patients.

[0292] In certain embodiments, the intraocular implant **5010** includes a mask **5020** embedded in or carried by a single piece comprising a soft acrylic, such as those described in U.S. Pat. Nos. 5,290,892, 5,403,901, 5,433,746, 5,674,960, 5,861,031 and 5,693,095, the disclosures of which are hereby incorporated by reference in their entirety. Such a material allows the intraocular implant **5010** to be rolled or folded so as to fit through a 3.5 mm or less surgical incision and implanted in the anterior chamber of an eye. The intraocular implant **5010** may also be made from a soft silicone or hydrogel material. In certain embodiments, the intraocular implant **5010** includes two opposing pairs of footplates **5012** joined to the implant body **5014** by haptics **5016** and ramps **5018**. The implant body **5014** may have any suitable diameter, but is preferably between 5.0 mm and 6.0 mm. The footplates **5012** are separated by the haptic **5016** by a distance S, that is preferably less than 1.5 times the diameter of implant body **5014**, and most preferably around 1.3 times the diameter of implant body **5014**. The footplates **5012** and haptics **5016** preferably are between 0.20 and 0.30 mm thick, which provides sufficient compressive force, while minimizing axial vaulting of intraocular implant **5010** to less than 1.5 mm and preferably less than 1.0 mm when the footplates **5012** and haptics **5016** are compressed 1 mm. As discussed above, the compressive force of the haptics **5016** and footplates **5012** can be sufficient for the stability of intraocular implant **5010**, but not so large to cause irritation or pupil ovaling. Preferably, the intraocular implant **5010** exhibits a force response of approximately less than 0.5 mN, and more preferably, approximately less than 0.3 mN, when the intraocular implant **5010** is compressed 1 mm according to industry standard test ISO/DIS 11979-3.

[0293] The mask **5020** has an aperture **5022** to improve the depth of focus of a human eye. In certain embodiments, the aperture **5022** is a pin-hole aperture. The mask **5020** can extend through the entire anterior-posterior dimension of the implant body **5014**, as illustrated in FIG. **48**A. Preferably, the mask will be no more than about 85% or 95% of the anterior-posterior thickness of the finished lens, so that the material of the lens body will overlay and encapsulate the mask to provide a continuous outer surface.

[0294] The implant of FIG. **46**, and other implants described below can be manufactured by lamination, or other techniques known in the art. For example, the mask may be placed into a mold cavity followed by introduction of monomer, polymer or other lens precursor material which is caused to change from a flowable state to a solid state to encapsulate the mask.

[0295] The mask **5021**, **5023** can be positioned on, neighboring, near or adjacent the anterior or posterior surface of the implant body **5011**, **5013**, as illustrated in FIGS. **48**B and **48**C, respectively. In certain embodiments, the mask is spaced apart from the surfaces of the implant body. For example, the mask **5025** can be positioned substantially at a central portion **5024**, e.g., midway between the posterior and anterior surfaces of the implant body **5015**, as illustrated in FIG. **48**D. In certain embodiments, the mask **5027** is positioned between the central portion **5024** and the posterior surface of the implant body **5017**, as illustrated in FIG. **48**E. Certain embodiments include the mask **5027** being positioned midway, one-third or two-thirds between the central portion **5024** and the posterior surface of the implant body **5017**. In certain other embodiments, the mask **5029** is positioned between the central portion **5024** and the anterior surface of the implant body **5019**, as illustrated in FIG. **48**F. Certain embodiments include the mask **5029** being positioned midway, one-third or two-thirds between the central portion **5024** and the anterior surface of the implant body **5019**.

VIII. Intraocular Implants with Masks

[0296] Intraocular implants for improving the vision of a patient, such as by increasing the depth of focus of an eye of a patient, can include different types of structures. FIGS. **49**A-C illustrate an embodiment of intraocular implant **6000** with an implant body **6002**. The implant body **6002** can include a mask **6006**, an aperture **6008** surrounded by the mask **6006**, and an outer hole region **6010** around the mask **6006**. The outer hole region **6010** can have an outer portion **6012** of the implant body **6002** around it.

[0297] The intraocular implant **6000** may include one or more haptics **6004** to prevent the intraocular implant **6000** from moving or rotating within the eye. The haptics **6004** can be a variety of shapes and sizes depending on the location the intraocular implant **6000** is implanted in the eye. For example, the haptics **6004** illustrated in FIGS. **49**A-C and the haptics **6104** illustrated in FIGS. **50**A-C have different haptics. The haptics **6004**, **6104** illustrated FIGS. **49-50** are generally suited for sulcus fixated intraocular implants **6000**, **6100**; however the intraocular implants **6000**, **6100** can be interchanged with any variety of haptic (e.g. haptics described above), and can be implanted into any suitable location within the eye (e.g. anterior chamber and posterior chamber).

[0298] As illustrated in FIGS. **49**A and **49**B, the outer hole region **6010** includes five outer holes **6014** that form an annulus around the aperture **6008**. The outer hole region **6010** can include one or more connection portions **6016**. The connection portions **6016** can be between at least two of the outer holes **6015**. The connection portion **6016** connects or links the mask **6006** and the outer portion **6012** of the implant body **6002**. In certain embodiments, the mask **6006**, the connection portions **6016** and the outer portion **6012** are a single integrated piece. In certain embodiments, the single integrated piece also includes haptics **6004**. The outer holes **6014** can be formed into the single integrated piece by stamped, cutting, burning, etching, etc.

[0299] In certain embodiments, at least a portion of the implant body is opaque. As used herein the term "opaque" is intended to indicate a transmission of no more than about 2% of incident visible light. In one embodiment, at least a portion of the implant body **6002** is configured to be opaque to more than 99% of the light incident thereon. In certain embodiments, at least a portion of the mask **6006** is opaque. In certain other embodiments, at least a portion of the mask **6006** is configured to transmit between 2 and 5% of incident visible light. In certain embodiments, the mask **6006** transmits no more than 95% of incident visible light. In certain embodiments, the intraocular implant **6000** is a single integrated opaque piece.

[0300] The size of the aperture **6008** may be any size that is effective to increase the depth of focus of an eye of a patient suffering from presbyopia. For example, the aperture **6008** can be circular. In one embodiment, the aperture **6008** has a diameter of less than about 2 mm. In another embodiment, the diameter of the aperture is between about 1.6 mm and about 2.0 mm. In another embodiment, the aperture **6008** has a diameter of about 1.6 mm or less. In another embodiment, the diameter of the aperture is about 1.4 mm. In certain embodiments, the diameter of the aperture is between about 0.85 mm to about 2.2 mm. In further embodiments, the diameter of the aperture is between about 1.1 mm to about 1.7 mm.

[0301] In certain embodiments, the outer hole region **6010** of intraocular implant s **6000** can improve low light vision. As the pupil of the eye enlarges, eventually light rays will enter and pass through the outer hole region **6010** of the intraocular implant **6000**. If the pupil of the eye is large enough so that light rays pass through outer hole region **6010** of the intraocular implant **6000**, additional light rays will strike the retina.

[0302] The outer hole region **6010** can be a variety of shapes and sizes. FIGS. **51-54** illustrate various embodiments of intraocular implants. FIGS. **51**A-E illustrate intraocular implants similar to the intraocular implant **6000** of FIGS. **49**A-C except that the number of connection portions **6016** that connect the mask **6006** with the outer portion **6012** of the implant body **6002** and the number of outer holes **6014** vary. FIGS. **51**A, **51**B, **51**C, **51**D and **51**E illustrate intraocular implants **6200***a*, **6200***b*, **6200***c*, **6200***d*, **6200***e* with one connection portion **6216***a* and one outer hole **6214***a* in the outer hole region **6010***a*, with two connection portions **6216***b* and two outer holes **6214***b* in the outer hole region **6010***b*, with three connection portions **6216***c* and three outer holes **6214***c* in the outer hole region **6010***c*, with four connection portions **6216***d* and four outer holes **6214***d* in the outer hole region **6010***d*, and with six connection portions **6216***e* and six outer holes **6214***e* in the outer hole region **6010***e*, respectively.

[0303] Intraocular implants **6000** can have any number of connection portions **6016**. Embodiments include intraocular implants with at least one connection portion, at least two connection portions, at least three connection portions, at least four connection portions, at least five connection por-

tions, at least six connection portions, less than ten connection portions, less than six connection portions, between one and ten connection portions.

[0304] Similarly, intraocular implants **6000** can have any number of outer holes **6014**. Embodiments include intraocular implants with at least one outer hole, with at least two outer holes, with at least three outer holes, with at least four outer holes, at least five outer holes, at least six outer holes, less than ten outer holes, less than six outer region holes, between one and ten outer region holes.

[0305] In certain embodiments, the cross-sectional area perpendicular to the length of an outer hole of at least one outer hole is at least about 1 mm^2. In certain embodiments, the cross-sectional area perpendicular to the length of the outer holes of at least two outer holes is at least about 1 mm for each of the at least two outer holes. In certain embodiments, area on the implant body of the outer hole region is at least about 5 mm^2 or at least about 10 mm^2.

[0306] The distance between the outer perimeter **6018** of the aperture **6008** (e.g. inner perimeter **6018** of the mask **6006**) and outer perimeter **6020** of the mask **6006** can also vary. For example, the distance between the outer perimeter **6018** of the aperture **6008** and outer perimeter **6020** of the mask **6006** can be adjusted depending on the particular patient and the location within the eye that the intraocular implant **6000** is positioned. Embodiments include the distance between the outer perimeter **6018** of the aperture **6008** and outer perimeter **6020** of the mask **6006** to be about 1.1 mm, between about 0.8 and about 1.4 mm, between about 0.4 and about 2.5 mm, greater than zero, greater than about 0.4 mm, and greater than about 0.8 mm.

[0307] In certain embodiments, the aperture **6008** and/or the outer hole region **6010** includes an optical power and/or refractive properties. For example, the aperture **6008** and/or the outer hole region **6010** can include an optic and can have an optical power (e.g. positive or negative optical power). In certain embodiments, the aperture **6008** and/or the outer hole region **6010** can correct for refractive errors of an eye.

[0308] The distance between the inner perimeter **6020** of the outer hole region **6010** (e.g. outer perimeter **6020** of the mask **6006**) and the outer perimeter **6022** of the outer hole region **6010** can be a variety of sizes. Embodiments include the distance between the inner perimeter **6020** of the outer hole region **6010** and the outer perimeter **6022** of the outer hole region **6010** to be about 0.85 mm, greater than about 0.7 mm, greater than about 0.4 mm, greater than zero, between about 0.6 and about 1.0 mm, and between about 0.2 and about 1.5 mm. FIG. **52** illustrates an embodiment of an intraocular implant **6300** where the outer perimeter **6322** of the outer hole region **6310** extends to near the outer perimeter **6324** of the implant body **6302**. For example, the distance between the outer perimeter **6322** of the outer hole region **6310** and the outer perimeter **6324** of the implant body **6302** can be less than 0.5 mm or less than 0.1 mm.

[0309] In certain embodiments, the outer hole region **6010** has a incident visible light transmission of at least 90% or at least 95%. In certain embodiments, the outer hole region **6010** area includes at least 90% or at least 95% outer holes **6014**. In certain embodiments, the outer hole region **6010** area includes no more than 10% or no more than 5% connection portions **6016**.

[0310] The outer hole region **6010** can have irregular annular shapes. FIGS. **53**A-C illustrate examples of variations in annular shapes. As illustrated in FIG. **53**A, the outer hole region **6410***a* has different sized outer holes **6414***a*. The distance between the inner perimeter **6420***a* of the outer hole region **6410***a* and the outer perimeter **6422***a* of the outer hole region **6410***a* can vary annularly around the outer hole region **6410***a*. The distance between the outer perimeter **6422***a* of the outer hole region **6410***a* and the outer perimeter **6424***a* of the implant body **6402***a* can also vary annularly around the outer hole region **6410***a*.

[0311] In certain embodiments, connection portions **6016** extend substantially radially out from the center of the implant body **6002**, as illustrated in FIG. **49**B. FIG. **53**B illustrates an embodiment where the connection portions **6416***b* do not extend radially out from the center of the implant body **6402***b*. For example, the lengths of the connection portions **6416***b* can be substantially parallel.

[0312] In certain embodiments, the outer hole region **6010** is substantially annularly circle-shaped, as illustrated in FIGS. **49-51**. As illustrated in FIG. **53**C, the outer hole region **6410***c* can be substantially annularly square-shaped. In certain embodiments, the outer hole region **6410***c* is annularly polygon-shaped.

[0313] In certain embodiments, the outer hole region **6010** can be a substantially continuous annulus, as illustrated in FIGS. **49-53**. As illustrated in FIG. **54**, the outer hole region **6500** can have a partial annular shape. In certain embodiments, the outer hole region **6010** at least partially surrounds the mask **6506** and/or the aperture **6508**.

[0314] In certain embodiments, the aperture **6008** is substantially centered in the mask **6006**, as illustrated in FIGS. **49-53**. The aperture **6608**, **6708** can also be off-center in the mask **6606**, **6706**, as illustrated in FIGS. **55** and **56**. FIG. **55** illustrates an embodiment with the aperture **6608** substantially centered in the implant body **6602** with the outer hole region **6610** off-center in the implant body **6602** (e.g. the outer hole region **6610** closer to one edge of the implant body **6602** than an opposite edge of the implant body **6602**). FIG. **56** illustrates an embodiment with the outer hole region **6710** substantially centered in the implant body **6702** with the aperture **6708** off-center within the outer hole region **6710**. The aperture **6008** can be substantially circular or any shape as described above.

[0315] The intraocular implant **6000** can be a variety of thicknesses (e.g. distance between the posterior and anterior surfaces). For example, the thickness of the intraocular implant **6000** can be about 0.2 mm, less than about 0.5 mm, less than about 0.3 mm, or less than about 0.2 mm.

[0316] The outer holes **6014** can be open holes or can be filled with a substantially transparent material. For example, the outer holes **6014** can be formed in the implant body **6002**, and a substantially transparent material can used to fill the outer holes **6014**.

[0317] The mask **6006** of the intraocular implant **6000** can be any of the variations described above. In certain embodiments, the mask **6006** includes light transmission holes. For example, the configuration of the mask **4000** illustrated in FIG. **24**A can be a configuration of a mask **6806** used in an intraocular implant **6800**, as illustrated in FIG. **57**.

[0318] FIG. **58** illustrates another embodiment of an intraocular implant **6900** with a mask region **6930** with light transmission holes **6932**. In certain embodiments, the intraocular implant **6900** is opaque in at least one region. For example, the mask region **6930** can be opaque. The light transmission holes **6932** can vary in size, density (e.g., number of holes per unit area) and/or surface area (e.g., percentage

of surface area of light transmission holes **6932** compared to the total surface area of the mask region **6930**) in one or more portions of the mask region **6930**. For example, the size, density and/or surface area of the light transmission holes **6932** can increase or decrease radially from the inner periphery **6918** of the mask region **6930** to the outer periphery **6924** of the implant body **6902**. The transition of the size and/or density of light transmission holes **6932** can be gradual or one or more steps. As illustrated in the embodiment in FIG. **58**, the size of the light transmission holes **6932** gradually increase in size radially out from the aperture **6908** while the number of light transmission holes per unit area decreases. In certain embodiments, the light transmission holes **6932** have irregular spacing or have an irregular pattern.

[0319] Various embodiments have been described above. Although the invention has been described with reference to these specific embodiments, the descriptions are intended to be illustrative and are not intended to be limiting. Various modifications and applications may occur to those skilled in the art without departing from the true spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1. A intraocular implant comprising:

an implant body comprising a body material;

a mask with an aperture positioned within the implant body, the mask comprises a plurality of holes that extend between a posterior surface and an anterior surface of the mask; and

wherein the body material extends through the plurality of holes of the mask, and further wherein the plurality of holes are characterized in that at least one of the hole size, shape, orientation, and spacing of the plurality of holes is varied to reduce the tendency of the holes to produce visible diffraction patterns.

2. The intraocular implant of claim **1**, wherein the plurality of holes are positioned at irregular locations.

3. The intraocular implant of claim **1**, wherein a plurality of the holes comprise first hole size, shape or spacing and at least another plurality of holes comprise a second hole size, shape, or spacing different from the first holes size, shape, or spacing.

4. The intraocular implant of claim **1**, wherein a first plurality of the holes comprise first hole size, a second plurality of the holes comprise a second hole size different form the third hole size, and a third plurality of holes comprise a third hole size different from the first holes size and the second hole size.

5. The intraocular implant of claim **1**, wherein the aperture comprises a diameter of from about 0.85 mm to about 1.8 mm.

6. The intraocular implant of claim **1**, wherein the mask comprises an outer diameter of from about 3 mm to about 5 mm.

7. The intraocular implant of claim **1**, wherein the mask increases depth of focus of a patient.

8. The intraocular device of claim **1**, further comprising at least one haptic attached to the implant body to support the intraocular device after being implanted within an eye.

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