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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F

A2

(11) International Publication Number: **WO 95/07059**

(43) International Publication Date: 16 March 1995 (16.03.95)

(21) International Application Number: PCT/US94/09792

(22) International Filing Date: 30 August 1994 (30.08.94)

(30) Priority Data:
08/117,407 3 September 1993 (03.09.93) US

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(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: SINGLE-PIECE INTRAOCULAR LENS WITH A RADIUSED TRANSITION REGION

(57) Abstract

An improved single-piece flexible intraocular lens (420) with a radiused transition region (422) between a lens element (424) and a winged support portion (426) of the intraocular lens (420). The radiused transition region (422) is formed by a fillet portion (428). The fillet portion (428) is used to reinforce the re-entry angle formed by the intersection of the lens element (424) and the winged haptic portion (426). The fillet portion (428) is incorporated into the lens junction to reduce the stress on the intraocular lens (420) which occurred at the sharp transition corner of prior art lenses. A preferred radius for the transition region (422) is between 0.01 mm and 0.25 mm. The single-piece lens (420) with the transition region (422) having a fillet (428) between the optical element (424) and the winged haptic (426) is preferably formed by a single-piece mold (440) to provide the most control over the radius of the transition portion (422).

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SINGLE-PIECE INTRAOCULAR LENS WITH A RADIUSED TRANSITION REGION

Background of the Invention

The present invention relates to the field of intraocular lenses and, more particularly, to a single-piece intraocular lens with a radiused transition region between a lens optic and a support portion.

Artificial intraocular lenses, used to replace damaged or diseased natural lenses in the eye, have been widely accepted in the last several decades. Typically, such intraocular lenses comprise some type of optical element and a support, or haptic, coupled thereto for properly positioning and centering the intraocular lens within the eye. In a conventional single-piece intraocular lens, a sharp corner is formed at the junction of the optical element and the haptic. This junction is the weakest portion of the lens due to the surface discontinuity at the junction. The surface discontinuity at the junction forms lines of stress which radiate from the sharp corner and cause the junction of the optical element and the haptic to be formed with an inherent weakness.

Many of the single-piece intraocular lenses are made from soft, biocompatible materials of an optical quality, such as silicone, which enable the lenses to bend and flex as they are inserted into the patient's eye. Silicone lenses have the advantage of being lighter in situ than older PMMA lenses, and because they are flexible, they can be folded to reduce their size during implantation into the eye in accordance with conventional surgical procedures.

A technique which has gained wide acceptance for the removal of the diseased or damaged native lens is called phacoemulsification. The phacoemulsification process is very advantageous because of the extremely small incision required to perform the technique. The incision can be as small as 2-4 millimeters in length. It is desirable to insert an artificial intraocular lens into the patient's eye to replace the native lens of the eye after the phacoemulsification procedure has been completed. With the latest advances in

surgical procedures performed on the lens capsule, such as a capsulorexis procedure, it is possible to remove the native lens of the eye while maintaining the lens capsule almost entirely intact. The capsulorexis procedure enables a small curvilinear tear to be made in the lens capsule through which the artificial lens is implanted. The small opening in the lens capsule through which the intraocular lens must be inserted further enhances the desirability of the foldable lens which can be inserted into the small capsulorexis opening. By maintaining the lens capsule intact and inserting the artificial lens into the lens capsule, a more natural lens replacement can be achieved. It is desirable to enable the insertion of the artificial lens into the eye without requiring the elongation of either the phacoemulsification incision or the capsulorexis opening.

Forceps are traditionally used to insert a looped multi-piece silicone intraocular lens into the eye and usually require the phacoemulsification incision and capsulorexis opening to be slightly elongated. In addition, the insertion procedure is technically difficult as the surgeon must hold the lens in the folded position while preventing the looped haptics from contacting sensitive areas of the eye such as the cornea. Therefore, the forceps procedure is risky as it is possible that the surgeon may unintentionally damage either the posterior capsule or the corneal endothelium with the looped haptics or the forceps during the insertion procedure.

A lens injector is traditionally used to insert a single-piece lens which is loaded into the injector and then inserted into the eye. The use of a lens injector to insert a foldable lens is more desirable than the use of forceps as the small phacoemulsification incision does not require elongation. In addition, the insertion procedure is significantly simplified by the loading and insertion feature of the intraocular lens injector. In addition, the entire lens is contained within an insertion tube until the lens is injected into the lens capsule, thereby reducing the likelihood of damaging the

surrounding eye tissue while the lens is being inserted. The simplification of the insertion procedure utilizing an intraocular lens injector has increased the frequency of their use. As the use of lens injectors for the insertion of an intraocular lens has increased, the demand for single-piece intraocular lens designs which are compatible for use with lens injectors has also increased.

One disadvantage of utilizing a lens injector is the damage that can occur to the single-piece lens as it is loaded and translated through the injector. The lens injectors must exert a force on the lens sufficient to deform the lens such that the lens element of the single-piece lens is deformed to a substantially smaller cross-sectional diameter than that of the lens in an unstressed state. One area of high stress is at the location where the optical element connects to the support haptic. The single-piece lens can tear at this weak junction due to the shearing forces which are exerted on the lens during loading, as the corner created by the optic and haptic segment of the lens will act as a stress riser junction. It would be advantageous to reduce the stresses due to loading and insertion of a single-piece lens so that the lens is not damaged during implantation.

As the use of single-piece intraocular lenses increases, other disadvantages have been noticed. For example, one phenomena which occurs with single-piece lenses is the "cusp effect" which has been recently reported by intraocular lens patients in Europe and is currently being studied by the FDA in the U.S.A. The "cusp effect" occurs when the iris of the eye is open to its widest point, i.e., in low light situations, thereby exposing the junction point of the spherical optical element to the plate haptic. As described above, the junction of the optical element and the haptic results in a sharp corner at the transition point from the haptic to the optical element. When light is incident on the exposed corner, the light is reflected by the sharp corner at the junction of the optical element and the flat plate haptic

and causes a bright halo to form around the patient's vision. This bright halo is extremely distracting to the patient and in more severe cases, the glare can be so blinding that it overwhelms the optic nerve and results in a momentary flash of blindness. Momentary blindness can be extremely problematic especially in a situation where an intraocular lens patient is driving at night and the headlights of an oncoming car reflect in the junction of the lens element and the haptic causing momentary blindness to occur resulting in an accident and is obviously undesirable.

Therefore, there exists a need in the prior art for a single-piece intraocular lens which will stand up to the shearing forces inflicted upon the lens by a typical intraocular lens injector and will eliminate the "cusp effect" from occurring.

Summary of the Invention

The present invention provides an improved soft single-piece intraocular lens with a radiused transition region between an optical element portion and a support portion, or haptic, of the intraocular lens. The support portion is a winged extension from the optical element and can take on any number of shapes which will be apparent to one of skill in the art. In a preferred embodiment of the invention, the winged support portion comprises a rectangular flat plate with rounded corners. The flexible single-piece lens is made of an optical grade soft biocompatible material, such as a flexible acrylic material, a hydrophilic material or a silicone material. Preferably, silicone is used to form the preferred embodiment of the flexible single-piece lens. The radiused junction can be implemented between the optical element and the support portion regardless of whether the optical element is a monofocal lens, a multifocal lens, a spherical lens or an aspheric lens.

Preferably, the radiused junction region between the optical element and the support haptic is formed by a fillet portion. The fillet is incorporated into the lens junction to reduce the stress on the intraocular lens which previously

occurred in the prior art lenses at the sharp transition corner between the optical element and the haptic support portion. Previously, the transition from the optical element to the haptic formed an obtuse-angled junction between the two portions of the lens. With the addition of the fillet portion, the inherent concavity of the fillet portion results in the elimination of the angle at the junction between the optical element and the support portion. An angle-free transition is considerably stronger than an obtuse angled transition, as the stresses incident at the transition region are spread out over a larger area. Therefore, the fillet portion re-enforces the weak junction of the optical element and the haptic, thereby improving the strength of the single-piece lens of the preferred embodiment over the single-piece lenses of the prior art.

The radius of the concave fillet portion must be sufficiently large to provide adequate re-enforcing strength at the transition region to prevent the intraocular lens from tearing at the junction region when the single-piece lens is deformed. However, the radius can not be so large that it prevents the necessary flexibility required by a soft intraocular lens which would prevent the lens from loading down to the desired size. A preferred radius for the fillet portion is between 0.01 mm and 0.25 mm. More desirably, the radius for the fillet portion is between 0.05 mm and 0.13 mm.

The fillet portion at the transition region between the optical element and the winged haptic results in a smooth transition such that the sharp corner at the transition region of prior art lenses is removed. Without the sharp corner at the transition region, the "cusp effect" is significantly reduced in the single-piece intraocular lenses of the preferred embodiment as there is no well defined surface at the transition region for the light to reflect into the eye of the patient. The smooth transition from the optical element to the support portion scatters the light incident on the transition region to the point where the "cusp effect" is undetectable. The radiused transition region of the

intraocular lens of the preferred embodiment is greatly preferred over the single-piece intraocular lenses of the prior art as the blinding reflection that is associated with the "cusp effect" is effectively eliminated.

Brief Description of the Drawings

Figure 1 is a perspective view of an intraocular lens, made by the techniques described herein.

Figure 2 is a perspective view of a reverse mold pattern, ten times the size of the final reverse mold, having an aspherical portion.

Figure 3 is an exploded perspective view of the pattern illustrated in Figure 2, showing the various sections of the pattern.

Figure 4 is a perspective view of a pantograph, used to replicate the pattern onto the surface of a coining mandrel, one-tenth of the original size.

Figure 5 is a perspective view of a reverse mold, or coining mandrel, having an optical surface polished thereon.

Figure 6 is an exploded perspective view of a mold forming assembly, used in the fabrication technique described herein.

Figure 7 is a cross-sectional view of the forming assembly of Figure 6, just prior to pressing the mold cavity.

Figure 8 is a perspective view of a mold half formed in the assembly of Figure 7.

Figure 9 is an enlarged cross-sectional view, taken along line 9-9 of Figure 8, showing the slight eruption of metal displaced during the mold forming process.

Figure 10 is an enlarged partial cross-sectional view of the mold half of Figure 11, showing the ground-off eruption in phantom lines and an overflow groove which has been machined around the optical cavity.

Figure 11 is a perspective view of a top half of a mold made in accordance with the technique of the present invention.

Figure 12 is a perspective view of a core pin and post assembly.

Figure 13 is a perspective view of a bottom half of a mold, showing the insertion of the core pin and post assembly of Figure 12 in dashed lines.

Figure 14 is a perspective view of the mold halves situated one over the other prior to the formation of a lens.

Figure 15 is a perspective view of a newly molded lens, showing the flashing, sporadically disposed about the periphery of the lens.

Figure 16 is a cross-sectional view, taken along line 16-16 of Figure 15.

Figure 17 is a perspective view of an edge of the lens adjacent the aperture formed by the core pin subsequent to the tumbling of the lens.

Figure 18 is a partially exploded perspective view of a forming mandrel used for making a control haptic.

Figure 19 is a top plan view of the forming mandrel illustrated in Figure 18.

Figure 20 is top plan view of the forming mandrel illustrated in Figures 18 and 19, showing the control haptic being formed.

Figure 21 is a plan view of a control haptic.

Figure 22 is a partial cross-sectional view of an edge of a lens, illustrating the aperture being filled with adhesive.

Figure 23 is a partial cross-sectional view of an edge of a lens, showing the tangential bonding of a haptic into the hole.

Figure 24 is a cross-sectional view, taken along line 24-24 of Figure 23, showing the angulation of the haptic within the hole.

Figure 25 is a perspective view of a dihedral holding fixture used to maintain the haptics at a predetermined angle within the lens while the adhesive cures.

Figure 26 is a cross-sectional view, taken along line 26-26 of Figure 25, showing the disposition of a lens within the dihedral holding fixture.

Figure 27 is a graph plotting the radius of curvature of the aspherical portion of the lens.

Figure 28 is a partial cross-sectional view of an alternative coining assembly. Figure 29 is a profile of an intraocular lens, schematically illustrating the dioptric power increase of light passing through various portions of the lens, having various radii of curvature.

Figure 30 is a perspective view of a preferred embodiment of a lens injector utilized with a single-piece intraocular lens of the present invention.

Figure 31 is an exploded perspective view of the lens injector as illustrated in Figure 30.

Figure 32 is an cross-sectional view of the lens injector through the line 32-32 illustrated in Figure 30.

Figure 33 is a right side view of the lens injector illustrated in Figure 30.

Figure 34 is a cross-sectional view of an injection handle which is used with one embodiment of a lens injector.

Figure 35a is a sectional view of a lens injector taken along the line 35a of Figure 35b with a single-piece intraocular lens inserted therein.

Figure 35b is a sectional view taken along the line 35b of the lens injector as illustrated in Figure 35a.

Figure 36a is a sectional view of a lens injector illustrating the intraocular lens beginning to compress into the rolled configuration.

Figure 36b is a sectional view of a lens injector with the intraocular lens in the same position as illustrated in Figure 36a.

Figure 37a is a sectional view of the lens injector with the intraocular lens in the completed rolled configuration.

Figure 37b is a sectional view of the intraocular lens injector with the intraocular lens in the same position as illustrated in Figure 37a.

Figure 38 is a sectional view of the intraocular lens injector with the insertion rod introduced into the cylindrical passageway.

Figure 39 is a sectional view of the intraocular lens injector with the insertion rod advanced to its fully inserted

position and the intraocular lens positioned in the insertion tube.

Figure 40 is a sectional view of the injection handle as illustrated in Figure 34 in combination with the injection tube containing an intraocular lens in the compressed state, wherein the intraocular lens is inserted through a small incision into the lens capsule of an eye.

Figure 41 is a top view of a second embodiment of an intraocular lens injector.

Figure 42 is a sectional view of the second embodiment of the intraocular lens injector in combination with the injection handle as illustrated in Figure 34.

Figure 43 is a cross-sectional view of a single-piece intraocular lens of the prior art.

Figure 44 is a cross-sectional view of a single-piece intraocular lens of the preferred embodiment wherein the optical element of the lens is a monofocal lens.

Figure 45 is a side view of the intraocular lens as illustrated in Figure 44.

Figure 46 is a top view of the intraocular lens as illustrated in Figure 44.

Figure 47 is a cross-sectional view of a single-piece intraocular lens wherein the optical element of the lens is a multifocal lens.

Figure 48 is a perspective view of a partially completed intraocular lens mold with a coining mandrel used to form an optical element portion of the mold before the mandrel is pressed into the mold to complete the mold.

Figure 49 is a cross-sectional view of a mostly completed intraocular lens mold used to form an intraocular lens as illustrated in Figures 44-46 with the coining mandrel shown forming a radiused transition region between a haptic and an optical element.

Figure 50 is a perspective view of a completed intraocular lens mold used to form an intraocular lens as illustrated in Figures 44-46.

Detailed Description of the Preferred Embodiment

The present invention provides an improved single-piece flexible intraocular lens with a radiused junction between a lens element portion and a haptic support portion of the intraocular lens. The improved single-piece lens is preferably formed by the lens forming process described in detail below.

Referring now to the drawings in detail, wherein like reference numerals designate like elements throughout the several views thereof, there is shown generally at 10 in Figure 1, an intraocular lens formed using the techniques described hereinafter. Preferably, the intraocular lens 10 is a biconvex lens having a first, or anterior side 12 and a second, or posterior side (not shown). The posterior side will reside in the capsule of the eye adjacent the vitreous humor, and is substantially spherical. The anterior side 12, however, as schematically illustrated, is asymmetric, and is formed of three sections 14, 16, 18. The upper, or superior section 14 occupies the upper half of the lens and is substantially spherical, having essentially the same radius curvature as that of the posterior side of the lens. The center section 16 adjacent the superior section 14, extends from the center of the lens to the lower quarter, and exhibits an aspherical surface, having a gradually decreasing radius of curvature. The third section 18 of the lens 10 is also spherical, but exhibits a longer radius of curvature than that of the superior section 14 so as to provide a flatter surface and thus greater strength and thickness near the edge 20 of the lens, at the juncture of the two spherical sections 14, 18. A pair of support members, or haptics 22, 24 are secured to the lens 10 on diametrically opposed sides, and aid in centering the lens 10 within the eye after implantation. The superior, or control haptic 22 is provided with a horseshoe-like, or eyelet shaped, kink 26 which enables the ophthalmic surgeon to readily determine which is the superior portion 14 of the lens 10 and permits manipulation of the lens 10 during surgery.

A pattern 28, or reverse mold of the desired surface of

the anterior side 12 of the lens 10, preferably made out of aluminum with a CNC machine and scaled ten times larger than the desired size, is illustrated in Figures 2 and 3. As most clearly illustrated in Figure 3, the pattern 28 comprises three major components: a large semi-circular block 30, a small semi-circular block 32, and an arcuate block 34, having an outer diameter corresponding to the diameter of the large semi-circular block 30, and an inner diameter corresponding to the diameter of the small semi-circular block 32. The blocks 30, 32, 34, are secured together by a plurality of bolts 36. The larger semi-circular block 30 has a spherical surface 38, and corresponds to that portion which will ultimately be the superior half 14 of the anterior side 12 of the lens 10. Likewise, the arcuate block 34 corresponds to the outer, inferior section 18 of the lens 10, and is also provided with a spherical surface 40, although somewhat flatter than that of the large semi-circular block.

It is noteworthy that when making the pattern, the radius of curvature of the various portions must be shorter than that of the desired surface of the mold cavity to allow for "spring back" of the coined surface. Specifically, it has been found that the center of the mold cavity, which is deeper than the periphery, "springs back" more than the periphery, since it has yielded more than the periphery. Empirical data has shown that for a stainless steel mold cavity, the coined mold will have a radius of curvature which is 1 to 2 % larger than the radius of curvature of the coining mandrel. A correction factor for this difference is made in the pattern by reducing its radii of curvature by 1 to 2 %. In addition, silicone lenses made in such a mold tend to shrink a uniform 3.7 % during the lens forming process. Therefore, the pattern, in addition to having shorter radii of curvature, should be enlarged by a factor of 3.7 % to allow for such shrinkage.

The radius of curvature of an optical element is proportional to the focal length of that element. As the radius of curvature of an optical element decreases, the dioptric power, which is defined as the inverse of the focal

length when measured in meters, increases. The small semi-circular block 32 is configured such that the radius of curvature, on the surface 42 thereof, steadily decreases from a first value, R_0, equal to the radius of curvature of the large semi-circular block 30, to a lower value, R_N, determined by the desired change in the base power of the varifocal, or aspherical portion 16 of the lens 10.

In a biconvex lens, as shown in Figure 1, and schematically illustrated in Figure 29, the entire posterior side 200 and the superior half 14 of the anterior side 12 of the lens are of fixed curvatures which determine the base power of the lens after implantation in the eye. The inferior half of the anterior side 12, is capable of providing varying levels of accommodation by virtue of the aspherical portion 16 of the lens. As noted above, the dioptric power of an intraocular lens is typically controlled by varying the anterior and/or posterior radii of the optical element. If, for example, as illustrated in Figure 29, the posterior side 200 is of a fixed radius of curvature, corresponding to a dioptric power of 9 diopters, and the superior half 14 of the anterior side 12 exhibits the same radius, and thus the same power of 9 diopters, then light impinging on the lens in this area, as designated by line 202, would be focused with a dioptric power of 18 (9 + 9) diopters. As the center section 16 of the anterior side 12 under goes a change in its radius of curvature, the focal point of light impinging therethrough would also change. If, for example, the intraocular lens were designed to provide a steadily increasing power of 6 diopters, light impinging on the lens 1/6 of the way down the aspherical section, as designated by line 204, would be focused with a power of 19 diopters (9 + 9 + 1), whereas light impinging on the lens at the bottom of the aspherical portion (line 206) would be focused with a power of 24 diopters (9 + 9 + 6). Finally, light impinging on the inferior portion of the lens, corresponding to the flatter spherical section of the lens 18, and designated by line 208, would have a power of 16 diopters (9 +7). This effect was demonstrated in theory by Lee T.

Nordan in U.S. Patent No. 4,769,033, entitled "Intraocular Multifocal Lens," issued on September 6, 1988, a continuation-in-part of U.S. Patent Application Serial No. 069,197, filed on July 2, 1987, now abandoned.

Figure 27 schematically illustrates the changing radius of curvature ($R_0 \ldots R_N$) throughout the varifocal portion of the lens. The radius of curvature (R_0) begins at the same radius as that of the spherical portion, and then gradually decreases. The radius of curvature (R_x) of the varifocal or aspherical portion of the lens, can be determined at any point by the equation:

$$R_x = \frac{R_0}{1 + KX}$$

where:

$$K = \frac{R_0 \Delta P}{V(N_2 - N_1)}$$

and where:

ΔP = the total change in power from R_0 to R_N;

V = the width of the varifocal portion of the lens;

N_2 = the index of refraction of the lens; and

N_1 = the index of refraction of aqueous in situ.

Thus, the aspherical portion of the lens is a solid of rotation, formed by rotating the curve generated by the above equations, about a line which passes through the initial radius R_0, to form the surface.

The power increase, or "add" P_x at any point may be defined by the equation:

$$P_x = P_0 + (X * \Delta P)/V$$

where:

P_0 = the power at R_0; and

X = the distance from P_0 to P_x.

As the radius of curvature of the varifocal portion of the lens decreases, the center of curvature for each radii shifts. The locus of the center of curvature of the changing radii follows an arcuate path, and is approximated by the equation:

$$S_x \approx V(1 - R_x/R_0).$$

A pantograph 44, which is an apparatus for transferring three-dimensional tracer pin motions to a cutting tool is illustrated in Figure 4. The cutting tool 46 moves in the same direction as the tracer pin 48, at a preset, duplicating ratio. The pantograph 44 is employed to replicate the contours of the pattern 28 onto a workpiece 50 which is, in the preferred embodiment, ten times smaller than that of the pattern itself. The pattern 28 and the workpiece 50 are clamped in conjugate positions at roughly the same level to ensure alignment of the cutter 46 and the tracer pin 48. Preferably, the cutter 46 is a high grade tungsten carbide tool, and spins at approximately 20,000 rpm. If the diameters of the tracer pin 48 and the cutter 46 are selected in accordance with the duplicating ratio, and if the points of the tracer pin and cutter are in alignment with the axis of the horizontal pivot shaft (not shown), the cutter 46 will replicate all of the pattern contours onto the workpiece 50 at the designated ratio. The pattern surface is replicated by carefully drawing the tracer pin 48 across the surface of the pattern 50 in small, circular strokes in steps of approximately .010". It is noteworthy that reproduction of the pattern 50 at one-tenth the desired size is advantageous in that any slight errors on the surface of the pattern will be proportionally reduced to the scale reduction out on the replica 54, to acceptable tolerances. The tracer pin 48 may be driven manually or by a CNC machine (not shown).

The replica 54 is to be used as a coining mandrel for coining optical surfaces. It is to be understood that the term coining is used to define the permanent deformation of a soft material, as impressed by a harder material. Preferably, the replica, or coining mandrel 54, is a small, cylindrical piece of high-grade, hardenable alloy tool steel, capable of reaching a hardness of 58 Rockwell, Scale C (R_c). Most preferably, D-2 steel is used. Once the coining mandrel 54 has been etched with a scaled-down reproduction of the pattern 50, the rough edges developed during the replication process are polished off. Significantly, the peripheral edge 55 of

the coining mandrel 54 (Figures 5 and 7) is radiused such that when an optical mold is coined, the convexity of the resultant mold cavity will yield a smoothly radiused product. Thus, when two coined mold halves are brought together to form a biconvex lens, the resultant lens will exhibit an ogive shape with a blended, radiused edge, eliminating squared corners typical of traditionally molded intraocular lenses. Further, lenses made in a coined mold cavity will exhibit only one flash line which can be easily abraded away using standard tumbling techniques, whereas the squared corners of a traditionally molded lens cannot be tumbled to produce an ogive shaped intraocular lens.

The coining mandrel 54 is then heat treated in an oven to harden the D-2 steel throughout to a hardness of between 58 to 62 Rockwell, Scale C (R_c), and most preferably, 60 R_c which corresponds to a tensile strength of 320,000 p.s.i. Because oxygen tends to leave an undesirable coating on the surface of the steel during the heat treating process which would have to be sand-blasted off, the coining mandrel 54 is preferably hardened in one of two ways. The preferred way is to evacuate the air out of the oven to produce a vacuum environment and heat the coining mandrel by radiation to approximately 1300°. The coining mandrel is then allowed to slowly cool and will emerge from the oven within the desired range of hardness. As the steel is heated and cooled, its grain structure changes in a predictable manner. Another way of heat treating the coining mandrel to a hardness of between 58 and 62 R_c is to heat it in a Nitrogen oven. This process is much slower than the vacuum method, as the coining mandrel is heated primarily by convection rather than by radiation.

During the heat treating process, the hardness, strength and wear resistance of the coining mandrel are increased, however nicks, scratches and impurities in the steel are also magnified. Thus, once the coining mandrel 54 has been heat treated and hardened to 60 R_c, the reverse mold surface 56 must be polished to an optical surface. The general practice is to polish the surface 56 of the mandrel 54 with a

succession of polishing agents, progressing from a coarse grit to a finer grit. Because of the nature and intended use of the coining mandrel, as well as the minute surface area of the reverse mold surface, the coining mandrel must be hand polished under a microscope, allowing a better polish.

Polishing the surface 56 of the coining mandrel 54 is a very tedious process, and requires hours of meticulous work. The first step in the optical polishing of the coining mandrel is to remove all of the crowns and crests from the surface which were magnified during the hardening process. This is accomplished by applying a small amount of fine machine oil and 600 grit silicone carbide material to the surface of the coining mandrel and polishing it with small, circular motions using the end of a brass rod followed by the use of 1000 grit silicone carbide. To ensure that the surface of the coining mandrel is not being over polished and that the precisely calculated radii of curvature are maintained, a comparator is used during each step. Once the crowns and crests have been polished off the surface of the coining mandrel, machine oil and aluminum oxide (Al_2O_3), having a grit size of one micron (1 m), is employed as a polishing agent, and the surface 56 of the coining mandrel 54 is further hand polished with wood sticks in small circular motions. Next, using a dremmel, or a hand held drill, having a hardened felt surface, the coining mandrel is optically lapped using .3 m Al_2O_3 and fine machine oil. Finally, the coining mandrel is tumbled in a standard tumbler, as commonly used in the field to tumble and polish intraocular lenses. The tumbler is filled with 1 and 2 mm glass beads, fine machine oil of the type used during the above polishing steps, an anti-settling agent and mineral spirits. Preferably, the anti-settling agent is fumed silicone dioxide, having a particle size of between .7 to 2.7 angstroms (Å), as made commercially available under the name Cab-O-Sil fumed silica. The fumed silica is used as a suspending or anti-settling agent in the tumbler and accelerates the polishing process during tumbling. In addition, it is noteworthy that tumbling media such as water

or alcohol are not suitable for use in the tumbler when polishing the coining mandrel 54 as these agents would cause electrolysis, which, in turn, would etch the surface 56 of the coining mandrel. Upon cessation of the tumbling process, the coining mandrel should emerge having a highly polished optical surface of the desired configuration.

Figure 5 illustrates a hardened, polished coining mandrel 54 which is to be used to stamp it's impression into a blank of a softer material, preferably having an optical finish on the face thereof, so as to form an optical power surface within a concave mold cavity. An optical power surface is one which is contoured to focus light rays so that they converge or diverge to form an image. As the coining mandrel has been hardened to 60 R_c, the choice of softer materials would appear endless. As illustrated in the partial cross-sectional assembly of Figure 28, for example, the coining mandrel 54 could be pressed into a polished piece of sheet metal 57, having a resilient backing 59, such as die rubber, placed thereunder. When coining a mold cavity into such a soft material, the coining mandrel 54 need not be hardened to 60 R_c, but can be as soft as 40 R_c. As the mandrel 54 is pressed into the sheet metal 57, the sheet metal permanently deforms to assume a reverse configuration of the surface 56 of the coining mandrel 54. The rubber backing 59 will yield to the deformation of the sheet metal 57 during the coining process, however will spring back after the coining is completed and the assembly disassembled. It is noteworthy that a minimal amount of pressure is required to create a mold cavity in the sheet metal 57 due to the resilient nature of the rubber backing 59, and the thinness of the sheet metal 57 itself. Molds formed in this manner have the advantage of being light and inexpensive, however, the longevity and number of uses of such a mold is severely limited. Accordingly, in the interest of making a long lasting mold, any grade of good quality stainless steel should be used. Preferably, the blank 58 (shown in Figures 6 and 7) is formed of either a 300 type series or a 400 type series stainless steel. Presently, the

400 series is preferred, with 410 or 420 stainless steel being particularly well suited. However, the 300 type series may also be used, with 203 or 303 stainless steel also being well suited. Additionally, it is preferred to use stainless steel of a purity level which is greater than commercial grade stainless steel. Impurities in the steel can cause pitting and flaws to occur in the mold which will in turn cause flaws in the molded lens. Therefore, aircraft quality stainless steel or electronically re-melted stainless steel is preferred over commercial grade stainless steel.

The blank 58 is machined in the desired shape and thickness, and the face 60 is optically lapped in a manner as is well known in the art. Preferably, the face 60 of the blank is polished in a series of steps, beginning with 320 grit sandpaper and oil, and proceeding to finer grades of sandpaper, having grit sizes of 400 and 600. The blank is then polished using a lapping plate, having a urethane cover using 1 m Al_2O_3 and water. Finally, the face 60 of the blank 58 is optically finished with a rotary polisher, having a urethane felt cover, in a .3 m Al_2O_3 and water slurry.

Following the optical polishing of the face of the blank, a mold cavity is ready to be formed. As shown in Figures 6 and 7, a pair of drill bushings 62, 64, are utilized to maintain the relative positioning of the coining mandrel 54 with respect to the diametric center of the polished blank 58. Preferably, the bushings are formed of tool steel, as they will ultimately be subjected to exceptionally high loads. The outer bushing 62 is cored and has an inner diameter 66 sized to receive and center the polished blank 58 with minimal clearance about the periphery thereof, so as to ensure that the blank will not move during the mold formation process. Similarly, the inner bushing 64 is also cored, having an outer diameter 68 selected such that the inner bushing 64 will be centered with respect to the outer bushing 62 and an inner diameter 70, for centering the coining mandrel 54 will be centered with respect to the blank 58. The inner bushing 64 is further equipped with a flange 72, adapted to rest on the

upper rim 74 of the outer bushing 62 to maintain a small gap 76 between the bottom surface 78 of the inner bushing 64 and the blank 58.

To form a mold cavity for the lens, the outer bushing 62 is placed on a hardened surface 80. The blank 58 is inserted into the core 66 of the outer drill bushing 62, with the polished side up. It is important to execute care in the insertion of the blank 58 into the bushing 62, as scratches on the surface 60 of the blank 58 may result in a mold cavity which yields flawed lenses. The inner bushing 64 is then inserted into the core 66 of the outer bushing 62, so that the flange 72 rests on the upper rim 74 of the outer drill bushing 62 and finally, the coining mandrel 54 is lowered into the core 70 of the inner bushing 64 until it just touches the surface 60 of the blank 58. A second hardened surface 82 is carefully set on top of the coining mandrel 54, and the formation assembly 84 is put into a hydraulic press (not shown).

It is noteworthy that the coining mandrel 54 should extend outwardly above the flange 72 of the inner bushing 64, by an amount equal to the desired final depth of the mold cavity, taking into account the amount of compression, or shrinkage of the coining mandrel expected during the pressing of the mold cavity. Preferably, the coining mandrel 54 extends .043 inches above the flanged surface 72, allowing .012 inches for compression of the coining mandrel under full load, and will yield an imprint having a final depth of .031 inches. Because the .043 inch gap 88 is directly related to the desired depth of the resultant mold cavity, the hydraulic press may be slowly and steadily loaded until the gap 88 disappears. In general, it takes a load of between 7 and 10 tons to stamp the coining mandrel impression of the lens, or optical element, into the steel blank at the desired depth. Preferably, the hydraulic press is loaded to 10 tons to ensure proper deformation of the mold cavity. A load of this magnitude imposes a pressure in excess of 400,000 p.s.i. upon the surface 56 of the coining mandrel 54. In order to allow

for the creeping of the materials, the press remains under full load for approximately 15 minutes after the gap 88 disappears.

As mentioned above, upon application of full load, the coining mandrel 54 compresses .012 inches. In addition, a radial expansion of approximately .001 inches in diameter is also experienced. However, the coining mandrel is not deformed beyond the elastic limit of the material, and therefore returns to its original form upon removal of the load. Unlike the coining mandrel 54, the stainless steel blank 58 has a much lower yield strength and therefore undergoes permanent deformation upon application of the load. Thus, not only does the newly formed mold half 90 exhibit a mold cavity 92, having a reverse imprint of the surface 56 of the coining mandrel 54 at the desired depth, as shown in Figure 8, but also undergoes a radial expansion, resulting in an interference fit within the core 66 of the outer bushing 62 as well as a slight eruption 94 (Figure 9) about the periphery of the mold cavity 92. After the load has been removed, the coining mandrel 54 and the inner bushing 64 are lifted from the formation assembly 84. The pressed mold half 90, however, must be forced out of the outer bushing 62 due to the interference fit caused by the radial expansion of the mold half 90. Significantly, during the mold forming process, slight imperfections present on the surface 60 of the blank 58 in the localized area of the mold cavity 92 are ironed out. Further, due to the tremendous force applied to the materials, the porosity in the mold cavity 92 is substantially decreased, resulting in a smoother, higher quality optical surface than was present on the original optically polished blank, and the deformation of the blank material work hardens, resulting in a harder, more durable surface.

As shown in Figure 14, the mold 96 used to form the biconvex intraocular lens 10 comprises an upper mold half 98 with an upper concave cavity 100 and a lower mold half 90 with a lower concave cavity 92. Thus, in order to complete the mold 96 for a biconvex lens 10, a second, or upper mold half

98 must be made. Preferably, the mold cavity 100 of the upper mold half 98 will have a spherical surface which will provide the desired additional base power of the lens. The upper mold half 98 is made in the same manner as the lower mold half 90 with the exception of the surface configuration of the mold cavity. The upper mold cavity 100 is preferably spherical, having a radius of curvature selected in accordance with the desired refractive power of the resultant lens. Having formed the concave cavities 92, 100 in each of the mold halves 90, 98, the eruptions 94 (Figure 9) surrounding the periphery of each cavity must be ground off. Advantageously, each mold cavity 92, 100 was pressed in to a depth of .031 inches to allow for imperfections in the blank 58, as well as these eruptions 94. To protect the optical surface of the mold cavities 92, 100 during subsequent processing, an adhesive backed disc 193, or other type of covering, having a light adhesive backing to prevent slippage and having a known thickness, is carefully placed on the surface of each mold cavity during the grinding and machining processes. As shown in Figure 10, the face 102 of each mold half 90, 98 is ground down until a final mold cavity depth of .025 inches is attained.

With the adhesive backed disc 193 still in place, an overflow groove 104 is machined using a lathe, around the periphery of each mold cavity 92, 100. A thin ridge 106, referred to as the mold shut off, or flash line, is created intermediate the groove 104 and the respective mold cavity 92, 100 so that concentric circles are formed about the mold cavity. The flash line 106 defines the outer limits of the molded lens. As illustrated in Figure 13, in order to ensure proper alignment of the mold halves 90, 98 during the molding process, a pair of alignment dowel pins 108, 110, are secured to the bottom half of the mold 90 in a conventional manner. Associated mating holes 112, 114 are drilled into the top half of the mold 98 (Figure 11) to receive and retain the dowel pins 108, 110 during the molding process. Each mold half 90, 98 is machined to provide a pair of elongate grooves 116, 118

on diametrically opposed sides of the mold. The elongate grooves 116, 118 are semi-cylindrical in cross-section and are adapted to receive and maintain the positioning of a pair of core pins 120, about which the silicone lens material will cure during its production. To further ensure the stability of the core pins within the mold cavity during the production of the lens, a pair of small dowel pins 122, 124 is provided in the overflow groove 104, on opposite sides of each core pin 120, to sandwich the core pin therebetween. Advantageously, as illustrated in Figures 12 and 13, each core pin 120 is secured to a post 126, which is removable from the bottom mold half 90. Thus, after the lens is formed, the core pins 120 may be lifted from the mold, together with the lens so that the core pins do not tear the lens during the removal of the lens from the mold. In actual practice, the lens is removed from the mold by pushing the posts 126 upwardly from the bottom half of the mold 90 through the hole 127 with a lifter pin (not shown). In this manner, the optical power surfaces of the mold are less likely to be damaged by removing tools being inserted under the lens.

Figure 14 illustrates a complete mold assembly 96. The upper and lower halves of the mold 90, 98 are relatively movable towards and away from each other to allow the introduction of material which will form the optical element therein. Preferably, the lenses are produced via compression molding, although other molding processes, such as transfer molding or liquid injection molding (LIM), may also be employed. Silicone, in a liquid form, having a volume somewhat greater than that of the two mold cavities is introduced into the lower mold cavity 99. Preferably, about .025 milliliters of uncured, liquid silicone polymer is used to form the lens. The upper half of the mold 98 is then brought into engagement with the lower half 92 so that the alignment dowel pins 108, 110 are met by the associated mating holes 112, 114. Once the mold 96 is closed, the excess volume of silicone will leak out between the mold parts and into the overflow grooves 104. The mold 96 is then heated for a

predetermined time at an elevated predetermined temperature that will polymerize the monomers located therein into a solid polymer. In the preferred embodiment, the mold is heated for 10 minutes at 300°F. Following the polymerization of the optical element material, the mold is opened, and the optical element is removed therefrom.

As mentioned above, the core pins 120 are lifted from the mold along with the optical element. The core pins are then carefully removed by slowly twisting and then withdrawing the them in a plane parallel to the lens. As illustrated in Figures 15 and 16, the resultant lens 128 includes a pair of diametrically opposed apertures 130, 132 corresponding to the area from which the core pins 120 were removed. In addition, a small amount of flash 134, created during the production of the lens at the flash line 106 will be sporadically disposed about the edge 136 of the lens 128. Significantly, there is only one flash line 106 on the just-formed lens 128, and the edge 136 is ogive in shape. The lens 128 is then tumbled to remove the flash 134 from the periphery of the lens and to polish the edges thereof.

Preferably, the tumbler is filled with 1 to 6 mm glass beads, isopropyl alcohol, and fumed silicone dioxide. Typically, Al_2O_3 is used as the polishing agent when tumbling PMMA lenses to speed up the tumbling process and water is used as the tumbling medium. Undesirably, however, Al_2O_3 tends to leave a residue on silicone lenses and therefore, fumed silicone dioxide is used as the polishing agent to accelerate the tumbling process. When using fumed silicone dioxide as a polishing agent and water, the silicone lenses tend to float out and not polish. Isopropyl alcohol, however, has a lower surface tension than water, and a lower specific gravity than silicone and will allow the lenses to sink, thereby making it an ideal tumbling matrix. The isopropyl alcohol has another advantage in that the silicone lens material absorbs a portion of the alcohol, causing the lenses to uniformly swell an average of 7%, which in turn, lowers the tear strength of the lens material. As the tear strength decreases, the abrading

process, caused by the tumbling action of the tumbler, is further accelerated.

The tumbling process tends to abrade more rapidly at lip or margin 138 of the holes 130, 132 formed by the core pins during the production of the lens because this area of the lens is thinner. This is significant in that, as illustrated in Figure 17, at the cessation of the tumbling process, the optical element 140 is left with an indentation 142 proximate the holes 130, 132. Further, the flash, created during the production of the lens in the area where the two mold halves met, substantially disappears after tumbling, leaving a smoothly radiused, ogive shaped lens having a blended, radiused edge. In addition, a thin layer of fumed silicone dioxide will be present on both the outer surface of the lens, as well as the surface within the holes 130, 132. It has been found that this residue improves subsequent adhesive bonding of the haptics 22, 24 within the holes 130, 132 and is therefore left on the inner surface thereof. The fumed silicone dioxide residue on the outer surface of the lens, however, will be rinsed off, using standard cleaning and extraction techniques.

Figures 18-20 illustrate a forming mandrel 144 for making control haptics 22. Haptics 22, 24 may be formed from any material, but are preferably formed from a solid polymer member, designed to be relatively thin and flexible, yet provide sufficient support for the optical element 140. Materials found well suited to the formation of haptics include polypropylene, PMMA, polyimide, polyethylene, nylon, and great number of extruded plastics. Preferably, the haptics are formed of polypropylene, or any 5-0 medical non-abradable suture, having a substantially circular cross-section of approximately .006 inches in diameter, as commonly available from Ethicon, a division of Johnson and Johnson, as well as Davis and Geck, a division of American Cyanamide. The forming mandrel 144 comprises a base 146 upon which a pair of forming blocks 148, 150 are mounted. Block 148 is adapted to form the distal, or free end 152 of the haptic while block 150 is

precisely formed to the desired contours of the proximal end 154 of the haptic. The blocks 148, 150 are positioned on the base 146, adjacent one another, leaving a small void 156 therebetween.

A control loop pin 158, sized slightly larger than the void 156, is provided for the formation of the horseshoe-like kink 26, characteristic of the control haptic 22. The control loop pin 158 is sized such that when the suture material is wrapped around it, as illustrated in Figures 18-20, the combination of the control loop pin 158 and the suture material is larger than the void 156. This is significant in that it will yield a control haptic 22, having a control loop 26 with a kinked portion which is greater than 180°, but less than 360°, to assist the ophthalmic surgeon in more readily determining which is the superior side of the lens. More simply stated, the kinked portion of the control loop 26 is at least semi-circular, having an eyelet-like shape, but does not form a complete circle. As illustrated more clearly in Figures 19 and 20, the control loop pin 158 is placed between the blocks 148, 150 and both ends of the suture are passed through the void 156. The suture 160 is then pulled tightly against the blocks 148, 150, conforming to the contours of the forming mandrel 144, and secured thereto, preferably by tying a knot in the suture material, intermediate blocks 148, 150 and opposite the control loop pin 158. A retaining bar (not shown) is placed against the control loop pin 158 intermediate the blocks 148, 150 to bias the suture material 160 toward the pin during the remainder of the control haptic forming process. The wrapped forming mandrel is then placed in a Nitrogen oven and heated at a temperature of between 300°F and 350°F for approximately one hour. Preferably, the suture material is heat set at 320°F, during which time it will deform to assume the shape of the forming mandrel 144, and produce a control haptic 22. After the mandrel and haptics have been allowed to cool, they are cut off of the forming mandrel with a razor blade along grooves 162 and 164. Haptics without the control loop may also be formed by the same

procedure, without the use of the control loop pin. The haptics are then tumbled in a standard intraocular lens tumbler, using the standard proportions of water, .3 m Al_2O_3 and glass beads to round off the ends of the haptics. The resultant control haptic 22 is illustrated in Figure 21. The proximal end 154 of the haptic is somewhat bent at an angle, so that the haptic, when bonded to the optical element 140, will be tangential thereto. Prior to bonding the haptics 22, 24 within the apertures 130, 132 formed in the lens, they must be surgically cleaned. This is accomplished by thoroughly rinsing the haptics in isopropyl alcohol, heated to about 150° F.

In order to improve the adhesive properties of the polypropylene suture material from which the haptics are made, a high frequency corona surface treater (not shown) is used to surface charge the proximal end 154 of the haptic. Such surface treatment is not permanent, and decays with time to some limiting value which is dependent upon the particular material being used. Further, corona treated surfaces are not mechanically durable, and should therefore be disturbed as little as possible. The proximal end of the haptic, which is to be surface treated by the corona discharge is passed beneath an emitting electrode at a speed and distance from the electrode which is determined by the amount of treatment required.

Because of the sensitivity of the surface treatment, the treated end of the haptic is preferably coated with a primer immediately after being passed through the corona discharge. Preferably, a specially formulated, one component unpigmented silicone primer, as available from McGhan NuSil Corporation, and sold under the name CF1-135 High Technology Silicone Primer, is used. This primer is an air-drying primer, designed to improve the adhesion of cured silicones to various substrates. A uniform thin coat of primer should be applied to the proximal end of the haptic following treatment of the surface. This may be accomplished by brushing, wiping, dipping or spraying the primer onto the haptic, although

dipping is the preferred method. The primer is then allowed to hydrolyze, or air-dry on the surface of the haptic, at least two hours prior to bonding. While the adhesion of the primer to the haptic is much improved after the haptic has been subjected to the corona discharge, it is sometimes necessary to dip the proximal end of the haptic in the primer several times before it is uniformly coated. To further improve the adhesion of the haptics 22, 24, within the holes 130, 132, the proximal end of the haptics may be dusted with fumed silicone dioxide after the primer has been allowed to dry.

Following the preparation of the haptics 22, 24 for bonding to the optical element 140, a silicone adhesive 166 is drawn into a 1 cc tuberculin syringe 168, shown in Figure 22. Preferably, the adhesive is RTV-118 silicone rubber adhesive sealant, as commonly available from the Silicone Products Division of General Electric. Alternatively, the adhesive can be medical adhesive silicone type A, as manufactured by Dow Corning Corporation, under the name Silastic. These adhesives are easily applied, translucent, non-flowing soft silicone adhesives, ideally suited for bonding silicone elastomers to itself as well as other synthetics. A 30 gauge needle 170, having a diameter of .012", and a blunt end 172 which has been cut off and polished round, as illustrated in Figure 22, is secured to the end of the syringe 168. Prior to the injection of the adhesive 166 into the apertures 130, 132, the needle 170 is fully inserted into the aperture. The adhesive 166 is then slowly injected and the syringe slowly withdrawn from the aperture until the aperture is approximately two-thirds full of adhesive. It is important that the syringe needle 170 be fully inserted into the aperture and backed out of the aperture while the adhesive is being injected, as air pressure in the aperture would tend to force the adhesive outward. The proximal end 154 of the haptic is then inserted into the adhesive-filled aperture as illustrated in Figure 23, displacing a small quantity of the adhesive, as illustrated in Figure 24.

It is beneficial to have as long a haptic as possible without unduly increasing the size of the intraocular lens. Longer haptics have the advantage over shorter haptics in that they are less rigid, substantially softer and more flexible and, most importantly, less traumatic to the eye after implantation. A haptic that completely encircles the optical element of the intraocular lens, however, would not be preferable, as it would increase the surface area of the lens, necessitating a larger incision into the eye for implanting. Fortunately, because of the indentation 142 at the lip 138 of the lens 140 formed during the tumbling process, and the angle at which the proximal end 154 of the haptic is subtended, the haptic emerges tangentially from the lens. The tangential alignment and bonding of the haptic with the lens enables the implementation of a haptic having the maximum possible length without necessitating an increase in width. This is significant in that it allows one to use a longer haptic, having the aforementioned advantages of suppleness and flexibility which are instrumental in providing a comfortable and non-irritating means for fixating and properly positioning the intraocular lens within the eye. In addition, since the width of the intraocular lens is not affected by the increased length of the haptic, the advantage of smaller incisions, made possible by the advances in phacoemulsification technology and associated with soft, foldable intraocular lenses is preserved. Advantageously, as shown in Figure 24, because the haptic is one half the diameter of the aperture, it may be disposed at any number of desirable angles with respect to the lens.

Figures 25 and 26 illustrate a dihedral fixture 174, having a pair of upwardly sloping sides 176, 178 and a pair of opposing sidewalls 180, 182 disposed along the upper edges 184, 186 of the sloping sides. Preferably, the dihedral fixture 174 has an included angle of 172° so as to provide for a 4° inclined surface on each of the sloping sides 176, 178. Centrally disposed between the opposing sidewalls 180, 182 of the fixture are a plurality of depressed receptacles 188,

resting in a valley 190 created by the sloping sides 176, 177 of the forming fixture 174. Each receptacle 188 is sized to accommodate one intraocular lens. Small coves 192 are cut into the opposing sidewalls 180, 182 to provide receptacles for the haptics 22, 24 during the time the adhesive 166 is curing. The intraocular lens 10 is carefully placed into the depressed receptacle 188 which, because of its sunken disposition, adds an extra degree to the angulation of the haptic with respect to the lens, resulting in an intraocular lens 10 having haptics 22, 24 set at a 5° angle with respect to the lens.

As a final production step, the lenses 10, with the haptics attached, are extracted, or rinsed in distilled, purified water to remove any residues from the adhesive or impurities which may be present on the lens. The intraocular lenses are further agitated in the purified water for a period of at least 12 hours to draw out such impurities. The lenses are then dried, and the haptic attachment is tested for durability on a gram scale.

It will be understood by those skilled in the art that the coining mandrel can assume any desired configuration, and that the mold forming process described herein may be used for intraocular lenses other than biconvex. Additionally, the coining and the mold forming process described herein may be used for forming intraocular lenses other than multi-piece lenses such as single-piece intraocular lenses.

The use of single-piece intraocular lenses has recently increased due to the simplification of the insertion procedure for single-piece lenses that can be achieved by utilizing an intraocular lens injector. These single-piece lens can be inserted through a small incision in the ocular tissue, such as those incisions which are employed with the phacoemulsification technique of cataract removal, utilizing simplified injection techniques which incorporate the improved intraocular lens injecting device described below.

FIGS. 30-33 illustrate a preferred embodiment of an intraocular lens injector which compresses and injects a

single-piece intraocular lens into an eye of a patient. The preferred embodiment of the intraocular lens injector 310 comprises a compression portion 312 and a insertion portion 314. The compression portion comprises a shuttle member 316, an intraocular lens receiving channel 318 and a mating cylindrical passageway 320.

The shuttle member 316 comprises a thin, rectangular-shaped pushing member 322 with a concave scoop end 324 and a rectangular handle portion 326 which is thicker than the pushing member 322 to enable a user to easily manipulate the shuttle member 316. The shuttle member 316 is designed such that the pushing member 322 fits tightly within the intraocular lens receiving channel 318 and the concave scoop end 324 terminates tangential to a bottom surface 328 of the cylindrical passageway 320. Preferably, the scoop end 324 of the shuttle member 316 mates with the cylindrical passageway 320 to form a complete cylinder when the intraocular lens shuttle member 316 is completely inserted into the intraocular lens receiving channel 318.

The shuttle member 316 is preferably keyed to match a compatible keying means on the intraocular lens receiving channel 318 such that the shuttle member 316 can only be inserted into the lens receiving channel in only one direction. In one embodiment, the keying means is formed by rounding a first end 330 of the pushing member 322 and rounding a corresponding first end 332 of the intraocular lens receiving channel 318 while squaring an opposite second end 334 of the pushing member 322 and squaring the corresponding opposite second end 336 of the intraocular lens receiving channel 318 such that the shuttle member 316 can only be inserted when the scoop end 324 is inserted tangential to the bottom surface 328 of the cylindrical passageway 320.

The cylindrical passageway 320 extends longitudinally through the compression portion 312 of the intraocular lens injector 310. A first end 338 of the cylindrical passageway 320 is open and enables the insertion of an insertion plunger 340 which urges the intraocular lens from the compression

portion 312 into the insertion portion 314 of the intraocular lens injector 310. The cylindrical passageway 320, or rolling chamber, defines the compressed diameter of the intraocular lens when it is rolled upon itself into a spiral defined by the dimensions of the compression portion 312. Preferably, the inner diameter of the cylindrical passageway 320 is approximately 2-3 mm. More preferably, the inner diameter of the cylindrical passageway 320 is as small as 1 mm for intraocular lenses of a reduced thickness. The intraocular lens receiving channel 318 preferably intersects the cylindrical passageway at a right angle and is off-axis to the passageway 320 at the intersection. A second end 342 of the cylindrical passageway 320 terminates at the insertion portion 314. Preferably, the second end 342 of the compression portion 312 is threaded to enable the attachment and removal of the insertion portion 314 from the compression portion 312.

The insertion portion 314 comprises a threaded attachment member 344 concentric with an insertion tube 346. Preferably, the threaded attachment member 344 utilizes a thread size which is identical to the threaded second end 342 of the insertion portion 312. It is important that the compression portion 312 and the insertion portion 314 be perfectly mated, such that there is no uneven ridge at the joining seam which may catch the intraocular lens and potentially damage the lens. The insertion tube 346 is preferably of a 1-3 millimeter inner diameter, which is uniform throughout the length of the insertion tube 346. The cylindrical passageway 320 and the insertion tube are concentric and form an injection channel of uniform diameter through which the intraocular lens is inserted into the eye of the patient. The outer diameter of the insertion tube 346 may be slightly tapered at the end to enable the insertion tube 346 to be placed into a small incision in the ocular tissue while being structurally sound. Preferably, the outer diameter of the insertion tube 346 is approximately 1-4 mm. The wall thickness of the insertion tube 346 is between approximately

.1 to .3 mm, depending on the material from which the insertion tube 346 is made. The type of mating threads on the attachment portion 344 and the second end 342 of the insertion portion 312 can be of the conventional screw-type fitting, a luer-lock fitting, bayonet, or any type of attachment known to those of skill in the art.

Preferably, the compression portion 312 is formed of a composite material, such as Teflon, polypropylene, polyethylene, polysulfone, polymethylpentene, polyvinyladine fluoride, or any other polymeric composite material known to one of skill in the art. The shuttle member 316 is preferably made from the same material as the compression portion 312. Alternatively, the cylindrical passageway 320 is formed from hypodermic metallic tubing. Further, the attachment member 344 is preferably made of the same type of composite material as the compression portion 312 to enable a smooth mating of similar materials. Further, the passageway 320, the scoop end 324 of the shuttle member 316 and the insertion tube 346 are line-bored after they are assembled to ensure a perfectly mated contiguous passageway 320 through the compression 312 and insertion portions 314 of the injector 310. In one embodiment, all of the parts of the compression portion 312 are molded in one mold to ensure that all of the elements which make up the passageway 320 are perfectly mated with each other to form a contiguous passageway. Preferably, the insertion tube 346 and the insertion plunger 340 are made from aluminum, stainless steel, titanium or any other material known to one of skill in the art, which can be easily machined to their desired shape and does not easily rust or corrode. In addition, if any element which comes into contact with the intraocular lens is made from a metallic material, the element must be chemically passivated or pickled to remove any impurities which could transfer to the lens. If such impurities are transferred to the lens, toxic substances other known adverse syndromes may be introduced into the patient's eye upon implantation. Further, it is important that all of the pieces which interact with the intraocular lens are de-

burred, blended smooth, and polished to a high luster to prevent any damage to occur when the lens comes into contact with an element of the intraocular injector device 310. The end of the insertion plunger 340 is preferably rounded and polished so that there are no sharp edges which come into contact with the intraocular lens.

FIG. 34 illustrates an injection handle 350 which can be used with the embodiment of the lens injector 310 illustrated in FIGS. 30-33. The injection handle 350 illustrated in FIG. 34 comprises an injection sleeve 352 and an injection rod 354. The injection sleeve 352 is threaded at a first end 356 to mate with threads of the attachment device 344 of the insertion portion 314. A second opposite end 358 of the injection sleeve 352 is preferably threaded to mate with the threads on the injection rod 354.

When used with the lens injector of FIGS. 30-33, the insertion portion 314 is detached from the compression portion 312 of the injector 310 illustrated in FIGS. 30-33 and is connected to the first end 356 of the injection sleeve 352. The threads on the first end 356 of the injection sleeve 352 are sized to match the threads on the attachment device 344 of the insertion portion 314 to enable a smooth connection between the two mating pieces.

A first end 360 of the injection rod 354 is preferably machined to a rounded finish similar to that of the insertion plunger 340 of the lens injector 310. A second opposite end 362 of the injection rod 354 is preferably threaded to enable a slow guided insertion of the intraocular lens and preferably terminates with an elongated handle 364 to enable the user to accurately control the progression of the injection rod 354.

Preferably, the injection sleeve 352 is a narrow cylindrical design which is long enough to enable the user to easily manipulate the injection handle 350 to direct the handle to the desired insertion location. Further, the injection handle 350 should have a small radius such that the handle 50 does not interfere with the patient's anatomy, i.e., the patient's nose or eye socket, during the insertion of the

intraocular lens.

Preferably, the injection handle 350 is made from aluminum, stainless steel, titanium or any other material known to one of skill in the art which is easy to machine and does not easily rust or corrode when sterilized prior to the surgery. In addition, the injection rod 354 is preferably made from a similar material as the remainder of the injection handle. Further, it is important that all of the elements which interact with the intraocular lens are de-burred, blended smooth, chemically cleaned and polished to a high luster to prevent any damage to occur when the lens comes into contact with any element.

The intraocular lens injector 310 can be used to both compress and insert a single-piece intraocular lens 365 into the patient's eye. Preferably, the intraocular lens comprises an optical element located in a central portion 372 of the lens 365 and a support portion, or haptic, 366 extending from the optical element which are formed as a one-piece unit. However, the intraocular lens injector can be used with any of a variety of multiple piece intraocular lenses which comprise an optical element and two haptics which are made from a different type of material than the optical element. The optical element is thicker than the haptic portion 366 and is curved in accordance with the vision correction which is required by the patient. Advantageously, if an intraocular lens 365 with a thinner optical element is used, the intraocular lens injector 320 can compress the intraocular lens 365 to a smaller diameter. Referring to FIGS. 35a and 35b, the intraocular lens 365 is first placed within the intraocular lens receiving channel 318 in the compression portion 312 of the injector 310. As illustrated in FIG. 35b, the lens 365 is preferably positioned such that the haptic portion 366 is perpendicular to the side walls 367 of the intraocular lens receiving chamber 318. The shuttle member 316 is then inserted into the intraocular lens receiving chamber 318 with the scoop end 324 such that the scoop end 324 is tangential to the bottom surface 328 of the cylindrical

passageway 320. Preferably, the entire compression portion 312, including the cylindrical passageway 320 and the intraocular lens receiving chamber 318, is lubricated with a sterile visco-elastic material, such as Helon, which is manufactured by Khabi-Pharmacia. The visco-elastic material lubricates all of the internal passageways, such as the lens receiving channel 318, the cylindrical passageway 320, and the insertion tube 346, to decrease the level of friction in these passageways. Friction between the lens 365 and the surface of the injector may cause damage to the lens 365; therefore, the use of a visco-elastic material is desirable.

As illustrated in FIGS. 36a and 36b, the shuttle 316 is gently manually urged forward and pushes the intraocular lens 365 towards the cylindrical passageway 320. The intraocular lens 365 advances into the cylindrical passageway 320 and a first end 370 of the intraocular lens 365 abuts a far wall 368 of the cylindrical passageway 320 which is across from the entry point of the intraocular lens receiving channel 318 into the cylindrical passageway 320. Once the intraocular lens 365 comes into contact with the far wall 368, continued urging of the intraocular lens 365 into the cylindrical passageway 320 causes the lens 365 to climb the far wall 368 and proceed in a circular path around the cylindrical passageway 320. The tangential entry of the lens 365 to the bottom surface 328 of the cylindrical passageway 320 forces the lens 365 to follow the walls of the cylindrical passageway 320 and to take on a cylindrical shape.

As illustrated in FIGS. 37a and 37b, the lens 365 will continue to progress around the cylindrical passageway 320 until the first end 370 of the lens 365 comes into contact with the central portion 372 of the intraocular lens 365 which has just advanced into the cylindrical passageway 320. The first end 370 of the lens 365 will come into contact with the central portion 372 of the lens 365 rather than the bottom surface 328 of the passageway 320, since the lens 365 is wider than the circumference of the passageway 320.

Once the first end 370 of the lens 365 comes into contact

with the central portion 372 of the lens 365 which is advancing into the chamber, the first end 370 of the lens 365 will roll up against the central portion 372 of the lens 370 and begin to form a tight spiral within the confines of the cylindrical passageway 320. As the intraocular lens 365 is continually urged into the cylindrical passageway 320, the intraocular lens 365 will continue to roll up about itself and form a tight spiral. As the intraocular lens 365 is continually compressed into the tight spiral shape, the axial length of the rolled up lens 365 will increase to enable the lens 365 to continue to compress to fit within the confines of the cylindrical passageway 320.

As the intraocular lens 365 is compressed in the cylindrical passageway 320, the length of the compressed intraocular lens 365 increases to enable the further compression of the lens 365 into the cylindrical shape of reduced diameter. When the shuttle 316 has been advanced the entire length of the intraocular lens receiving channel 318 and the scoop end 324 mates with the opening into the cylindrical passageway 320 to form a complete cylinder, the lens 365 is compressed into the smallest diameter possible. As illustrated in FIG. 37b, once the lens 365 is compressed into a spiral of the final reduced diameter, the axial length of the lens 365 has increased to enable the lens to compress into the confines of the cylindrical passageway 320. Preferably, the elongated length of the compress intraocular lens 365 is less than the length of the shuttle member 316. This ensures that the shuttle member 316 does not damage the lens 365 by clipping the elongated lens 365 with either of the ends 330, 334 of the shuttle member 316.

As illustrated in FIGS. 38 and 39, an insertion plunger 340 is introduced into the second end 342 of the cylindrical passageway 320 and is advanced until it comes into contact with the intraocular lens 365. The insertion plunger 340 is continuously advanced and, in turn, pushes the intraocular lens 365 through the cylindrical passageway 320 and into the mating insertion tube 346. As illustrated in FIG. 39, the

insertion plunger 340 progresses through the cylindrical passageway 320 until the compressed intraocular lens 365 is completely contained within the insertion tube 346.

In an alternate embodiment of the intraocular lens injector, the insertion plunger 340 is elongated such that the insertion tube 346 can be placed directly into an eye of the patient and the lens 365 is injected directly from the insertion tube 346 into the patient's eye.

In a preferred embodiment, the insertion portion 314, with the lens 365 rolled up inside, is detached from the compression portion 312 of the lens injector 310 and is attached to the injection handle 350, as illustrated in FIG. 34. Preferably, the insertion tube 346 is attached onto the first end 356 of the injection sleeve 352 via the attachment device 344 to form a lightweight and streamlined lens injector to insert the sterile lens 365 into the eye of a patient. The injection rod 354 is introduced into the second end 358 of the injection sleeve 352 and is advanced through the injection sleeve 352 and into the injection tube 346. As the injection rod 354 approaches the insertion tube 354, the threads on the injection rod 354 will engage with the threads on the second end 358 of the injection sleeve 352. Turning of the injection rod 354 within the threads of the injection sleeve 352 will slowly advance the injection rod 354 until it comes into contact with the intraocular lens 365 in the insertion tube 346.

As illustrated in FIG. 40, at this point, the injection handle 350 is positioned such that the insertion tube is introduced into an eye 376 through a small 2-4 millimeter incision 378 in a cornea 380 of the eye 376 formed by the phacoemulsification process which previously removed the native lens of the eye. Next, the insertion tube 346 is preferably inserted through a small incision 381 in the lens capsule 382. The insertion tube 346 is positioned such that the compressed lens 365 exits the insertion tube 346 in the desired position. The injection rod 354 is continually advanced as the second end 362 of the injection rod 354 is

turned within the threads of the second end 358 of the injection sleeve 352 which advances the intraocular lens 365 until it is forced out of the injection tube 346 and into the lens capsule 382. As the lens 365 is expelled from the injection tube 346, the lens 308 will expand from its compressed state into its original unstressed state and the user will position the injection handle 350 in such a manner that the lens 365 is expelled into the desired location and orientation within the lens capsule 382.

FIGS. 41 and 42 illustrate an alternative embodiment of the intraocular lens injector in which the compression portion 312 and insertion portion 314 are formed from a single piece 390 of composite material which can be disposed of after each use. Preferably, a viewing hole 392 is formed in a top surface 394 of the one-piece compression and insertion portion 390 to enable the user to view the intraocular lens 365 within the receiving channel 318 to verify that it has been properly aligned within the channel 318. In one embodiment, a small raised button detent 393 is molded onto the shuttle member 316 which will index and audibly snap into place within the viewing hole 392 when the shuttle has been completely inserted within the intraocular lens receiving channel and the scoop end 324 of the shuttle is in proper alignment with the opening to the cylindrical passageway 320. Further, the raised button 393 will act to resist the compression forces on the lens 365 and will hold the shuttle member 316 in alignment with the cylindrical passageway 320 to prevent any damage from occurring to the lens during injection. As illustrated in FIG. 42, the single piece compression and injection portion 390 is mated to a tubular injection handle 350 using threads 396 and a set of mating threads 398. The mating threads 396 and 398 may be of a standard screw type thread, a luer-lock thread or any other connection means known to one of skill in the art. The first end 356 of the injection sleeve 352 is mated with an injection rod 354. Preferably, the second end 358 of the injection sleeve 352 is threaded to enable the injection rod 354 to be slowly advanced into the one-piece

compression and injection unit 390. Preferably, the advancement of the injection rod 354 is controlled by turning the injection rod 354 within the threaded second end 358 of the injection handle 350. Preferably, the injection handle 350 and insertion rod 354 are formed of a stainless steel, titanium, or aluminum material which can be easily machined into the desired configuration. In addition, the one-piece compression and insertion portion 390 is made from a composite or plastic material which is inexpensive, as the embodiment of the one-piece compression and injection portion 390 is preferably disposable.

In use, the injection rod 354 is placed within the tubular steel handle 350 such that the rod 354 is positioned just above the opening of the IOL receiving channel 318 and the threads of the insertion rod 354 begin to engage the threads of the second end 358 of the injection sleeve 352. The intraocular lens 365 is then placed within the receiving channel 318 and the alignment of the intraocular lens 365 is checked through the viewing hole 392. As described above, the shuttle member 316 is advanced toward the cylindrical passageway 320 which advances the lens 365 into the cylindrical passageway 320 and the lens 365 begins rolling upon itself. Once the lens 365 is completely advanced into the cylindrical passageway 320, the raised button 393 on the shuttle member 316 snaps into place within the viewing hole 392, to maintain the alignment of the shuttle member 316 with the cylindrical passageway 320 and to prevent the compression force of the lens from forcing the shuttle 316 out of alignment. At this point, the lens 365 is formed into the elongated tight spiral configuration which conforms to the diameter of the cylindrical passageway 320. The injection rod 354 is advanced by turning the rod 354 in the threads on the second end 358 of the injection sleeve 352 to slowly advance the insertion rod 354 and the compressed intraocular lens 365. The intraocular lens 365 is slowly advanced through the cylindrical passageway 320 and out the opening 399 at the end of the once piece compression and injection portion 390.

In one embodiment, the one-piece unit 390 is made from a disposable plastic material which can be thrown away after each use. This disposable one-piece compression and injector unit 390 is advantageous, as it does not require the continual sterilization of the injection piece 390 for each patient. Further, the user does not have to be concerned with the problems associated with wear and tear on the injector which may result in rough edges or barbs forming within the lens injector which may damage the intraocular lens 365 upon compression or insertion of the lens.

The lens can be stored within the lens receiving channel 318 in the one-piece compression injection portion 390 during shipping, so that the only assembly required is attaching the one-piece compression and injection portion 390 to the injection handle 350. Preferably, the shuttle member 316 is held in a storage position by a detent or strap (not shown) which extends from the shuttle member 316. The storage position is such that the lens 365 remains within the lens receiving channel 318 without being compressed by the shuttle member 316. Preferably, the one-piece compression and injection portion 390 is sterilized and sealed in the storage position before the one-piece unit 390 is shipped.

Once the lens 365 is to be inserted, the seal is broken and the one-piece unit 390 is attached to the injection handle 350. The storage detent on the shuttle member 316 is broken by applying a force to the shuttle member 316 which sheers the storage detent and enables advancement of the shuttle member 316. The shuttle member 316 is advanced and the lens 365 is compressed into the cylindrical shape of the cylindrical passageway 320. The alignment and progression of the lens 365 within the intraocular lens receiving channel 318 can be verified through the viewing hole 392 until the lens 365 is completely inserted into the cylindrical passageway 320. This one-piece embodiment 390 is advantageous over prior art lens injectors as the one-piece compression and insertion portion 390 can be used as both a shipping container and as a means for compressing and inserting the lens 365 into the eye.

Preferably, an improved single-piece flexible intraocular lens with a radiused junction between a lens element portion and a haptic support portion of the intraocular lens is used with an intraocular lens injector as described above. Figure 43 shows a single-piece flexible intraocular lens of the prior art 410 which has a sharp corner or angle 412 at the junction between a lens element 414 and a support portion 416 which was previously used with the intraocular lens injector as described above. This sharp corner 412 is a surface discontinuity which is a natural result of the meeting of a spherically shaped lens element 414 with the support portion 416. The single-piece flexible intraocular lenses of the prior art 410 are typically formed from multi-piece molds. One piece of the mold forms the lens element 414 and the other piece of the mold forms the haptic support portion 416. The junction of the two mold pieces forms the sharp corner surface irregularity 412 at the junction of the lens element 414 and the haptic 416. As described above, this sharp corner 412 is undesirable for several reasons. One reason is the sharp corner 412 can result in the occurrence of the "cusp effect" when the patient is in low light conditions. The "cusp effect" causes a bright halo of light to surround the patient's field of vision and is extremely distracting to the patient. In addition, as is known to one of skill in the art, the sharp corner 412 at the transition of the lens element 414 to the haptic 416 forms a surface irregularity which creates the weakest point in the lens construction. This weak point is subject to tearing when the lens 410 is loaded into an injector and implanted into a patient.

As illustrated in Figures 44-46, a preferred embodiment single-piece flexible intraocular lens 420 has a radiused transition region, or junction, 422 between an optical element 424 and a winged support portion, or haptic, 426. The support portion 426 at least partially surrounds the optical element 424 and can take on any number of shapes which will be apparent to one of skill in the art. In a preferred embodiment, the winged support portion comprises a rectangular

flat plate with rounded ends. The length of the intraocular lens of the preferred embodiment 420, in which the winged haptic 426 is a rectangular flat plate, along the longest length of the winged haptic 426 is 9-12 mm, depending upon the size of the lens capsule of the person into which it is being implanted. More preferably, the total length of the intraocular lens 420 along this longest side is 10.5 mm.

Preferably, the transition region 422 between the optical element 424 and the winged support haptic 426 is formed by a fillet portion 428. The fillet portion 428 is used to reinforce the re-entry angle formed by the intersection of the two surfaces of the optical element 424 and the winged haptic portion 426. The fillet portion 428 is incorporated into the junction 422 to reduce the stresses on the intraocular lens 420 associated with the sharp cornered transition region 412 of prior art lenses (Figure 43). Therefore, the fillet portion 428 re-enforces the weak junction 422 of the optical element 424 and the winged haptic portion 426, and eliminates a surface discontinuity which could serve as a tear-initiating region, thereby improving the strength of the single-piece lens 420 of the preferred embodiment over the single-piece lenses of the prior art 410 (Figure 43).

As will be recognized by one of skill in the art, the radius of the transition region 422 must be sufficiently large to provide adequate re-enforcing strength to prevent the single-piece lens 420 from tearing at the transition region 422 when the single-piece lens 420 is loaded into a lens injector or folded by insertion forceps. However, the radius of the transition region 422 cannot be so large as to encroach into the optic zone that it prevents the necessary flexibility required by a soft deformable intraocular lens 420 to deform to fit within the small incision remaining from the phacoemulsification procedure. Further, the desirable radius of the transition region 422 will vary depending on the diopter power of the soft foldable lens 420. The diopter power of the lens 420 effects the shape of the optical element 424, and will therefore effect the severity of the transition

from the optical element 424 to the support portion 426. A preferred radius for the transition portion 422 is between 0.01 mm and 0.25 mm. More desirably, the radius for the transition portion 422 is between 0.05 mm and 0.13 mm. Further, the radius of the transition portion should not be so large that it reduces the optic area by more than 15%.

Additionally, the winged haptic portion 426 has positioning holes (sometimes called fixation holes) 427 on each end of the haptic 426 to enable the surgeon to properly align the intraocular lens 420 within the eye during implantation. An intraocular lens positioning tool (not shown) is inserted into the eye through the same incision that a lens injector is inserted. The positioning tool is inserted into one of the positioning holes 427 and the intraocular lens 420 is moved into the desired position within the lens capsule. After the surgery, small cells will grow through the positioning holes 427 and anchor the lens in place in the eye.

Further, the radiused transition region 422 is incorporated in all types of single-piece intraocular lenses 420, regardless of the type of optical element 424 that is included in the lens 420. Therefore, a radiused transition portion 422 between the optical element 424 and the support portion 426 can be used with an optical element 424 which is a monofocal lens, a multifocal lens, a spherical lens, an aspheric lens or any other lens shape known to one of skill in the art. Figures 44-46 illustrate a preferred embodiment of the one-piece soft foldable intraocular lens 420 which comprises a monofocal lens as the optical element 424 in combination with the radiused transition region 422. Figure 47 illustrates a cross-sectional view of an alternate embodiment of a soft foldable intraocular lens 430 which utilizes a multifocal lens 432 as the optical element 424 in combination with the radiused transition region 422 between the optical element 424 and the support portion 426. Figure 47 clearly demonstrates that the radiused transition zone 422 can be utilized with optical elements 424 of different configurations, such as the multi-focal lens embodiment 430

that is illustrated.

The flexible single-piece lens 420 is made of a soft optical grade biocompatible material, such as a flexible acrylic material, a hydrophilic material or a silicone material. Preferably, silicone is used to form the preferred embodiment of the flexible single-piece lens 420.

The single-piece intraocular lens 420 of the preferred embodiment is preferably formed by a single-piece mold. The single-piece mold is formed by the coining technique disclosed above. In the case of the single-piece intraocular lens 420 of the preferred embodiment, it is possible to form the intraocular lens mold utilizing one or more coining mandrels.

In a single-mandrel embodiment, the shape of the entire optical element 424 and the support haptic 426 is coined on a single mandrel utilizing the techniques disclosed above. The transition region 422 from the optical element 426 to the support haptic is carefully formed on the mandrel to the desired radius to ensure that the transition region 422 on the lens 420 is smooth and without the angularity of the transition regions 416 of the prior art lenses 410 (Figure 43). The single mandrel is pressed into a stainless steel mold blank 440 under a load sufficient to deform the stainless steel mold blank 440 with the reverse imprint of the surface of the coining mandrel (not shown), thereby forming a mold cavity as illustrated in Figure 50. Assuming 410 or 420 stainless steel is used for the mold cavity, approximately 15-20 tons of pressure will be required to deform the mold blank utilizing a single mandrel if an intraocular lens 420 of 10.5 mm in length is being formed.

In the dual mandrel embodiment, a first mandrel is made with the reverse impression of the haptic portion 426 of the lens 420. A second mandrel is formed with the reverse impression of the optical element 424. The haptic portion 426 of the lens 420 does not have to be of optical quality; therefore, all the extra polishing steps required by the second mandrel to form an optical surface which is flaw-free do not have to be taken for the first mandrel which forms the

haptic 426.

In the dual-mandrel embodiment, the first mandrel is pressed into a mold blank until the mold blank is coined into the shape of the winged haptic. If 410 or 420 stainless steel is used, approximately 15-20 tons of pressure will be required to deform the mold blank with the first mandrel of the dual mandrel embodiment if an intraocular lens 420 of 10.5 mm in length is being formed. The pressure required to deform only the haptic portion of the mold in the dual-mandrel embodiment is approximately the same as the pressure required to form the entire imprint of the lens utilizing the single-mandrel technique. It will be recognized by one of skill in the art that since that haptic portion does not have to be of optical quality, alternatively the haptic portion of the mold can be formed by CNC milling, electrical discharge machining (EDM), electro-forming or any other suitable machining operation on the mold blank to form the shape of the haptic 426.

Figure 48 illustrates a mold blank 440 which has been coined by a first mandrel (not shown) and has made a support haptic forming portion 442 of the mold 440. Additionally, Figure 48 illustrates a pair of hole positioning pins 444 which are used to form the positioning holes 427 in the intraocular lens 420. The positioning hole pins 444 can be coined by one of two methods. A first method is by coining a first haptic mandrel which forms the haptic positioning hole pins 444 simultaneously with the coining of the support haptic forming portion 442 of the mold 440. A second method is by coining two holes 447 in the bottom of the mold 440 through almost the entire length of the mold at the approximate location of the desired positioning hole pins 444. Two hardened steel pins (not shown) are inserted into the holes 447 and are pressed into the remaining steel of the mold 440 with sufficient force to push the metal around the pins forward into a first haptic forming mandrel (not shown) thereby forming two protrusions from the mold 440. The amount of force that is required to form the positioning hole pins 444 is considerably less force than required to form the

support haptic forming portion 442 of the mold 440. Next, the two hardened steel pins are removed from the holes 447 and the holes 447 are fitted with pins which are made from the same material as the mold 440. If the holes 447 are not filled with pins of a material that is similar to the mold material, subsequent optic forming may not occur with the desired consistency and uniformity required by intraocular lens manufacturing. After the protrusions are formed, the same haptic forming mandrel is pressed into the mold 440 as described above, but this time under the entire 10-20 ton load. The haptic mandrel presses the haptic area with the positioning hole pins 444 into the mold 440 thereby forcing the haptic area with the positioning hole pins 444 into the mold thereby coining the desired molding cavity for the support haptic forming portion 442 as illustrated in Figure 48. Further, Figure 48 illustrates the alignment of the second coining mandrel 445 having the reverse imprint of the optical element 424 with its proper location in the mold blank 440.

As illustrated in Figure 49, after the second mandrel 445 is aligned with the center of the support haptic forming portion 442 of the mold 440, the mandrel 445 is pressed into the mold blank. Because the surface area of the mandrel 445 which forms an optical element forming portion 446 of the mold 440 is considerably smaller than surface area of the mandrel which formed the support haptic forming portion 442 of the mold 440, considerably less force is required to coin the mold with the second mandrel 445 to form the optical element forming portion 446 of the mold 440. Approximately 5-10 tons of force must be applied onto the second mandrel 445 to form the optical element portion of the mold.

Also illustrated in the cross-sectional view of Figure 49, as the second mandrel 445 is pressed into the mold blank 440, the force of the second coining mandrel 445 on the mold blank pulls the material surrounding the mandrel 445 along with the material which is actually in contact with the surface of the mandrel 445. The pulling of the surrounding

material forms the radiused transition region 448 between the optical element forming portion 446 and the winged support haptic forming portion 442 of the mold 440. The coining of the mold 440 results in a lens 420 with a radiused transition region 422 between the optical element 424 and the haptic portion 426 of the lens 420 and not the sharp cornered transition 412 of the lenses 410 of the prior art (Figure 43).

After two mold halves are coined by either method describe above, the mold fabrication is completed by grinding and lapping the mold surface until the surfaces are completely flat. Next, the mold halves are aligned together, utilizing a haptic indexing tool which is machined to precisely fit within the haptic area of the mold. After the mold halves are aligned such that the haptic indexing tool is accurately positioned in the mold, holes are drilled through the surrounding mold area and immediately fitted with dowel pins to indicate the mating position of the mold halves per conventional precision machine shop procedures. A final cleaning step is performed on the optic surfaces utilizing a 0.1 micron diamond polish and oil lapping compound in combination with an adjustable 5,000- 50,000 RPM rotary polishing hand tool. After the single-piece mold 440 is fabricated either by the single or dual mandrel embodiments, the single-piece lens 420 of the preferred embodiment is formed in the resulting mold. Preferably, the lenses are produced via compression molding as described in detail above, although other molding processes, such as transfer molding or liquid injection molding (LIM), may also be employed.

Figure 50 illustrates one half of a mold 440 which has been formed utilizing the coining techniques described above. By coining the mold 440, a mold transition region 448 between a support haptic forming portion 442 of the mold 440 to an optical element forming portion 446 of the mold 440 can be more carefully controlled. The coining procedure which forms the molds 440 results in a smoother mold transition region 448 than other mold forming techniques of the prior art. In addition, the coining process itself causes a smoother

transition region 448 to result in the mold 440 because the controlled application of the force onto the mold blank 440 results in a smooth deformation of the metal which forms the transition region 448 in the mold 440. The transition region 422 of an intraocular lens 420 of the preferred embodiment which is formed by molding can only be as smooth as the mold transition region 448 in which it is formed; therefore, it is important that the mold transition region 448 be as smoothly formed as possible. Thus, a single-piece mold as described above is defined as a lens mold with cavity halves which form a mold cavity, wherein each mold half has a single surface uninterrupted by separate detail pieces, inserts, or parts which would result in flash lines, witness lines or corners.

A multi-piece mold can be used to form the single-piece lens 420 of the preferred embodiment using conventional multi-piece mold manufacturing technology. However, it is very difficult to form the fillet portion 428 in the transition region 422 utilizing a multi-piece mold as it is difficult to control the mating point of the mold pieces which will always result in a line or corner in the transition region 422. Even if initially the mold appears to be perfectly aligned, the heating, cooling and continuous use of such a mold in a manufacturing production process will always result in some variation in the multi-piece mold alignment which will undoubtedly leave a visible corner or flash line in the final lens product at this junction. Additionally, even if this junction in the mold is machined or polished after mold assembly to attempt to form a blended radius to eliminate mismatch, a witness line, indicating the mating point of the mold pieces will still remain. The witness line is always present in a lens which is made by a multi-piece mold. Even if the line is not visible to the naked eye, under magnification or on an optical bench the witness line can easily be detected. The witness line no matter how small will induce higher stresses during implantation procedures.

As described above, the fillet portion 428 at the transition region 422 between the optical element 424 and the

winged haptic portion 426 results in a stronger and smoother transition between the two planar surfaces such that the sharp corner 412 at the transition region of prior art lens 410 (Figure 43) is removed. Without the sharp corner 412 at the transition region, the "cusp effect" is significantly reduced in the single-piece intraocular lenses 420 of the preferred embodiment, as there is no well defined separate detail from which the light reflects onto the retina of the intraocular lens patient. The smooth transition region 422 from the optical element 424 to the winged haptic support portion 426 of the single-piece intraocular lens 420 of the preferred embodiment scatters the light incident on the transition region 422 to the point where the "cusp effect" is undetectable. Even if the fillet radius size is increased by a polishing process, the transition zone 422 will always be smooth even after many production lenses have been formed.

Lastly, the radiused transition region 422 results in a single-piece intraocular lens 420 which is easier to clean and sterilize before insertion. The sharp cornered transition region 412 of the prior art lenses 410 resulted in an area in which contamination commonly collected. This contamination buildup in some cases is difficult to remove and requires additional cleaning steps. By radiusing the transition zone 422 in the preferred embodiment of the single-piece lens 420, the sharp cornered contamination collection area is removed such that contamination buildup is less likely to occur. Any contamination that settles in the radiused transition region 422 will be easier to remove because of the concave shape of the radiused transition region 422 and will not require additional cleaning steps.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than the foregoing description. All changes which come within the meaning and

range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A soft single-piece intraocular lens, comprising:

an optical portion;

a support portion at least partially surrounding said optical portion; and

a junction portion between said optical portion and said support portion, said junction portion radiused to form a smooth transition between said optic portion and said support portion.

2. The soft single-piece intraocular lens, as defined in Claim 1, wherein said optical portion is a monofocal lens.

3. The soft single-piece intraocular lens, as defined in Claim 1, wherein said optical portion is a multifocal lens.

4. The soft single-piece intraocular lens, as defined in Claim 1, wherein the radius of said junction portion is between 0.01 mm and 0.25 mm.

5. The soft single-piece intraocular lens, as defined in Claim 4, wherein the radius of said junction portion is between 0.05 mm and 0.13 mm.

6. The soft single-piece intraocular lens, as defined in Claim 1, wherein said soft single-piece intraocular lens is made of a soft optical grade biocompatible material selected from the group consisting of: silicone, flexible acrylic materials, and hydrophilic materials.

7. The soft single-piece intraocular lens, as defined in Claim 6, wherein said soft single-piece intraocular lens is made of silicone.

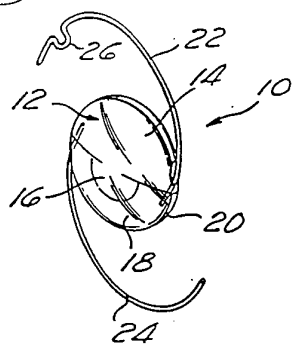
8. The soft single-piece intraocular lens, as defined in Claim 1, wherein siad junction portion between said optical portion and said support portion is a fillet portion.

9. The soft single-piece intraocular lens, as defined in Claim 1, wherein said transition region between said optical element and said support portion has a concave shape, said concave shape reinforcing the transition region against stresses applied to said lens.

10. A method of avoiding the cusp effect from occurring in a soft single-piece intraocular lens, comprising:

forming a radiused transition region in said soft intraocular lens at a junction between an optical element portion of said lens and a support haptic portion of said lens, wherein said radiused transition region scatters light incident on said transition region thereby avoiding the cusp effect.

Fig. 1



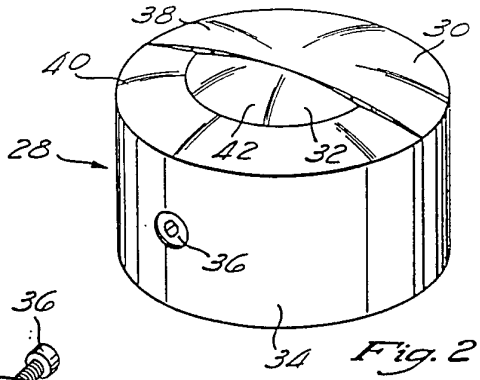


Fig. 2

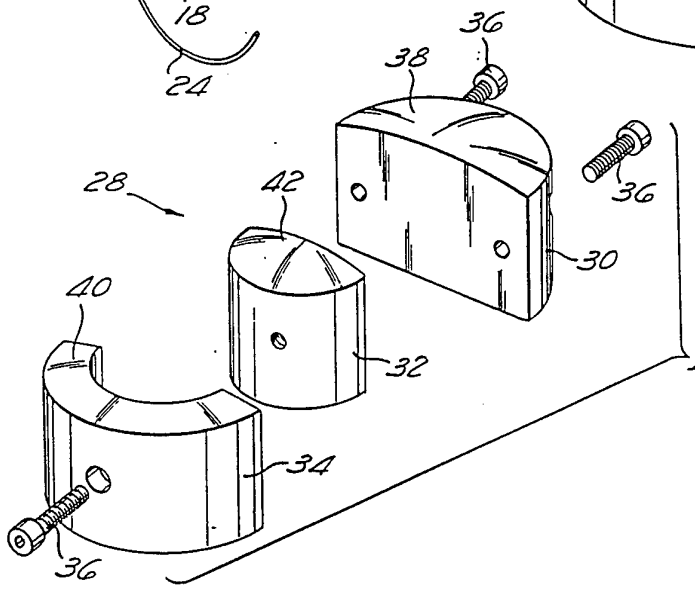


Fig. 3

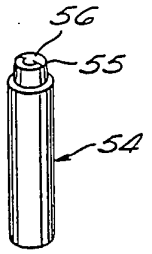


Fig. 5

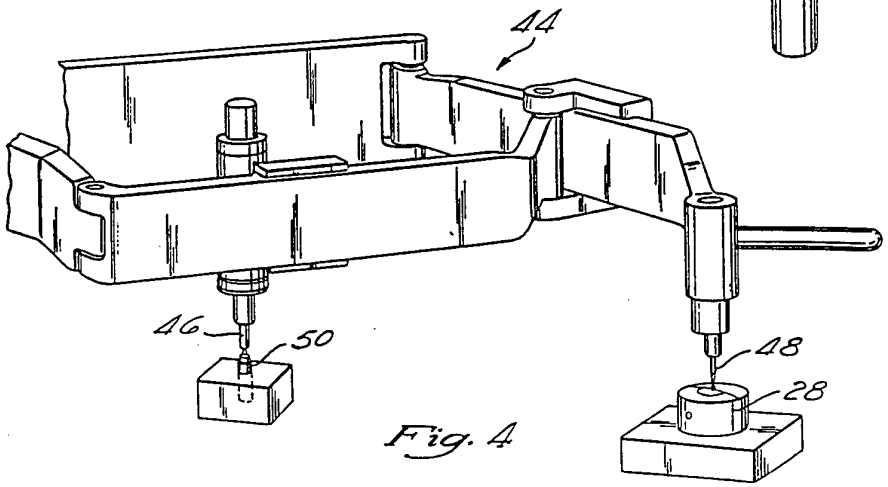


Fig. 4

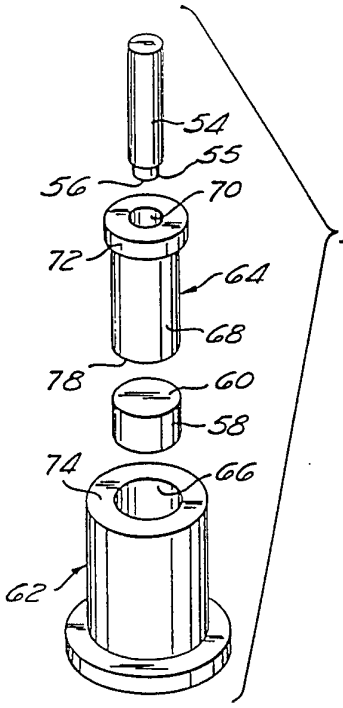
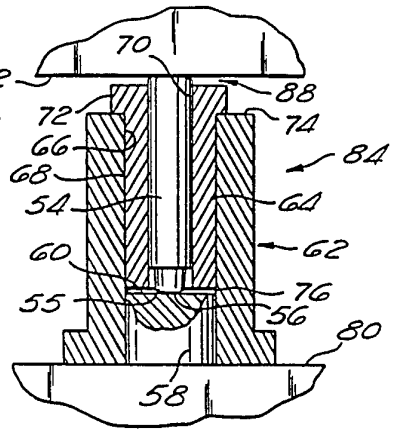


Fig. 6

Fig. 7



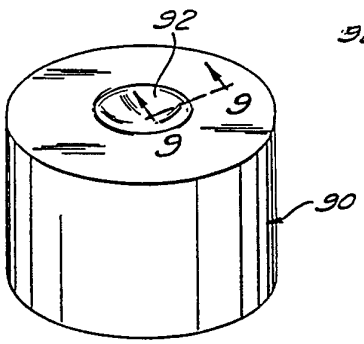


Fig. 8

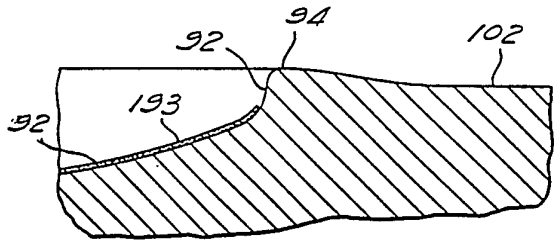


Fig. 9

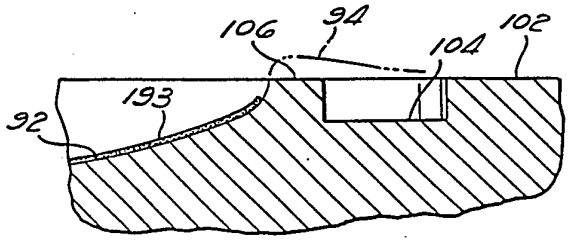


Fig. 10

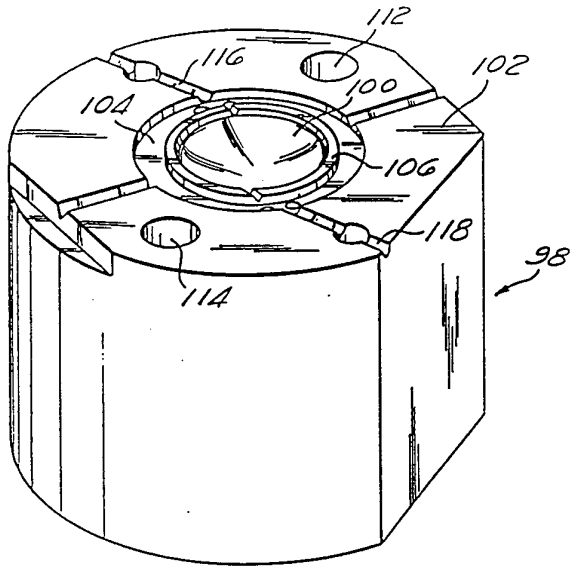


Fig. 11

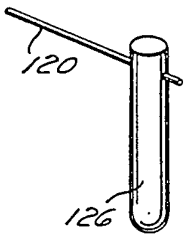


Fig. 12

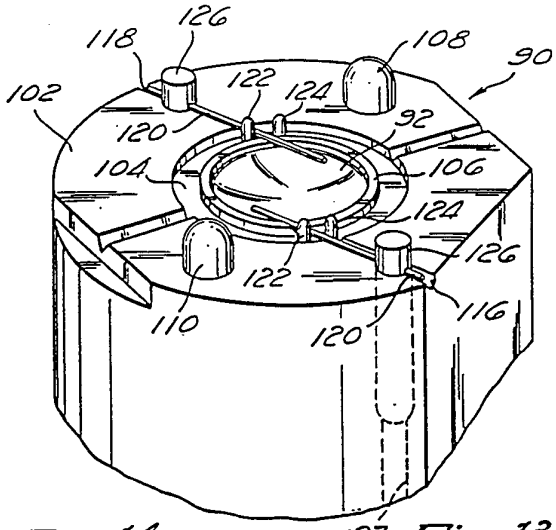


Fig. 13

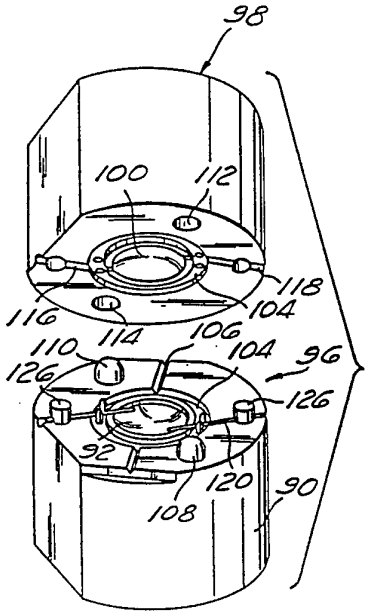


Fig. 14

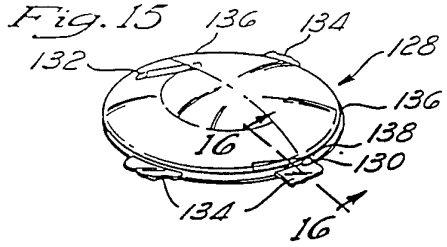


Fig. 15

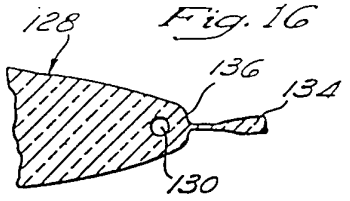


Fig. 16

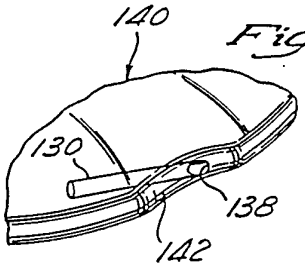


Fig. 17

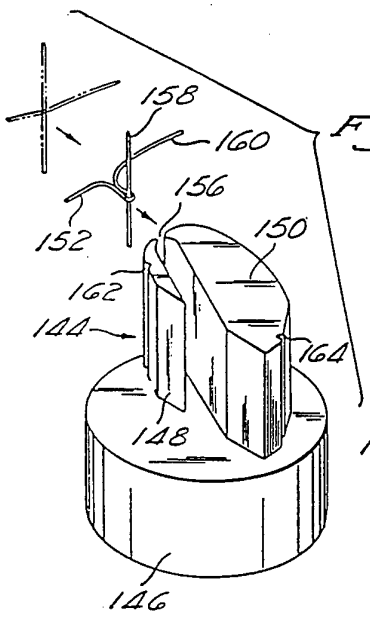


Fig. 18

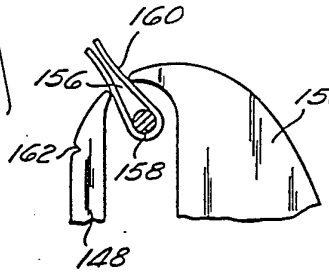


Fig. 19

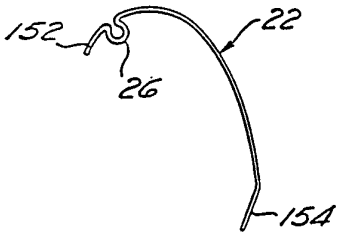


Fig. 21

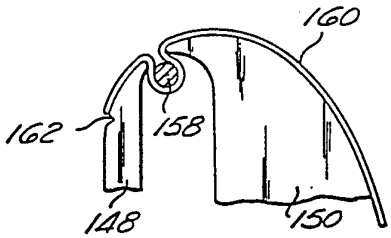


Fig. 20

Fig. 22

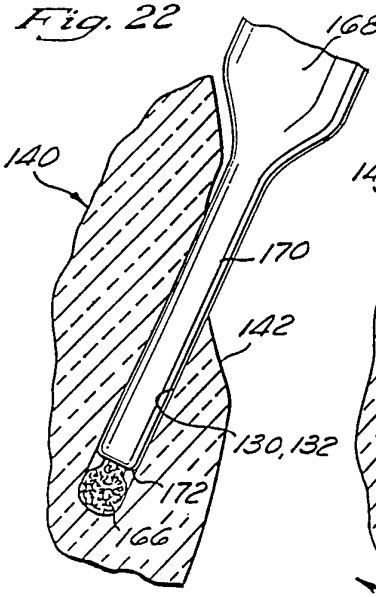


Fig. 23

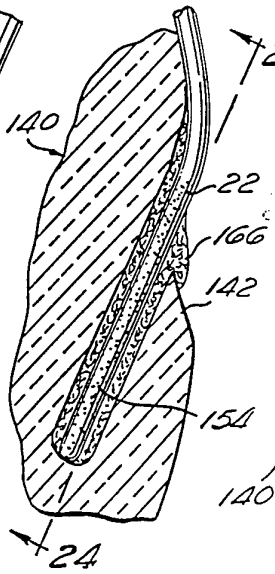
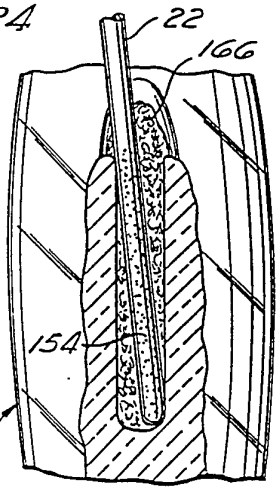


Fig. 24



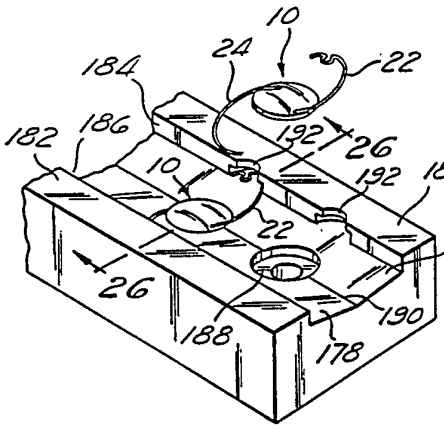


Fig. 25

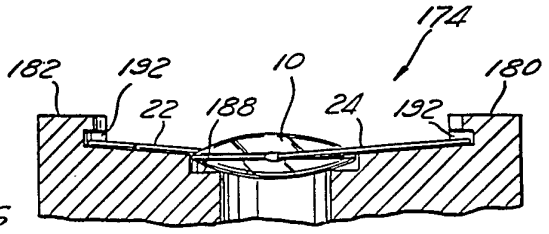


Fig. 26

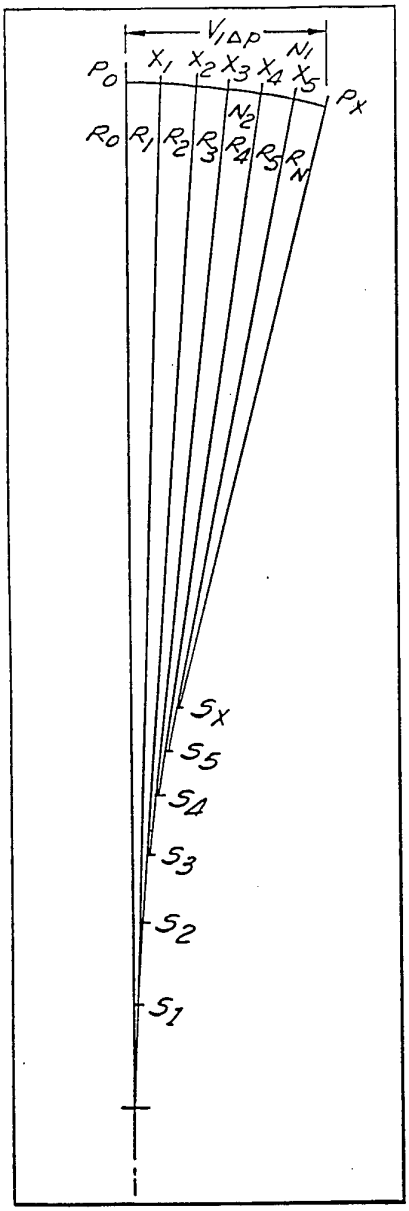


Fig. 27

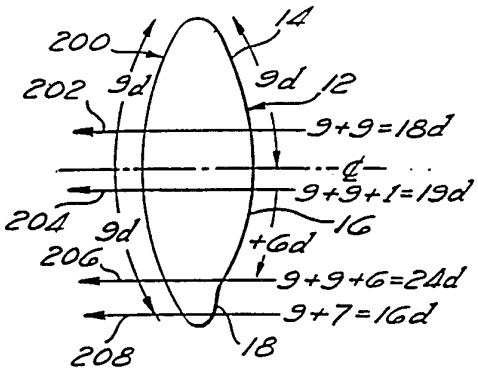


Fig. 29

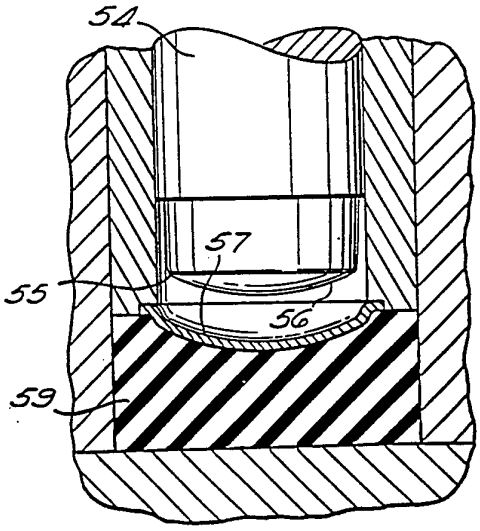


Fig. 28

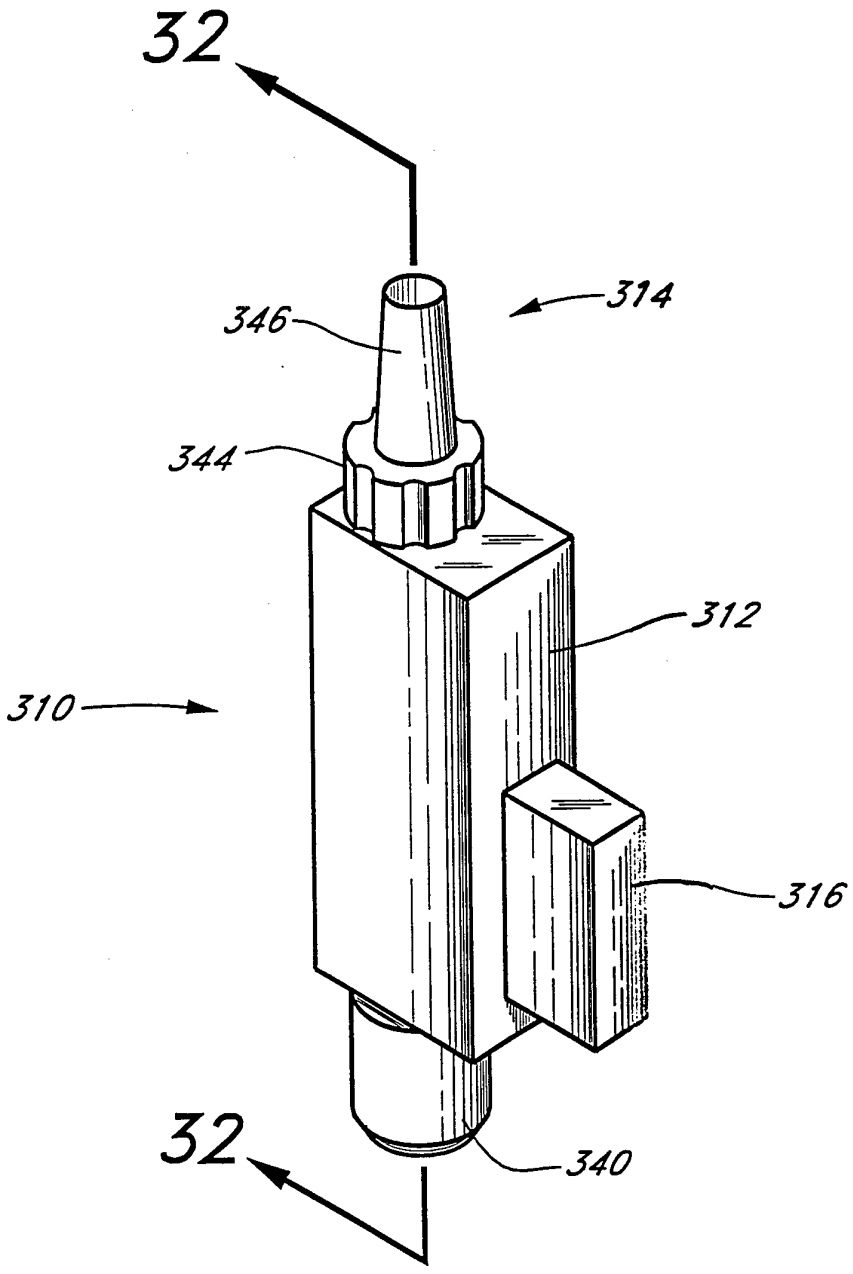


FIG.30

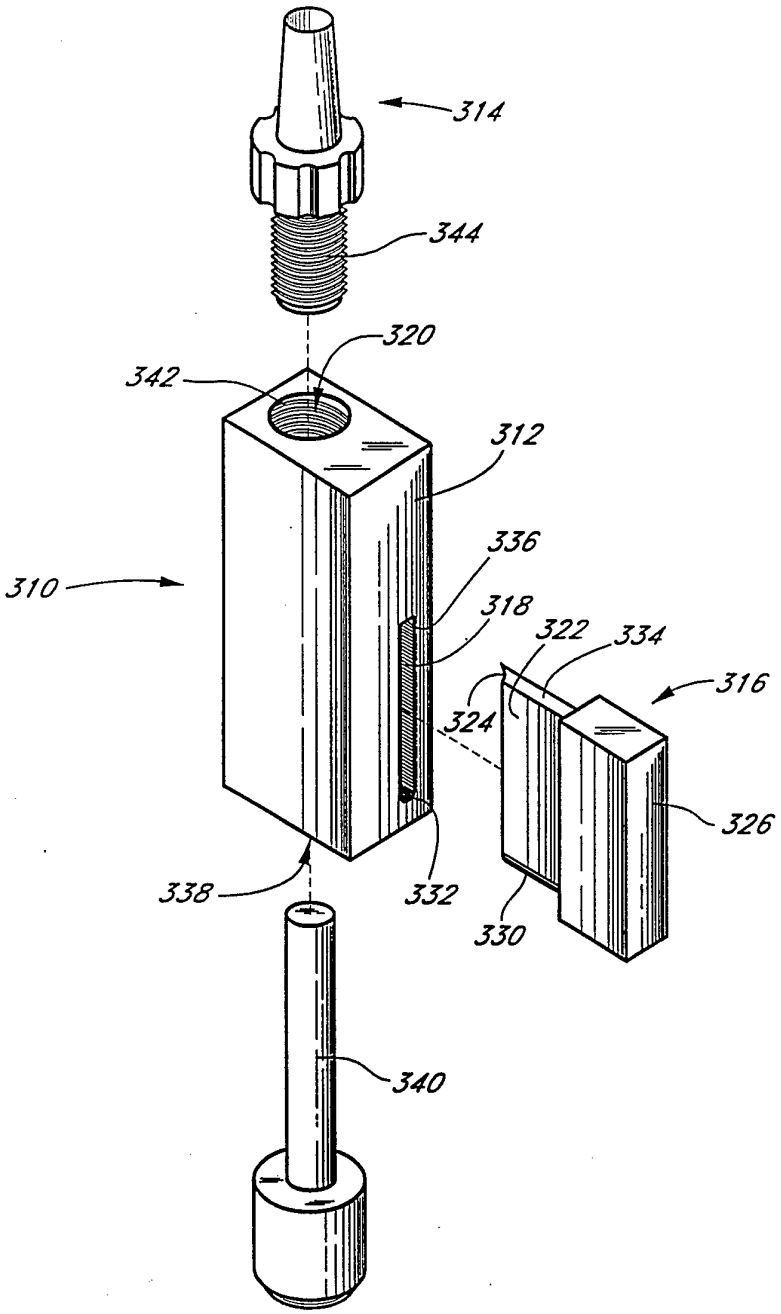

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FIG. 31

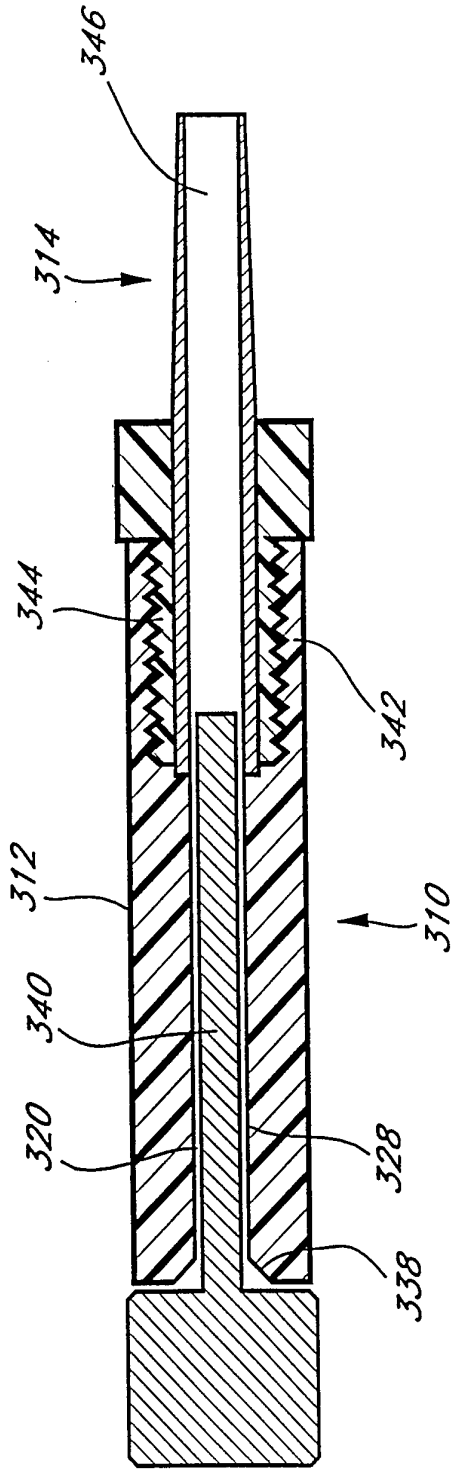

FIG. 32

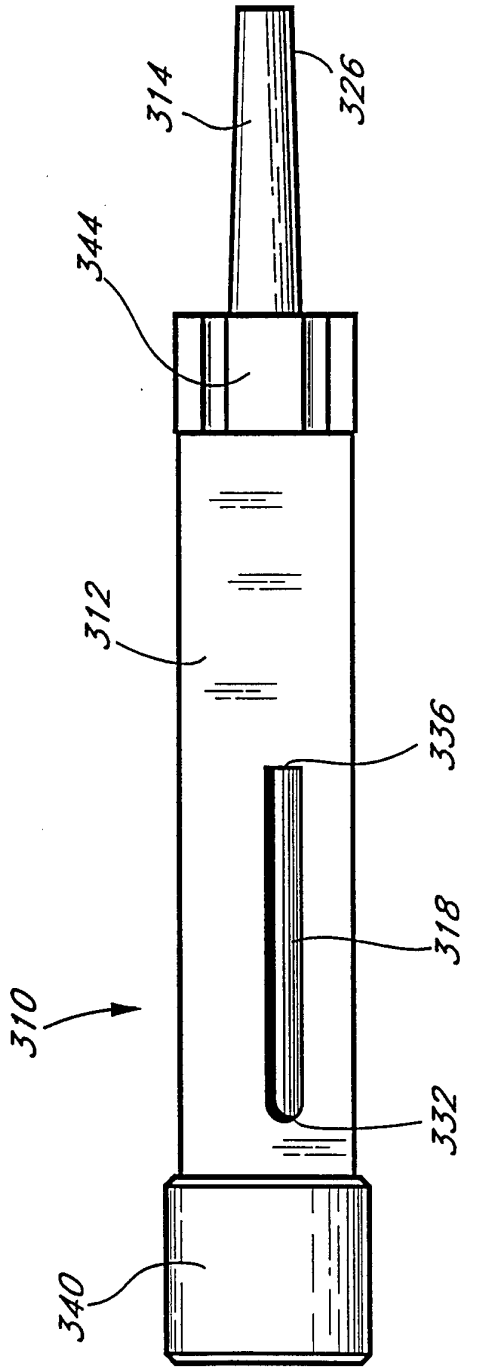

FIG. 33

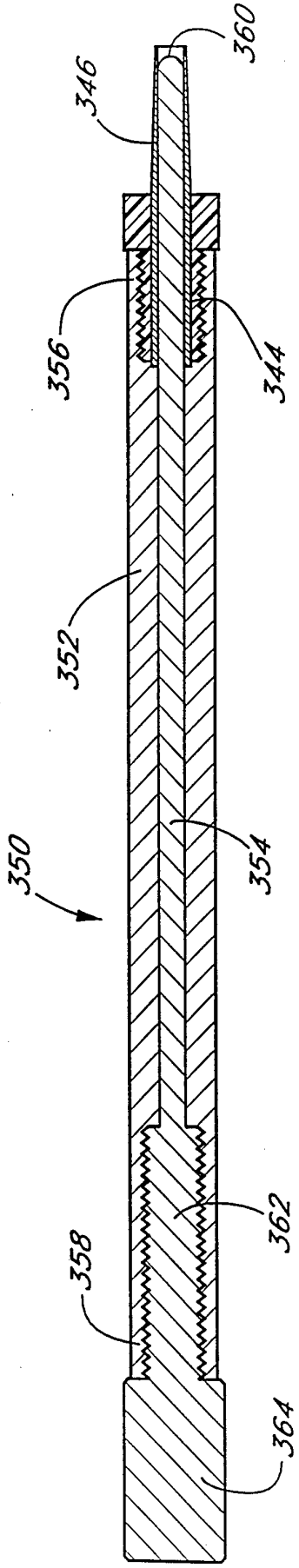

FIG. 34

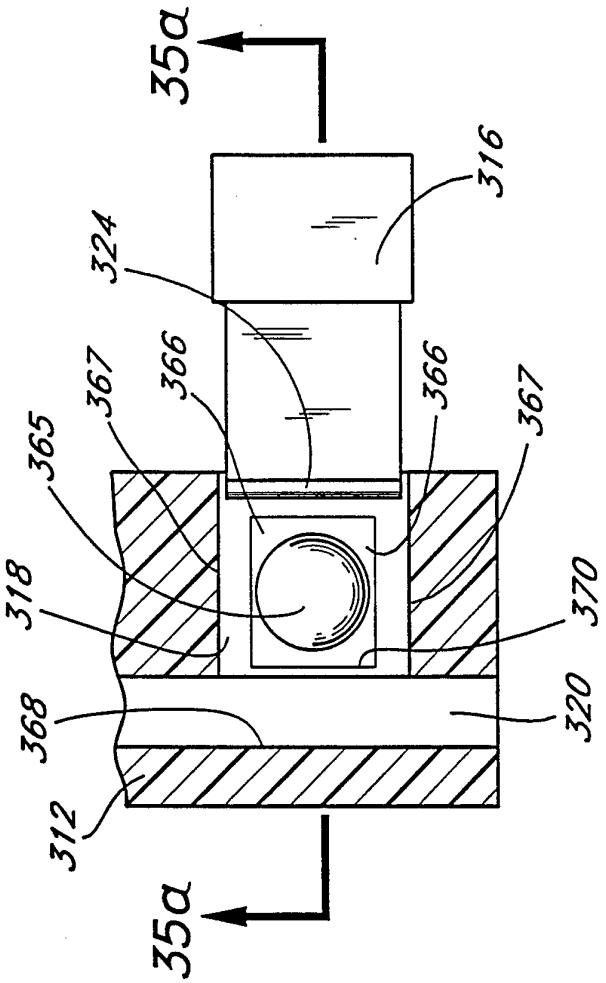

FIG. 35b

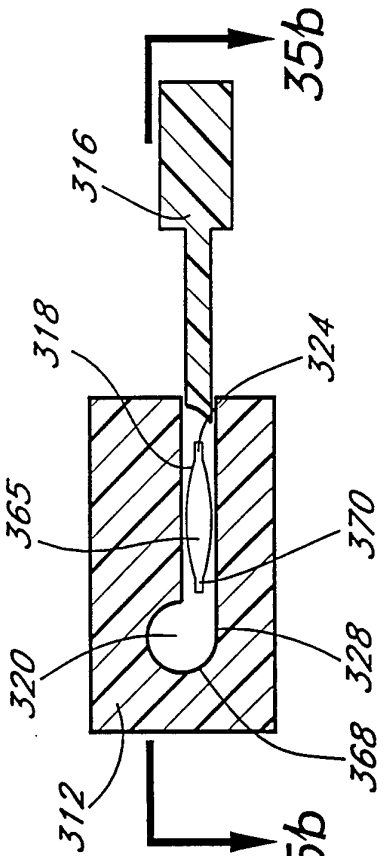

FIG. 35a

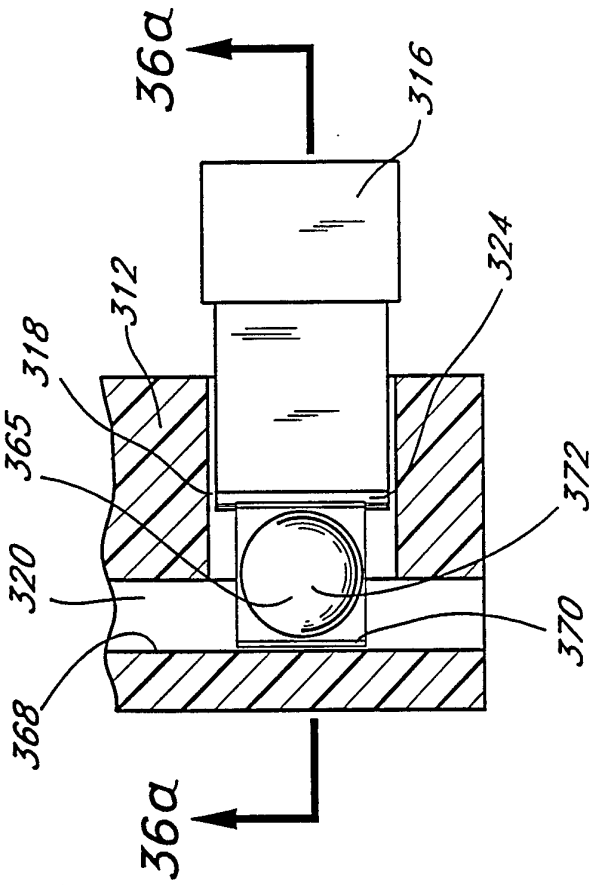

FIG. 36b

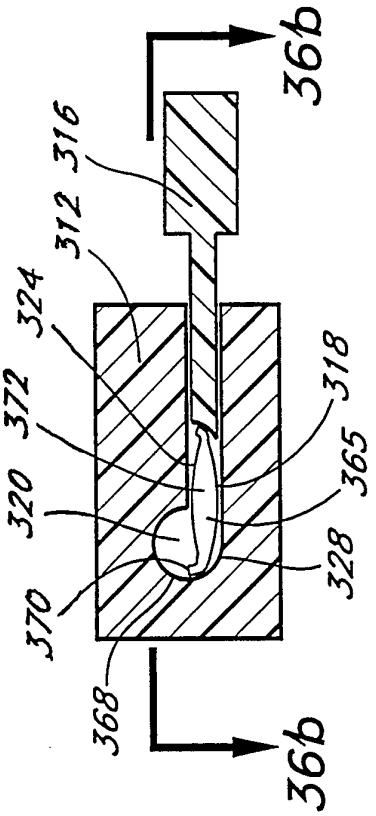

FIG. 36a

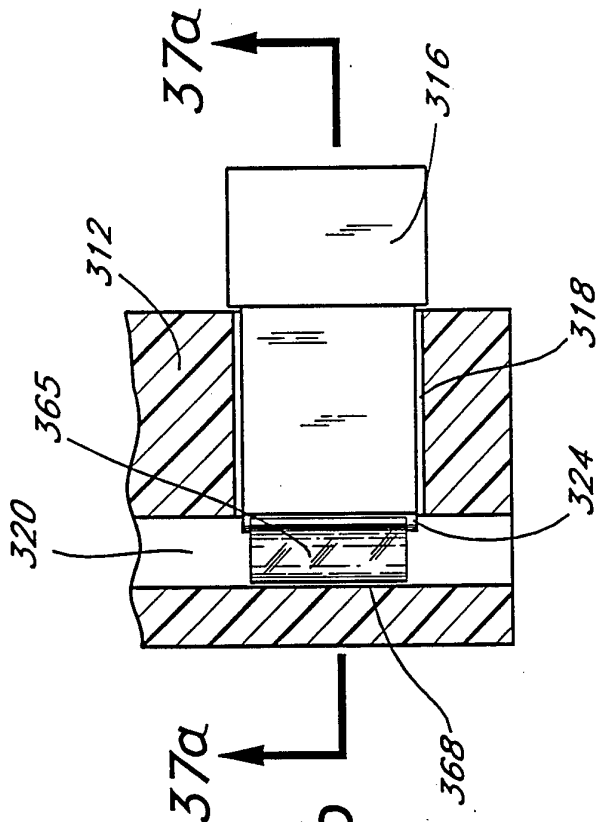

FIG. 37b

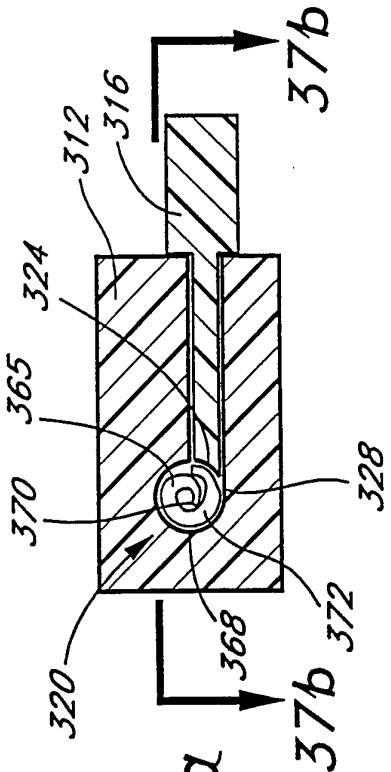

FIG. 37a

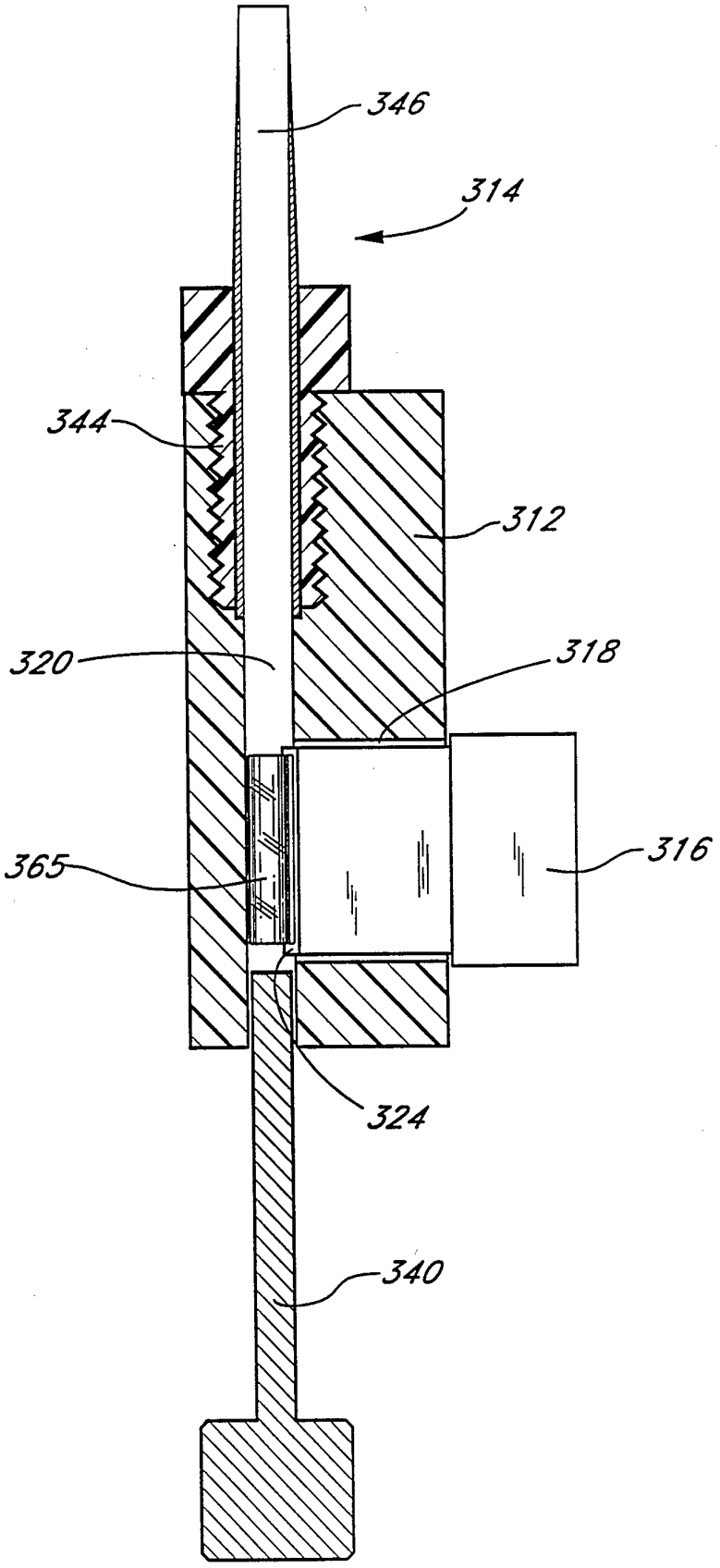

FIG. 38

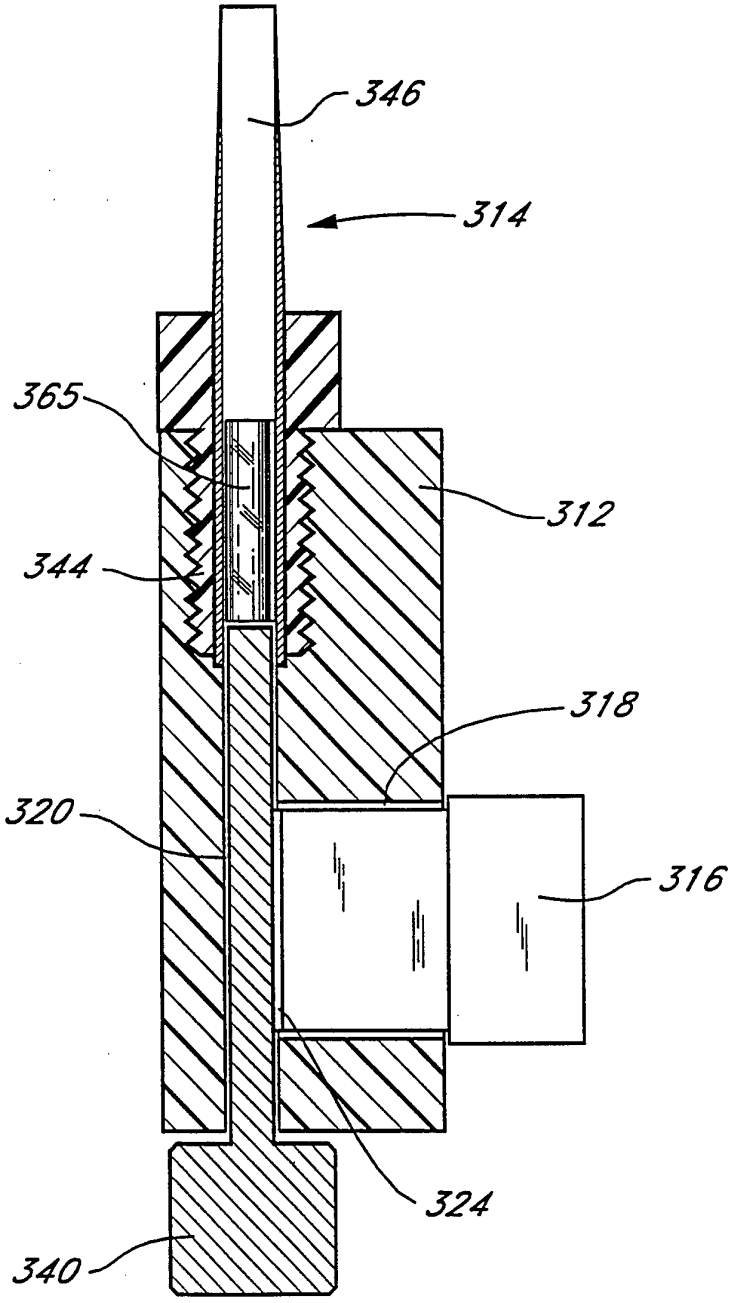

FIG. 39

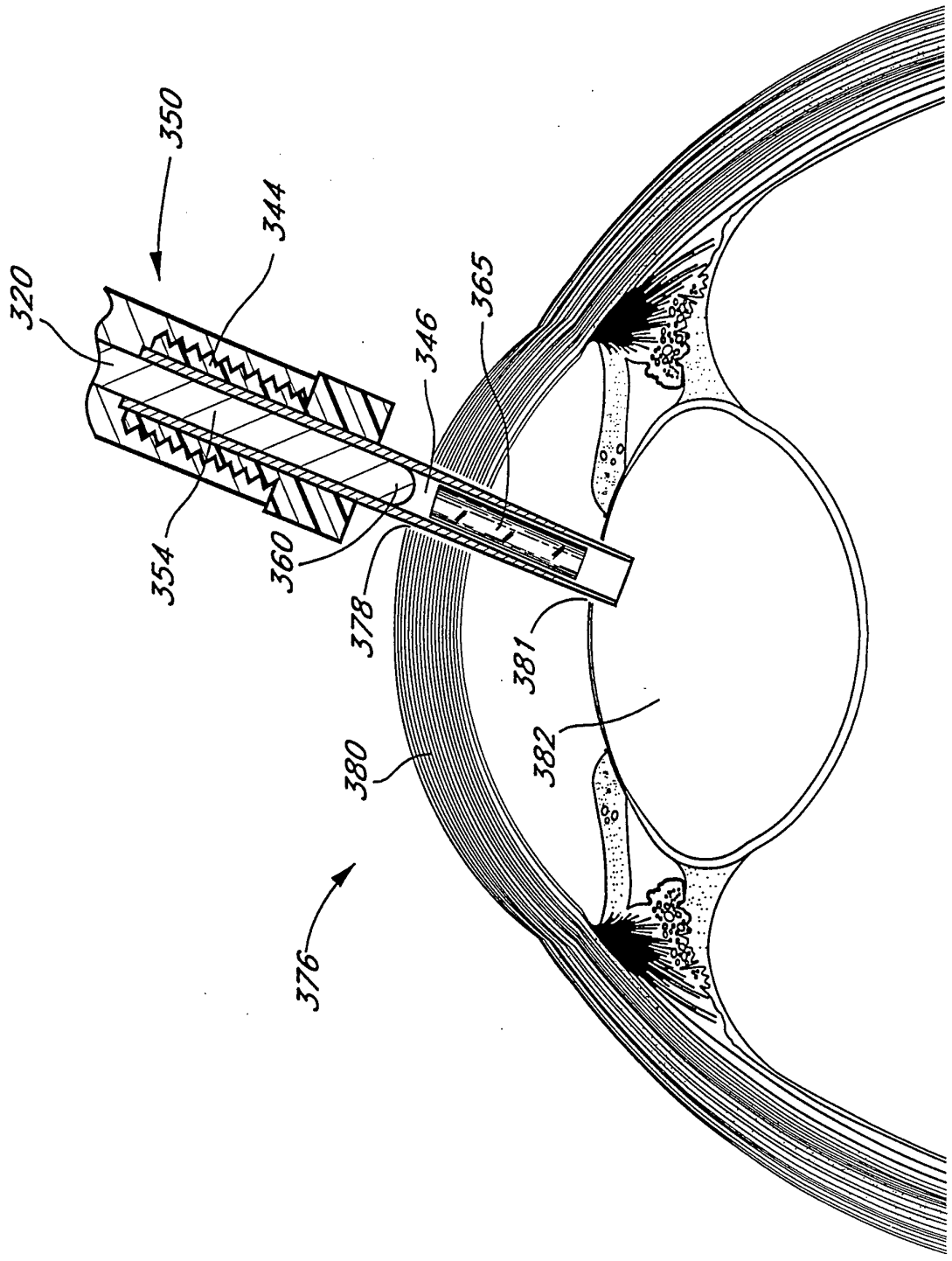

FIG. 40

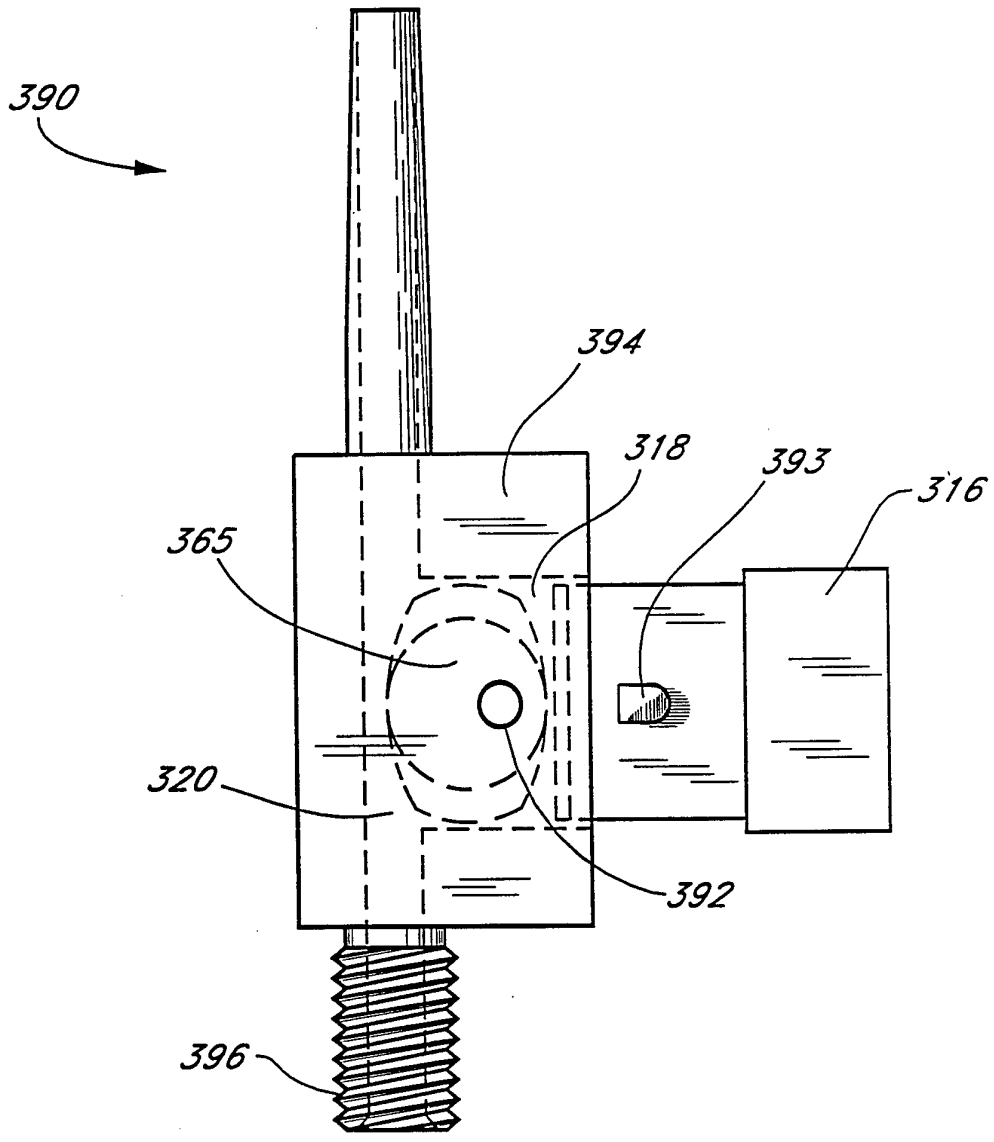

FIG. 41

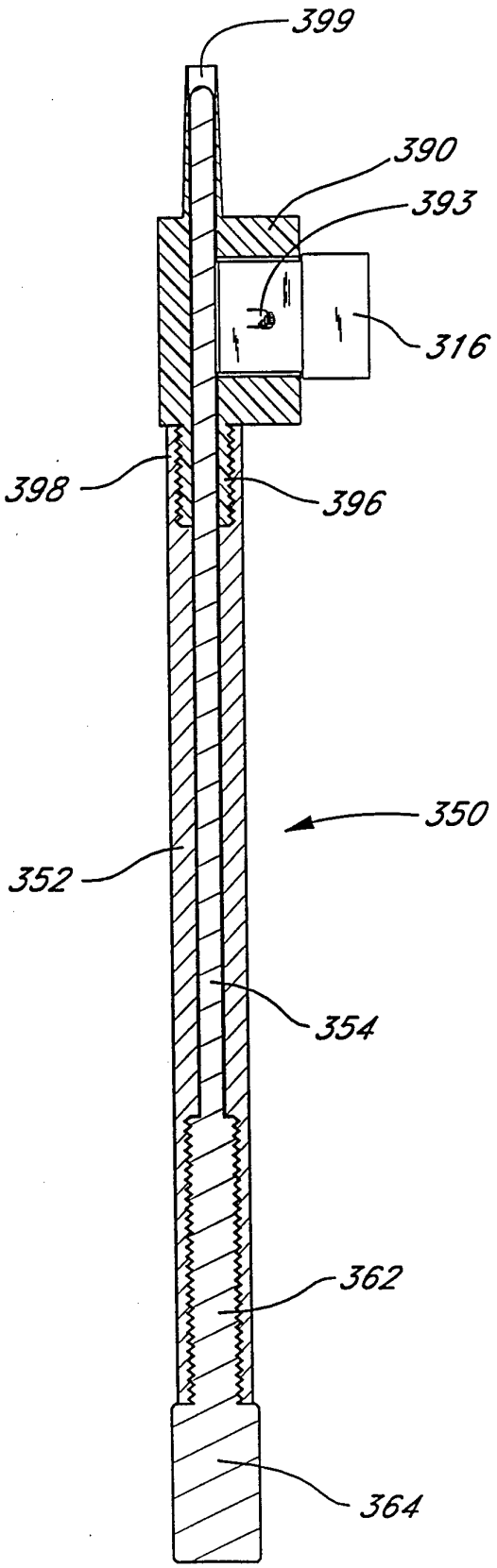

FIG. 42

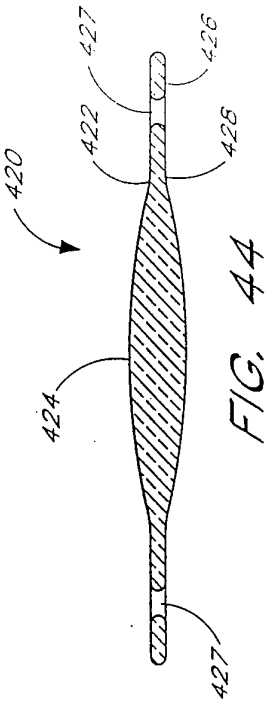

FIG. 44

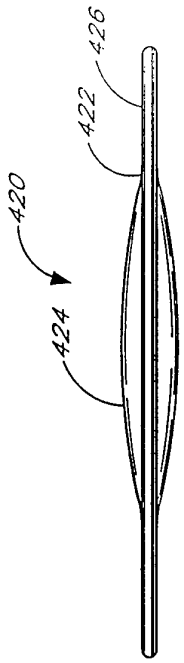

FIG. 45

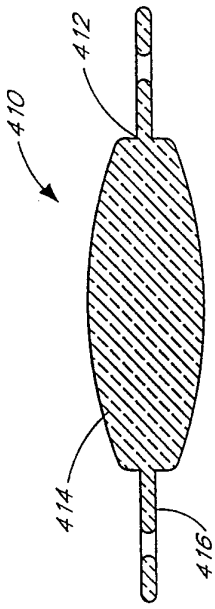

FIG. 43
(PRIOR ART)

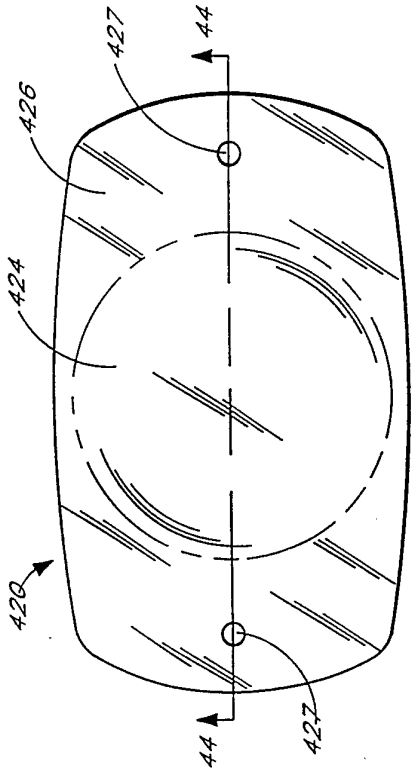

FIG. 46

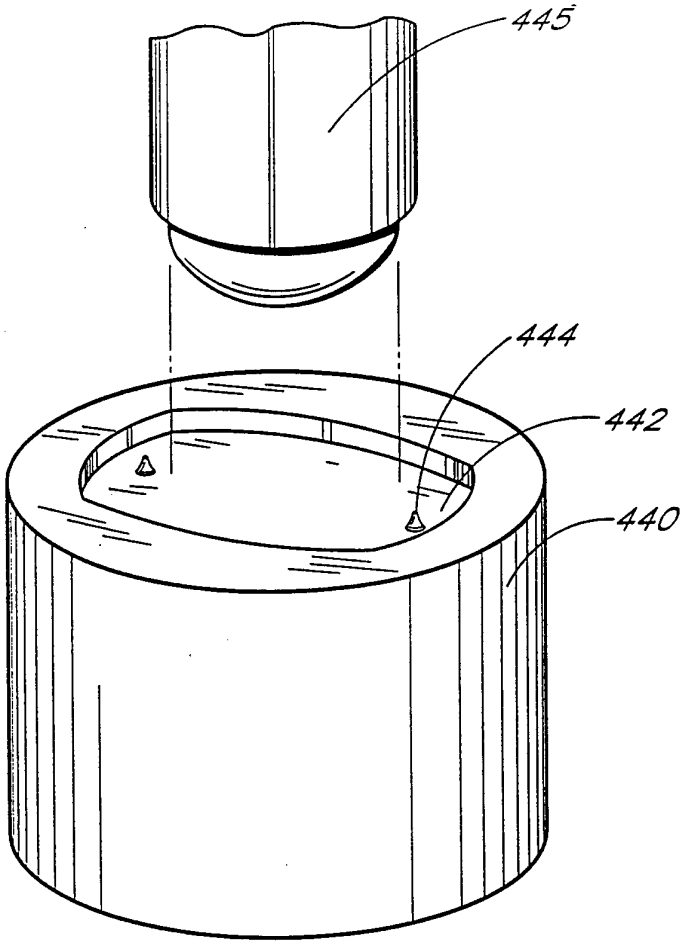

FIG. 48

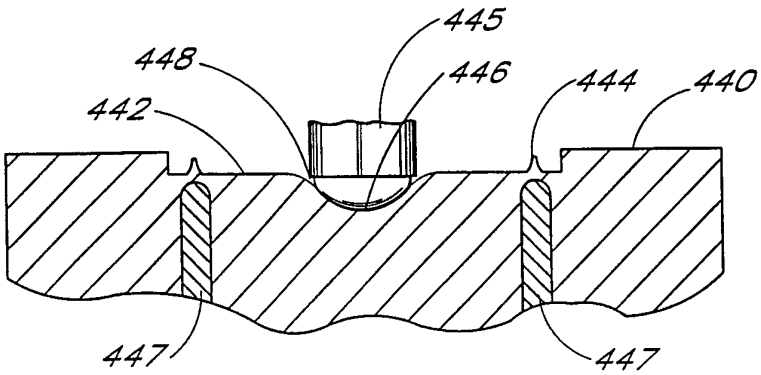

FIG. 49

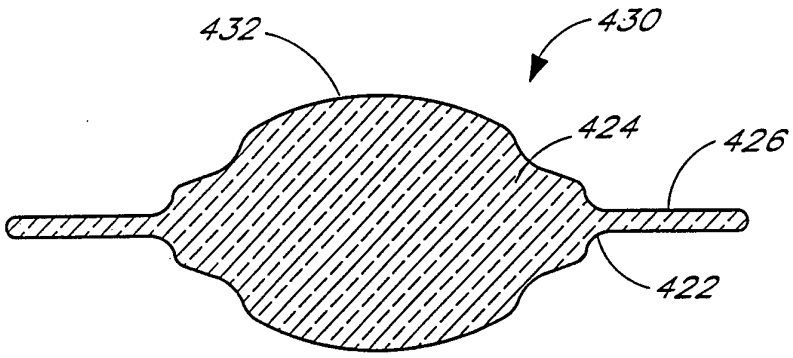

FIG. 47

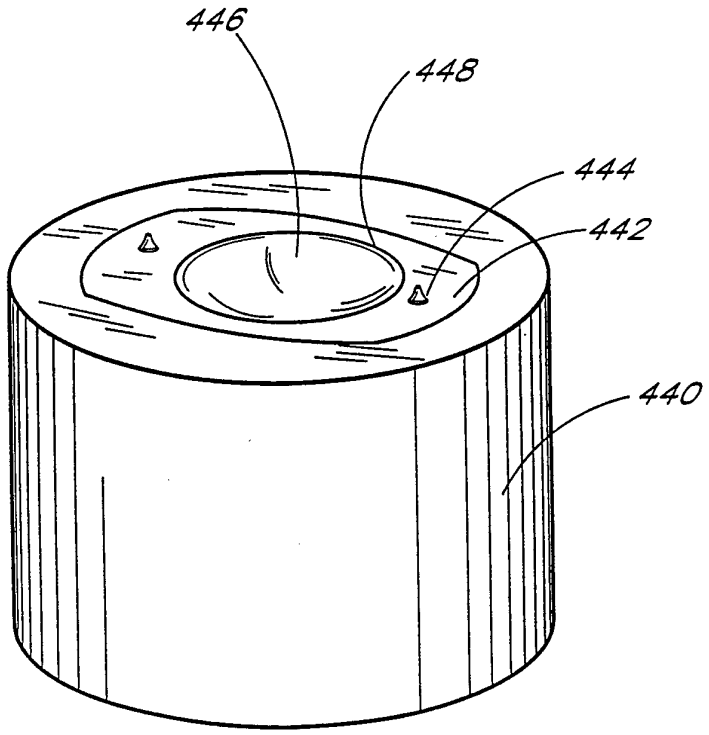

FIG. 50