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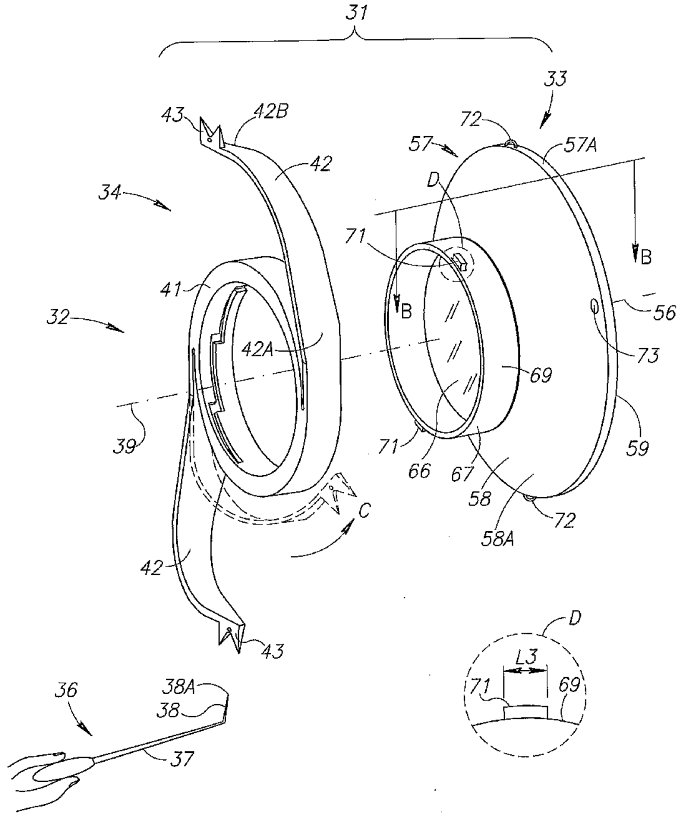
(54) Title: ACCOMMODATING INTRAOCULAR LENS (AIOL) ASSEMBLIES, AND DISCRETE COMPONENTS THERFOR



(57) Abstract: Accommodating intraocular (AIOL) assemblies for enabling post implantation in situ manual selective displacement of an AIOL along a human eye's visual axis relative to stationary anchor points. Axial displacement may be over a continuous range or alternatively at discrete axial stopping positions typically from about 100μm to about 300 μm apart. Novels AIOLs designed to be at least partially folded for facilitating insertion into a human eye through a relatively small incision.

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ACCOMMODATING INTRAOCULAR LENS (AIOL) ASSEMBLIES, AND DISCRETE COMPONENTS THEREFOR

Field of the Invention

The invention pertains to accommodating intraocular lens assemblies.

Background of the Invention

Commonly owned PCT International Application No. PCT/IL02/00693 entitled Accommodating Lens Assembly and published on 27 February 2003 under PCT International Publication No. WO 03/015669 illustrates and describes accommodating intraocular lens (hereinafter AIOL) assemblies, the contents of which are incorporated herein by reference. The AIOL assemblies each include a haptics system adapted to be securely fixed in a human eye's annular ciliary sulcus at at least two spaced apart stationary anchor points so that it may act as a reference plane for an AIOL of continuously variable Diopter strength affected by a human eye's capsular diaphragm under control of its sphincter-like ciliary body and acting thereagainst from a posterior direction. The haptics systems include a rigid planar haptics plate with a telescoping haptics member for sliding extension. The haptics plate and the haptics member are preferably self-anchoring as illustrated and described in commonly owned PCT International Application No. PCT/IL02/00128 entitled Intraocular Lens and published on 29 August 2002 under PCT International Publication No. WO 02/065951, the contents of which are incorporated herein by reference.

Commonly owned PCT International Application No. PCT/IL2005/000456 entitled Accommodating Intraocular Lens Assemblies and Accommodation Measurement Implant and published on 10 November 2005 under PCT International Publication No. WO 2005/104994 illustrates and describes AIOL assemblies enabling post implantation *in situ* manual selective displacement of an AIOL along a human eye's visual axis relative to at least two spaced apart stationary anchor points to a desired position to ensure that an AIOL assumes a non-compressed state in a human eye's constricted ciliary body state. Such *in situ* manual selective displacement can be effected post implantation to correct for capsular contraction which is a natural reaction which typically develops over a few months following extraction of the contents of a human eye's natural crystalline lens, and also a subject's changing eyesight overtime with minimal clinical intervention. Such *in situ* manual selective displacement can be achieved as follows: First, a discrete haptics system for retaining a discrete AIOL which is manually displaceable relative thereto. And second, a haptics system with at least two haptics having radiation sensitive regions capable of undergoing plastic deformation for *in situ* manual displacement of an integrally formed AIOL.

Commonly owned PCT International Application No. PCT/IL2005/001069 entitled Accommodating Intraocular Lens (AIOL), and AIOL Assemblies Including Same illustrates and describes an AIOL including a biasing mechanism for elastically deforming an elastically deformable shape memory disk-like optical element for affording the AIOL a natural positive Diopter strength for near vision. The AIOL is intended to be implanted in a human eye such that relaxation of its ciliary body causes its capsular diaphragm to apply an external force for overcoming the biasing mechanism to reduce the AIOL's natural positive Diopter strength for distance vision.

Other AIOLs are illustrated and described in US Patent No. 4,254,509 to Tennant, US Patent No. 4,409,691 to Levy, US Patent No. 4,888,012 to Horn et al., US Patent No. 4,892,543 to Turley, US 4,932,966 to Christie et al., US Patent No. 5,476,514 to Cumming, US Patent No. 5,489,302 to Skottun, US Patent No. 5,496,366 to Cumming, US Patent No. 5,522,891 to Klaas, US Patent No. 5,674,282 to Cumming, US Patent No. 6,117,171 to Skottun, US Patent No. 6,197,059 to Cumming, US Patent No. 6,299,641 to Woods, US Patent No. 6,342,073 to Cumming et al., US Patent No. 6,387,126 to Cumming, US Patent No. 6,406,494 to Laguette et al., US Patent No. 6,423,094 to Sarfarazi, US Patent No. 6,443,985 to Woods, US Patent No. 6,464,725 to Skotton, US Patent No.

6,494,911 to Cumming, US Patent No. 6,503,276 to Lang et al., US Patent No. 6,638,306 to Cumming, US Patent No. 6,645,245 to Preussner, US Patent Application Publication No. US 2004/0169816 to Esch, and EP 1 321 112.

Summary of the Invention

One aspect of the present invention is directed towards accommodating intraocular (AIOL) assemblies each including at least one shape memory optical element resiliently elastically deformable between a non-compressed shape with a first Diopter strength and a compressed shape with a second Diopter strength different than its first Diopter strength such that an AIOL has a continuously variable Diopter strength between a minimum Diopter strength for distance vision purposes and a maximum Diopter strength for near vision purposes. The AIOL assemblies are intended for *in situ* manual selective displacement of an AIOL along a human eye's visual axis relative to stationary anchor points after implantation for enabling accurate AIOL deployment to take full advantage of the reciprocal movement of a human eye's capsular diaphragm between its constricted ciliary body position and its relaxed ciliary body position. Axial displacement may be over a continuous range in a similar manner to aforesaid WO 2005/104994 or alternatively at discrete axial stopping positions typically from about 100μm to about 300μm apart. Stepwise axial displacement is preferably enabled by a so-called "push and twist" bayonet arrangement similar to a conventional light bulb fitting having a single stopping position. The AIOL assemblies each include a haptics system also suitable for self-anchoring implantation of a fixed Diopter strength IOL in a human eye as opposed to an AIOL having a variable Diopter strength.

Another aspect of the present invention is directed towards AIOLs which lend themselves to be at least partially folded under reasonable forces as can be applied using conventional ophthalmic surgical tools, for example, tweezers, for facilitating insertion into a human eye through a relatively small incision. The AIOLs can be provided as discrete components for use with discrete haptics systems for enabling aforesaid *in situ* axial displacement. The discrete AIOLs are provided with typically two or more manipulation apertures accessible from an anterior side for receiving the tip of a handheld manipulation tool for enabling *in situ* manipulation. The manipulation apertures may be in the form of peripheral disposed manipulation rings, blind manipulation notches, and the like. Alternatively, the AIOLs can be integrally formed with a haptics system including at least two elongated haptics having radiation sensitive regions capable of undergoing plastic deformation for enabling aforesaid *in situ* axial displacement.

Brief Description of the Drawings

In order to understand the invention and to see how it can be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings in which similar parts are likewise numbered, and in which:

Fig. 1 is a cross section view of an anterior part of a human eye in its natural near vision condition in an axial plane of the human body;

Fig. 2 is a cross section view of an anterior part of a human eye in its natural distance vision condition in an axial plane of the human body;

Fig. 3 is a pictorial view of a disassembled "push and twist" AIOL assembly including a discrete haptics system and a discrete AIOL with a flattened spherical shaped housing a shape memory optical element;

Fig. 4 is a close-up front view of a bifurcated attachment plate of Figure 3's haptics system;

Fig. 5 is a pictorial view of a stepped track of Figure 3's haptics system;

Fig. 6 is a pictorial view of a Figure 3's AIOL being folded by tweezers for insertion into a human eye through a small incision;

Fig. 7 is a pictorial view of a unitary AIOL assembly including a haptics system integrally formed with Figure 3's AIOL;

Fig. 8 is a longitudinal cross section view of the Figure 3's AIOL in its non-compressed state along line B-B in Figure 3;

Fig. 9 is a longitudinal cross section of Figure 3's AIOL in its compressed state along line B-B in Figure 3;

Fig. 10 is a side view of Figure 3's AIOL assembly prior to assembly;

Fig. 11 is a side view of Figure 3's AIOL assembly at its most posterior axial stopping position;

Fig. 12 is a side view of Figure 3's AIOL assembly at an intermediate axial stopping position;

Fig. 13 is a side view of Figure 3's AIOL assembly at its most anterior axial stopping position;

Fig. 14 is a cross section view of an anterior view of a human eye in an axial plane of the human body implanted with Figure 3's AIOL assembly in an initial position along the human eye's visual axis;

Fig. 15 is a cross section view of an anterior view of a human eye in an axial plane of the human body implanted with Figure 3's AIOL assembly at a subsequent position along the human eye's visual axis to compensate for capsular contraction;

Fig. 16 is a pictorial view of a disassembled "push and twist" AIOL assembly including a discrete haptics system and a discrete dual bellows-like AIOL;

Fig. 17 is a pictorial view of a unitary AIOL assembly including a haptics system integrally formed with Figure 16's dual bellows-like AIOL;

Fig. 18 is a longitudinal cross section view of Figure 16's dual bellows-like AIOL in its non-compressed state;

Fig. 19 is a longitudinal cross section of Figure 16's dual bellows-like AIOL in its compressed state;

Fig. 20 is a cross section view of an anterior view of a human eye in its contracted ciliary body state in an axial plane of the human body implanted with Figure 16's AIOL assembly;

Fig. 21 is a cross section view of an anterior view of a human eye in its relaxed ciliary body state in an axial plane of the human body implanted with Figure 16's AIOL assembly;

Fig. 22 is an exploded view of a still yet another discrete AIOL for use in a haptics system adapted to be securely fixed in a human eye's annular ciliary sulcus;

Fig. 23 is a longitudinal cross section view of Figure 22's AIOL in its non-compressed state;

Fig. 24 is a longitudinal cross section view of Figure 22's AIOL in its compressed state;

Fig. 25 is a side view of a still yet another discrete AIOL in its non-compressed state for use in a haptics system adapted to be securely fixed in a human eye's annular ciliary sulcus;

Fig. 26 is a side view of Figure 25's AIOL in its compressed state;

Fig. 27 is a cross section view of Figure 25's AIOL in its non-compressed state;

Fig. 28 is a cross section view of Figure 25's AIOL in its compressed state;

Fig. 29 is longitudinal cross section view of a still yet another discrete AIOL in its non-compressed state for use in a haptics system adapted to be securely fixed in a human eye's annular ciliary sulcus;

Fig. 30 is a longitudinal cross section of Figure 29's AIOL in its compressed state;

Fig. 31 is a longitudinal cross section of still yet another discrete AIOL in its non-compressed state for use in a haptics system adapted to be securely fixed in a human eye's annular ciliary sulcus;

Fig. 32 is a longitudinal cross section of a still yet another discrete AIOL in its non-compressed state for use in a haptics system adapted to be securely fixed in a human eye's annular ciliary sulcus;

Fig. 33 is a pictorial view of a disassembled “push and twist” AIOL assembly in accordance with another “push and twist” bayonet arrangement;

Fig. 34 is a pictorial view of a disassembled “push and twist” AIOL assembly in accordance with yet another “push and twist” bayonet arrangement; and

Fig. 35 is a pictorial view of a disassembled AIOL assembly with a screw thread arrangement for enabling *in situ* manual selective axial displacement of an AIOL along a human eye’s visual axis.

Detailed Description of Preferred Embodiments of the Present Invention

Figures 1 and 2 are cross section views of an anterior part of a human eye 10 having a visual axis VA in its natural near and distance vision conditions, respectively, in an axial plane of the human body. The human eye 10 has a cornea 11 peripherally connected to a spherical exterior body made of tough connective tissue known as the sclera 12 at an annular sclero-corneal juncture 13. An iris 14 inwardly extends into the human eye 10 from its root 16 at the sclero-corneal juncture 13 to divide the human eye’s anterior part into an anterior chamber 17 and a posterior chamber 18. A sphincter-like peripheral structure known as the ciliary body 19 includes ciliary processes housing ciliary muscles 21 fired by parasympathetic nerves. The ciliary muscles 21 are connected to zonular fibers 22 which in turn are peripherally connected to the equatorial edge of a membrane known as the capsular bag 23 with an anterior capsule 24 and a posterior capsule 26 enrobing a natural crystalline lens 27. The iris’s root 16 and the ciliary body 19 delimit a portion of the interior surface of the sclera 12 at the sclero-corneal juncture 13 known as the ciliary sulcus 28. Remnants of the anterior capsule 24 which may remain after extraction of the natural crystalline lens 27 and the intact posterior capsule 26 are referred to hereinafter as the capsular diaphragm 29. Contraction of the ciliary body 19 allows the lens 27 to thicken to its natural thickness T1 along the visual axis VA for greater positive optical power for near vision (see Figure 1). Relaxation of the ciliary body 19 tensions the zonular fibers 22 which draws the capsular bag 23 radially outward as shown by arrows A for compressing the lens 27 to shorten its thickness along the visual axis VA to T2<T1 for lower positive optical power for distance vision (see Figure 2).

Figure 3 shows a "push and twist" AIOL assembly 31 for self-anchoring in a human eye's ciliary sulcus 28 for preferably enabling spectacle free vision over the nominal range of human vision. The AIOL assembly 31 includes a discrete haptics system 32 for selectively retaining a discrete AIOL 33, and a "push and twist" bayonet arrangement 34 for effecting stepwise axial displacement of the AIOL 33 relative to the haptics system 32 and therefore along a human eye's visual axis. A handheld manipulation tool 36 with an elongated shaft 37 and an inclined end piece 38 with a tip 38A is employed for assembling the AIOL assembly 31 *in situ* and for manipulating the AIOL 33 for stepwise axial displacement relative to the haptics system 32.

The haptics system 32 is made from suitable rigid bio-compatible transparent polymer material such as PMMA, and the like. The haptics system 32 has a longitudinal axis 39 intended to be co-directional with a human eye's visual axis. The haptics system 32 includes a tubular main body 41 with a diameter D1 in the region of 4mm - 5mm corresponding to a human eye's pupil, and an axial length L1 of 1mm±0.5mm along the longitudinal axis 39 (see Figure 10). The haptics system 32 has a pair of diametrically opposite elongated C-shaped haptics 42 extending from its main body 41 in opposite directions in a plane perpendicular to its longitudinal axis 39. The haptics 42 have a thin profile in the plane perpendicular to the longitudinal axis 39 such that they are sufficiently flexible under reasonable forces as can be applied using conventional ophthalmic surgical tools for encircling around the main body 41 shown by arrow C for facilitating insertion of the haptics system 32 into a human eye through a relatively small incision. Figure 3 shows a haptics 42 in dashed lines for showing its encircling around the main body 41. The haptics 42 have a wide profile along the longitudinal axis 39 such that they are rigid against a compression force therealong. The haptics' wide profile preferably tapers from its proximal end 42A adjacent the main body 41 to its distal end 42B remote therefrom and terminating at a bifurcated attachment plate 43.

Figure 4 shows an attachment plate 43 has a near square shape in a front view in the plane perpendicular to the longitudinal axis 39 and is formed with a pair of spaced apart pointed puncturing members 44 of sufficient strength for forced penetration into the tough connective tissue of a human eye's sclera 12. The attachment plate 43 has an isosceles shaped cutout 46 pointing towards its haptics 42 to leave a central narrow juncture 47 for determining the maximal penetration of the attachment plate 43 into a human eye's sclera 12 on its abutment thereagainst. The puncturing members 44 have tips 44A with a minimum tip separation TS of at least 1 mm and preferably between about 2 mm and 3 mm in the plane perpendicular to the longitudinal axis 39. The puncturing members 44 have a minimum tip height TH of at least 0.5 mm as measured between the tips 44A and the juncture 47 such that they can penetrate slightly more than half of a sclera's thickness of about 1mm. The tip height TH is preferably between about 0.8 mm and 1.3 mm. The attachment plates 43 are formed with a manipulation aperture 48 in the central portion between the cutout 46 and the haptics 42 for selectively receiving the handheld manipulation tool's tip 38A for *in situ* manipulation purposes. The manipulation aperture 48 is preferably constituted by an about 0.4mm diameter throughgoing bore.

The main body 41 has an internal surface 51 formed with two or more equidistant stepped tracks 52 only one of which is visible in Figure 3. Figure 5 shows a stepped track 52 has three axial directed channels 53A, 53B and 53C enabling axial displacement of the AIOL 33 relative to the haptics system 32 and three peripheral grooves 54A, 54B and 54C enabling rotational displacement of the AIOL 33 relative to the haptics system 32 and precluding inadvertent slipping of the AIOL 33 in an axial direction relative to a human eye's visual axis. The axial directed channels have peripheral widths W. The peripheral grooves 54A correspond to a most posterior stopping position, the peripheral grooves 54B correspond to an intermediate position, and the peripheral grooves 54C correspond to a most anterior position of an AIOL along a human eye's visual axis, respectively.

Figures 3, 8 and 9 show the AIOL 33 has a longitudinal axis 56 intended to be co-directional with a human eye's visual axis, and a hollow flattened spherical shaped housing 57, an annular anterior member 58 with a leading surface 58A, and a posterior member 59 having a trailing surface 59A. The leading surface 58A has an internal rim 61 defining an anterior facing aperture 62 having a diameter slightly smaller than that of the main body 41. The housing 57 defines a cavity 63 housing a shape memory optical element 64 with a leading surface 66 with a central portion 66A exposed through the aperture 62. The posterior member 59 can be formed without any optical power or preferably as a plano-convex optical member with positive Diopter strength as shown. The housing 57 has a diameter D2 of at least 6mm for an adult sized AIOL 33, and preferably of about 7mm ± 1mm so as to bear against a major portion of a human eye's capsular diaphragm 29 (see Figure 10).

The AIOL 33 includes a rigid tubular casing 67 having an axial length L2 and a leading end 67A for facing in an anterior direction in a human eye, and a trailing end 67B for facing in a posterior direction in a human eye (see Figure 10). The trailing end 67B is formed with a groove 68 for receiving the internal rim 61 whereupon the casing 67 can reciprocate relative thereto for selectively compressing the optical element 64. The casing 67 has a peripheral cylindrical surface 69 with lugs 71 for traveling along the stepped tracks 52. The lugs 71 have peripheral lengths L3 where $W = L3 + \Delta$. The housing 57 is formed with manipulation rings 72 on its peripheral rim 57A and/or blind manipulation notches 73 on its leading surface 58A for selectively receiving the handheld manipulation tool's tip 38A for enabling *in situ* manipulation of the AIOL 33 from an anterior direction on implantation of the AIOL 33 in a human eye.

The housing 57, the optical element 64 and the casing 67 are preferably formed from suitable biocompatible transparent polymer material of different consistencies which can be elastically deformed under reasonable forces as can be applied using conventional ophthalmic surgical tools, for example, tweezers 74, and the like, for facilitating insertion of the AIOL 33 into a human eye through a relatively small incision (see Figure 6). The casing 67 is typically formed from a relatively rigid polymer material, for example, PMMA, whilst the housing 57 is formed from less rigid silicone or acrylic based polymer material, and the optical element 64 is formed from still softer silicone gel, or softer acrylic based polymer material. For example, the housing 57 can be formed from MED6400 polymer material and the optical element 64 can be formed from MED3-6300 polymer material both polymer materials being commercially available from NuSil Silicon Technology, Inc., California, USA (**www.nusil.com**).

Figure 7 shows a unitary AIOL assembly 80 having a longitudinal axis 81 intended to be co-directional with a human eye's visual axis, and a haptics system 82 integrally formed with the AIOL 33 which thereby effectively acts as the haptics system's main body. The haptics system 82 includes a pair of diametrically opposite elongated C-shaped haptics 83 extending from its AIOL 33 in opposite directions in a plane perpendicular to the longitudinal axis 81 in a similar manner to the haptics system 32. In this case, the haptics 83 have regions 84 impregnated with radiation sensitive bio-compatible materials such as IR sensitive indocyanine green (ICG), and the like, such that they are capable of being plastically deformed on heating to a so-called glass transmission temperature to enable post implantation *in situ* axial displacement as illustrated and described in aforesaid WO2005/104994.

Figure 8 shows the non-compressed shape of the optical element 64 has a continuous slightly curvilinear leading surface 66 including its exposed central portion 66A in the AIOL's non-compressed state. Figure 9 shows the compressed shape of the optical element 64 bulging anteriorly into the casing 67 on applying a compression force F along its longitudinal axis 39 for compressing the AIOL 33 into its compressed state. The bulging shape is dependent on the compression force and bulges more in its compressed shape than its non-compressed shape whereby the AIOL 33 has a continuously variable Diopter strength from a minimum Diopter strength suitable for distance vision and a maximum Diopter strength suitable for near vision. The optical element 64 typically has a refractive index similar to that of the natural crystalline lens 27 or greater whereupon its non-compressed state is suitable for distance vision and its compressed state is suitable for near vision. In the case that the optical element 64 has a refractive index less than the human eye's aqueous humor, the optical element 64 acts as a concave lens such that its non-compressed state is suitable for near vision and its compressed state is suitable for distance vision.

Figures 10-13 show the use of the "push and twist" bayonet arrangement 34 for *in situ* adjustment of the AIOL 33 along a human eye's visual axis. The AIOL 33 is deployed posterior to the haptics system 32 and is rotated to align its lugs 71 with the channels 53A. The AIOL 33 is displaced in an anterior direction to insert its lugs 71 into the channels 53A and is rotated in a clockwise direction on facing the AIOL 33 from a posterior direction to midway along the grooves 54A for assuming its most posterior position (see Figure 11). Positioning the AIOL 33 at its intermediate stopping position along a human eye's visual axis denoted by S2<S1 involves a further clockwise rotation of the AIOL 33 relative to the haptics system 32 to reach the channels 53B, displacing the AIOL 33 in an anterior direction along the channels 53B to reach the grooves 54B, and a clockwise rotation of the AIOL 33 relative to the haptics system 32 (see Figure 12). Positioning the AIOL 33 at its most anterior position along a human eye's visual axis denoted by S3<S2 involves a further clockwise rotation of the AIOL 33 relative to the haptics system 32 to reach the channels 53C, displacing the AIOL 33 in an anterior direction along the channels 53C to reach the grooves 54C, and a further clockwise rotation of the AIOL 33 relative to the haptics system 32 (see Figure 13).

Implantation of the AIOL assembly 31 in a human eye 10 after removal of its natural crystalline lens 27 to leave its double layered capsular diaphragm 29 including remnants of its anterior capsule 24 overlying its still intact posterior capsule 26 is now described with reference to Figures 14 and 15. The AIOL assembly 31 is set up such that the AIOL's longitudinal axis 56 coincides with the haptics system's longitudinal axis 39. The AIOL assembly 31 is typically implanted into a human eye 10 after administration of topical drops of a cycloplegic drug for relaxing its iris muscles, thereby dilating its pupil for facilitating access to its posterior chamber 18 immediately behind its iris 14. Such administration also induces the human eye 10 into its relaxed ciliary body state thereby tensioning its capsular diaphragm 29 which has some slack by virtue of the removal of its natural crystalline lens 27 leaving its capsular diaphragm 29 for accommodation purposes. Figure 14 shows that the haptics system's puncturing members 44 are forcibly inserted into the sclera 12 at stationary anchor points AP for retaining the AIOL assembly 31 in the annular ciliary sulcus 28. Figure 14 also shows that the AIOL assembly 31 is deployed such that its longitudinal axes 41 and 56 are co-directional and preferably co-axial with the human eye's visual axis VA and the trailing surface 59A is urged in a posterior direction against the capsular diaphragm 29 tensioning same to become sufficiently taut to urge the AIOL 33 to its compressed state as shown in Figure 9. The AIOL 33 is so deployed that constriction of the ciliary body 19 is intended to enable the AIOL 33 to assume its non-compressed state as shown in Figure 8 thereby affording accommodation over the full range of the reciprocal movement of the human eye's capsular diaphragm 29. However, in the case of capsular contraction, the AIOL 33 is unable to assume its fully non-compressed state in the human eye's constricted ciliary body state such that it remains at least partially compressed depending on the degree of the capsular contraction thereby diminishing its accommodation ability. The accommodation ability of the AIOL 33 is restored by moving the AIOL 33 in an anterior direction to either its intermediate stopping position or its most anterior stopping position (see Figure 15).

Figure 16 show an AIOL assembly 90 including a discrete haptics system 32 and a discrete dual bellows-like AIOL 91. The AIOL 91 has a longitudinal axis 92 intended to be co-directional with a human eye's visual axis, and a housing 93 having a ring 94 with lugs 96 for traveling along the stepped tracks 52, an anterior member 97 with a leading surface 98, and a posterior member 99 with a trailing surface 101. The housing 93 includes a leading shape memory resiliently elastically deformable bellows-like optical element 102 between the ring 94 and the anterior member 97, and a trailing shape memory resiliently elastically deformable bellows-like optical element 103 between the ring 94 and the posterior member 99. The anterior member 97 is formed with blind manipulation notches 104 for selectively receiving the handheld manipulation tool's tip 38A for enabling *in situ* manipulation of the AIOL 33.

The ring 94, the anterior member 97, the posterior member 99, and the optical elements 102 and 103 are preferably formed from suitable polymer based biocompatible transparent material of different consistencies. The ring 94 is typically formed from a relatively rigid polymer material, for example, PMMA, whilst the anterior member 97 and the posterior member 99 are formed from less rigid silicone or acrylic based polymer material, and the optical elements 102 and 103 are formed from still softer silicone gel or softer acrylic based polymer material. For example, the anterior member 97 and the posterior member 99 can be formed from aforesaid MED6400 polymer material and the optical elements 102 and 103 can be formed from aforesaid MED3-6300 polymer material. Alternatively, the ring 94 can be formed with a membrane for dividing the AIOL 91 into two compartments which can be injected with a suitable silicone or water based gel. The anterior member 97 and the posterior member 99 can be formed as flat optical members without any optical power or preferably as plano-convex optical members as shown.

Figure 17 shows a unitary AIOL assembly 110 having a longitudinal axis 111 intended for to co-directional with a human eye's visual axis, and a haptics system 112 integrally formed with the AIOL 91 which thereby effectively acts as the haptics system's main body. The haptics system 112 includes a pair of diametrically opposite C-shaped elongated haptics 113 extending from its AIOL 91 in opposite directions in a plane perpendicular to the longitudinal axis 111 in a similar manner to the haptics system 32. In this case, the haptics 113 have regions 114 impregnated with radiation sensitive bio-compatible materials such as IR sensitive indocyanine green (ICG), and the like, such that they are capable of being plastically deformed on heating to a so-called glass transmission temperature to enable post implantation *in situ* axial displacement as illustrated and described in aforesaid WO2005/104994.

Figure 18 show the non-compressed shapes of the optical elements 102 and 103 having a flat surface 104A in a non-compressed state of AIOL 91. Figure 19 shows the optical element 103 bulging into the optical element 102 to create a curved surface 104B on applying a compression force F against the trailing surface 101 in the direction of the anterior member 97 on retaining the ring 94 in a fixed position which in turn causes the optical element 102 to expand in an anterior direction for distancing the anterior member 97 away from the ring 94. The optical element 103 bulges more into the optical element 102 with a greater compression force whereby the AIOL 91 has a continuously variable Diopter strength from a minimum Diopter strength suitable for distance vision and a maximum Diopter strength suitable for near vision.

The optical element 102 preferably has a refractive index n2 which is greater than the optical element's refractive index n1 whereby the curved surface 104B acts as a concave lens with a negative optical power such that the AIOL 91 is suitable for near vision in its non-compressed state (see Figures 18 and 20) and distance vision in its compressed state (see Figures 19 and 21). The AIOL 91 can be engineered to produce very high negative refractive power in its compressed state so that a subject's eye will have a total negative power on application of a compression force F. In this case, a subject can wear spectacles with positive lenses whereby the subject's eye and his spectacles constitute a Gallilean telescope enabling him to see far objects in a magnified fashion.

Figures 22-24 show a discrete AIOL 120 suitable for use in the haptics system 32 for self-anchoring implantation in a human eye's annular ciliary sulcus. The AIOL 120 has a longitudinal axis 120A intended to be co-direction with a human eye's visual axis, a cylindrical housing 121 having a leading end 121A fitted with an anterior member 122 and a trailing end 121B fitted with a piston 123 reciprocal with respect to the housing 121. The housing 121 is formed from a suitable rigid bio-compatible transparent material, for example, PMMA, and the like. The anterior member 122 is formed with a pair of clamp members 124 for snap fit insertion in a pair of apertures 126 formed in the housing 121. The piston 123 is formed with a pair of keys 127 for insertion in a pair of keyways 128 formed in a trailing surface 129 of the housing 121. Quarter turn rotation of the piston 123 in the housing 121 prevents the piston 123 from being disengaged from the housing 121 but enables reciprocation with respect thereto. The housing 121 is provided with peripheral apertures 131 relative to the longitudinal axis 120A and an annular flange 132 deployed between the trailing surface 129 and the apertures 131 (see Figures 23 and 24). Preferably both the anterior member 122 and the piston 123 have positive optical power or alternatively only one of them has positive optical power as in the case of the plano-convex anterior member 122 and the flat piston 123.

The housing 121 houses a pair of shape memory disc-like optical elements 133 and 134 in a similar fashion as the AIOL 91 insofar that the optical elements 133 and 134 have a flat surface 136A in a compressed state of the AIOL 120 (see Figure 23) and a curved surface 136B in its compressed state (see Figure 24). Figure 24 shows the optical element 134 bulging into the optical element 133 which in turn causes the optical element 133 to bulge radially through the apertures 131. In the case that the optical element 133 has a greater refractive index than the optical element 134, the curved surface 136B acts as a concave lens such that the AIOL 120 is suitable for near vision in its non-compressed state (see Figure 23) and distance vision in its compressed state (see Figure 24). The leading end 121A is formed with lugs 137 for traveling along the stepped tracks 52. The anterior member 122 is formed with blind manipulation notches 138 (not shown) for selectively receiving the handheld manipulation tool's tip 38A for enabling *in situ* manipulation of the AIOL 120.

Figures 25-28 show a discrete AIOL 140 suitable for use in the haptics system 32 for self-anchoring implantation in a human eye's annular ciliary sulcus. The AIOL 140 is similar in operation to be AIOL 120 but differs therefrom insofar as it is constructed as a single monolithic structure for facilitating insertion into a subject's eye through a relatively small incision. The AIOL 140 includes a housing 141 having an anterior member 142, a piston member 143 joined to the housing 141 by a flexible membrane 144 enabling reciprocation between a non-compressed state and a compressed state, peripheral apertures 146, and an annular flange 147. The housing 141 houses optical elements 148 and 149 which can be injected therein, and which have a flat surface 151A in the non-compressed state of the AIOL 140 (see Figure 27) and a curved surface 151B in its compressed state (see Figure 28). In the case that the optical element 148 has a greater refractive index than the optical element 149, the curved surface 151B acts as a concave lens such that the AIOL 140 is suitable for near vision in its non-compressed state (see Figure 27) and distance vision in its compressed state (see Figure 28). The housing 141 is formed with lugs 152 for traveling along the stepped tracks 52. The anterior member 142 is formed with blind manipulation notches 153 for selectively receiving the handheld manipulation tool's tip 38A for enabling *in situ* manipulation of the AIOL 140.

Figures 29 and 30 show a discrete AIOL 170 suitable for use in the haptics system 32 for self-anchoring implantation in a human eye's annular ciliary sulcus. The AIOL 170 includes a cup-shaped housing 171 with an anterior member 172 and a trailing tubular piston 173 reciprocal between a most extended position (see Figure 29) and a most compressed position (see Figure 30). The housing 171 houses a shape memory optical element 174 resiliently elastically deformable between a non-compressed disc-like shape (see Figure 29), and a compressed shape bulging into the piston 173 in a posterior direction on application of a compression force F (see Figure 30). The housing 171 is formed from a suitable rigid bio-compatible material, for example, PMMA, and the like. The optical element 174 is typically constituted by a suitable silicone or water based gel having a refractive index greater than the refractive index of a human eye's aqueous humor such that the AIOL 170 is suitable for distance vision in its non-compressed state (see Figure 29) and near vision in its compressed state (see Figure 30).

Figure 31 shows a discrete AIOL 180 suitable for use in the haptics system 32 for self-anchoring implantation in a human eye's annular ciliary sulcus. The AIOL 180 includes a cup-shaped housing 181 with an anterior member 182 having a central aperture 183, a shape memory disc-like optical element 184, and a semi-spherical posterior member 186. The optical element 184 is resiliently elastically deformable between its natural disc-like shape and bulging through the aperture 183 on application of a compression force F. The housing 181 is formed from a suitable rigid bio-compatible material, for example, PMMA, and the like. The optical element 184 is typically constituted by a suitable silicone or water based gel having a refractive index greater than the refractive index of a human eye's aqueous humor whereupon such that the AIOL 180 is suitable for distance vision in its natural state and near vision in its compressed state.

Figure 32 shows a discrete AIOL 190 suitable for use in a haptics system adapted to be securely fixed in a human eye's annular ciliary sulcus. The AIOL 190 includes a cup-shaped housing 191 with an anterior member 192 and a shape memory spherical optical element 193 resiliently elastically deformable between a natural spherical shape and a flattened shape on application of a compression force F thereagainst in the direction of the anterior member 192. The optical element 193 is typically constituted by a suitable silicone or water based gel having a refractive index greater than the refractive index of a human eye's aqueous humor such that the AIOL 190 is suitable for near vision in its natural state and distance vision in its compressed state.

Figure 33 shows a "push and twist" AIOL assembly 200 similar in construction and operation to the "push and twist" AIOL assembly 31 but differing therefrom insofar that a discrete AIOL 201 is inserted into a discrete haptics system 202 from an anterior direction as opposed to a posterior direction. In this case, the AIOL 201 is provided with a pair of blind manipulation notches 203 for enabling *in situ* manipulation by means of a handheld manipulation tool 36.

Figure 34 shows a "push and twist" AIOL assembly 210 similar in construction and operation to the "push and twist" AIOL assembly 31 but differing therefrom insofar that it has a reverse "push and twist" bayonet arrangement with respect to the "push and twist" bayonet arrangement 34. In other words, the AIOL assembly 210 includes a haptics system 211 and an AIOL 212, and the former is provided with lugs 213 and the latter is formed with two or more equidistant stepped tracks 214. The reverse "push and twist" bayonet arrangement is advantageous over the "push and twist" bayonet arrangement 34 insofar that a discrete AIOL can be formed with an axial length L2 which is greater than a main body's axial length L1 for enabling *in situ* manual selective axial displacement along an adjustment stroke longer than the main body's axial length L1. The AIOL 212 is formed with blind manipulation notches 216 for enabling *in situ* manipulation by means of a handheld manipulation tool 36. The reverse "push and twist" bayonet arrangement can be implemented with an AIOL 212 inserted into a haptics system 211 from either an anterior direction as shown or a posterior direction similar to the "push and twist" bayonet arrangement 34.

Figure 35 shows an AIOL assembly 220 similar to the AIOL assembly 31 but employing a screw thread arrangement 221 instead of the "push and twist" bayonet arrangement 34 for enabling relative movement of a discrete AIOL 222 with respect to a discrete haptics system 223. The AIOL assembly 220 can also be readily implemented to enable an adjustment stroke along a human eye's visual axis longer than a main body's axial length L1. The AIOL 222 is provided with a pair of blind manipulation notches 224 for enabling *in situ* manipulation by means of a handheld manipulation tool 36.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims. The discrete AIOLs 120, 140, 170, and 180 can be readily formed as unitary AIOL assemblies similar to the unitary AIOL assemblies 80 and 110.

Claims:

1. An accommodating intraocular lens (AIOL) assembly for self-anchoring implantation in a human eye having a visual axis, a sclera of tough connective tissue, an annular ciliary sulcus, and a sphincter-like ciliary body for tensioning a capsular diaphragm in an anterior direction along the visual axis on its relaxation from a contracted ciliary body state to a relaxed ciliary body state, the AIOL assembly comprising:

(a) an accommodating intraocular lens (AIOL) having a longitudinal axis intended to be co-directional with the human eye's visual axis, a leading surface, a trailing surface, and at least one shape memory optical element resiliently elastically deformable between a non-compressed shape with a first Diopter strength in a non-compressed state of said AIOL and a compressed shape with a second Diopter strength different than said first Diopter strength in a compressed state of said AIOL whereby said AIOL has a continuously variable Diopter strength between a minimum Diopter strength for distance vision and a maximum Diopter strength for near vision; and

(b) a haptics system having a longitudinal axis intended to be co-directional with the human eye's visual axis, and a main body with at least two elongated haptics extending therefrom in opposite directions in a plane perpendicular to its longitudinal axis, each said haptics having at least one pointed puncturing member for penetrating the tough connective tissue of the human eye's sclera for self-anchoring implantation of said haptics system in the human eye's annular ciliary sulcus at at least two spaced apart stationary anchor points for retaining said AIOL along the human eye's visual axis at an *in situ* manually selectively displaceable desired position therealong relative to said at least two stationary anchor points for urging said trailing surface against the human eye's capsular diaphragm from an anterior direction for determining said AIOL's Diopter strength at said desired position whereupon relaxation of the human eye's ciliary body tensions its capsular diaphragm against said trailing surface from a posterior direction for affecting said AIOL's Diopter strength.

2. The AIOL assembly according to Claim 1 wherein said haptics system is a discrete component for selectively retaining a discrete AIOL therein.

3. The AIOL assembly according to Claim 2 wherein said discrete haptics system and said discrete AIOL have a push and twist bayonet arrangement for enabling stepwise axial displacement of said discrete AIOL at at least two discrete axial stopping positions along the human eye's visual axis relative to said at least spaced apart two stationary anchor points.

4. The AIOL assembly according to Claim 3 wherein said main body has an internal surface with at least two equidistant stepped tracks and said discrete AIOL has a corresponding number of lugs for push and twist travel along their associated stepped tracks.

5. The AIOL assembly according to Claim 2 wherein said discrete haptics system and said discrete AIOL have a screw thread arrangement for enabling continuous axial displacement of said discrete AIOL along the human eye's visual axis relative to said at least two spaced apart stationary anchor points.

6. The AIOL assembly according to any one of Claims 1 to 5 wherein said main body has an axial length L1 along its longitudinal axis and said discrete AIOL has an axial length L2 along its longitudinal axis where L2>L1 for enabling *in situ* manual selective axial displacement of said discrete AIOL along the human eye's visual axis relative to said at least two spaced apart stationary anchor points along an adjustment stroke longer than said discrete haptics system's axial length L1.

7. The AIOL assembly according to any one of Claims 1 to 6 wherein said discrete AIOL is inserted into said discrete haptics system from a posterior direction.

8. The AIOL assembly according to Claim 1 wherein said haptics system is integrally formed with said AIOL acting as said main body and said at least two elongated haptics each have a plastically deformable radiation sensitive region for enabling *in situ* manual selective axial displacement of said AIOL along the human eye's visual axis relative to said at least two spaced apart stationary anchor points.

9. The AIOL assembly according to Claim 8 wherein said radiation sensitive regions are adjacent said AIOL and remote from their respective pointed puncturing members.

10. The AIOL assembly according to any one of Claims 1 to 9 wherein each said haptics has a thin profile in a plane perpendicular to said haptics system's longitudinal axis such that each said haptics is sufficiently flexible for encircling around said main body in said plane perpendicular to its longitudinal axis, and a wide profile along its longitudinal axis such that each said haptics is rigid against a compression force therealong.

11. The AIOL assembly according to Claim 10 wherein said wide profile tapers from a haptics' proximal end adjacent said main body towards its distal end remote therefrom.

12. The AIOL assembly according to any one of Claims 1 to 11 wherein said AIOL includes a hollow flattened sphere shaped housing having an annular anterior member with said leading surface having an internal rim defining an aperture, a posterior member with said trailing surface, and said at least one shape

memory optical element has a leading surface including a central portion exposed through said aperture, and a tubular casing mounted on said housing for reciprocation relative to said posterior member for selectively compressing said at least one shape memory optical element from its non-compressed shape to its compressed shape for bulging into said casing relative to said non-compressed shape whereby said AIOL has a continuously variable Diopter strength from a minimum Diopter strength for distance vision and a maximum Diopter strength for near vision.

13. The AIOL assembly according to any one of Claims 1 to 11 wherein said AIOL includes a housing with an anterior member with a leading surface, a posterior member with a trailing surface, a leading shape memory optical element resiliently elastically deformable between a non-compressed shape in a non-compressed state of the AIOL and a compressed shape in a compressed state of the AIOL, and a trailing shape memory optical element elastically deformable between a non-compressed shape in the AIOL's said non-compressed state and a compressed shape in the AIOL's said compressed state for selectively bulging into said leading shape memory optical element on application of a compression force along said longitudinal axis against said trailing surface from a posterior direction for modifying the shape of said leading shape memory optical element with respect to its non-compressed shape in the AIOL's said non-compressed state.

14. The AIOL assembly according to Claim 13 wherein said housing includes a ring between said leading shape memory optical element and said trailing shape memory optical element, and said leading shape memory optical element and said trailing shape memory optical element each have a bellows-like shape whereupon said leading shape memory bellows-like optical element expands in an anterior direction for distancing said anterior member away from said ring in the AIOL's compressed state.

15. The AIOL assembly according to Claim 13 wherein the AIOL includes a cylindrical housing with at least one peripheral aperture relative to the AIOL's longitudinal axis whereupon said leading shape optical element bulges radially through said at least one peripheral aperture in the AIOL's compressed state.

16. An accommodating intraocular lens (AIOL) for implantation in a human eye having a visual axis, a sclera of tough connective tissue, an annular ciliary sulcus, and a sphincter-like ciliary body for tensioning a capsular diaphragm in an anterior direction along the visual axis on its relaxation from a contracted ciliary body state to a relaxed ciliary body state, the AIOL having a longitudinal axis intended to be deployed co-directional with the human eye's visual axis, the AIOL comprising:

(a) a hollow flattened sphere shaped housing including an annular anterior member with a leading surface having an internal rim defining an aperture, a posterior member with a trailing surface, and a shape memory optical element resiliently elastically deformable between a non-compressed shape with a first Diopter strength in a non-compressed state of the AIOL and a compressed shape with a second Diopter strength different than said first Diopter strength in a compressed state of the AIOL, said at least one shape memory optical element having a leading surface including a central portion exposed through said aperture; and

(b) a tubular casing mounted on said housing for reciprocation relative to said posterior member for selectively compressing said shape memory optical element from its non-compressed shape to its compressed shape for bulging into said casing relative to said non-compressed shape whereby said AIOL has a continuously variable Diopter strength from a minimum Diopter strength for distance vision and a maximum Diopter strength for near vision.

17. The AIOL according to Claim 16 wherein said casing has a leading end and a trailing end formed with a groove for receiving said internal rim whereupon said casing is reciprocal with respect to said posterior member.

18. The AIOL according to either Claim 16 or 17 wherein said housing has a diameter of at least 6mm and said casing has a diameter of at least 4mm in a plane perpendicular to said longitudinal axis.

19. An accommodating intraocular lens (AIOL) assembly comprising:

(a) an AIOL according to any one of Claims 16 to 18; and

(b) a haptics system having a longitudinal axis intended to be deployed co-directional with the human eye's visual axis and a main body with at least two elongated haptics extending therefrom in a plane perpendicular to said haptics system's longitudinal axis, each haptics having at least one pointed puncturing member for penetrating the tough connective tissue of the human eye's sclera for self-anchoring implantation of said haptics system in the human eye's annular ciliary sulcus at at least two spaced apart stationary anchor points for retaining said AIOL at a manually selected axial position along the human eye's visual axis whereupon relaxation of the human eye's ciliary body from its constricted ciliary body state to its relaxed ciliary body state tensions its capsular diaphragm for applying a compression force against said trailing surface along the direction of the human eye's visual axis from a posterior direction for compressing said AIOL from its non-compressed state to its compressed state.

20. The AIOL assembly according to Claim 19 wherein said haptics system is a discrete component for selectively retaining a discrete AIOL therein.

21. The AIOL assembly according to Claim 20 wherein said discrete haptics system and said discrete AIOL have a push and twist bayonet arrangement for enabling stepwise axial displacement of said discrete AIOL at at least two

discrete axial stopping positions along the human eye's visual axis relative to said at least two spaced apart stationary anchor points.

22. The AIOL assembly according to Claim 21 wherein said main body has an internal surface with at least two equidistant stepped tracks and said discrete AIOL has a corresponding number of lugs for push and twist travel along their associated stepped tracks.

23. The AIOL assembly according to Claim 20 wherein said discrete haptics system and said discrete AIOL have a screw thread arrangement for enabling continuous axial displacement of said discrete AIOL along the human eye's visual axis relative to said at least two spaced apart stationary anchor points.

24. The AIOL assembly according to any one of Claims 20 to 23 wherein said main body has an axial length L1 along its longitudinal axis and said discrete AIOL has an axial length L2 along its longitudinal axis where L2>L1 for enabling *in situ* manual selective axial displacement of said discrete AIOL along the human eye's visual axis relative to said at least two spaced apart stationary anchor points along an adjustment stroke longer than said discrete haptics system's axial length L1.

25. The AIOL assembly according to any one of Claims 20 to 24 wherein said discrete AIOL is inserted into said discrete haptics system from a posterior direction.

26. The AIOL assembly according to Claim 19 wherein said haptics system is integrally formed with said AIOL acting as said main body and said at least elongated two haptics each have a plastically deformable radiation sensitive region for enabling *in situ* manual selective axial displacement of said AIOL

along the human eye's visual axis relative to said at least two spaced apart stationary anchor points.

27. The AIOL assembly according to Claim 26 wherein said radiation sensitive regions are adjacent said AIOL and remote from their respective pointed puncturing members.

28. The AIOL assembly according to any one of Claims 19 to 26 wherein each said haptics has a thin profile in a plane perpendicular to said haptics system's longitudinal axis such that each said haptics is sufficiently flexible for encircling around said main body in said plane perpendicular to said haptics system's longitudinal axis, and a wide profile along said haptics system's longitudinal axis such that each said haptics is rigid against a compression force therealong.

29. The AIOL assembly according to Claim 28 wherein said wide profile tapers from a haptics' proximal end adjacent said main body towards its distal end remote therefrom.

30. An accommodating intraocular lens (AIOL) for implantation in a human eye having a visual axis, a sclera of tough connective tissue, an annular ciliary sulcus, and a sphincter-like ciliary body for tensioning a capsular diaphragm in an anterior direction along the visual axis on its relaxation from a contracted ciliary body state to a relaxed ciliary body state, the AIOL having a longitudinal axis intended to be deployed co-directional with the human eye's visual axis,

the AIOL comprising a housing including an anterior member with a leading surface, a posterior member with a trailing surface, a leading shape memory optical element adjacent said anterior member and resiliently elastically deformable between a non-compressed shape in a non-compressed state of the AIOL and a compressed shape in a compressed state of the AIOL, and a trailing shape memory optical element adjacent said posterior member and elastically deformable between a non-compressed shape in the AIOL's said non-compressed state and a compressed shape in the AIOL's said compressed state for selectively bulging into said leading shape memory optical element on application of a compression force along said longitudinal axis against said trailing surface from a posterior direction for modifying the shape of said leading shape memory optical element with respect to its non-compressed shape in the AIOL's said non-compressed state.

31. The AIOL according to Claim 30 wherein said housing includes a ring between said leading shape memory optical element and said trailing shape memory optical element, and said leading shape memory optical element and said trailing shape memory optical element each have a bellows-like shape whereupon said leading shape memory bellows-like optical element expands in an anterior direction for distancing said anterior member away from said ring in the AIOL's compressed state.

32. The AIOL according to Claim 30 wherein said housing includes at least one peripheral aperture relative to the AIOL's longitudinal axis whereupon said leading shape optical element bulges radially through said at least one peripheral aperture in the AIOL's compressed state.

33. An accommodating intraocular lens (AIOL) assembly comprising:

(a) an AIOL according to any one of Claims 30 to 32; and

(b) a haptics system having a longitudinal axis intended to be deployed co-directional with the human eye's visual axis and a main body with at least two elongated haptics extending therefrom in a plane perpendicular to said haptics system's longitudinal axis, each haptics having at least one pointed puncturing member for penetrating the tough connective tissue of the human eye's sclera for self-anchoring implantation of said haptics system in the human eye's annular ciliary sulcus at at least two spaced apart stationary anchor points for retaining said AIOL at a manually selected axial position along the human eye's visual axis whereupon relaxation of the human eye's ciliary body from its constricted ciliary body state to its relaxed ciliary body state tensions its capsular diaphragm for applying a compression force against said trailing surface along the direction of the human eye's visual axis from a posterior direction for compressing said AIOL from its non-compressed state to its compressed state.

34. The AIOL assembly according to Claim 33 wherein said haptics system is a discrete component for selectively retaining a discrete AIOL therein.

35. The AIOL assembly according to Claim 34 wherein said discrete haptics system and said discrete AIOL have a push and twist bayonet arrangement for enabling stepwise axial displacement of said discrete AIOL at at least two discrete axial stopping positions along the human eye's visual axis relative to said at least two spaced apart stationary anchor points.

36. The AIOL assembly according to Claim 35 wherein said main body has an internal surface with at least two equidistant stepped tracks and said discrete AIOL has a corresponding number of lugs for push and twist travel along their associated stepped tracks.

37. The AIOL assembly according to Claim 34 wherein said discrete haptics system and said discrete AIOL have a screw thread arrangement for enabling continuous axial displacement of said discrete AIOL along the human eye's visual axis relative to said at least two spaced apart stationary anchor points.

38. The AIOL assembly according to any one of Claims 34 to 37 wherein said main body has an axial length L1 along its longitudinal axis and said discrete AIOL has an axial length L2 along its longitudinal axis where L2>L1 for enabling *in situ* manual selective axial displacement of said discrete AIOL along

the human eye's visual axis relative to said at least two spaced apart stationary anchor points along an adjustment stroke longer than said main body's axial length L1.

39. The AIOL assembly according to any one of Claims 34 to 38 wherein said discrete AIOL is inserted into said discrete haptics system from a posterior direction.

40. The AIOL assembly according to Claim 33 wherein said haptics system is integrally formed with said AIOL acting as said main body and said at least two haptics each have a plastically deformable radiation sensitive region for enabling *in situ* manual selective axial displacement of said AIOL along the human eye's visual axis relative to said at least two spaced apart stationary anchor points.

41. The AIOL assembly according to Claim 40 wherein said radiation sensitive regions are adjacent said AIOL and remote from their respective pointed puncturing members.

42. The AIOL assembly according to any one of Claims 33 to 41 wherein each said haptics has a thin profile in a plane perpendicular to said haptics system's longitudinal axis such that each said haptics is sufficiently flexible for encircling around said main body in said plane perpendicular to said haptics system's longitudinal axis, and a wide profile along said haptics system's longitudinal axis such that each said haptics is rigid against a compression force therealong.

43. The AIOL assembly according to Claim 42 wherein said wide profile tapers from a haptics' proximal end adjacent said main body towards its distal end remote therefrom.

44. A haptics system for retaining an intraocular lens in a human eye having a visual axis and including a sclera of tough connective tissue, and an annular ciliary sulcus, the haptics system having a longitudinal axis intended to be co-directional with the human eye's visual axis, the haptics system comprising a main body with at least two elongated haptics extending therefrom in opposite directions in a plane perpendicular to the longitudinal axis, each haptics having an attachment plate with at least two pointed puncturing members each terminating at a tip for penetrating the tough connective tissue of the human eye's sclera for self-anchoring implantation of the haptics system in the human eye's annular ciliary sulcus at at least two spaced apart stationary anchor points, said at least two pointed puncturing members having a minimum tip separation between their tips of at least 1mm in said plane perpendicular to said longitudinal axis.

45. The haptics system according to Claim 44 wherein said tip separation is between about 2mm and about 3mm.

46. The haptics system according to either Claim 44 or 45 wherein said attachment member has a bifurcated shape including a central narrow juncture between a pair of spaced apart pointed puncturing members for enabling a minimum penetration of at least 0.5mm on abutment against a human eye's sclera on self-anchoring implantation of the haptics system in the human eye's annular ciliary sulcus.

47. The haptics system according to any one of Claims 44 to 46 for use with a handheld manipulation tool including an elongated handle having a tip wherein said attachment plate includes a manipulation aperture accessible from an anterior direction for selectively receiving the manipulation tool's tip for enabling *in situ* manipulation of said attachment plate.

48. The haptics system according to any one of Claims 44 to 47 and integrally formed with an AIOL having a hollow flattened sphere shaped housing having an annular anterior member with said leading surface having an internal rim defining an aperture, a posterior member with said trailing surface, and said at least one shape memory optical element has a leading surface including a central portion exposed through said aperture; and a tubular casing mounted on said housing for reciprocation relative to said posterior member for selectively compressing said at least one shape memory optical element from its non-compressed shape to its compressed shape for bulging into said casing relative to said non-compressed shape whereby said AIOL has a continuously variable Diopter strength from a minimum Diopter strength for distance vision and a maximum Diopter strength for near vision.

49. The haptics system according to any one of Claims 44 to 47 and integrally formed with an AIOL having a housing with an anterior member with a leading surface, a posterior member with a trailing surface, a leading shape memory optical element resiliently elastically deformable between a non-compressed shape in a non-compressed state of the AIOL and a compressed shape in a compressed state of the AIOL, and a trailing shape memory optical element elastically deformable between a non-compressed shape in the AIOL's said non-compressed state and a compressed shape in the AIOL's said compressed state for selectively bulging into said leading shape memory optical element on application of a compression force along said longitudinal axis against said trailing surface from a posterior direction for modifying the shape of said leading shape memory optical element with respect to its non-compressed shape in the AIOL's said non-compressed state.

50. The haptics system according to Claim 49 wherein said housing includes a ring between said leading shape memory optical element and said trailing shape memory optical element, and said leading shape memory optical element and said

trailing shape memory optical element each have a bellows-like shape whereupon said leading shape memory bellows-like optical element expands in an anterior direction for distancing said anterior member away from said ring in the AIOL's compressed state.

51. The haptics system according to Claim 49 wherein said housing includes at least one peripheral aperture relative to the AIOL's longitudinal axis whereupon said leading shape optical element bulges radially through said at least one peripheral aperture in the AIOL's compressed state.

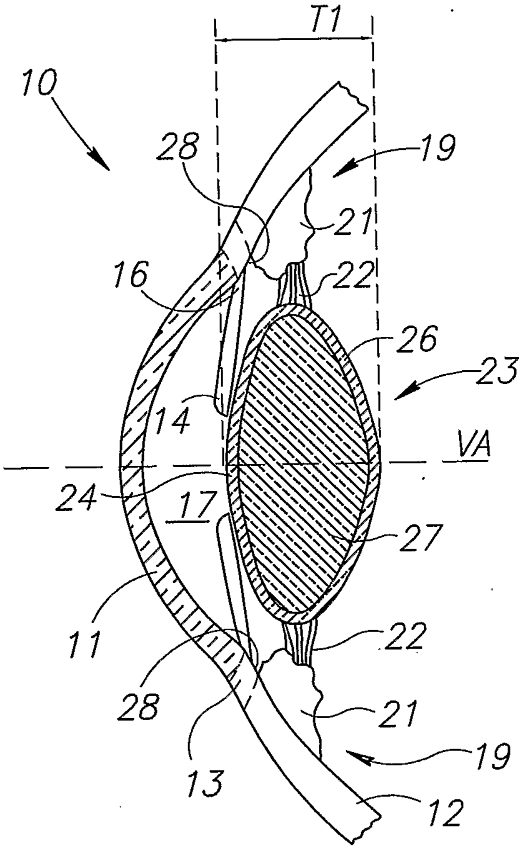
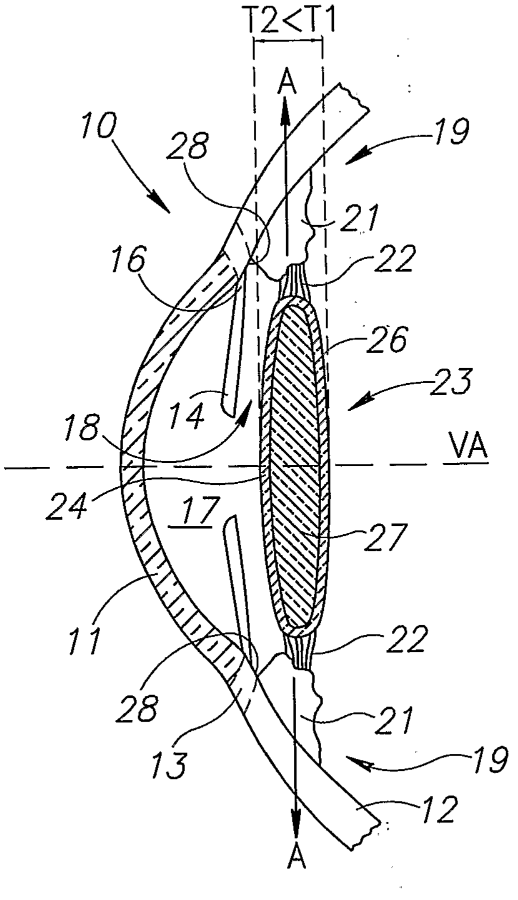

T1
10
28
19
21
22
16
26
23
14
VA
24
17
27
11
22
28
21
19
13
12

FIG.1


T2<T1
A
10
28
19
21
22
16
26
23
18
14
VA
24
17
27
11
22
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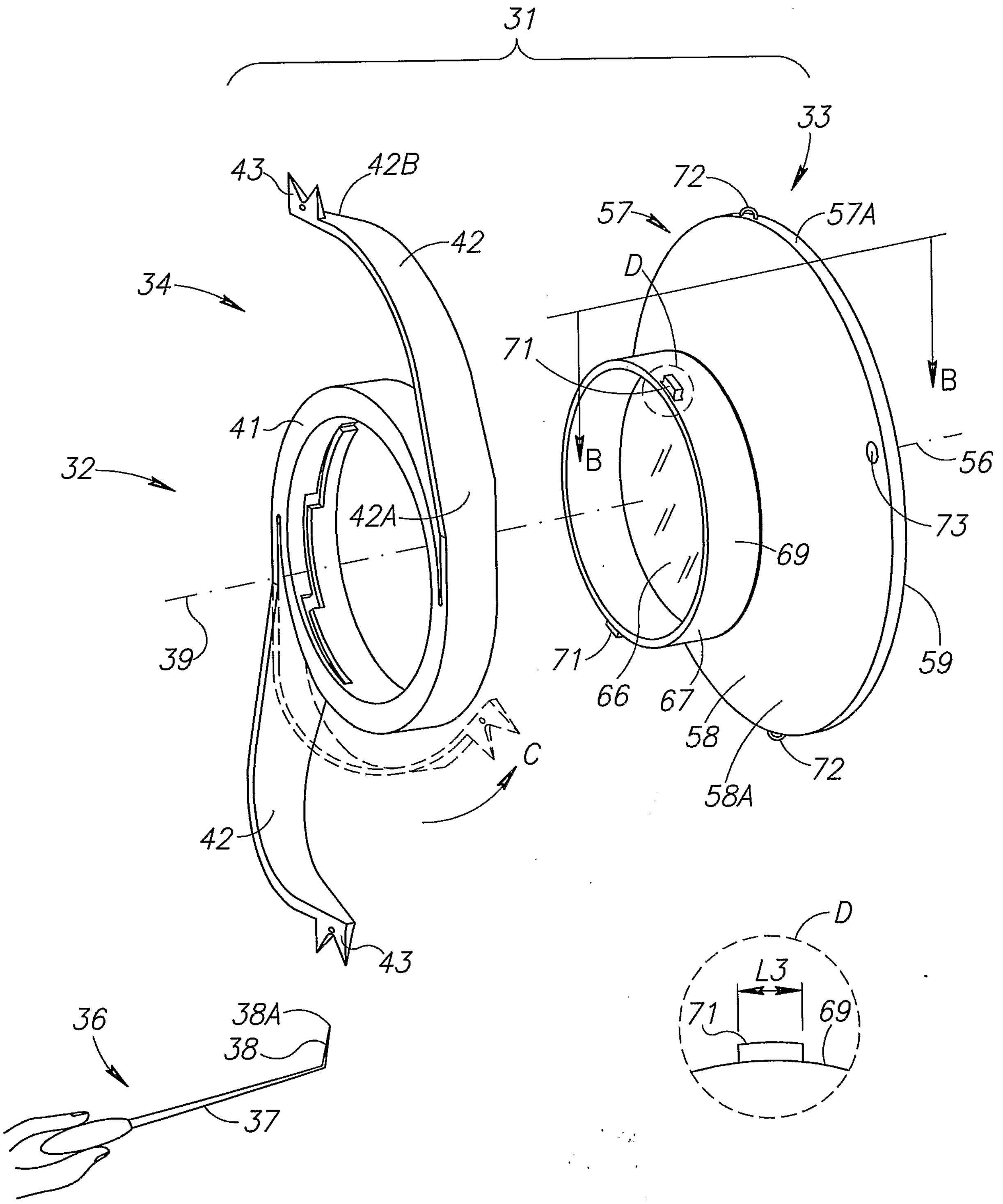
13
19
12
A

FIG.2


31
33
43
42B
72
57
57A
42
D
34
71
B
B
41
56
32
42A
73
69
39
71
59
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L3
36
38A
71
69
38
37

FIG.3

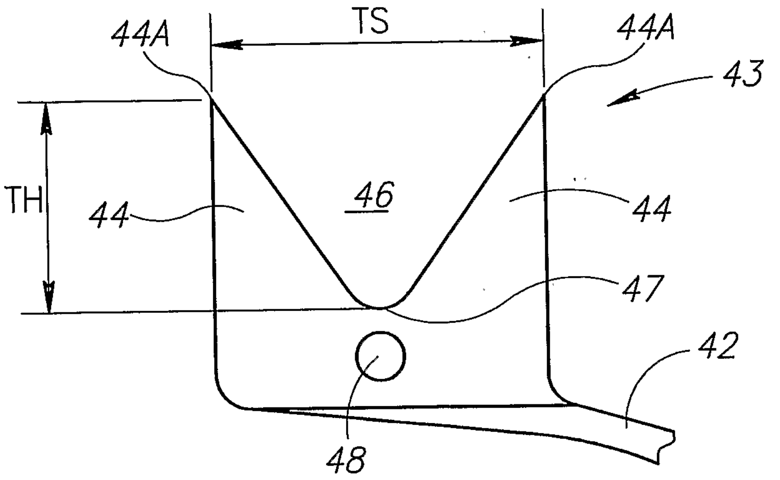

TS
44A
44A
43
TH
44
46
44
47
42
48

FIG.4

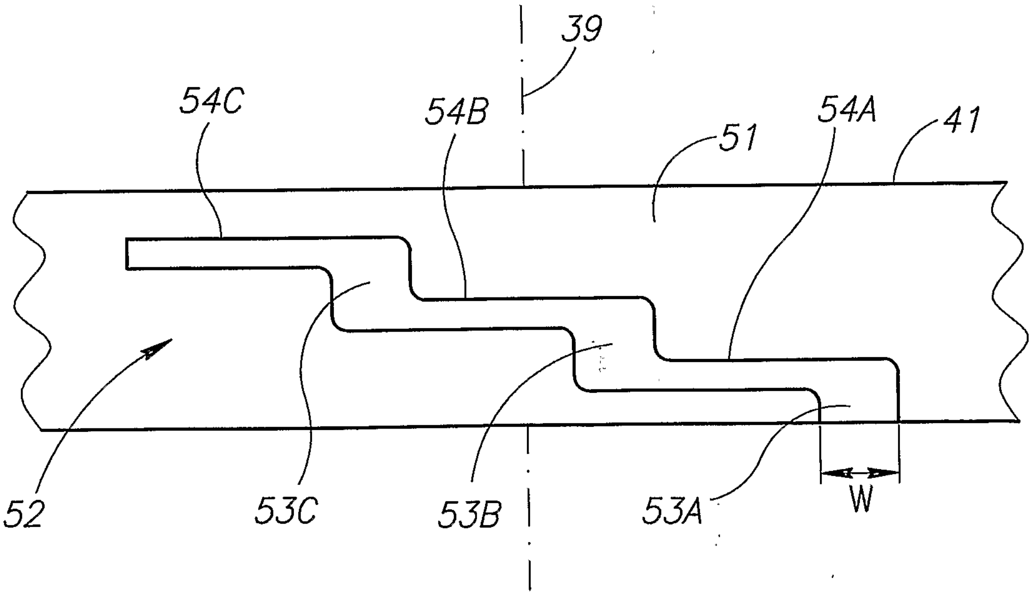

39
54C
54B
51
54A
41
52
53C
53B
53A
W

FIG.5

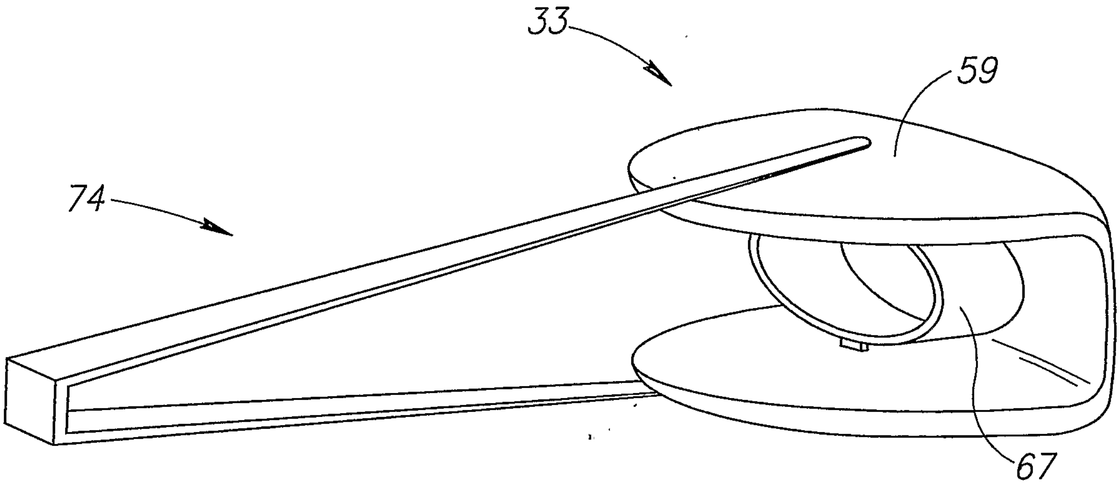


FIG.6

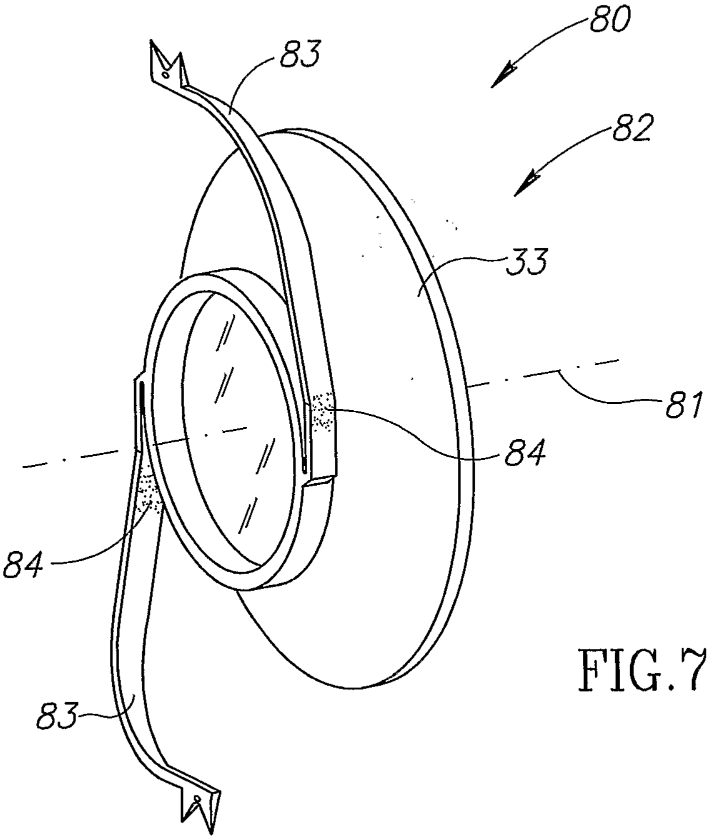
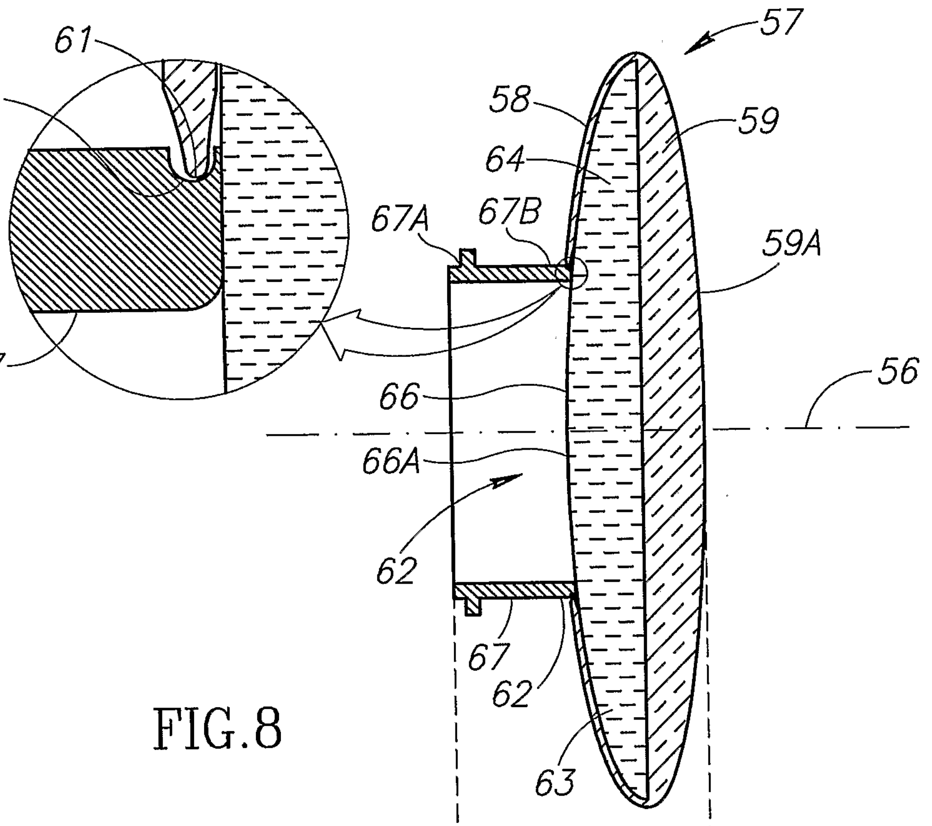


FIG.7


57
61
68
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67A
67B
59A
67
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66A
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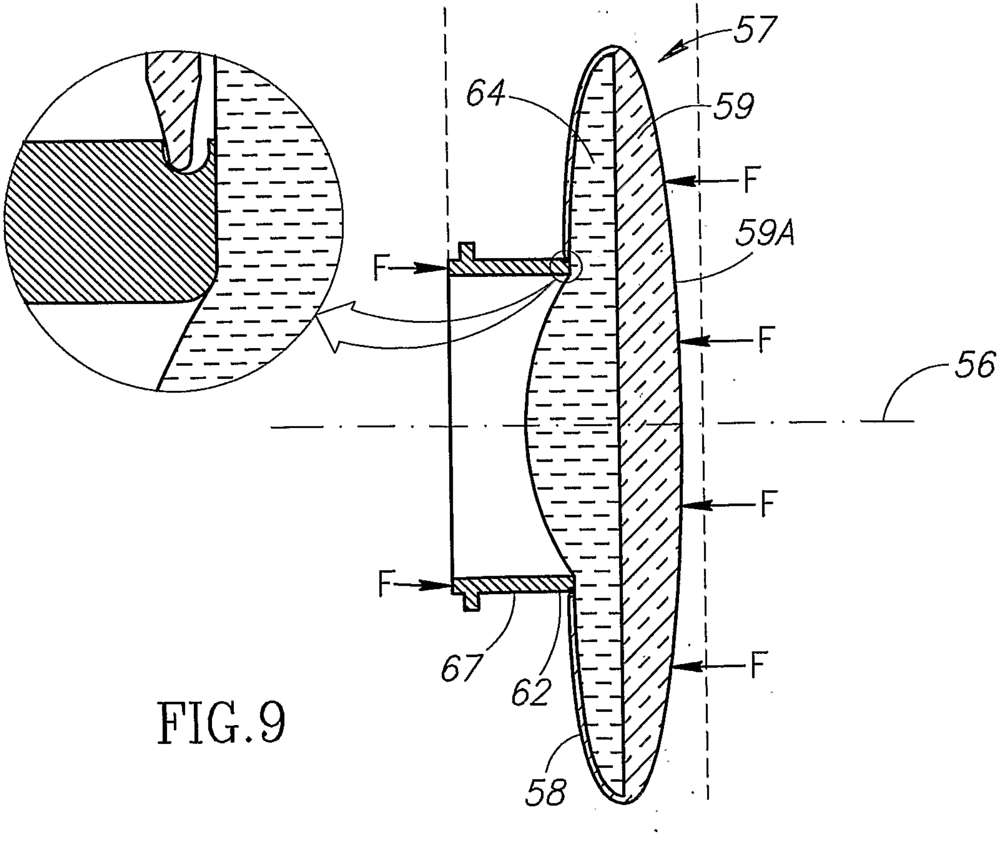
FIG.8


57
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59A
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F
56
F
F
F
67
62
58

FIG.9

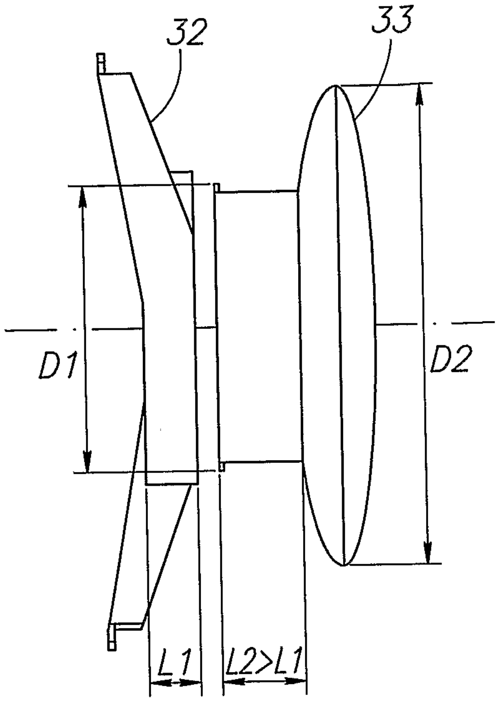


FIG.10

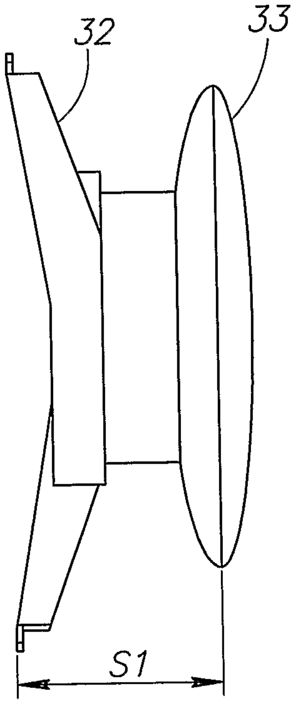


FIG.11

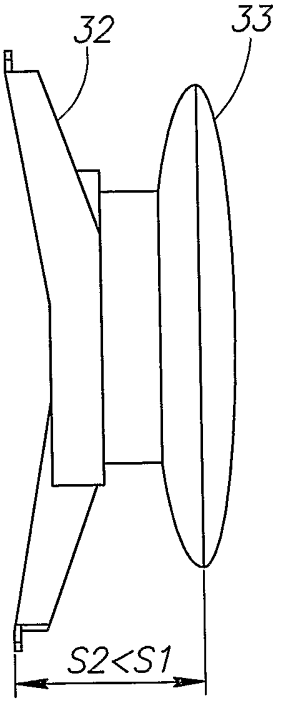


FIG.12

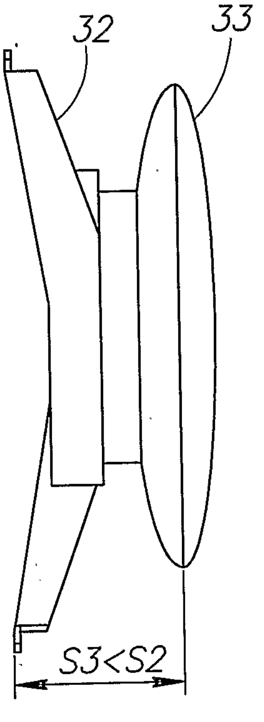


FIG.13

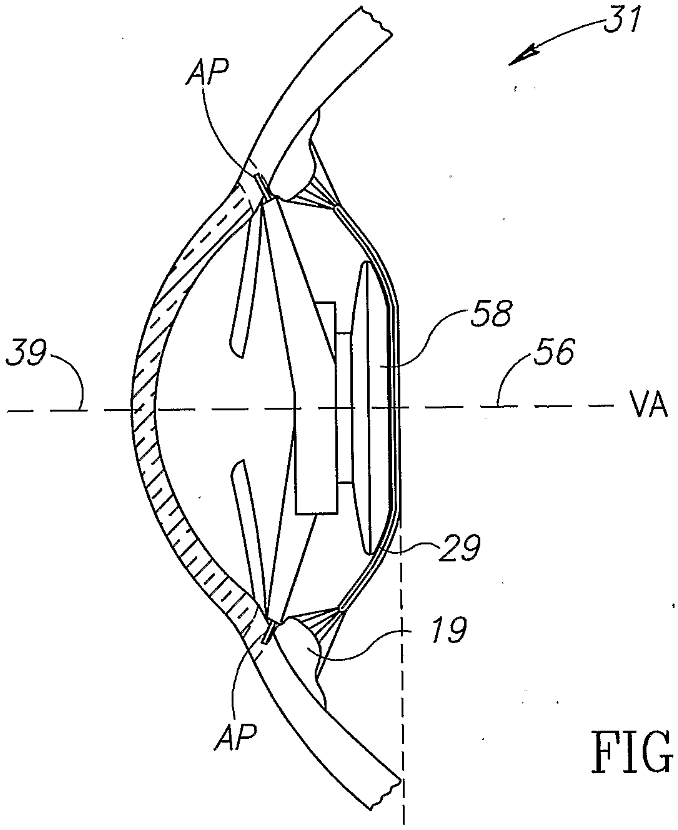


FIG.14

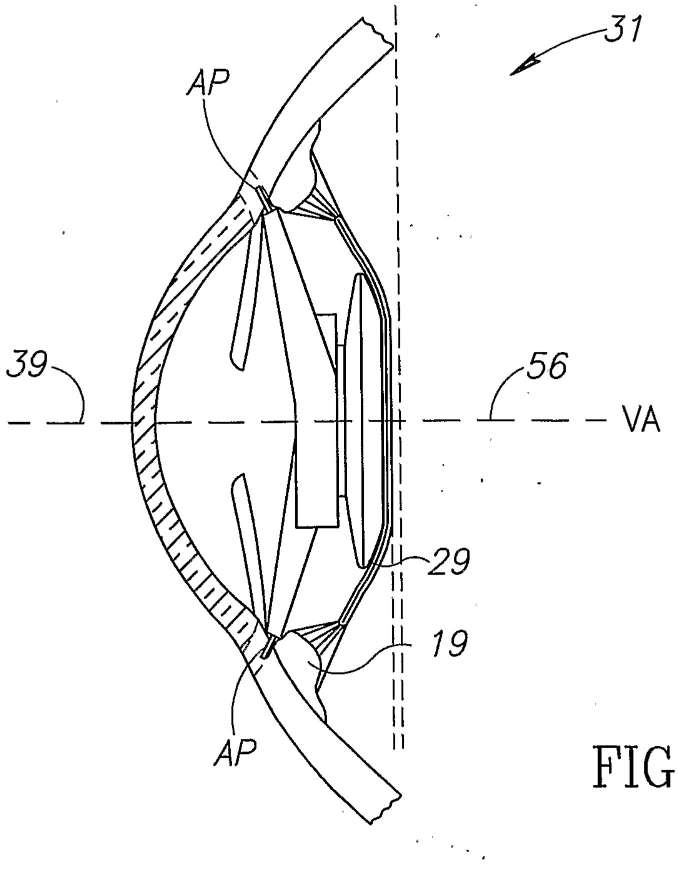
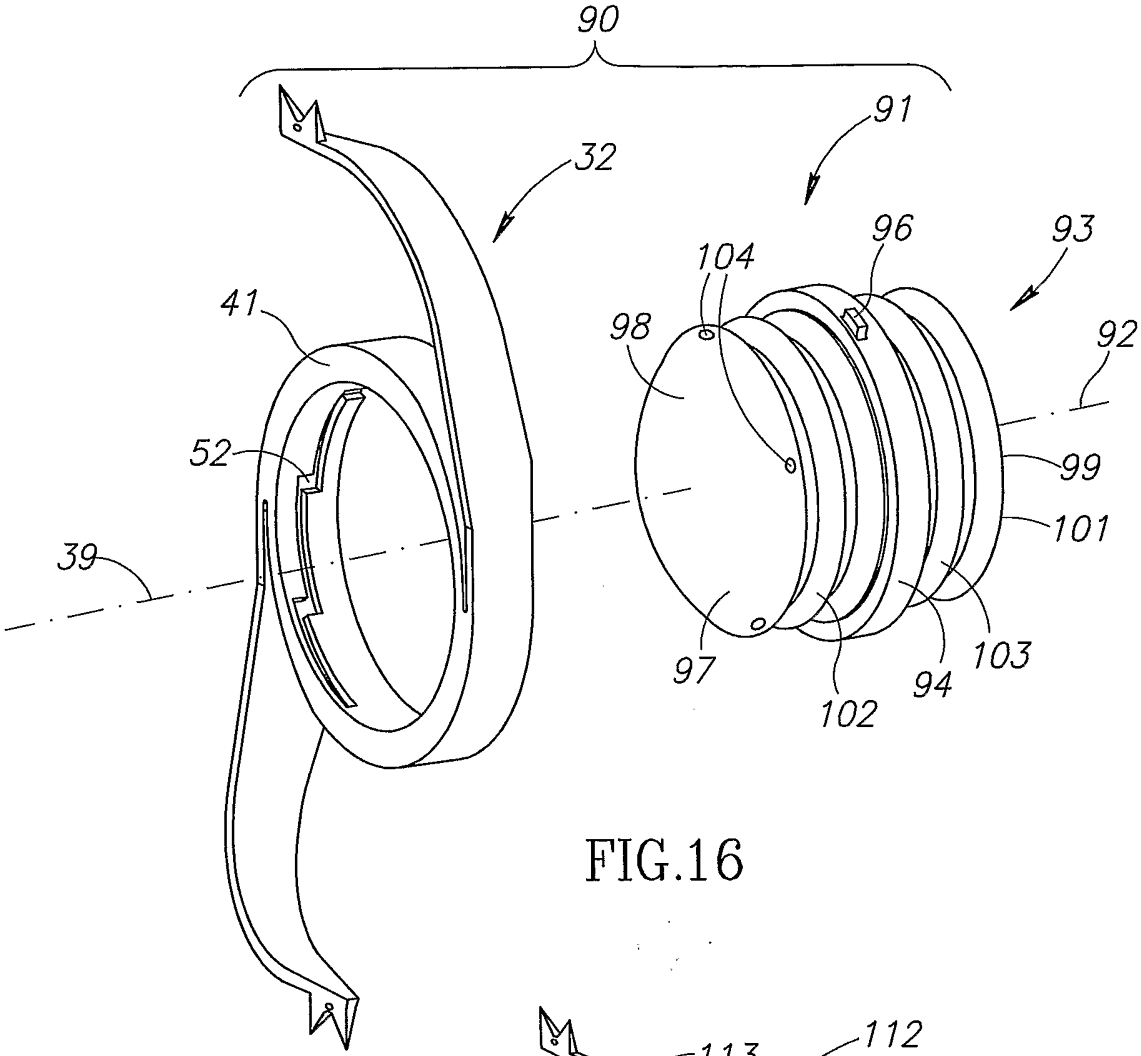


FIG.15


90
91
32
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104
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102

FIG.16

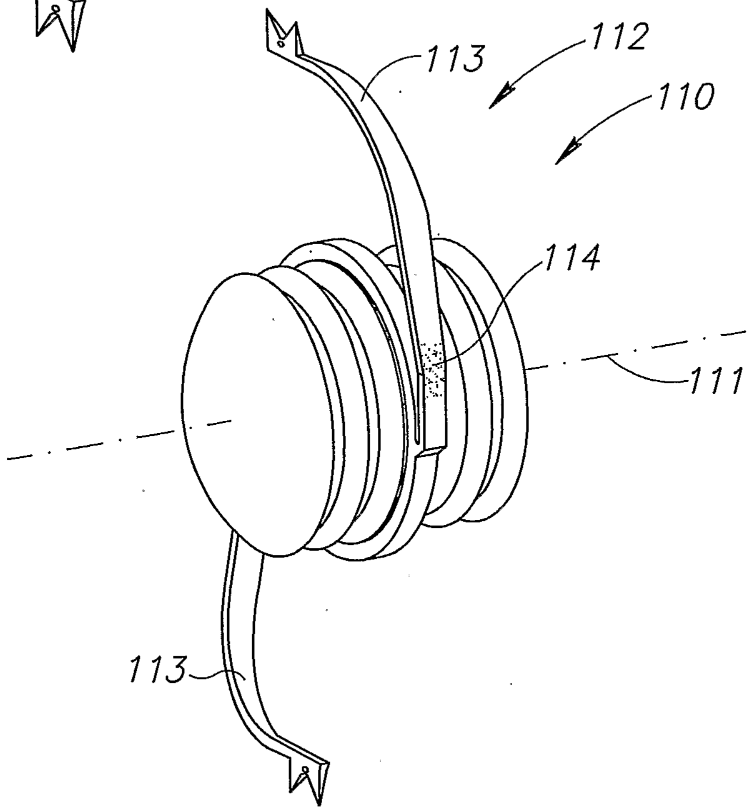

113
112
110
114
111
113

FIG.17

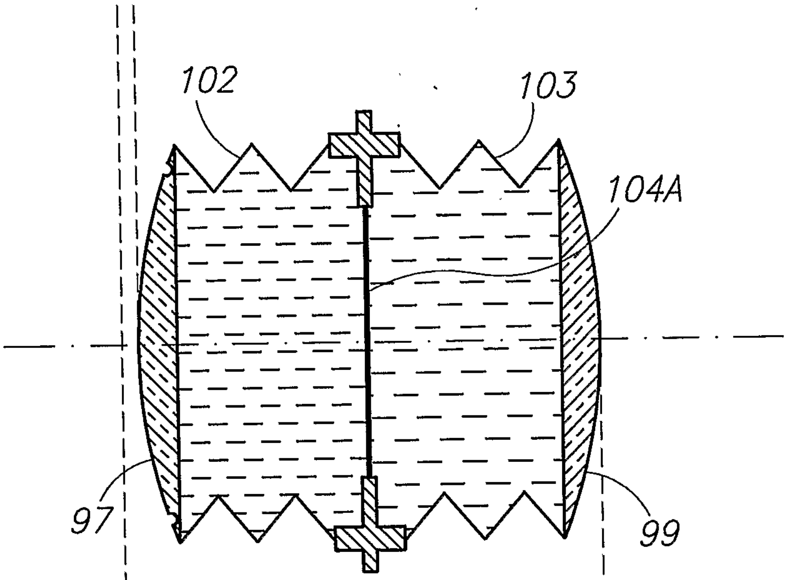


FIG.18

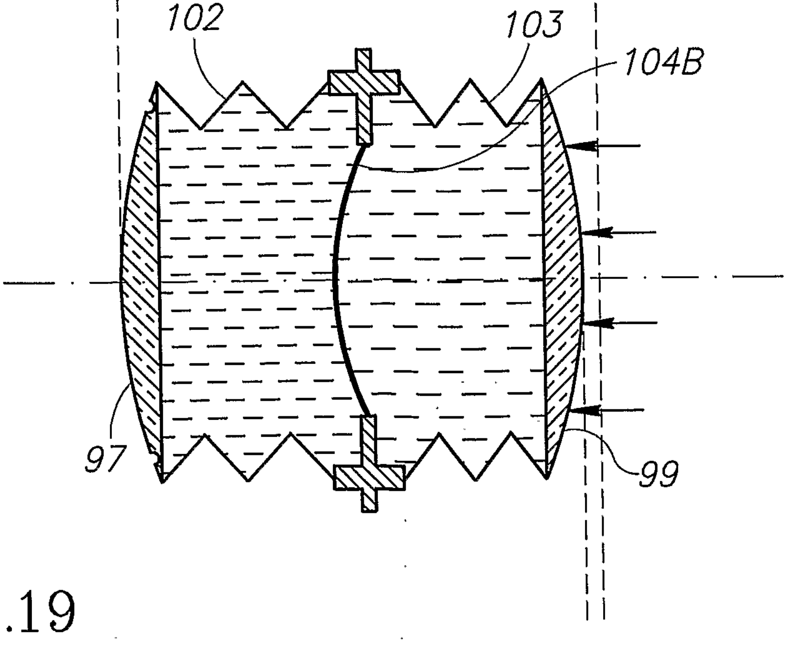


FIG.19

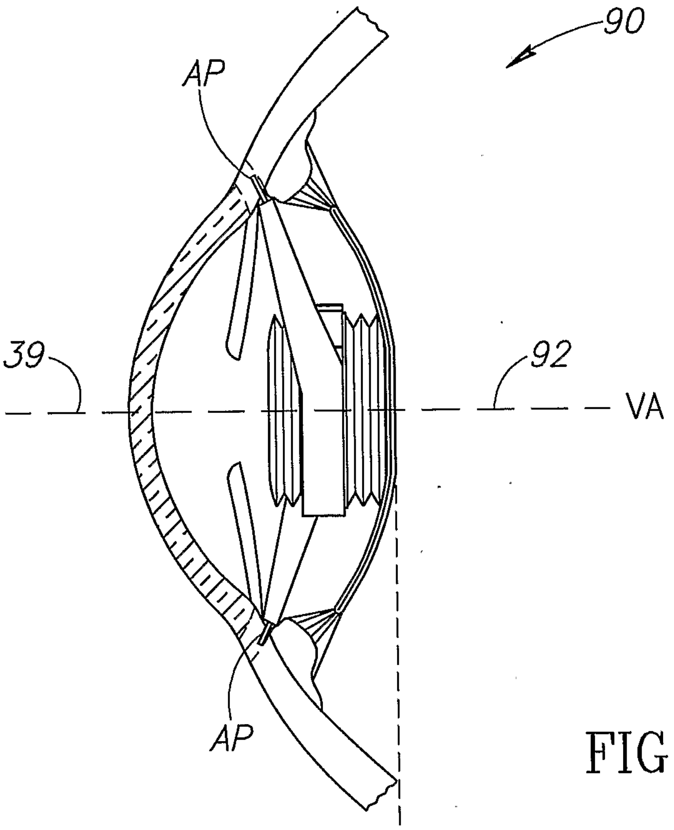


FIG.20

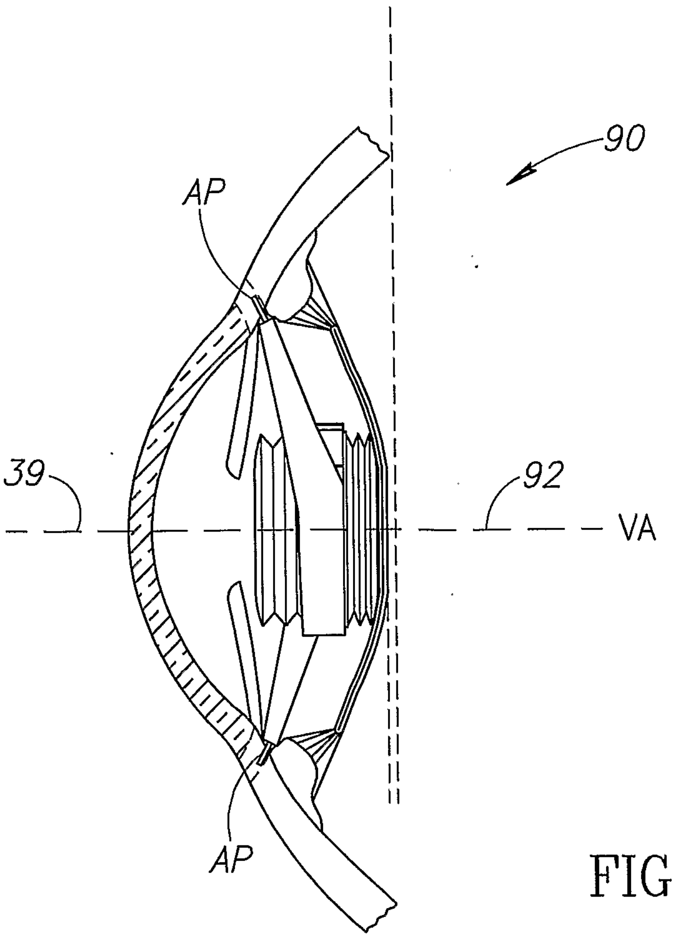
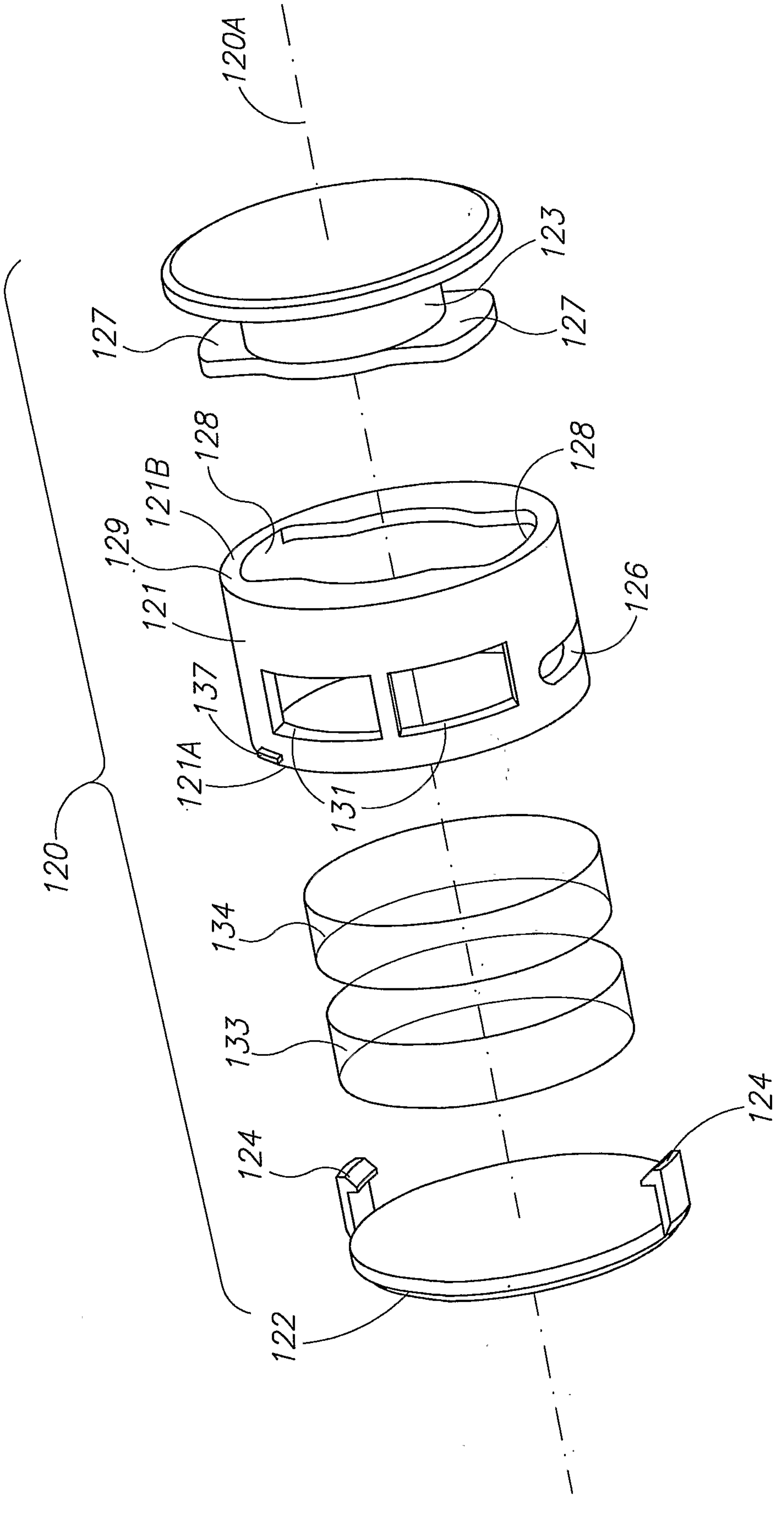


FIG.21


120A
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121B
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121A
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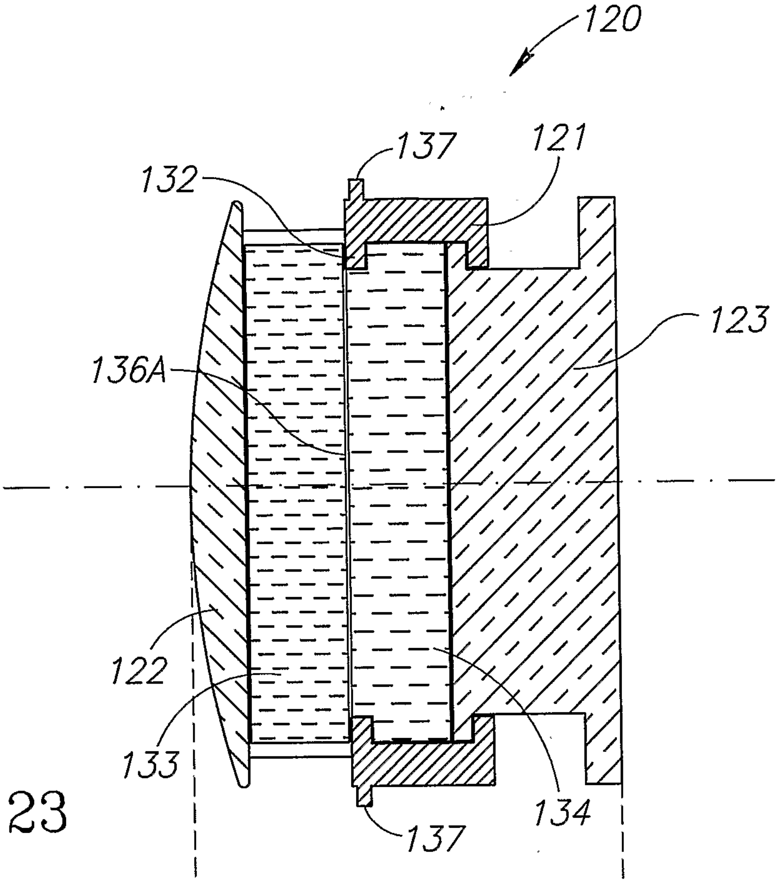
FIG.22


120
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136A
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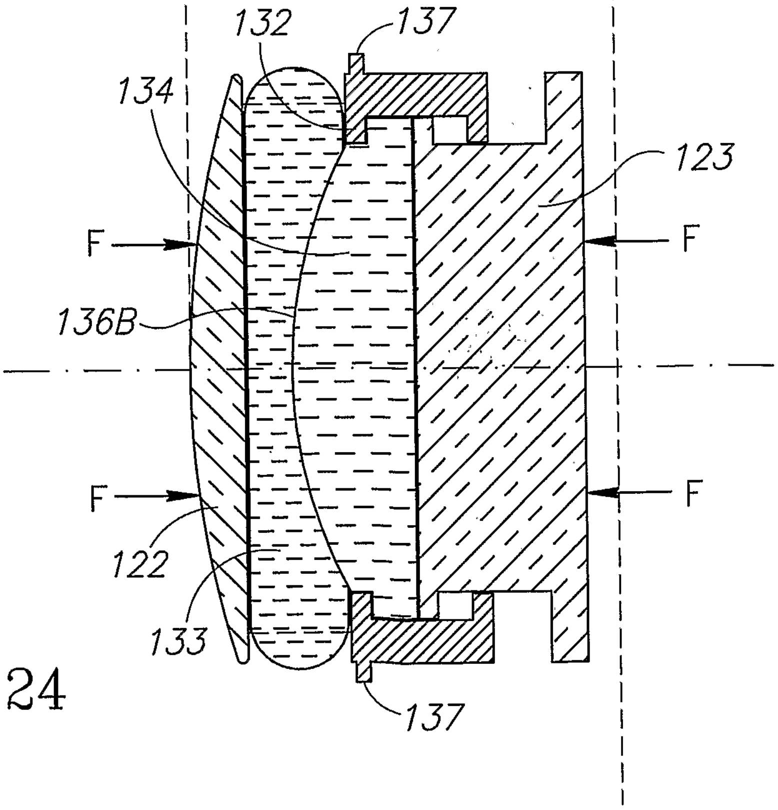
134
137

FIG.23


132
137
134
123
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136B
F
F
122
133
137

FIG.24

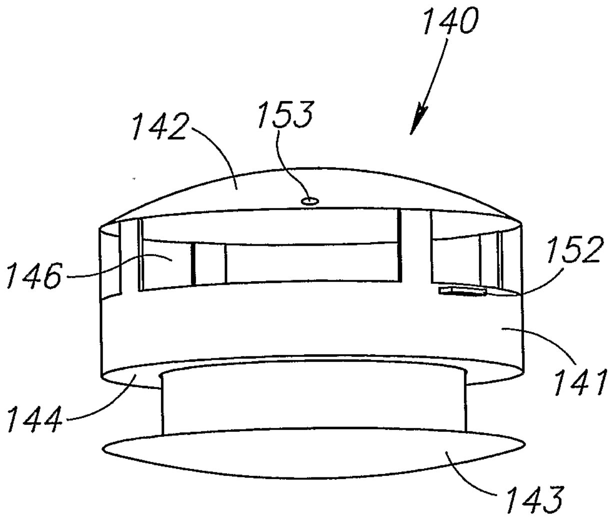

FIG.25

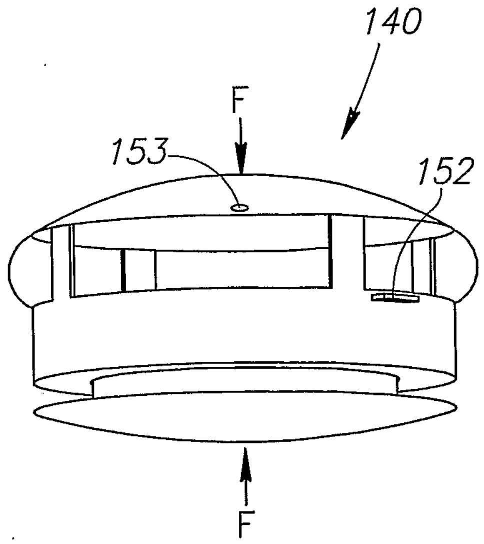

FIG.26

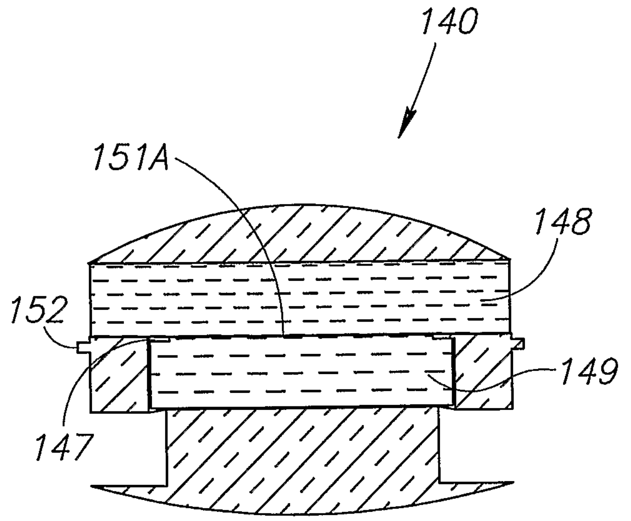

FIG.27

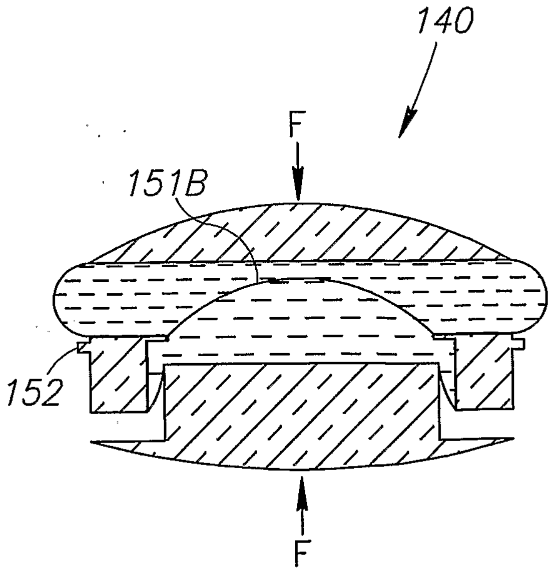

FIG.28

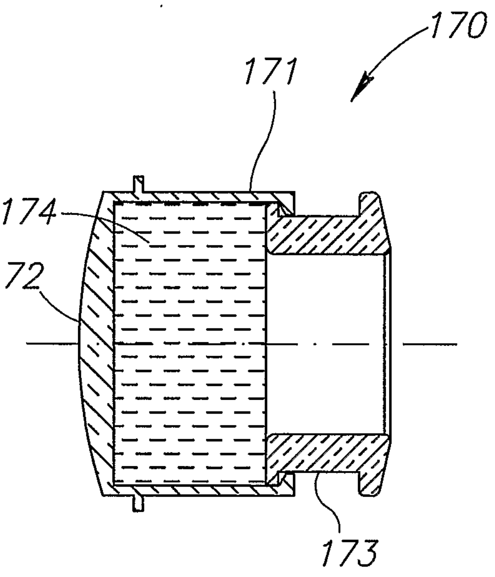

FIG.29

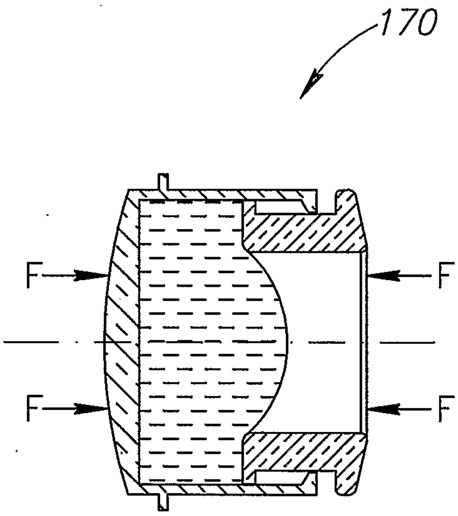

FIG.30

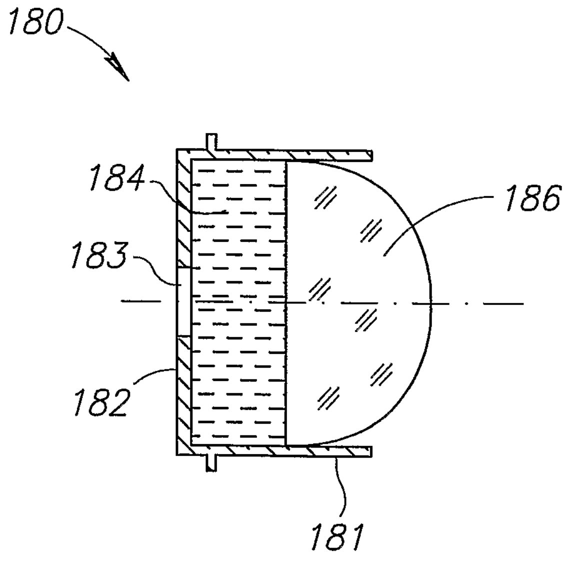

FIG.31

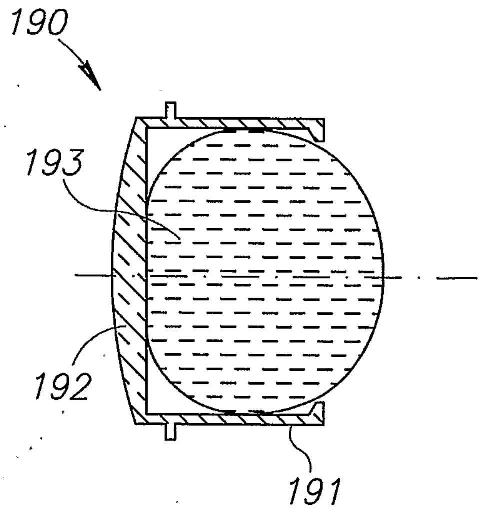

FIG.32

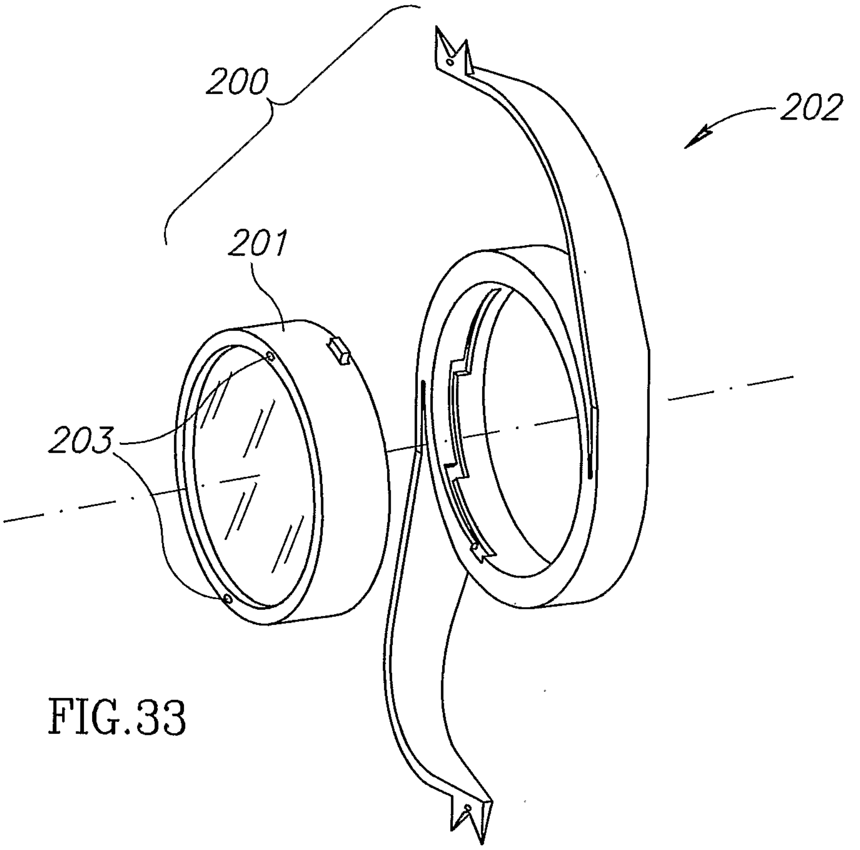

FIG.33

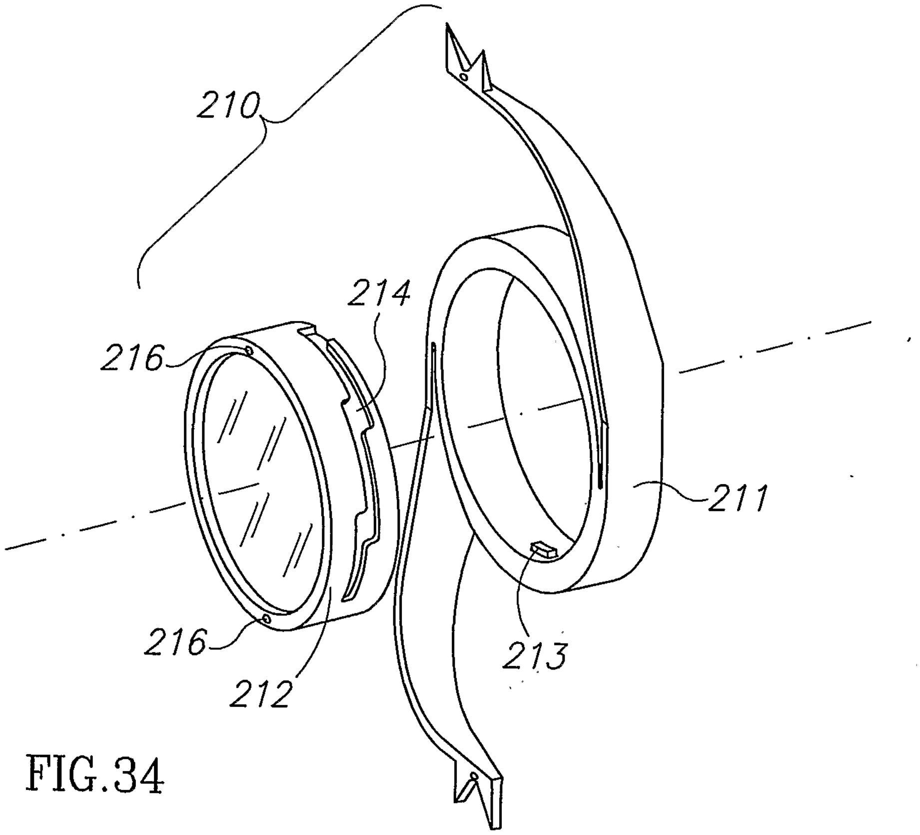

FIG.34

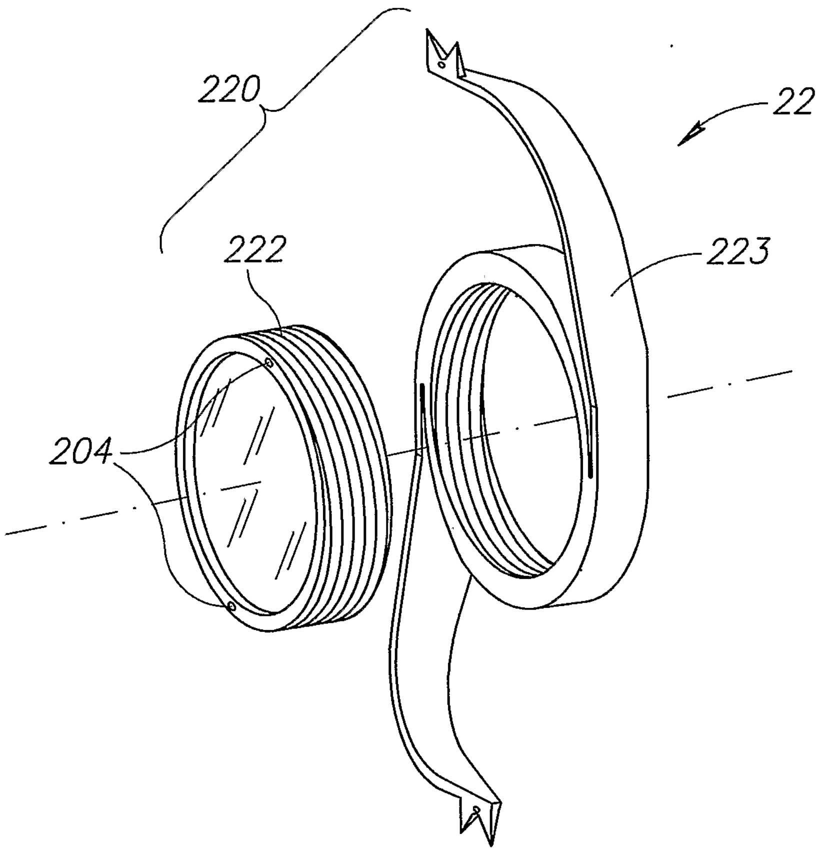

FIG.35