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**ADJUSTABLE DEVICES FOR CORNEAL
CURVATURE ADJUSTMENT**

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Field of the Invention

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This invention is in the general field of medical technology and relates specifically to an intrastromal corneal ring designed such that its thickness can be varied in a manner so as to vary the corneal curvature to correct vision.

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Background of the Invention

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Anomalies in the shape of the eye and specifically the shape as defined in part by the corneal can cause visual disorders. Hyperopia occurs when the eyeball is too short. In such a case, parallel rays from greater than 20 feet focus behind the retina. Myopia, on the other hand occurs when the eyeball is too long. The focus of parallel rays in this case is in front of the retina. Astigmatism is a condition in which the parallel rays of light do not come to a single point, but rather have a variable focus due to the fact that the cornea is aspherical and refracts light in a different meridian at different distances. Some degree of astigmatism is normal, but where it is too high, it must be corrected in order to provide acceptable vision.

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Conditions such as hyperopia, myopia and astigmatism are usually corrected by glasses or contact lenses. Surgical methods for the correction of such disorders have been cited in the literature and include radial keratotomy (see e.g. U.S. Patents Nos. 4,815,463

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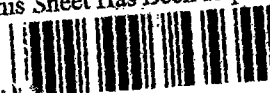
and 4,688,570) and laser corneal ablation (see e.g. U.S. Patent No. 4,941,093). Further, the general method of implanting rings in the corneal stroma to change the curvature of the cornea is known. Previous work
5 involving the implantation of polymethylmethacrylate (PMMA) rings, allograft corneal tissue and hydrogels is well documented. One of the ring devices involves a ring design that allows a split ring to be inserted into a channel. The channel is formed by dissecting the stromal
10 layer of the cornea using a minimally invasive incision. Thereafter, the implant is inserted into the channel and the channel is sutured shut.

U.S. Patent No. 4,452,235, which is herein incorporated by reference in its entirety, describes a
15 method and apparatus for corneal curvature adjustment. The method involves inserting one end of a split end adjusting ring into the cornea of the eye and moving the ring in a circular path until its ends meet. The ends are thereafter adjusted relative to each other so that
20 the ends can be connected. When so connected the shape of the eye will have assumed a desired curvature.

Various devices were required in order to facilitate the implantation of the rings of the type described in U.S. Patent 4,452,235. Such a holder for
25 inserting corneal curvature adjustable rings is described within U.S. Patent 4,961,744 issued October 9, 1990. Further, prior to inserting the ring it is necessary to cut an annular channel within the cornea and a device for cutting such a channel is disclosed within U.S. Patent
30 4,766,895 issued October 30, 1988.

Other devices for adjusting the corneal curvature have been disclosed such as the device shown within U.S. Patent 4,671,276 issued June 9, 1987. In addition, devices for affecting other parts of the eye
35 such as an iris retaining device are disclosed within

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U.S. Patent 4,782,820 issued November 8, 1988 and a variable focus lens which is disclosed within U.S. Patent 5,066,301 issued November 19, 1991. More recently a method of changing cornea curvature by injecting a gel into the cornea was disclosed in U.S. Patent 5,090,955 issued February 25, 1992.

The present invention describes split ring devices which are inserted in the corneal stroma and have adjustable thicknesses which provide certain advantages and improvements as compared to earlier intrastromal corneal rings.

Summary of the Invention

The present invention is an intrastromal corneal ring (ICR) of adjustable thickness which has an elongated, flexible body which forms a circle. The ICR is of a size such that it can be inserted into a human eye and specifically into the outer periphery of the cornea of a human eye. The ICR is comprised of a material which is compatible with human ocular tissue and specifically compatible with corneal tissue. The means for adjusting the thickness of the ring may be formed in several different configurations or embodiments. Two open ended annular body members may be interconnected in such a manner that the distance between the body members can be adjusted to provide different thicknesses and thereby obtain different degrees of change in the shape of the eye effecting the focus of light on the retina.

The essence of the present invention lies in the ability of the ring to be adjusted in thickness so that it is not necessary to stock a plurality of different rings of different sizes to be used in connection with the method for adjusting the shape of the cornea of an eye. Accordingly, the present invention provides a plurality of different embodiments of ICRs

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which are each adjustable in terms of their thickness. The thickness adjustment may occur prior to the insertion of the ICR into the cornea and may not be further adjustable after insertion. However, in the preferred
5 embodiments of the invention the ICR is inserted at a thickness which is believed to be proper and may be adjusted thereafter in order to precisely define the desired thickness and thereby more precisely adjust the shape of the cornea and focus the light entering the eye
10 on the retina.

A primary object of the invention is to provide an ICR having an adjustable thickness.

An advantage of the invention is that a single ring of adjustable thickness can be used thereby
15 eliminating the need for multiple rings of different thickness.

A feature of the invention is that the ring thickness can be adjusted while the ring is in place.

Another advantage of the ring is that it can be
20 readjusted at later times in order to readjust the curvature of the eye as needed.

These and other objects, advantages and features of the present invention will become apparent to those persons skilled in the art upon reading the details
25 of the structure and operation as more fully set forth below, reference being made to the accompanying drawings forming a part hereof wherein like symbols refer to like components throughout.

30 Brief Description of the Drawings

Figure 1 is a schematic representation of a horizontal section of the eye.

Figure 2 is a schematic illustration of the anterior portion of the eye showing the various layers of
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the cornea with an intrastromal corneal ring inserted therein.

Figure 3 is a schematic representation showing how light moves through a normal eye to focus on the retina.

Figure 4 is a schematic representation showing how light moves through a myopic eye and focuses in front of the retina.

Figure 5 is a perspective view of one embodiment of the ICR of the invention inserted within a cornea of a human eye.

Figure 6 includes a plane view (6A) and a perspective sectional view (6B) of an ICR of the invention.

Figures 7A and 7B are perspective views showing a ratcheted height adjustment embodiment in two positions.

Figures 8A and 8B are perspective views showing a threaded height adjustment embodiment in two positions.

Figures 9A and 9B are perspective views of an inflatable embodiment in a deflated and inflated state.

Figure 10 is a cross sectional view of a tube centered embodiment.

Figures 11A and 11B are perspective views of a notched embodiment in two positions.

Figures 12A and 12B are perspective views of a smooth surface embodiment in two positions.

Figures 13, 13A, 13B, 13C, 13D and 13E are different views showing how the ends of the annular body member might overlap.

Figures 14A and 14B show a stacked shim embodiment of the invention with and without the shims in place.

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Figures 15A and 15B show a spiral spring embodiment of the invention in a collapsed position and as the spiral might be inserted.

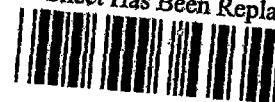
Detailed Description of the Invention

5 Before the adjustable intrastromal corneal ring and its various embodiments and configurations and methods of use are described, it is to be understood that this invention is not limited to the particular
10 embodiments, configurations, materials and steps described as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting, since the scope of the present invention will be limited only by the appended
15 claims.

The basic structure, function and operation of the adjustable intrastromal corneal rings of the invention is shown and discussed in connection with
20 Figures 1-6. Figures 7-15 show eight different embodiments of the invention which show six basic configurations whereby the rings can vary in terms of their thickness and/or height. Further, the ring ends can be connected to each other without the use of
25 additional components in a manner so as to provide a smooth and continuous interconnection between the ends so that the surface of the ring appears substantially smooth and continuous along its entire surface even at the interconnection of the ring ends.

The different embodiments shown in Figures 7-15
30 can each include a number of different subembodiments by varying features such as the material, the manner in which the ring ends are interconnected and the cross sectional surface parameters of the ring e.g. forming the ring from cross sections in the form of a circle, square,
35 rectangle, triangle, oval, etc. Although a number of

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configurations are shown others are possible and are contemplated by this invention. Further, other possible means of adjusting the ring thickness are contemplated by this invention. It is preferable if the invention is
5 constructed such that the ring size can be adjusted while the ring is in place in the eye.

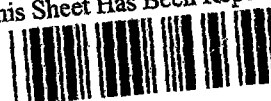
Before discussing the specific embodiments of Figures 7-15 the general structure and method of use of adjustable intrastromal corneal rings will be described
10 in connection with Figures 1-4 and thereafter generalized information relating to the rings of the present invention in connection with Figures 5 and 6.

Figure 1 shows a horizontal section of the eye with the globe 11 of the eye resembling a sphere with an
15 anterior bulged spherical portion representing the cornea 12.

The globe 11 of the eye consists of three concentric coverings enclosing the various transparent media through which the light must pass before reaching
20 the sensitive retina 18. The outermost covering is a fibrous protective portion the posterior five-sixths of which is white and opaque and called the sclera 13, and sometimes referred to as the white of the eye where visible to the front. The anterior one-sixth of this
25 outer layer is the transparent cornea 12.

A middle covering is mainly vascular and nutritive in function and is comprised of the choroid 14, ciliary body 16 and iris 17. The choroid 14 generally functions to maintain the retina 18. The ciliary body 16
30 is involved in suspending the lens 21 and accommodation of the lens. The iris 17 is the most anterior portion of the middle covering of the eye and is arranged in a frontal plane. It is a thin circular disc corresponding to the diaphragm of a camera, and is perforated near its
35 center by a circular aperture called the pupil 19. The

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size of the pupil varies to regulate the amount of light which reaches the retina 18. It contracts also to accommodation, which serves to sharpen the focus by diminishing spherical aberration. The iris 17 divides the space between the cornea 12 and the lens 21 into an anterior chamber 22 and posterior chamber 23. The innermost portion of covering is the retina 18, consisting of nerve elements which form the true receptive portion for visual impressions.

10 The retina 18 is a part of the brain arising as an outgrowth from the fore-brain, with the optic nerve 24 serving as a fiber tract connecting the retina part of the brain with the fore-brain. A layer of rods and cones, lying just beneath a pigmented epithelium on the anterior wall of the retina serve as visual cells or photoreceptor which transform physical energy (light) into nerve impulses.

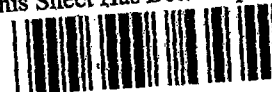
15 The vitreous body 26 is a transparent gelatinous mass which fills the posterior four-fifths of the globe 11. At its sides it supports the ciliary body 16 and the retina 18. A frontal saucer-shaped depression houses the lens.

20 The lens 21 of the eye is a transparent bi-convex body of crystalline appearance placed between the iris 17 and vitreous body 26. Its axial diameter varies markedly with accommodation. A ciliary zonule 27, consisting of transparent fibers passing between the ciliary body 16 and lens 21 serves to hold the lens 21 in position and enables the ciliary muscle to act on it.

30 Referring again to the cornea 12, this outermost fibrous transparent coating resembles a watch glass. Its curvature is somewhat greater than the rest of the globe and is ideally spherical in nature. However, often it is more curved in one meridian than another giving rise to astigmatism. A central third of

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the cornea is called the optical zone with a slight flattening taking place outwardly thereof as the cornea thickens towards its periphery. Most of the refraction of light striking the eye takes place as the light passes
5 through the cornea.

Referring to Figure 2, a more detailed drawing of the anterior portion of the globe shows the various layers of the cornea 12 comprising an epithelium 31. Epithelial cells on the surface thereof function to act
10 as the main protection layer of the cornea 12. These epithelial cells are rich in glycogen, enzymes and acetylcholine and their activity regulates the corneal corpuscles and controls the transport of water and electrolytes through the lamellae of the stroma 32 of the
15 cornea 12.

An anterior limiting lamina 33, referred to as Bowman's membrane or layer, is positioned between the epithelium 31 and the stroma 32 of the cornea. The stroma 32 is comprised of lamella having bands of fibrils
20 parallel to each other and crossing the whole of the cornea. While most of the fibrous bands are parallel to the surface, some are oblique, especially anteriorly. A posterior limiting lamina 34 is referred to as Descemet's membrane. It is a strong membrane sharply defined from
25 the stroma 32 and resistant to pathological processes of the cornea.

The endothelium 36 is the most posterior layer of the cornea and consists of a single layer of cells which aid in maintaining the transparency of the cornea.
30 The limbus 37 is the transition zone between the conjunctiva 38 and sclera 13 on the one hand and the cornea 12 on the other.

A cross sectional view of an intrastromal corneal ring 47 of the invention is shown within the
35 stroma 32 of the cornea 12. The ring 47 is placed in the

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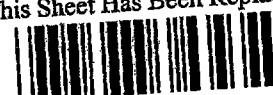
stroma 32 by making an initial incision into the cornea 12 and then continuing to separate the stroma of the cornea in a circular direction from the initial incision beneath the surface of the cornea so as to provide a
5 complete annular channel within the cornea 12. The ring 47 is placed within the annular channel.

Figure 3 shows the globe of the eye having a cornea with a normal curvature 41. If parallel rays of light pass through the corneal surface 41 of Figure 3,
10 they are refracted by the corneal surfaces to converge eventually near the retina of the eye. The diagram of Figure 3 discounts, for the purposes of this discussion, the refractive effect of the lens or other portions of the eye. The eye depicted in Figure 4 is myopic. The
15 corneal curvature 43 causes the light rays to refract into focus at a point in the vitreous body which is short of the retinal surface. If an ICR is implanted into the chord of the cornea such that the radius of curvature of the cornea is uniformly increased, the central curvature
20 of the cornea is flattened. Light rays refracted by the now flattened corneal surface will be refracted at a smaller angle and thus converge at a more distant point such as directly on the retina.

The ICRs of the present invention make it
25 possible to adjust the radius of curvature of the cornea without adversely affecting its natural sphericity. Where there is serious astigmatism, the natural sphericity will not be altered such that the astigmatism will be significantly increased. However, where there is
30 significant astigmatism that results in impaired vision, the ICR of the invention may actually improve the sphericity to reduce such astigmatism and improve vision.

As is shown in Figures 3 and 4 by changing the curvature from a curvature 43 to a curvature 41 the focal
35 point can be correctly positioned on the retina. A small

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degree of curvature change can affect the focal point of the light entering the eye. Accordingly, it is difficult to choose the correct thickness of an intrastromal corneal ring to be inserted in the stroma of the cornea so that it will correctly affect the focal point of the light entering the eye. The difficulty with respect to choosing the correct thickness is the point where the advantages of the present invention become most apparent. When the present invention is used the intrastromal corneal ring is first adjusted to have a thickness which is believed to be the correct thickness. However, after inserting the ring into the stroma of the cornea the thickness of the ring can be further adjusted in order to precisely focus the light entering the eye on the retina.

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As shown in Figure 2, an intrastromal corneal ring (ICR) 47, having a cross sectional shape as shown in Figure 6B is shown implanted in the stromal layer of the cornea. The thickness of the ring can be adjusted prior to placing the ring in the eye. Preferably the ring thickness can be further adjusted in situ to precisely adjust the amount of correction necessary. By such adjustments the rays refracted by the cornea and other eye components can be brought to focus directly on the retina (not shown in Figure 2).

20

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Figure 5 shows a perspective view of the ICR 47 with its threaded height adjustment means is inserted within a cornea 50 of a human eye. In the embodiment shown within Figure 5, the ICR is placed in a manner such that the widest faces 51 and 52 face outward along the line of sight 53 and away from the eye, whereas the narrower faces 54 and 55 face radially inward toward the center of the eye and the wide and narrow faces are perpendicular to each other. However, it should be noted that other configurations are possible. Height or

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thickness adjustment is carried out by screwing the threaded body members 47' and 47" so that they move away from or toward each other depending on whether an increase or decrease in thickness is required.

- 5 A plane view of the ICR 47 of the invention is shown in Figure 6A. As shown, the ICR is circular in shape and is comprised of two elongated, flexible body members 47' and 47" each of which forms a circle. One possible cross sectional configuration is shown in
- 10 Figure 6B which configuration is basically rectangular with angled outer edges. Other cross sectional configurations are possible, such as square, circular, and variations therebetween. Because the body of the ring is circular, it has the same diameter D in all
- 15 directions. However, it is possible to configure the body of the ring in other slightly noncircular configurations, e.g., ovals and elongated ovals. However, in these configurations the two rings are not interconnected by threading but by other adjustable means
- 20 such as ratched slots. In its preferred circular configuration, the diameter conforms to the size of a human cornea which is approximately 1 cm in diameter. The ring is comprised of a biocompatible material such as a biocompatible polymer. Such biocompatible materials
- 25 and polymers are particularly designed with eye tissue characteristics in mind. Accordingly, materials such as those used in making contact lenses can be used. It is pointed out that the ocular tissues is generally quite sensitive and may react upon the implantation of the
- 30 ring. However, after a period of time, any inflammation and/or adverse reaction will be eliminated. In order to decrease the probability of adverse reactions, it is desirable to choose a biocompatible material which will not create an immune reaction, be nontoxic and
- 35 biologically benign. Metals and metal alloys are

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generally undesirable as are other types of materials which react with the ocular tissue.

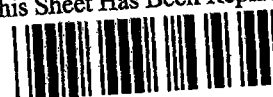
5 The rings 47' and 47" in Figure 6A each show one end 48 and 50. Because Figure 6A is a planar view, the ends 48 and 50 are each shown as a single line. The other ends 49 and 51 are each shown by a dotted line in that this end is visible only from the other side of the rings 47' and 47". The corresponding ends 48 and 49 and corresponding ends 50 and 51 may be structured in several
10 different configurations, as discussed in connection with Figures 13 and 6A.

As shown in Figures 6A and 13, the corresponding ends 48 and 49 are overlapping each other as the ends 50 and 51. The rings can be screwed toward
15 each other as shown by the arrows f or in the opposite direction as shown by the arrows f'.

The thickness of the ring may be between adjusted within a range of about 0.05 mm and 1.5 mm. Such a ring placed approximately at the 8 mm chord of the
20 cornea provides a means for making such a corrective adjustment.

As indicated above Figures 5 and 6A show an ICR of the invention which is comprised of a generally circular body member. The ring is comprised of a
25 material which has sufficient stiffness to maintain its generally circular shape. The material should have properties that render it physiologically compatible with the tissue of the cornea. An illustrative material is a plastic type material sold under the trade name of
30 PLEXIGLASS™, however many other biocompatible polymers are useful in the invention, including but not limited to polyolefins (e.g., polypropylene and polybutylene), polycarbonates, acrylic resins (e.g., acrylates and methacrylates, including polymethylmethacrylate (PMMA)
35 and polyhydroxyethyl methacrylate (polyHEMA)), poly-

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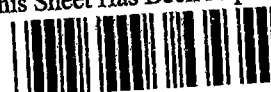
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acetals, polyesters, polyamides (e.g., nylon),
polyurethanes, epoxy resins, silicones or other natural
or synthetic rubbers, copolymers that are composed of
hard and soft segments (e.g., NYTREX, Dupont, Wilmington,
5 DE), polytetrafluoroethylene (PTFE), polyvinyl-
pyrrolidone, polyethers/ether ketones, polysulfones,
glass, and copolymers (discrete or block), blends and
mixtures of the above. As discussed above, the means of
adjusting ring thickness can vary. When a cross section
10 of the ring is circular, it is generally dimensioned to
be about 0.05 mm to 1.5 mm in thickness.

A particular cross sectional configuration is
schematically shown in Figure 6B. When this
configuration is used, the dimension shown from point to
15 point (dimension x) may be within the range of
approximately 0.25 mm to 3.25 mm and the thickness
(dimension y) generally can be adjusted in the range from
about 0.05 mm to about 1.5 mm.

There are a number of factors which affect the
20 degree of flattening of the cornea obtained depending
upon the thickness of the ring being inserted.
Accordingly, it is not always possible to deduce a direct
relationship between the ring thickness and the degree of
flattening and therefore the change in focal point.
25 Variations are caused by factors such as the type of
mammal in which the ring is being inserted and the size
and shape of the eye. However, in certain experiments,
it has been found that optical corrections can be carried
out at the rate of 1 diopter of flattening for each
30 0.02 mm increase in ICR thickness when the size of the
ICR is in the range of about 0.26 mm to about 0.46 mm in
thickness. Thus, it is advantageous to set the threading
on the interconnected ring so that one 360°, 180°, or 90°
turn of one ring relative to the other changes the
35 thickness by 0.02 mm. Alternatively, in a ratched

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embodiment one increment change will change the thickness by 0.02 mm or some fraction or multiple thereof.

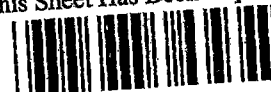
Even where the eye is not myopic, the ICRs of the present invention may be useful to alleviate
5 excessive astigmatism.

A typical panel of ICRs will consist of 5 ICRs with the following thicknesses: 0.25 mm, 0.30 mm, 0.35 mm, 0.40 mm and 0.45 mm. The corrective refraction for those ICRs are as follows: between 0.5 and 3.0
10 diopters for the 0.25 mm ICR, between 1.0 and 5.0 diopters for the 0.30 mm ICR, between 2.0 and 8.0 diopters for the 0.35 mm ICR, between 3.0 and 10.0 diopters for the 0.40 mm ICR, and between 4.0 and 15.0 diopters for the 0.45 mm ICR. It should be noted that
15 these values are for conventional ICRs and that value of between 0.5 to 18.0 might be used. The amount of corrective refraction for the various thicknesses of ICRs of different cross sectional shaped rings may differ from those values.

20 The essence of the present invention lies in the ability of the ring to be adjusted in thickness so that it is not necessary to stock a plurality of different rings of different sizes to be used in connection with the method for adjusting the shape of the
25 cornea of an eye. Accordingly, the present invention provides a plurality of different embodiments of ICRs which are each adjustable in terms of their thickness. The thickness adjustment may occur prior to the insertion of the ICR into the cornea and may not be further
30 adjustable after insertion. However, in the preferred embodiments of the invention the ICR is inserted at a thickness which is believed to be proper and may be adjusted thereafter in order to precisely define the desired thickness and thereby more precisely adjust the

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shape of the cornea and focus the light entering the eye on the retina.

The ICR is inserted into the corneal stroma of the eye through an oblique keratotomy incision placed peripherally into the corneal stroma. The size of the insertion will vary somewhat depending on factors such as the size of the ring or rings being inserted. In general, the size of the insertion is approximately 0.5 mm to 5.0 mm in length with an incision of approximately 2.5 mm being typical. Prior to ring insertion, a channeling blade is inserted at the depth of the incision and a circular channel is cut into the corneal stroma. Proper centering of the cut is accomplished by use of a centering device that aligns the channeling blade. The ring is then inserted and the ends are secured by fastening one end to the other.

Specific Preferred Embodiments

Eight different basic preferred embodiments are shown in Figures 7-15. In addition, many of the basic embodiments are further illustrated by means of subembodiments which include, for example, different configurations of the cross sectional parameter of the ring. It is emphasized that each of the embodiments and subembodiments may be interchanged and be comprised of different materials and provided in different sizes in accordance with the size limitations indicated above. Further, the disclosures of these different embodiments may demonstrate to others skilled in the art that other embodiments are possible which provide substantially the same results in terms of providing a ring structure which is adjustable in terms of its thickness.

A ratched height adjustment embodiment is shown in Figures 7A and 7B. Cross sectional views of the embodiment in different relative positions to create

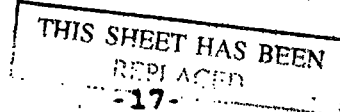
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thickness variations are shown in Figures 7A and 7B. The lower ring 70 is surrounded by the outer upper ring 71 and the two rings are interconnected by means of ratched slots 72 and 73 and protuberances 74 and 75. The protuberances 74 and 75 fit within the slots 72 and 73 respectively. The ring 71 can be pulled upward in the direction of the arrow f in order to reposition the protuberances 74 and 75 as shown within Figure 7B. In the configuration shown within Figure 7B the thickness of the dual ring structure is increased as compared with the thickness of the structure positioned as per Figure 7A. This embodiment is simple to produce and provides desirable results as compared with the use of a multiplicity of different rings. However, the embodiment is not desirable in that it is somewhat difficult to adjust the thickness of the rings after the rings have been inserted within the cornea.

In Figure 8A the rings 80 and 81 are shown in a cross sectional view. The inner ring 80 includes threadings 82 on its outer circumference while the ring 81 includes threadings 83 on its inner circumference. The threadings 82 and 83 mesh into each other and the rings 80 and 81 can be turned in directions opposite to each other. In the position shown in Figure 8A the rings have been turned so that the ring 81 has been increased in height relative to the ring 82 thereby increase the thickness. This height adjustment can be carried out in situ.

In Figure 9A the ring 90 is substantially deflated in that no fluid has been injected into the ring via the nozzle 91. In Figure 9B the ring 90 has been substantially inflated by the injection of a fluid into the ring 90 via the nozzle 91. By injecting the fluid into the ring the thickness of the ring is increased. It is also possible to design the ring such that its outer



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end or inner diameters are also increased with the injection of fluid. There are two separate subembodiments of the inflatable ring which can provide particular advantages. In a first subembodiment, the ring is designed so that when it is inflated it will only increase in thickness and not increase radially. In the second subembodiment, the ring is designed such that when it is inflated, it will not increase in thickness but only increase radially. It is possible to design a cross breed subembodiment which allows a certain, predetermined degree of thickness increase and a certain, predetermined degree of radial increase, each within specific limitations designed to obtain a specific effect. The nozzle 91 is preferably a check valve, i.e. one-way valve which allows a fluid to be injected in but which will not allow a fluid to flow out. However, fluid could be extracted by inserting a hypodermic needle into the valve opening and vacuuming fluid from the interior of the ring 90. As shown within Figure 9A the valve 91 is preferably positioned on a separate piece 92 which can then be completely encompassed by and sealed with respect to the outer walls of the ring 90. However, other embodiments are possible. The material injected into the ring 90 can be any suitable material including water and biocompatible liquids and gels. For example, see the gel injection system disclosed within U.S. Patent 5,090,955 issued February 25, 1992 which is incorporated herein by reference.

In Figure 9A a method for including the inflatable ring 90 into the cornea of the eye is shown. In essence, the ring 90 is placed on a blade 93 which has a blade width approximately equal to or slightly larger than the internal diameter of the ring 90. The point 94 of the blade cuts annularly into the cornea followed by the ring 90. When a complete circular incision is made

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the entire ring 90 is inserted within that incision.

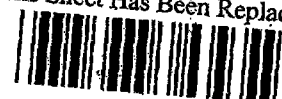
Thereafter, by holding the ring 90 in place the blade 93 can be withdrawn leaving the ring 90 in place.

Thereafter, the interconnector including the nozzle 91 is inserted into one end of the ring and thereafter into the other ring in order to form a complete circle.

A cross section of a tube centered embodiment is shown Figure 10 wherein the upper ring 100 is separated from the lower ring 101 by a tube 102. In that the ring is placed within a relatively small incision within the ocular tissue, the components of the ring will be held together by the pressure provided by the ocular tissue. Accordingly, there is generally no need to provide any additional forces to bring the components together. However, the two rings can be held together by a supplemental means including by the inclusion of magnetic material within both of the rings. Alternatively the tube 102 may be comprised of a magnetic material and the rings 100 and 101 may include a material such as iron which is attracted by the magnetic material. In accordance with this embodiment the thickness of the overall ring structure is increased by increasing the size of the tubes 102 which are included between and separate the rings 100 and 101.

Figures 11A and 11B provide perspective views of the notched embodiment of the invention. In Figure 11A the notches of the rings 111 and 112 are intermeshed to provide the thinnest possible ring structure. In Figure 11B the notches are aligned so as to provide the maximum thickness. This embodiment may be easily constructed. However, it has disadvantages in that the adjustment is only in a single increment. This can be accounted for to a certain extent by including a plurality of notches of different heights and aligning the desired height notch in order to achieve the desired

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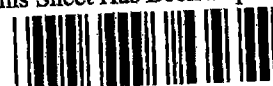
thickness and thereafter locking the rings into place by any appropriate means such as the use of sutures, adhesives, pins, etc.

5 Figures 12A and 12B shows a smooth surface interlocking embodiment. In Figure 12A the rings are intermeshed so as to provide the thinnest possible structure whereas Figure 12B shows the thicker structure. Due to the smooth surfaces of the interlocking components it is possible to vary the height of the rings and when
10 the desired height is achieved lock the rings into place by an appropriate means such as the use of an adhesive or sutures.

 In all or any of the above embodiments variations are possible with respect to the cross
15 sectional configuration of the rings, the type of material and other parameters. For example, all of the ring structures shown above must be open ended rings so that they can be inserted into the cornea via an entry incision and then fed around a circular incision made in
20 the cornea. The ends may then be interconnected to each other. This can be done in a variety of ways. For example, the use of two rings makes it possible for each of the rings to act as a closure means for the other when the rings are rotated relative to each other so that
25 their ends are not aligned. This can be done after inserting the rings in the eye. When two rings are not present (e.g. the inflatable embodiment) the ends of the ring can be interconnected as shown in Figure 13.

 Figure 13 shows a tapered overlapping
30 configuration. The tapered effects of the ends 130 and 131 is dramatically shown within Figures 13 and 13E. One end 130 gradually narrows at the same rate that the end 131 narrows. The ends 130 and 131 are held together by horizontal and vertical force vectors which oppose each
35 other and are shown as hf, hf', vf and vf' as shown in

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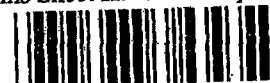
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Figure 13A. The cross sectional structure of the ring can be circular as indicated by the different configurations in Figures 13B, 13C and 13D. However, as shown in these figures the manner in which the ends 130 and 131 fit together along their adjacent surfaces can vary from the planar interconnection of Figure 13B to the curved plane of Figure 13C and the peaked interconnection of Figure 13D. A cross section is shown in Figure 13E.

In Figure 14A a stacked shim embodiment is shown. The embodiment includes at least a lower disk 140 and an upper disk 141. Each of the disks have openings in their center. The lower disk 140 may include a radially raised area (not shown) protruding upwardly. This raised area fits within an indentation (not shown) in the upper disk. Each of the disks are open ended, i.e. they are not continuous but have ends 142. The multiple disks 140 and 141 may be stacked on top of each other and inserted into the cornea, as shown within Figure 14B. Thereby, the size of the ring structure inserted into the eye can be increased in thickness to any degree.

Figure 15A shows a spiral shaped spring embodiment of the invention. This embodiment is comprised of a singular spiral or spring shaped piece of material 150. As shown within Figure 15B the end of the spiral is inserted into the annular channel formed in the cornea and set into the channel. The device is continually fed into the channel in a manner such that each circular movement of the spring will cause another layer to be added making it possible to increase thickness to any desired amount. When the desired amount of thickness is obtained, the material is cut. The spiral ring 150 can be designed in a variety of different ways. For example, the ring can be designed so that each successive ring has the same diameter and fits tightly

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against the next ring. When this shaped device is used, the cornea is increased in thickness as additional layers are added but is not increased radially. In another embodiment, the spring-shaped piece of material 150 can be designed so that each successive ring is slightly larger in diameter. Thereby, increases in the diameter of the inserted ring can be obtained by including additional rings into the cornea.

Modifications of the above described modes for carrying out the invention may occur to persons of skill in the fields of medicine, ophthalmology, optometry and/or related fields upon reading the disclosure and are all intended to be within the scope of the following claims.

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Claims

1. A method for adjusting the shape of the cornea of an eye, comprising the steps of:

5 cutting an initial incision into the cornea of the eye;

continuing to separate into the cornea of the eye from the point of the initial incision in a circular direction from the incision beneath the surface of the cornea so as to provide a complete annular channel within the cornea;

10 inserting into the initial incision an end of an intrastromal corneal ring having an adjustable thickness, the ring being comprised of an elongated, flexible annular body;

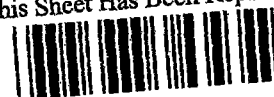
progressively moving the inserted end of the ring into the initial incision in a circular path within the annular channel until the ring is fully inserted; and adjusting the thickness of the ring and thereby adjusting the shape of the cornea to focus light entering the eye.

2. The method as claimed in claim 1, wherein the ring having an adjustable thickness is comprised of a first and a second annular body member which are individually inserted into the annular channel and thereafter joined together in manner which provides for relative movement of the body members to allow for adjusting thickness.

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3. The method as claimed in claim 1, wherein the ring having an adjustable thickness is comprised of a first and a second annular body member which are joined together in a manner which allows for relative movement of the body members to adjust the thickness of the ring prior to insertion into the annular channel.

4. The method as claimed in claim 1, wherein the ring thickness is adjusted by providing a first body member having threadings on its outer circumference and a second body member having threadings on its inner circumference wherein the threadings on each ring intermesh each other and by turning each ring in a direction opposite to the other ring the thickness provided is changed.

5. The method as claimed in claim 1, wherein the ring includes ends which are each tapered toward a narrow end with opposing ends being tapered in opposite directions such that when the ends fit together they form the substantially smooth and continuous surface.

6. The method as claimed in claim 1, wherein the rings are adjusted by providing a first and a second body member wherein the first body member includes ratched protuberances on its outer circumference and the second body member includes ratched protuberances on its inner circumference whereby the two body members can be intermeshed so that the protuberances on each the body members together and make it possible to adjust the thickness provided by the combination of the two body members.

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7. The method as claimed in claim 1, wherein the thickness of the ring is adjusted by injecting a fluid into the ring which ring is comprised of an inflatable open ended body member.

5

8. The method as claimed in claim 1, wherein the adjustment of thickness is carried out by providing a first and a second body member each of which body member includes protuberances and indentations on a surface which faces the protuberances and indentations of the surface of the other body member so as to allow for thickness adjustment by turning the rings so as to align or misalign the protuberances and indentations.

10

9. The method as claimed in claim 1, wherein the ring thickness is adjusted by providing smooth continuous peaks and valleys on opposing surfaces of two annular body members, the peaks and valleys being positioned such that the body members can be turned relative to each other so as to adjust the thickness provided by the combination of the body members.

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10. The method as claimed in claim 1, wherein the ring thickness is adjusted by providing a coil-shaped ring with a plurality of coils, whereby ring thickness is increased by inserting additional coils of the ring into the cornea until the desired thickness is obtained.

25

11. The method as claimed in claim 1, wherein the ring thickness is adjusted by providing a plurality of rings into the cornea which rings have surfaces which intermesh with each other whereby rings are inserted until a desired thickness is obtained.

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12. An intrastromal corneal ring for refractive correction of a human eye to improve the vision of the eye, comprising:

5 a first elongated, flexible body member in the form of an open circle; and

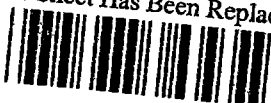
a second elongated, flexible body member in the form of an open circle wherein the first and second bodies are adjustably interconnected in a manner such that the thickness dimension of the two bodies when
10 interconnected can be changed.

13. The intrastromal corneal ring as claimed in claim 12, wherein the ends of the first body member and second body member each have ends which ends overlap
15 and mesh to each other in a manner so as to provide for a smooth and continuous surface.

14. The intrastromal corneal ring as claimed in claim 12, wherein the first and second body members
20 are adjustably interconnected by including a plurality of protuberances on an outer circumference of the first body member and a plurality of protuberances on an inner circumference of the second body wherein the
protuberances and circumferences of the first and second
25 body members are designed such that the first and second bodies fit within each other by the intermeshing of the protuberances.

15. The intrastromal corneal ring as claimed
30 in claim 12, wherein the first body member and second body member are adjustably interconnected by providing threads on an outer circumference of the first body member and corresponding threads on an inner
circumference of the second body member wherein the
35 threads and diameters of the first and second body

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members are designed such that the threads interlock each other and when the first body member is moved circularly in a direction opposite to the second body member the thickness dimension is changed.

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16. The intrastromal corneal ring as claimed in claim 12, wherein the first body member includes a first surface which faces a second surface of the second body member wherein the first surface and the second surface have corresponding notches and protuberances thereon and the first surface and the second surface are forced together by an attachment means the protuberances and notches being designed such that when the first body member is moved circularly relative to the second body member the notches and protuberances cause the thickness dimension to be changed.

17. The intrastromal corneal ring of claim 12, wherein the thickness of the ICR is adjustable between 0.05 and 1.5 mm.

18. The intrastromal ring of claim 12, wherein the body of the ring has a width in the range of 0.25 mm to 3.25 mm.

25

19. The intrastromal ring as claimed in claim 12, wherein the ring is comprised of a biocompatible, nontoxic, biologically benign material, has a diameter in the range of 0.5 mm to 10 mm and a thickness in the range of 0.05 mm to 1.5 mm.

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20. An intrastromal corneal ring for refractive correction of a human eye to improve the vision of the eye, comprising:

- an elongated, flexible, inflatable, annular body member, the inflatable body member having an inflation stem positioned thereon wherein the inflation stem is designed such that fluid can be injected into the inflatable body so that the thickness dimension of the body is changed.

21. A mammalian eye, having inserted within its cornea an intrastromal ring which is adjustable in thickness while present within the cornea of the eye.

22. A method for adjusting the shape of the cornea of an eye, comprising the steps of:

providing a coil shaped cutting device and covering the device by progressively moving a hollow intrastromal ring over the cutting device until the entire ring is included on the device with a tip portion of the cutting device extending outwardly from the hollow ring;

cutting an initial incision into the cornea of the eye;

continuing to separate into the cornea of the eye from the point of the initial incision using the point of the cutting device and cutting in a circular direction from the incision beneath the surface of the cornea so as to provide a complete annular channel within the cornea;

holding the hollow ring in place and withdrawing the cutting device from the ring while leaving the ring in place.



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23. The method of claim 22, further comprising inserting an interconnector into a first end and a second end of the hollow ring wherein the interconnector device includes an inflation stem having a check valve therein.

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24. The method of claim 22, further comprising:

injecting fluid into the inflation stem so as to expand the hollow ring.

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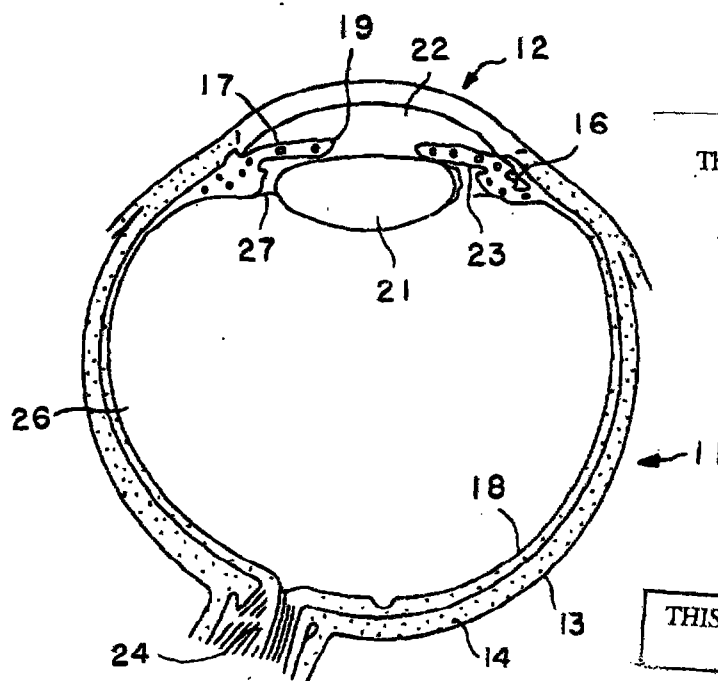


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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: ADJUSTABLE DEVICES FOR CORNEAL CURVATURE ADJUSTMENT

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THIS SHEET HAS BEEN
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The intrastromal corneal ring (ICR) (47) is adjustable in thickness and has an elongated, flexible preferably transparent or translucent body which forms a circle. The thickness may be adjusted prior to insertion into the cornea and may not be further adjustable after insertion. In preferred embodiments, the thickness of the ICR may be adjusted after insertion to more precisely adjust the shape of the cornea (12) and focus the light entering the eye on the retina (18).

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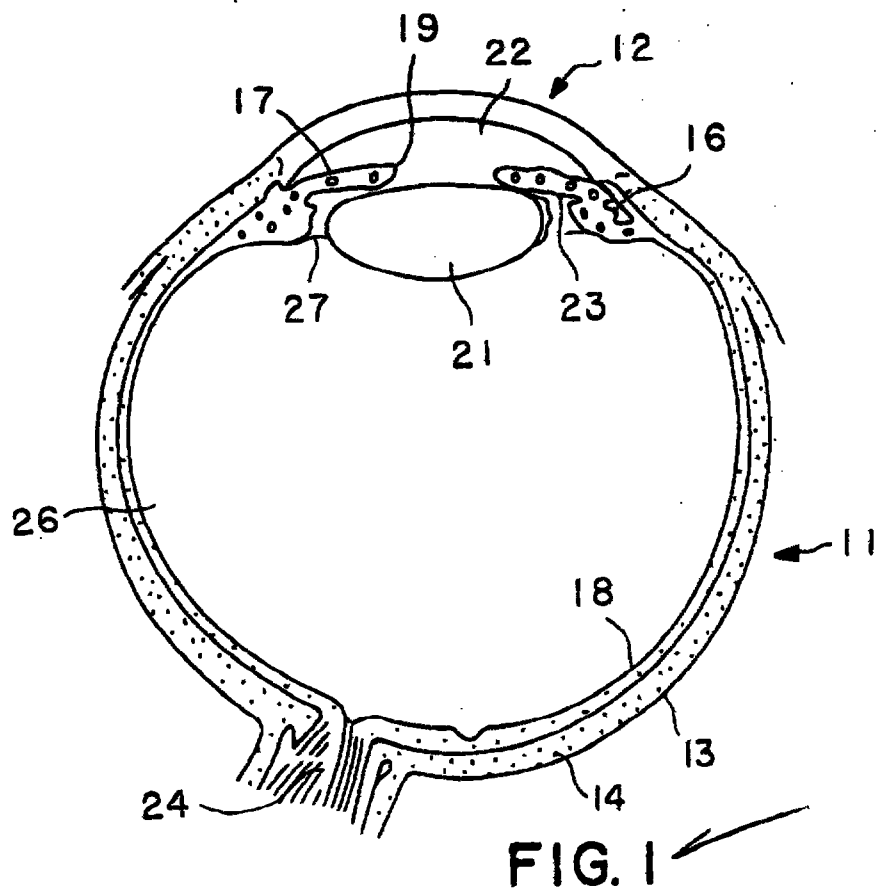
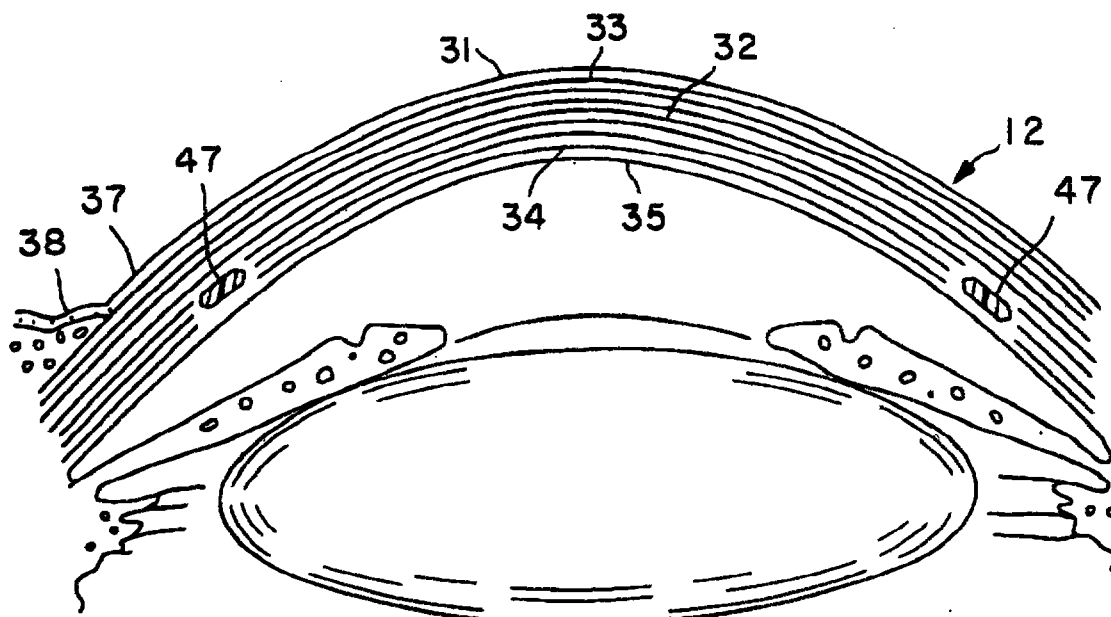


FIG. 2

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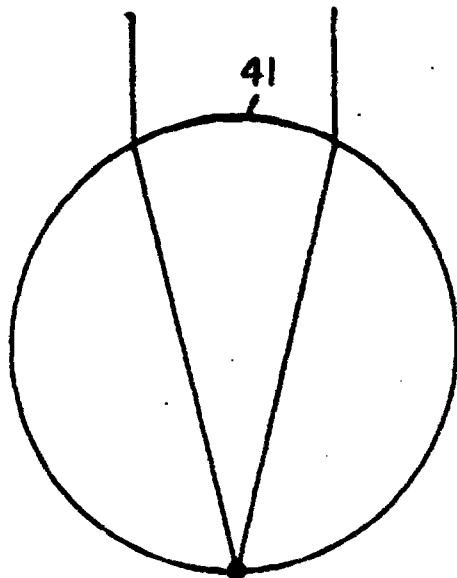


FIG.3

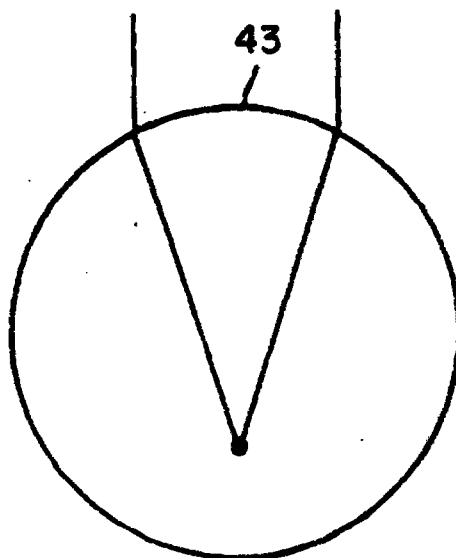


FIG.4

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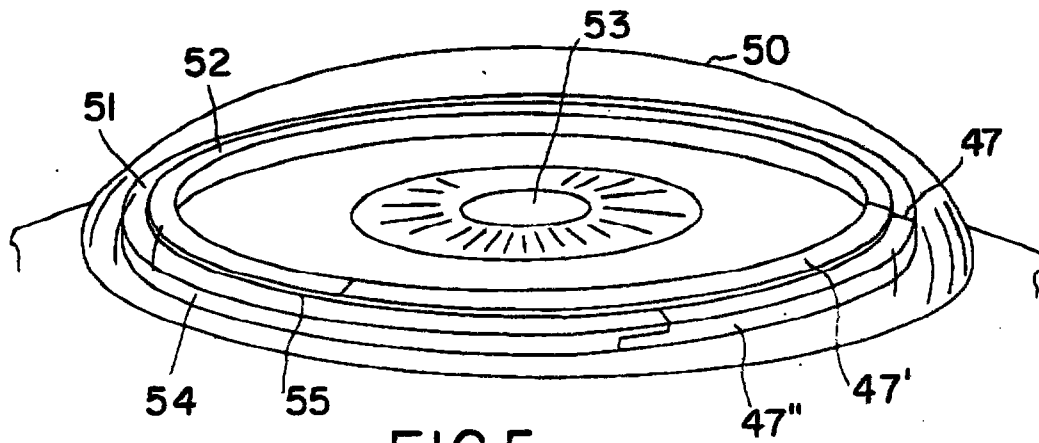


FIG. 5

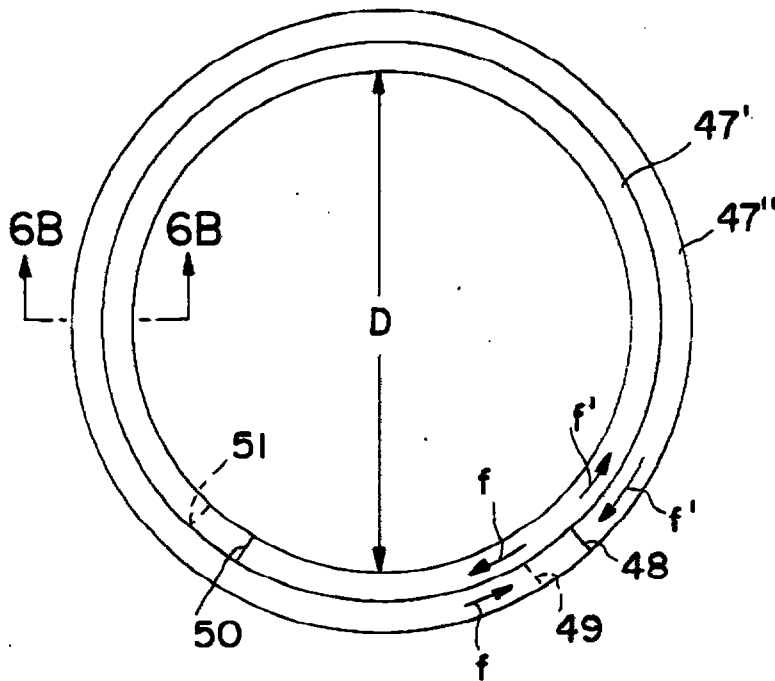


FIG. 6A

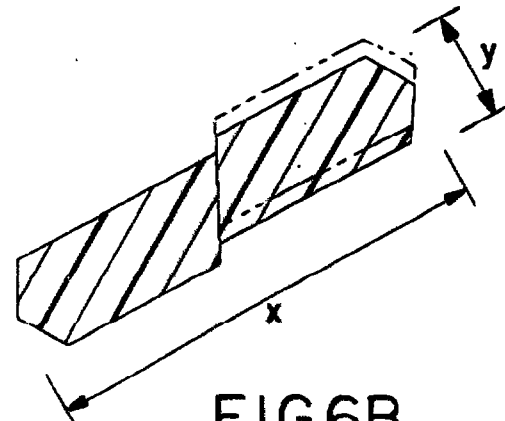


FIG. 6B

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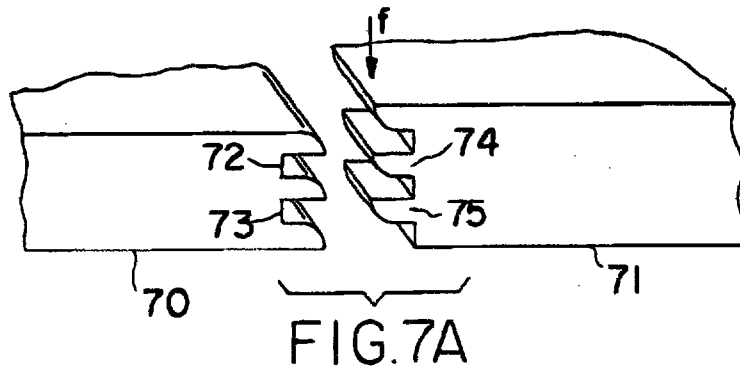
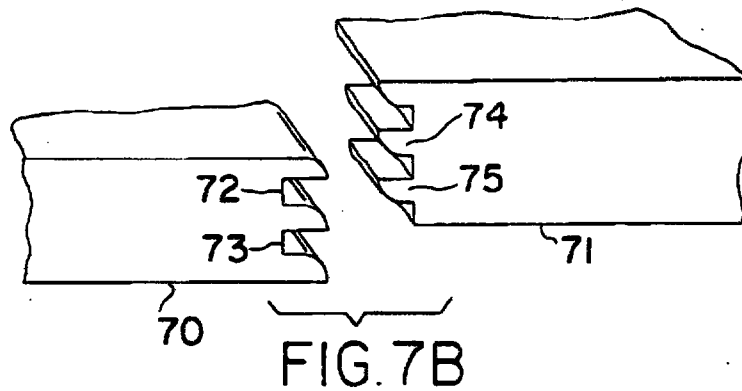
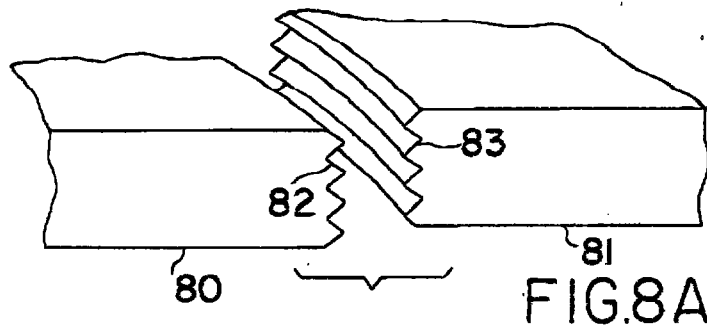
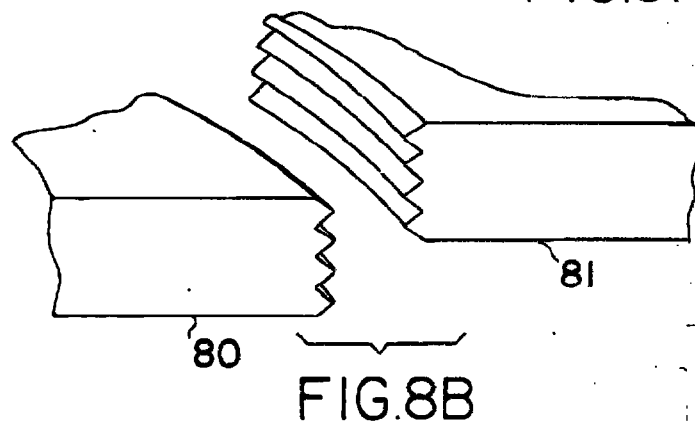


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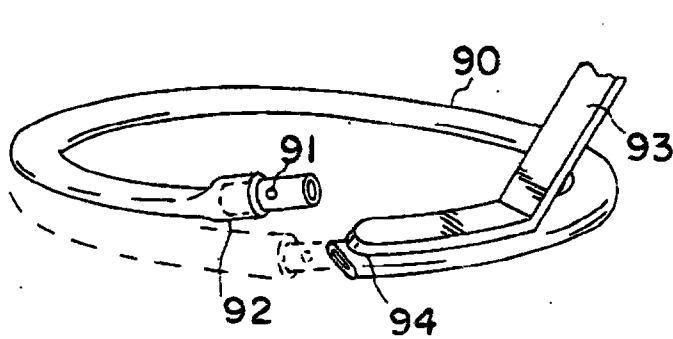


FIG. 9A

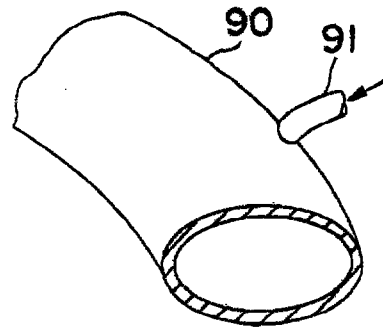


FIG. 9B

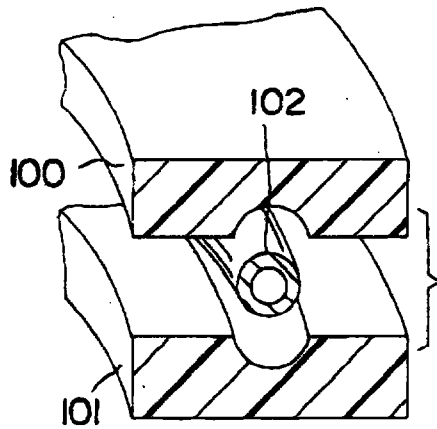


FIG. 10

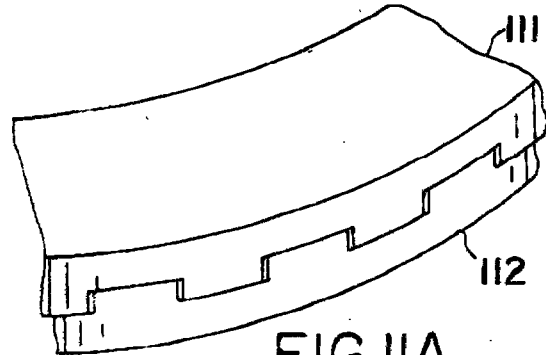


FIG. 11A

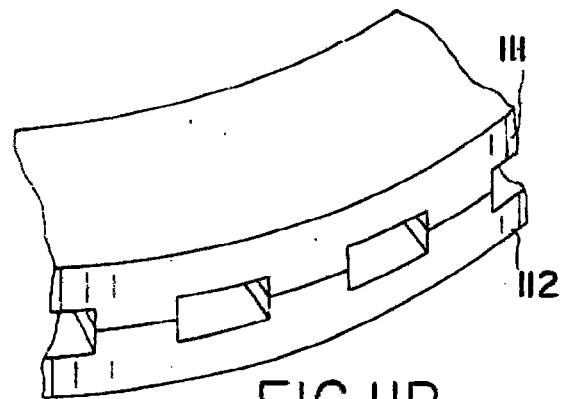


FIG. 11B

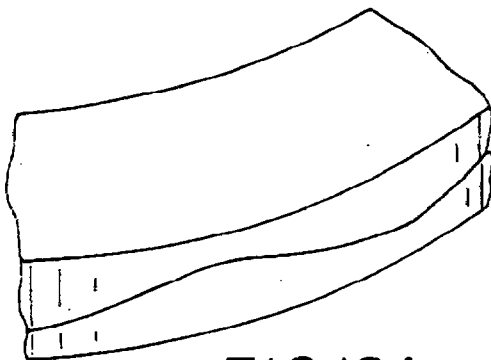


FIG. 12A

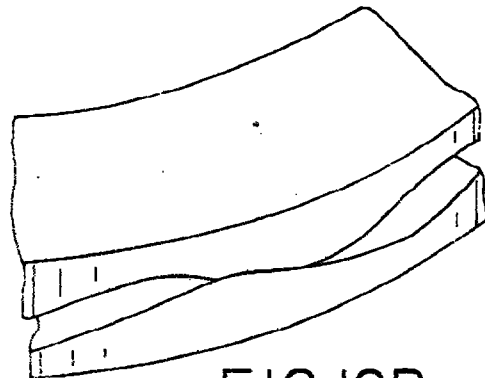
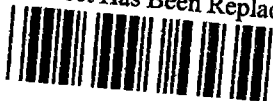


FIG. 12B

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FIG. 13

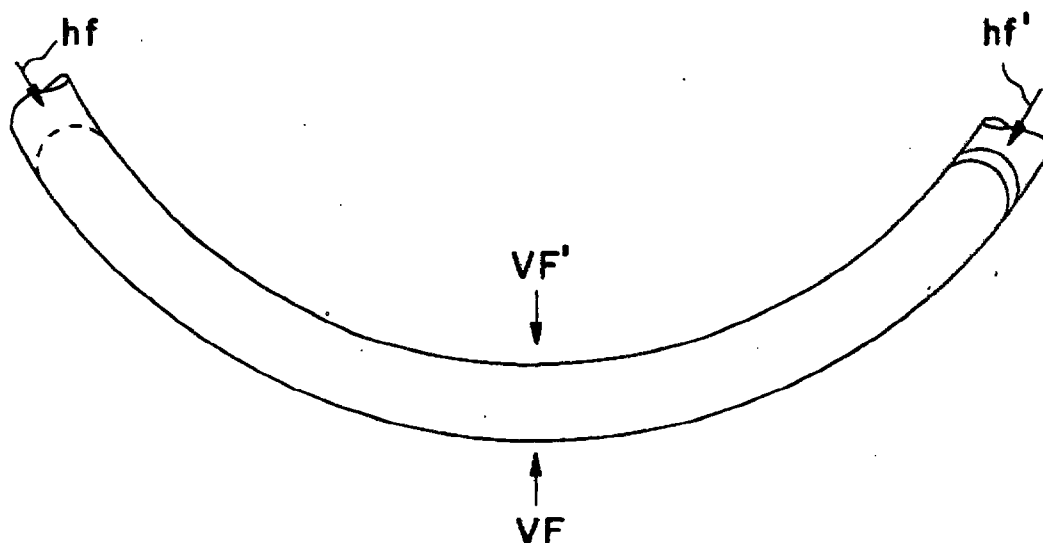


FIG. 13A

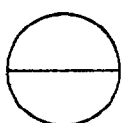


FIG. 13B

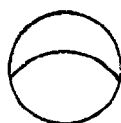


FIG. 13C



FIG. 13D

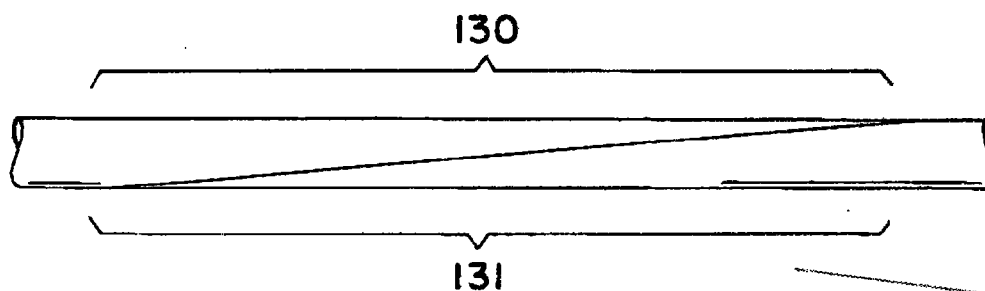


FIG. 13E

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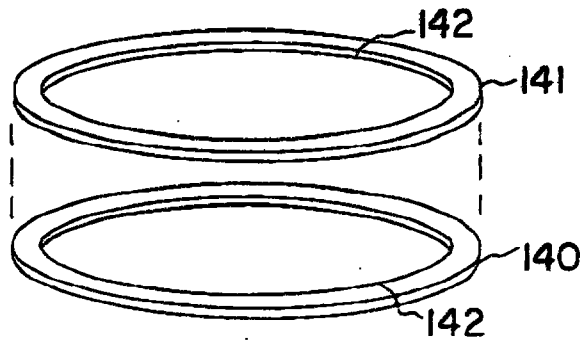


FIG. 14A

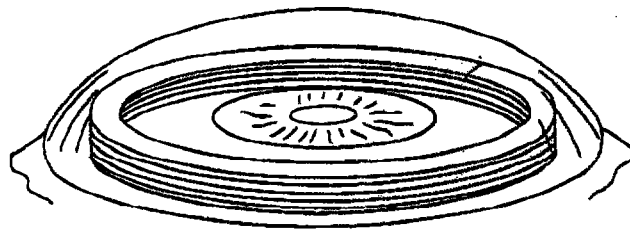


FIG. 14B

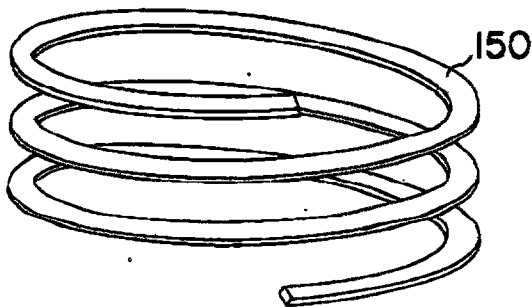


FIG. 15A

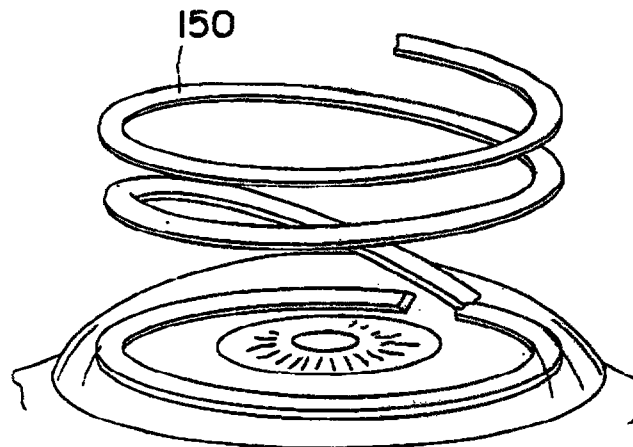


FIG. 15B

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ADJUSTABLE DEVICES FOR CORNEAL
CURVATURE ADJUSTMENTField of the Invention

10 This invention is in the general field of medical technology and relates specifically to an intrastromal corneal ring designed such that its thickness can be varied in a manner so as to vary the corneal curvature to correct vision.

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Background of the Invention

Anomalies in the shape of the eye and specifically the shape as defined in part by the corneal can cause visual disorders. Hyperopia occurs when the eyeball is too short. In such a case, parallel rays from greater than 20 feet focus behind the retina. Myopia, on the other hand occurs when the eyeball is too long. The focus of parallel rays in this case is in front of the retina. Astigmatism is a condition in which the parallel rays of light do not come to a single point, but rather have a variable focus due to the fact that the cornea is aspherical and refracts light in a different meridian at different distances. Some degree of astigmatism is normal, but where it is too high, it must be corrected in order to provide acceptable vision.

Conditions such as hyperopia, myopia and astigmatism are usually corrected by glasses or contact lenses. Surgical methods for the correction of such disorders have been cited in the literature and include radial keratotomy (see e.g. U.S. Patents Nos. 4,815,463

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and 4,688,570) and laser corneal ablation (see e.g. U.S. Patent No. 4,941,093). Further, the general method of implanting rings in the corneal stroma to change the curvature of the cornea is known. Previous work
5 involving the implantation of polymethylmethacrylate (PMMA) rings, allograft corneal tissue and hydrogels is well documented. One of the ring devices involves a ring design that allows a split ring to be inserted into a channel. The channel is formed by dissecting the stromal
10 layer of the cornea using a minimally invasive incision. Thereafter, the implant is inserted into the channel and the channel is sutured shut.

U.S. Patent No. 4,452,235, which is herein incorporated by reference in its entirety, describes a
15 method and apparatus for corneal curvature adjustment. The method involves inserting one end of a split end adjusting ring into the cornea of the eye and moving the ring in a circular path until its ends meet. The ends are thereafter adjusted relative to each other so that
20 the ends can be connected. When so connected the shape of the eye will have assumed a desired curvature.

Various devices were required in order to facilitate the implantation of the rings of the type described in U.S. Patent 4,452,235. Such a holder for
25 inserting corneal curvature adjustable rings is described within U.S. Patent 4,961,744 issued October 9, 1990. Further, prior to inserting the ring it is necessary to cut an annular channel within the cornea and a device for cutting such a channel is disclosed within U.S. Patent
30 4,766,895 issued October 30, 1988.

Other devices for adjusting the corneal curvature have been disclosed such as the device shown within U.S. Patent 4,671,276 issued June 9, 1987. In addition, devices for affecting other parts of the eye
35 such as an iris retaining device are disclosed within

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U.S. Patent 4,782,820 issued November 8, 1988 and a
variable focus lens which is disclosed within U.S. Patent
5,066,301 issued November 19, 1991. More recently a
method of changing cornea curvature by injecting a gel
5 into the cornea was disclosed in U.S. Patent 5,090,955
issued February 25, 1992.

The present invention describes split ring
devices which are inserted in the corneal stroma and have
adjustable thicknesses which provide certain advantages
10 and improvements as compared to earlier intrastromal
corneal rings.

Summary of the Invention

The present invention is an intrastromal
15 corneal ring (ICR) of adjustable thickness which has an
elongated, flexible body which forms a circle. The ICR
is of a size such that it can be inserted into a human
eye and specifically into the outer periphery of the
cornea of a human eye. The ICR is comprised of a
20 material which is compatible with human ocular tissue and
specifically compatible with corneal tissue. The means
for adjusting the thickness of the ring may be formed in
several different configurations or embodiments. Two
open ended annular body members may be interconnected in
25 such a manner that the distance between the body members
can be adjusted to provide different thicknesses and
thereby obtain different degrees of change in the shape
of the eye effecting the focus of light on the retina.

The essence of the present invention lies in
30 the ability of the ring to be adjusted in thickness so
that it is not necessary to stock a plurality of
different rings of different sizes to be used in
connection with the method for adjusting the shape of the
cornea of an eye. Accordingly, the present invention
35 provides a plurality of different embodiments of ICRs

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which are each adjustable in terms of their thickness. The thickness adjustment may occur prior to the insertion of the ICR into the cornea and may not be further adjustable after insertion. However, in the preferred
5 embodiments of the invention the ICR is inserted at a thickness which is believed to be proper and may be adjusted thereafter in order to precisely define the desired thickness and thereby more precisely adjust the shape of the cornea and focus the light entering the eye
10 on the retina.

A primary object of the invention is to provide an ICR having an adjustable thickness.

An advantage of the invention is that a single ring of adjustable thickness can be used thereby
15 eliminating the need for multiple rings of different thickness.

A feature of the invention is that the ring thickness can be adjusted while the ring is in place.

Another advantage of the ring is that it can be
20 readjusted at later times in order to readjust the curvature of the eye as needed.

These and other objects, advantages and features of the present invention will become apparent to those persons skilled in the art upon reading the details
25 of the structure and operation as more fully set forth below, reference being made to the accompanying drawings forming a part hereof wherein like symbols refer to like components throughout.

30 Brief Description of the Drawings

Figure 1 is a schematic representation of a horizontal section of the eye.

Figure 2 is a schematic illustration of the anterior portion of the eye showing the various layers of
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the cornea with an intrastromal corneal ring inserted therein.

5 Figure 3 is a schematic representation showing how light moves through a normal eye to focus on the retina.

Figure 4 is a schematic representation showing how light moves through a myopic eye and focuses in front of the retina.

10 Figure 5 is a perspective view of one embodiment of the ICR of the invention inserted within a cornea of a human eye.

Figure 6 includes a plane view (6A) and a perspective sectional view (6B) of an ICR of the invention.

15 Figures 7A and 7B are perspective views showing a ratcheted height adjustment embodiment in two positions.

Figures 8A and 8B are perspective views showing a threaded height adjustment embodiment in two positions.

20 Figures 9A and 9B are perspective views of an inflatable embodiment in a deflated and inflated state.

Figure 10 is a cross sectional view of a tube centered embodiment.

25 Figures 11A and 11B are perspective views of a notched embodiment in two positions.

Figures 12A and 12B are perspective views of a smooth surface embodiment in two positions.

30 Figures 13, 13A, 13B, 13C, 13D and 13E are different views showing how the ends of the annular body member might overlap.

Figures 14A and 14B show a stacked shim embodiment of the invention with and without the shims in place.

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Figures 15A and 15B show a spiral spring embodiment of the invention in a collapsed position and as the spiral might be inserted.

Detailed Description of the Invention

5 Before the adjustable intrastromal corneal ring and its various embodiments and configurations and methods of use are described, it is to be understood that this invention is not limited to the particular
10 embodiments, configurations, materials and steps described as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting, since the scope of the present invention will be limited only by the appended
15 claims.

 The basic structure, function and operation of the adjustable intrastromal corneal rings of the invention is shown and discussed in connection with Figures 1-6. Figures 7-15 show eight different
20 embodiments of the invention which show six basic configurations whereby the rings can vary in terms of their thickness and/or height. Further, the ring ends can be connected to each other without the use of additional components in a manner so as to provide a
25 smooth and continuous interconnection between the ends so that the surface of the ring appears substantially smooth and continuous along its entire surface even at the interconnection of the ring ends.

 The different embodiments shown in Figures 7-15
30 can each include a number of different subembodiments by varying features such as the material, the manner in which the ring ends are interconnected and the cross sectional surface parameters of the ring e.g. forming the ring from cross sections in the form of a circle, square,
35 rectangle, triangle, oval, etc. Although a number of

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configurations are shown others are possible and are contemplated by this invention. Further, other possible means of adjusting the ring thickness are contemplated by this invention. It is preferable if the invention is
5 constructed such that the ring size can be adjusted while the ring is in place in the eye.

Before discussing the specific embodiments of Figures 7-15 the general structure and method of use of adjustable intrastromal corneal rings will be described
10 in connection with Figures 1-4 and thereafter generalized information relating to the rings of the present invention in connection with Figures 5 and 6.

Figure 1 shows a horizontal section of the eye with the globe 11 of the eye resembling a sphere with an
15 anterior bulged spherical portion representing the cornea 12.

The globe 11 of the eye consists of three concentric coverings enclosing the various transparent media through which the light must pass before reaching
20 the sensitive retina 18. The outermost covering is a fibrous protective portion the posterior five-sixths of which is white and opaque and called the sclera 13, and sometimes referred to as the white of the eye where visible to the front. The anterior one-sixth of this
25 outer layer is the transparent cornea 12.

A middle covering is mainly vascular and nutritive in function and is comprised of the choroid 14, ciliary body 16 and iris 17. The choroid 14 generally
30 functions to maintain the retina 18. The ciliary body 16 is involved in suspending the lens 21 and accommodation of the lens. The iris 17 is the most anterior portion of the middle covering of the eye and is arranged in a frontal plane. It is a thin circular disc corresponding to the diaphragm of a camera, and is perforated near its
35 center by a circular aperture called the pupil 19. The

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size of the pupil varies to regulate the amount of light which reaches the retina 18. It contracts also to accommodation, which serves to sharpen the focus by diminishing spherical aberration. The iris 17 divides the space between the cornea 12 and the lens 21 into an anterior chamber 22 and posterior chamber 23. The innermost portion of covering is the retina 18, consisting of nerve elements which form the true receptive portion for visual impressions.

10 The retina 18 is a part of the brain arising as an outgrowth from the fore-brain, with the optic nerve 24 serving as a fiber tract connecting the retina part of the brain with the fore-brain. A layer of rods and cones, lying just beneath a pigmented epithelium on the
15 anterior wall of the retina serve as visual cells or photoreceptor which transform physical energy (light) into nerve impulses.

 The vitreous body 26 is a transparent gelatinous mass which fills the posterior four-fifths of
20 the globe 11. At its sides it supports the ciliary body 16 and the retina 18. A frontal saucer-shaped depression houses the lens.

 The lens 21 of the eye is a transparent bi-convex body of crystalline appearance placed between the
25 iris 17 and vitreous body 26. Its axial diameter varies markedly with accommodation. A ciliary zonule 27, consisting of transparent fibers passing between the ciliary body 16 and lens 21 serves to hold the lens 21 in position and enables the ciliary muscle to act on it.

30 Referring again to the cornea 12, this outermost fibrous transparent coating resembles a watch glass. Its curvature is somewhat greater than the rest of the globe and is ideally spherical in nature. However, often it is more curved in one meridian than
35 another giving rise to astigmatism. A central third of

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the cornea is called the optical zone with a slight flattening taking place outwardly thereof as the cornea thickens towards its periphery. Most of the refraction of light striking the eye takes place as the light passes through the cornea.

Referring to Figure 2, a more detailed drawing of the anterior portion of the globe shows the various layers of the cornea 12 comprising an epithelium 31. Epithelial cells on the surface thereof function to act as the main protection layer of the cornea 12. These epithelial cells are rich in glycogen, enzymes and acetylcholine and their activity regulates the corneal corpuscles and controls the transport of water and electrolytes through the lamellae of the stroma 32 of the cornea 12.

An anterior limiting lamina 33, referred to as Bowman's membrane or layer, is positioned between the epithelium 31 and the stroma 32 of the cornea. The stroma 32 is comprised of lamella having bands of fibrils parallel to each other and crossing the whole of the cornea. While most of the fibrous bands are parallel to the surface, some are oblique, especially anteriorly. A posterior limiting lamina 34 is referred to as Descemet's membrane. It is a strong membrane sharply defined from the stroma 32 and resistant to pathological processes of the cornea.

The endothelium 36 is the most posterior layer of the cornea and consists of a single layer of cells which aid in maintaining the transparency of the cornea. The limbus 37 is the transition zone between the conjunctiva 38 and sclera 13 on the one hand and the cornea 12 on the other.

A cross sectional view of an intrastromal corneal ring 47 of the invention is shown within the stroma 32 of the cornea 12. The ring 47 is placed in the

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stroma 32 by making an initial incision into the cornea 12 and then continuing to separate the stroma of the cornea in a circular direction from the initial incision beneath the surface of the cornea so as to provide a
5 complete annular channel within the cornea 12. The ring 47 is placed within the annular channel.

Figure 3 shows the globe of the eye having a cornea with a normal curvature 41. If parallel rays of light pass through the corneal surface 41 of Figure 3,
10 they are refracted by the corneal surfaces to converge eventually near the retina of the eye. The diagram of Figure 3 discounts, for the purposes of this discussion, the refractive effect of the lens or other portions of the eye. The eye depicted in Figure 4 is myopic. The
15 corneal curvature 43 causes the light rays to refract into focus at a point in the vitreous body which is short of the retinal surface. If an ICR is implanted into the chord of the cornea such that the radius of curvature of the cornea is uniformly increased, the central curvature
20 of the cornea is flattened. Light rays refracted by the now flattened corneal surface will be refracted at a smaller angle and thus converge at a more distant point such as directly on the retina.

The ICRs of the present invention make it
25 possible to adjust the radius of curvature of the cornea without adversely affecting its natural sphericity. Where there is serious astigmatism, the natural sphericity will not be altered such that the astigmatism will be significantly increased. However, where there is
30 significant astigmatism that results in impaired vision, the ICR of the invention may actually improve the sphericity to reduce such astigmatism and improve vision.

As is shown in Figures 3 and 4 by changing the curvature from a curvature 43 to a curvature 41 the focal
35 point can be correctly positioned on the retina. A small

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degree of curvature change can affect the focal point of the light entering the eye. Accordingly, it is difficult to choose the correct thickness of an intrastromal corneal ring to be inserted in the stroma of the cornea so that it will correctly affect the focal point of the light entering the eye. The difficulty with respect to choosing the correct thickness is the point where the advantages of the present invention become most apparent. When the present invention is used the intrastromal corneal ring is first adjusted to have a thickness which is believed to be the correct thickness. However, after inserting the ring into the stroma of the cornea the thickness of the ring can be further adjusted in order to precisely focus the light entering the eye on the retina.

As shown in Figure 2, an intrastromal corneal ring (ICR) 47, having a cross sectional shape as shown in Figure 6B is shown implanted in the stromal layer of the cornea. The thickness of the ring can be adjusted prior to placing the ring in the eye. Preferably the ring thickness can be further adjusted in situ to precisely adjust the amount of correction necessary. By such adjustments the rays refracted by the cornea and other eye components can be brought to focus directly on the retina (not shown in Figure 2).

Figure 5 shows a perspective view of the ICR 47 with its threaded height adjustment means is inserted within a cornea 50 of a human eye. In the embodiment shown within Figure 5, the ICR is placed in a manner such that the widest faces 51 and 52 face outward along the line of sight 53 and away from the eye, whereas the narrower faces 54 and 55 face radially inward toward the center of the eye and the wide and narrow faces are perpendicular to each other. However, it should be noted that other configurations are possible. Height or

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thickness adjustment is carried out by screwing the threaded body members 47' and 47" so that they move away from or toward each other depending on whether an increase or decrease in thickness is required.

5 A plane view of the ICR 47 of the invention is shown in Figure 6A. As shown, the ICR is circular in shape and is comprised of two elongated, flexible body members 47' and 47" each of which forms a circle. One possible cross sectional configuration is shown in
10 Figure 6B which configuration is basically rectangular with angled outer edges. Other cross sectional configurations are possible, such as square, circular, and variations therebetween. Because the body of the ring is circular, it has the same diameter D in all
15 directions. However, it is possible to configure the body of the ring in other slightly noncircular configurations, e.g., ovals and elongated ovals. However, in these configurations the two rings are not interconnected by threading but by other adjustable means
20 such as ratched slots. In its preferred circular configuration, the diameter conforms to the size of a human cornea which is approximately 1 cm in diameter. The ring is comprised of a biocompatible material such as a biocompatible polymer. Such biocompatible materials
25 and polymers are particularly designed with eye tissue characteristics in mind. Accordingly, materials such as those used in making contact lenses can be used. It is pointed out that the ocular tissues is generally quite sensitive and may react upon the implantation of the
30 ring. However, after a period of time, any inflammation and/or adverse reaction will be eliminated. In order to decrease the probability of adverse reactions, it is desirable to choose a biocompatible material which will not create an immune reaction, be nontoxic and
35 biologically benign. Metals and metal alloys are

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generally undesirable as are other types of materials which react with the ocular tissue.

5 The rings 47' and 47" in Figure 6A each show one end 48 and 50. Because Figure 6A is a planar view, the ends 48 and 50 are each shown as a single line. The other ends 49 and 51 are each shown by a dotted line in that this end is visible only from the other side of the rings 47' and 47". The corresponding ends 48 and 49 and corresponding ends 50 and 51 may be structured in several different configurations, as discussed in connection with
10 Figures 13 and 6A:

As shown in Figures 6A and 13, the corresponding ends 48 and 49 are overlapping each other as the ends 50 and 51. The rings can be screwed toward each other as shown by the arrows f or in the opposite
15 direction as shown by the arrows f'.

The thickness of the ring may be between adjusted within a range of about 0.05 mm and 1.5 mm. Such a ring placed approximately at the 8 mm chord of the cornea provides a means for making such a corrective
20 adjustment.

As indicated above Figures 5 and 6A show an ICR of the invention which is comprised of a generally circular body member. The ring is comprised of a material which has sufficient stiffness to maintain its generally circular shape. The material should have properties that render it physiologically compatible with the tissue of the cornea. An illustrative material is a plastic type material sold under the trade name of
25 PLEXIGLASS™, however many other biocompatible polymers are useful in the invention, including but not limited to polyolefins (e.g., polypropylene and polybutylene), polycarbonates, acrylic resins (e.g., acrylates and methacrylates, including polymethylmethacrylate (PMMA)
30 and polyhydroxyethyl methacrylate (polyHEMA)), poly-

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acetals, polyesters, polyamides (e.g., nylon), polyurethanes, epoxy resins, silicones or other natural or synthetic rubbers, copolymers that are composed of hard and soft segments (e.g., HYTREL, Dupont, Wilmington, DE), polytetrafluoroethylene (PTFE), polyvinylpyrrolidone, polyethers/ether ketones, polysulfones, glass, and copolymers (discrete or block), blends and mixtures of the above. As discussed above, the means of adjusting ring thickness can vary. When a cross section of the ring is circular, it is generally dimensioned to be about 0.05 mm to 1.5 mm in thickness.

A particular cross sectional configuration is schematically shown in Figure 6B. When this configuration is used, the dimension shown from point to point (dimension x) may be within the range of approximately 0.25 mm to 3.25 mm and the thickness (dimension y) generally can be adjusted in the range from about 0.05 mm to about 1.5 mm.

There are a number of factors which affect the degree of flattening of the cornea obtained depending upon the thickness of the ring being inserted. Accordingly, it is not always possible to deduce a direct relationship between the ring thickness and the degree of flattening and therefore the change in focal point. Variations are caused by factors such as the type of mammal in which the ring is being inserted and the size and shape of the eye. However, in certain experiments, it has been found that optical corrections can be carried out at the rate of 1 diopter of flattening for each 0.02 mm increase in ICR thickness when the size of the ICR is in the range of about 0.26 mm to about 0.46 mm in thickness. Thus, it is advantageous to set the threading on the interconnected ring so that one 360°, 180°, or 90° turn of one ring relative to the other changes the thickness by 0.02 mm. Alternatively, in a ratched

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embodiment one increment change will change the thickness by 0.02 mm or some fraction or multiple thereof.

Even where the eye is not myopic, the ICRs of the present invention may be useful to alleviate
5 excessive astigmatism.

A typical panel of ICRs will consist of 5 ICRs with the following thicknesses: 0.25 mm, 0.30 mm, 0.35 mm, 0.40 mm and 0.45 mm. The corrective refraction for those ICRs are as follows: between 0.5 and 3.0
10 diopters for the 0.25 mm ICR, between 1.0 and 5.0 diopters for the 0.30 mm ICR, between 2.0 and 8.0 diopters for the 0.35 mm ICR, between 3.0 and 10.0 diopters for the 0.40 mm ICR, and between 4.0 and 15.0 diopters for the 0.45 mm ICR. It should be noted that
15 these values are for conventional ICRs and that value of between 0.5 to 18.0 might be used. The amount of corrective refraction for the various thicknesses of ICRs of different cross sectional shaped rings may differ from those values.

20 The essence of the present invention lies in the ability of the ring to be adjusted in thickness so that it is not necessary to stock a plurality of different rings of different sizes to be used in connection with the method for adjusting the shape of the
25 cornea of an eye. Accordingly, the present invention provides a plurality of different embodiments of ICRs which are each adjustable in terms of their thickness. The thickness adjustment may occur prior to the insertion of the ICR into the cornea and may not be further
30 adjustable after insertion. However, in the preferred embodiments of the invention the ICR is inserted at a thickness which is believed to be proper and may be adjusted thereafter in order to precisely define the desired thickness and thereby more precisely adjust the

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shape of the cornea and focus the light entering the eye on the retina.

The ICR is inserted into the corneal stroma of the eye through an oblique keratotomy incision placed peripherally into the corneal stroma. The size of the insertion will vary somewhat depending on factors such as the size of the ring or rings being inserted. In general, the size of the insertion is approximately 0.5 mm to 5.0 mm in length with an incision of approximately 2.5 mm being typical. Prior to ring insertion, a channeling blade is inserted at the depth of the incision and a circular channel is cut into the corneal stroma. Proper centering of the cut is accomplished by use of a centering device that aligns the channeling blade. The ring is then inserted and the ends are secured by fastening one end to the other.

Specific Preferred Embodiments

Eight different basic preferred embodiments are shown in Figures 7-15. In addition, many of the basic embodiments are further illustrated by means of subembodiments which include; for example, different configurations of the cross sectional parameter of the ring. It is emphasized that each of the embodiments and subembodiments may be interchanged and be comprised of different materials and provided in different sizes in accordance with the size limitations indicated above. Further, the disclosures of these different embodiments may demonstrate to others skilled in the art that other embodiments are possible which provide substantially the same results in terms of providing a ring structure which is adjustable in terms of its thickness.

A ratched height adjustment embodiment is shown in Figures 7A and 7B. Cross sectional views of the embodiment in different relative positions to create

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thickness variations are shown in Figures 7A and 7B. The lower ring 70 is surrounded by the outer upper ring 71 and the two rings are interconnected by means of ratched slots 72 and 73 and protuberances 74 and 75. The

5 protuberances 74 and 75 fit within the slots 72 and 73 respectively. The ring 71 can be pulled upward in the direction of the arrow f in order to reposition the protuberances 74 and 75 as shown within Figure 7B. In the configuration shown within Figure 7B the thickness of

10 the dual ring structure is increased as compared with the thickness of the structure positioned as per Figure 7A. This embodiment is simple to produce and provides desirable results as compared with the use of a multiplicity of different rings. However, the embodiment

15 is not desirable in that it is somewhat difficult to adjust the thickness of the rings after the rings have been inserted within the cornea.

In Figure 8A the rings 80 and 81 are shown in a cross sectional view. The inner ring 80 includes

20 threadings 82 on its outer circumference while the ring 81 includes threadings 83 on its inner circumference. The threadings 82 and 83 mesh into each other and the rings 80 and 81 can be turned in directions opposite to each other. In the position shown in Figure 8A the rings

25 have been turned so that the ring 81 has been increased in height relative to the ring 82 thereby increase the thickness. This height adjustment can be carried out in situ.

In Figure 9A the ring 90 is substantially

30 deflated in that no fluid has been injected into the ring via the nozzle 91. In Figure 9B the ring 90 has been substantially inflated by the injection of a fluid into the ring 90 via the nozzle 91. By injecting the fluid into the ring the thickness of the ring is increased. It

35 is also possible to design the ring such that its outer

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end or inner diameters are also increased with the injection of fluid. There are two separate subembodiments of the inflatable ring which can provide particular advantages. In a first subembodiment, the ring is designed so that when it is inflated it will only increase in thickness and not increase radially. In the second subembodiment, the ring is designed such that when it is inflated, it will not increase in thickness but only increase radially. It is possible to design a cross breed subembodiment which allows a certain, predetermined degree of thickness increase and a certain, predetermined degree of radial increase, each within specific limitations designed to obtain a specific effect. The nozzle 91 is preferably a check valve, i.e. one-way valve which allows a fluid to be injected in but which will not allow a fluid to flow out. However, fluid could be extracted by inserting a hypodermic needle into the valve opening and vacuuming fluid from the interior of the ring 90. As shown within Figure 9A the valve 91 is preferably positioned on a separate piece 92 which can then be completely encompassed by and sealed with respect to the outer walls of the ring 90. However, other embodiments are possible. The material injected into the ring 90 can be any suitable material including water and biocompatible liquids and gels. For example, see the gel injection system disclosed within U.S. Patent 5,090,955 issued February 25, 1992 which is incorporated herein by reference.

In Figure 9A a method for including the inflatable ring 90 into the cornea of the eye is shown. In essence, the ring 90 is placed on a blade 93 which has a blade width approximately equal to or slightly larger than the internal diameter of the ring 90. The point 94 of the blade cuts annularly into the cornea followed by the ring 90. When a complete circular incision is made

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the entire ring 90 is inserted within that incision.

Thereafter, by holding the ring 90 in place the blade 93 can be withdrawn leaving the ring 90 in place.

5 Thereafter, the interconnector including the nozzle 91 is inserted into one end of the ring and thereafter into the other ring in order to form a complete circle.

10 A cross section of a tube centered embodiment is shown Figure 10 wherein the upper ring 100 is separated from the lower ring 101 by a tube 102. In that the ring is placed within a relatively small incision within the ocular tissue, the components of the ring will be held together by the pressure provided by the ocular tissue. Accordingly, there is generally no need to provide any additional forces to bring the components
15 together. However, the two rings can be held together by a supplemental means including by the inclusion of magnetic material within both of the rings.

Alternatively the tube 102 may be comprised of a magnetic material and the rings 100 and 101 may include a material
20 such as iron which is attracted by the magnetic material. In accordance with this embodiment the thickness of the overall ring structure is increased by increasing the size of the tubes 102 which are included between and separate the rings 100 and 101.

25 Figures 11A and 11B provide perspective views of the notched embodiment of the invention. In Figure 11A the notches of the rings 111 and 112 are intermeshed to provide the thinnest possible ring structure. In Figure 11B the notches are aligned so as to provide the
30 maximum thickness. This embodiment may be easily constructed. However, it has disadvantages in that the adjustment is only in a single increment. This can be accounted for to a certain extent by including a plurality of notches of different heights and aligning
35 the desired height notch in order to achieve the desired

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thickness and thereafter locking the rings into place by any appropriate means such as the use of sutures, adhesives, pins, etc.

Figures 12A and 12B shows a smooth surface interlocking embodiment. In Figure 12A the rings are intermeshed so as to provide the thinnest possible structure whereas Figure 12B shows the thicker structure. Due to the smooth surfaces of the interlocking components it is possible to vary the height of the rings and when the desired height is achieved lock the rings into place by an appropriate means such as the use of an adhesive or sutures.

In all or any of the above embodiments variations are possible with respect to the cross sectional configuration of the rings, the type of material and other parameters. For example, all of the ring structures shown above must be open ended rings so that they can be inserted into the cornea via an entry incision and then fed around a circular incision made in the cornea. The ends may then be interconnected to each other. This can be done in a variety of ways. For example, the use of two rings makes it possible for each of the rings to act as a closure means for the other when the rings are rotated relative to each other so that their ends are not aligned. This can be done after inserting the rings in the eye. When two rings are not present (e.g. the inflatable embodiment) the ends of the ring can be interconnected as shown in Figure 13.

Figure 13 shows a tapered overlapping configuration. The tapered effects of the ends 130 and 131 is dramatically shown within Figures 13 and 13E. One end 130 gradually narrows at the same rate that the end 131 narrows. The ends 130 and 131 are held together by horizontal and vertical force vectors which oppose each other and are shown as hf , hf' , vf and vf' as shown in

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Figure 13A. The cross sectional structure of the ring can be circular as indicated by the different configurations in Figures 13B, 13C and 13D. However, as shown in these figures the manner in which the ends 130 and 131 fit together along their adjacent surfaces can vary from the planar interconnection of Figure 13B to the curved plane of Figure 13C and the peaked interconnection of Figure 13D. A cross section is shown in Figure 13E.

In Figure 14A a stacked shim embodiment is shown. The embodiment includes at least a lower disk 140 and an upper disk 141. Each of the disks have openings in their center. The lower disk 140 may include a radially raised area (not shown) protruding upwardly. This raised area fits within an indentation (not shown) in the upper disk. Each of the disks are open ended, i.e. they are not continuous but have ends 142. The multiple disks 140 and 141 may be stacked on top of each other and inserted into the cornea, as shown within Figure 14B. Thereby, the size of the ring structure inserted into the eye can be increased in thickness to any degree.

Figure 15A shows a spiral shaped spring embodiment of the invention. This embodiment is comprised of a singular spiral or spring shaped piece of material 150. As shown within Figure 15B the end of the spiral is inserted into the annular channel formed in the cornea and set into the channel. The device is continually fed into the channel in a manner such that each circular movement of the spring will cause another layer to be added making it possible to increase thickness to any desired amount. When the desired amount of thickness is obtained, the material is cut. The spiral ring 150 can be designed in a variety of different ways. For example, the ring can be designed so that each successive ring has the same diameter and fits tightly

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against the next ring. When this shaped device is used, the cornea is increased in thickness as additional layers are added but is not increased radially. In another embodiment, the spring-shaped piece of material 150 can be designed so that each successive ring is slightly larger in diameter. Thereby, increases in the diameter of the inserted ring can be obtained by including additional rings into the cornea.

Modifications of the above described modes for carrying out the invention may occur to persons of skill in the fields of medicine, ophthalmology, optometry and/or related fields upon reading the disclosure and are all intended to be within the scope of the following claims.

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Claims

1. A method for adjusting the shape of the cornea of an eye, comprising the steps of:

5 cutting an initial incision into the cornea of the eye;

continuing to separate into the cornea of the eye from the point of the initial incision in a circular direction from the incision beneath the surface of the cornea so as to provide a complete annular channel within the cornea;

15 inserting into the initial incision an end of an intrastromal corneal ring having an adjustable thickness, the ring being comprised of an elongated, flexible annular body;

progressively moving the inserted end of the ring into the initial incision in a circular path within the annular channel until the ring is fully inserted; and
20 adjusting the thickness of the ring and thereby adjusting the shape of the cornea to focus light entering the eye.

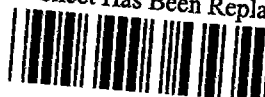
2. The method as claimed in claim 1, wherein the ring having an adjustable thickness is comprised of a first and a second annular body member which are
25 individually inserted into the annular channel and thereafter joined together in manner which provides for relative movement of the body members to allow for adjusting thickness.

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3. The method as claimed in claim 1, wherein
the ring having an adjustable thickness is comprised of a
first and a second annular body member which are joined
together in a manner which allows for relative movement
5 of the body members to adjust the thickness of the ring
prior to insertion into the annular channel.

4. The method as claimed in claim 1, wherein
the ring thickness is adjusted by providing a first body
10 member having threadings on its outer circumference and a
second body member having threadings on its inner
circumference wherein the threadings on each ring
intermesh each other and by turning each ring in a
direction opposite to the other ring the thickness
15 provided is changed.

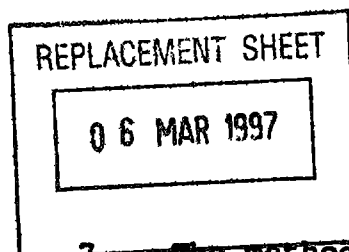
5. The method as claimed in claim 1, wherein
the ring includes ends which are each tapered toward a
narrow end with opposing ends being tapered in opposite
20 directions such that when the ends fit together they form
the substantially smooth and continuous surface.

6. The method as claimed in claim 1, wherein
the rings are adjusted by providing a first and a second
25 body member wherein the first body member includes
ratched protuberances on its outer circumference and the
second body member includes ratched protuberances on its
inner circumference whereby the two body members can be
intermeshed so that the protuberances on each the body
30 members together and make it possible to adjust the
thickness provided by the combination of the two body
members.

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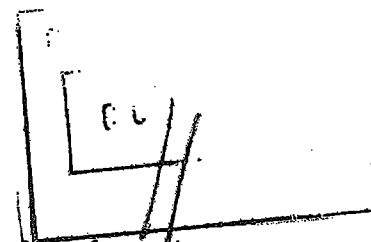
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7. The method as claimed in claim 1, wherein the thickness of the ring is adjusted by injecting a fluid into the ring which ring is comprised of an inflatable open ended body member.

5

8. The method as claimed in claim 1, wherein the adjustment of thickness is carried out by providing a first and a second body member each of which body member includes protuberances and indentations on a surface which faces the protuberances and indentations of the surface of the other body member so as to allow for thickness adjustment by turning the rings so as to align or misalign the protuberances and indentations.

10

9. The method as claimed in claim 1, wherein the ring thickness is adjusted by providing smooth continuous peaks and valleys on opposing surfaces of two annular body members, the peaks and valleys being positioned such that the body members can be turned relative to each other so as to adjust the thickness provided by the combination of the body members.

15

20

10. The method as claimed in claim 1, wherein the ring thickness is adjusted by providing a coil-shaped ring with a plurality of coils, whereby ring thickness is increased by inserting additional coils of the ring into the cornea until the desired thickness is obtained.

25

11. The method as claimed in claim 1, wherein the ring thickness is adjusted by providing a plurality of rings into the cornea which rings have surfaces which intermesh with each other whereby rings are inserted until a desired thickness is obtained.

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12. An intrastromal corneal ring for refractive correction of a human eye to improve the vision of the eye, comprising:

5 a first elongated, flexible body member in the form of an open circle; and

a second elongated, flexible body member in the form of an open circle wherein the first and second bodies are adjustably interconnected in a manner such that the thickness dimension of the two bodies when
10 interconnected can be changed.

13. The intrastromal corneal ring as claimed in claim 12, wherein the ends of the first body member and second body member each have ends which ends overlap
15 and mesh to each other in a manner so as to provide for a smooth and continuous surface.

14. The intrastromal corneal ring as claimed in claim 12, wherein the first and second body members
20 are adjustably interconnected by including a plurality of protuberances on an outer circumference of the first body member and a plurality of protuberances on an inner circumference of the second body wherein the protuberances and circumferences of the first and second
25 body members are designed such that the first and second bodies fit within each other by the intermeshing of the protuberances.

15. The intrastromal corneal ring as claimed
30 in claim 12, wherein the first body member and second body member are adjustably interconnected by providing threads on an outer circumference of the first body member and corresponding threads on an inner circumference of the second body member wherein the
35 threads and diameters of the first and second body



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members are designed such that the threads interlock each other and when the first body member is moved circularly in a direction opposite to the second body member the thickness dimension is changed.

5

16. The intrastromal corneal ring as claimed in claim 12, wherein the first body member includes a first surface which faces a second surface of the second body member wherein the first surface and the second surface have corresponding notches and protuberances thereon and the first surface and the second surface are forced together by an attachment means the protuberances and notches being designed such that when the first body member is moved circularly relative to the second body member the notches and protuberances cause the thickness dimension to be changed.

15

17. The intrastromal corneal ring of claim 12, wherein the thickness of the ICR is adjustable between 0.05 and 1.5 mm.

20

18. The intrastromal ring of claim 12, wherein the body of the ring has a width in the range of 0.25 mm to 3.25 mm.

25

19. The intrastromal ring as claimed in claim 12, wherein the ring is comprised of a biocompatible, nontoxic, biologically benign material, has a diameter in the range of 0.5 mm to 10 mm and a thickness in the range of 0.05 mm to 1.5 mm.

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20. An intrastromal corneal ring for refractive correction of a human eye to improve the vision of the eye, comprising:

5 an elongated, flexible, inflatable, annular body member, the inflatable body member having an inflation stem positioned thereon wherein the inflation stem is designed such that fluid can be injected into the inflatable body so that the thickness dimension of the body is changed.

10

21. A mammalian eye, having inserted within its cornea an intrastromal ring which is adjustable in thickness while present within the cornea of the eye.

15

22. A method for adjusting the shape of the cornea of an eye, comprising the steps of:

providing a coil shaped cutting device and covering the device by progressively moving a hollow intrastromal ring over the cutting device until the entire ring is included on the device with a tip portion of the cutting device extending outwardly from the hollow ring;

20

cutting an initial incision into the cornea of the eye;

25

continuing to separate into the cornea of the eye from the point of the initial incision using the point of the cutting device and cutting in a circular direction from the incision beneath the surface of the cornea so as to provide a complete annular channel within the cornea;

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holding the hollow ring in place and withdrawing the cutting device from the ring while leaving the ring in place.

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23. The method of claim 22, further comprising
inserting an interconnector into a first end and a second
end of the hollow ring wherein the interconnector device
includes an inflation stem having a check valve therein.

5

24. The method of claim 22, further
comprising:

injecting fluid into the inflation stem so as
to expand the hollow ring.

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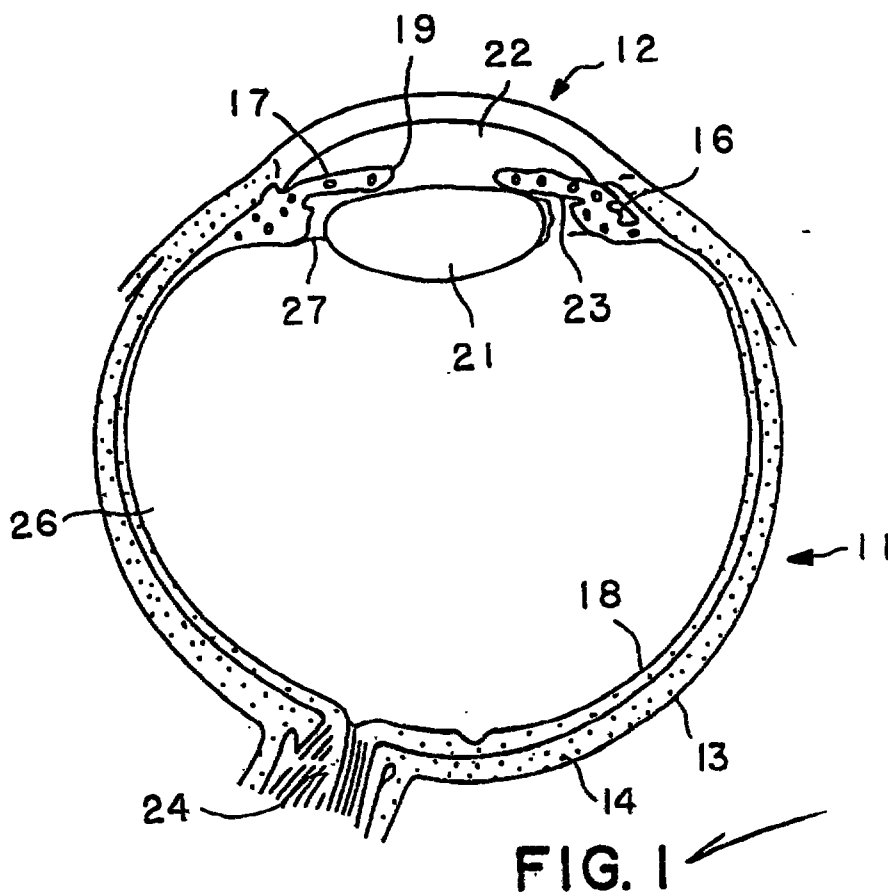
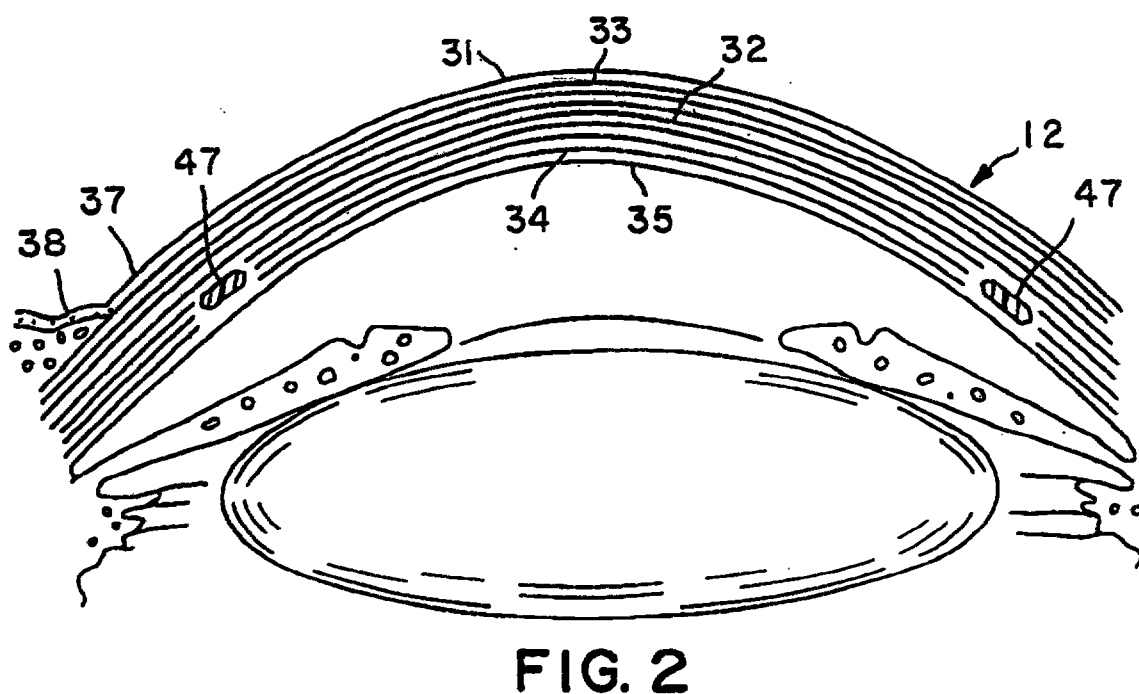
ABSTRACT**ADJUSTABLE DEVICES FOR CORNEAL CURVATURE ADJUSTMENT**

The intrastromal corneal ring (ICR) (47) is adjustable in thickness and has an elongated, flexible preferably transparent or translucent body which forms a circle. The thickness may be adjusted prior to insertion into the cornea and may not be further adjustable after insertion. In preferred embodiments, the thickness of the ICR may be adjusted after insertion to more precisely adjust the shape of the cornea (12) and focus the light entering the eye on the retina (18).

Figure 1

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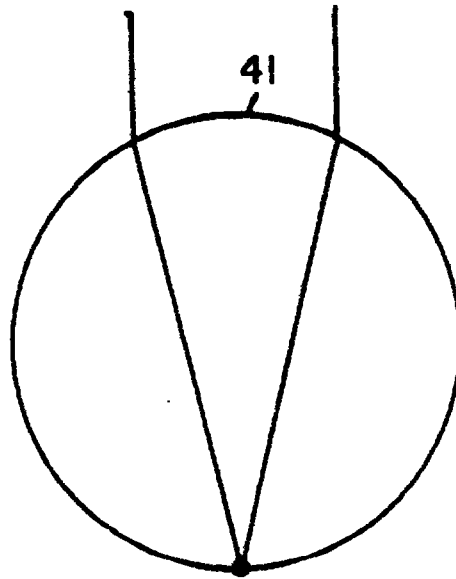


FIG.3

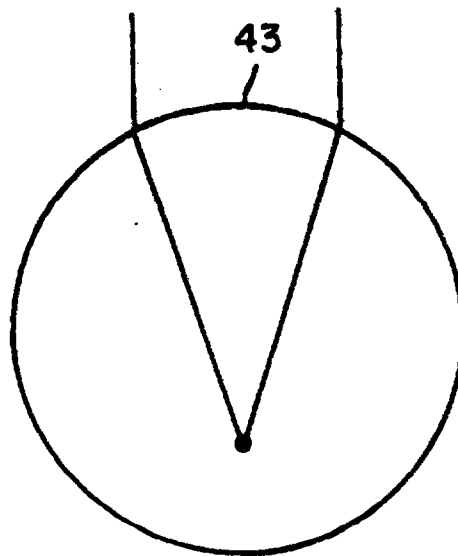


FIG.4

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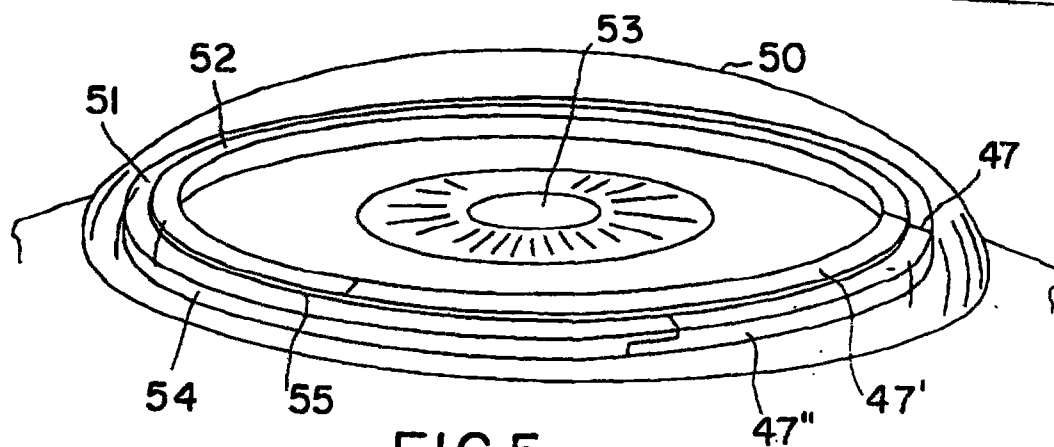


FIG. 5

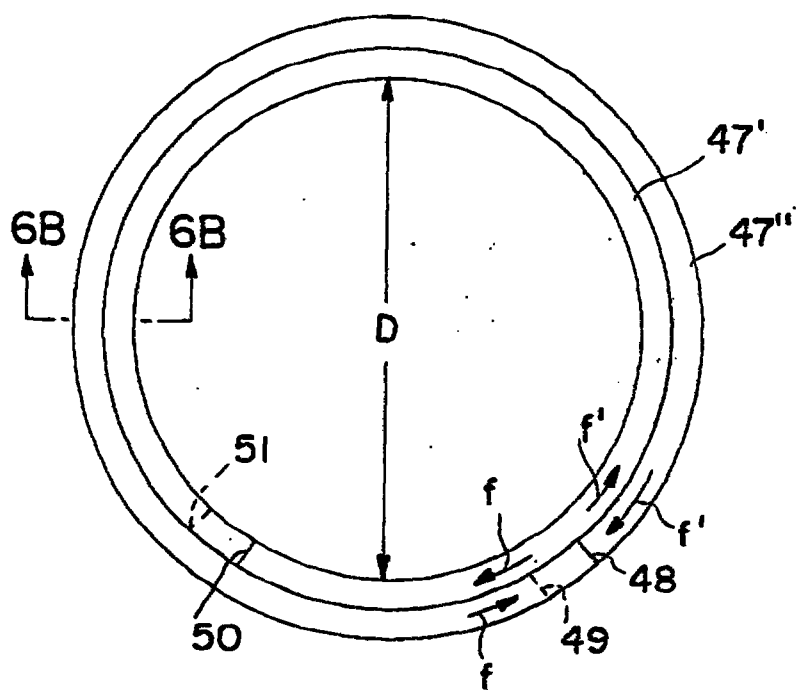


FIG. 6A

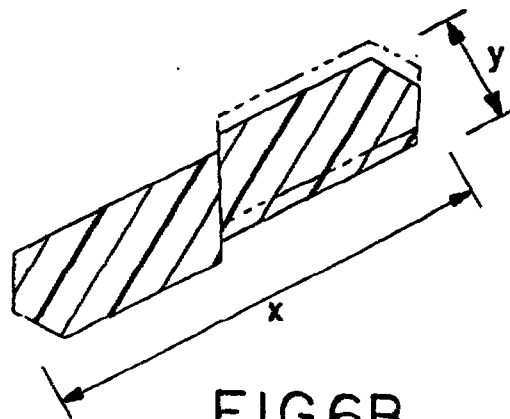
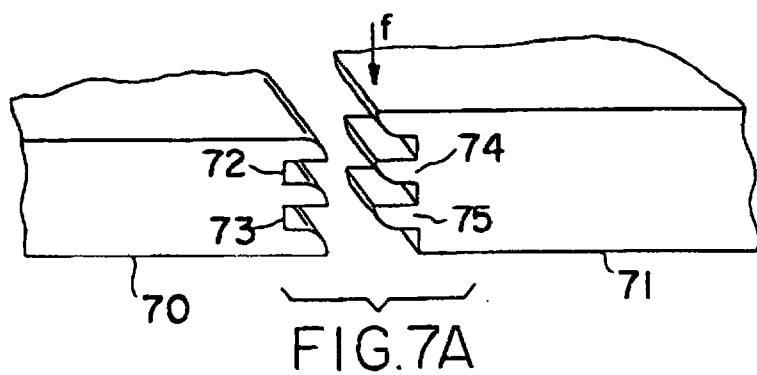
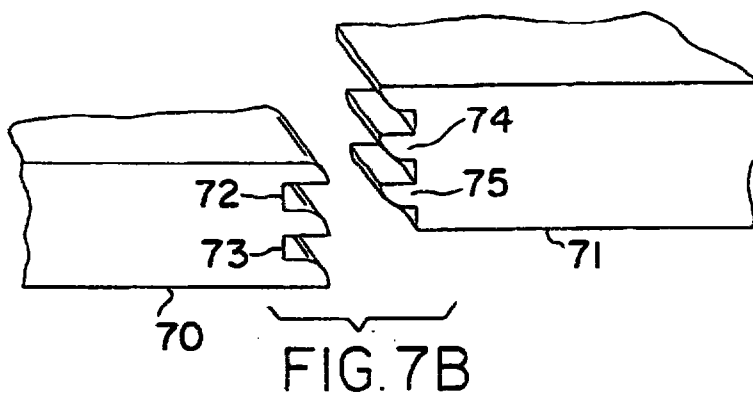
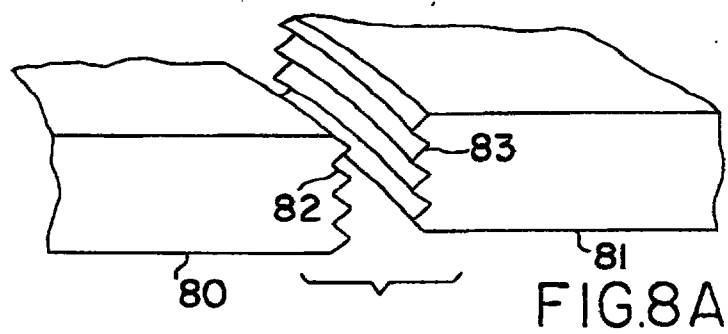
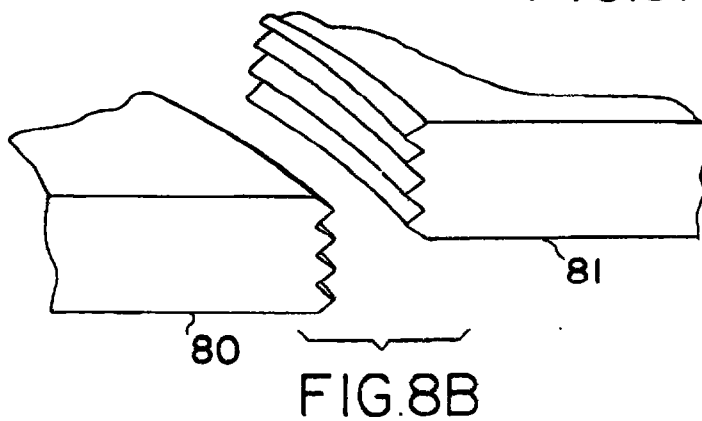


FIG. 6B

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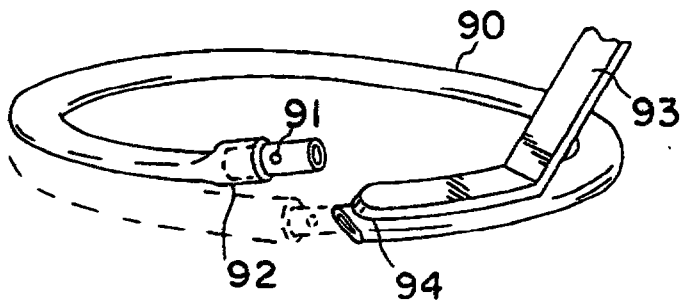


FIG. 9A

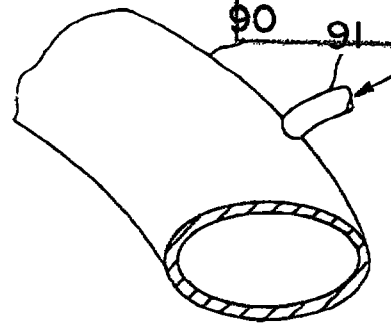


FIG. 9B

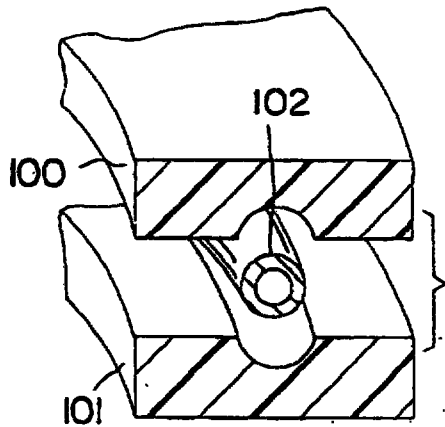


FIG. 10

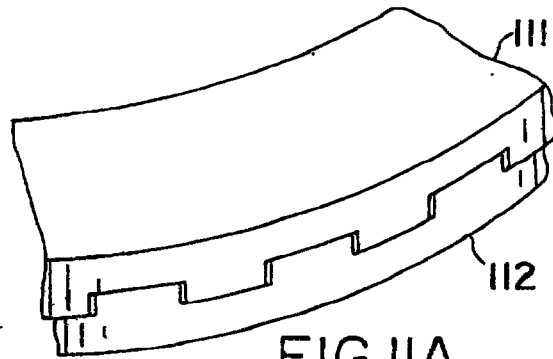


FIG. 11A

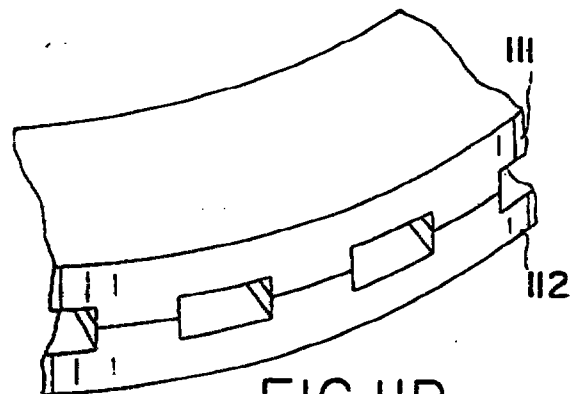


FIG. 11B

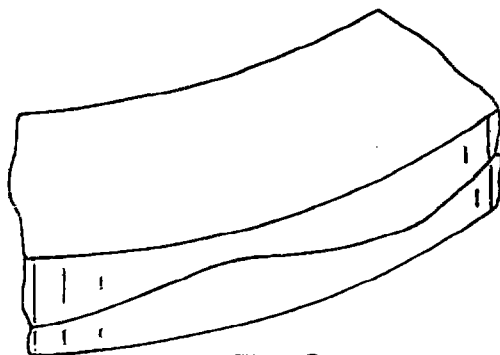


FIG. 12A

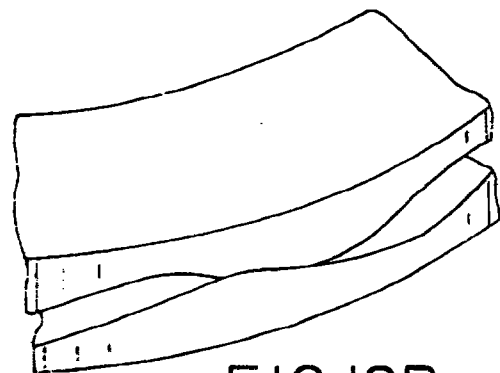


FIG. 12B

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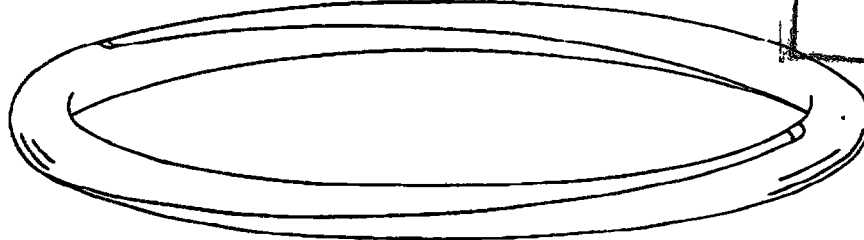


FIG. 13

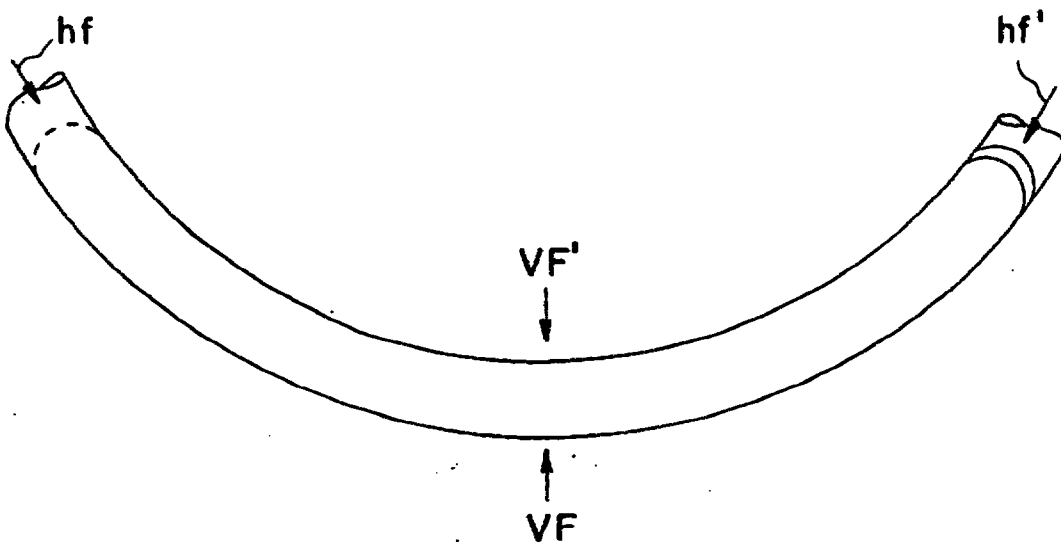


FIG. 13A

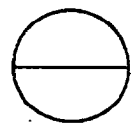


FIG. 13B

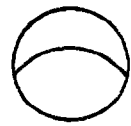


FIG. 13C

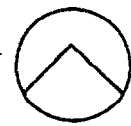


FIG. 13D

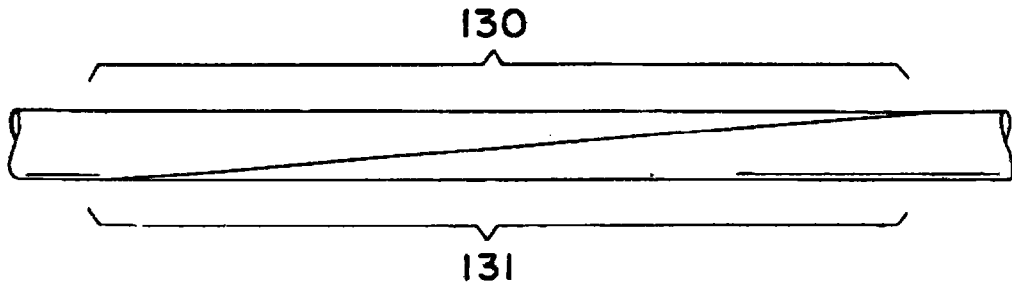


FIG. 13E

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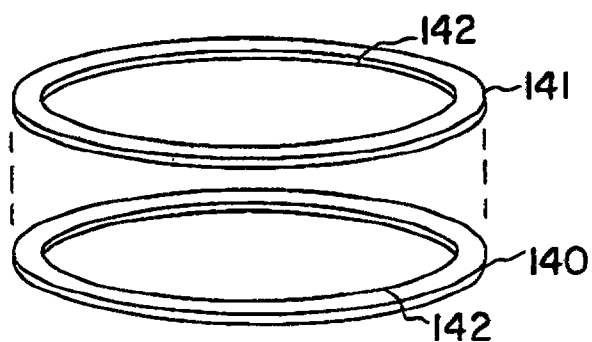


FIG. 14A

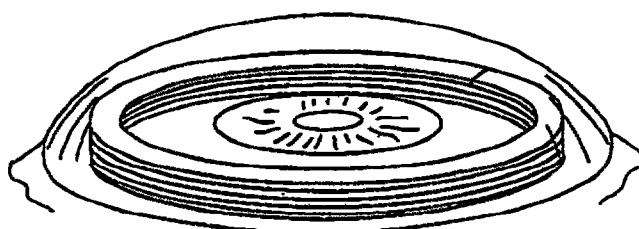


FIG. 14B

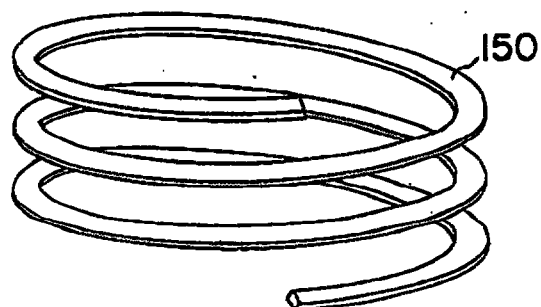


FIG. 15A

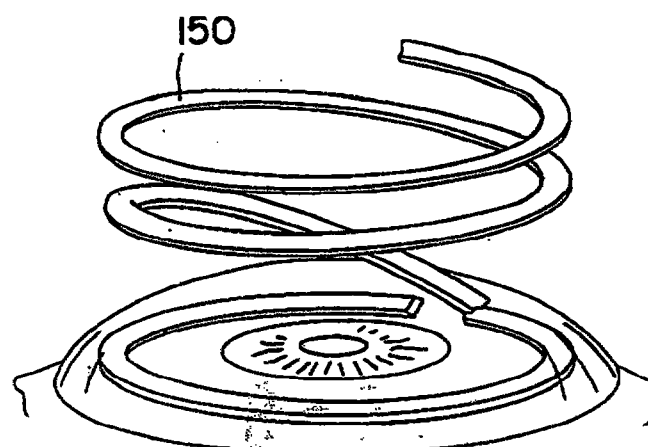


FIG. 15B

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1. An intrastromal corneal ring for refractive correction of a human eye to improve the vision of the eye, comprising:

a first elongated, flexible body member in the form of an open circle; and

a second elongated, flexible body member in the form of an open circle wherein the first and second bodies are adjustably interconnected in a manner such that the thickness dimension of the two bodies when interconnected can be changed.

2. The intrastromal corneal ring as claimed in claim 1, wherein the ends of the first body member and second body member each have ends which ends overlap and mesh to each other in a manner so as to provide for a smooth and continuous surface.

3. The intrastromal corneal ring as claimed in claim 1, wherein the first and second body members are adjustably interconnected by including a plurality of protuberances on an outer circumference of the first body member and a plurality of protuberances on an inner circumference of the second body wherein the protuberances and circumferences of the first and second body members are designed such that the first and second bodies fit within each other by the intermeshing of the protuberances.

4. The intrastromal corneal ring as claimed in claim 1, wherein the first body member and second body member are adjustably interconnected by providing threads on an outer circumference of the first body member and corresponding threads on an inner circumference of the second body member wherein the threads and diameters of the first and second body



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members are designed such that the threads interlock each other and when the first body member is moved circularly in a direction opposite to the second body member the thickness dimension is changed.

5. The intrastromal corneal ring as claimed in claim 1, wherein the first body member includes a first surface which faces a second surface of the second body member wherein the first surface and the second surface have corresponding notches and protuberances thereon and the first surface and the second surface are forced together by an attachment means the protuberances and notches being designed such that when the first body member is moved circularly relative to the second body member the notches and protuberances cause the thickness dimension to be changed.

6. The intrastromal corneal ring of claim 1, wherein the thickness of the ICR is adjustable between 0.05 and 1.5 mm.

7. The intrastromal ring of claim 1, wherein the body of the ring has a width in the range of 0.25 mm to 3.25 mm.

8. The intrastromal ring as claimed in claim 1, wherein the ring is comprised of a biocompatible, nontoxic, biologically benign material, has a diameter in the range of 0.5 mm to 10 mm and a thickness in the range of 0.05 mm to 1.5 mm.

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q. An intrastromal corneal ring for refractive correction of a human eye to improve the vision of the eye, comprising:

- 5 an elongated, flexible, inflatable, annular body member, the inflatable body member having an inflation stem positioned thereon wherein the inflation stem is designed such that fluid can be injected into the inflatable body so that the thickness dimension of the body is changed.

10

10. A substantially ring-shaped insert adapted for implantation within a human cornea and effecting refractive correction, said insert having a width dimension and a thickness dimension wherein at least one of said dimensions is variable.

11. The insert of claim 10 wherein said insert is variable in width.

12. The insert of claim 11 wherein said insert comprises a fillable tube.

13. The insert of claim 12 wherein said insert is variable in thickness.

14. The insert of claim 10 wherein said insert is variable in thickness.

15. The insert of claim 14, wherein said insert comprises first and second body members threadably engaged with each other, insert thickness being variable by rotating said members relative to each other.

16. The insert of claim 14 wherein said insert comprises inner and outer members, said outer member having an inner surface and said inner member having an outer surface, said members having protuberances and indentations on said surfaces configured so that protuberances of one surface may seat with the indentations of the other.

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17. The insert of claim 14 wherein said insert comprises top and bottom members, said top member having a bottom surface and said bottom member having a top surface, said members having protuberances and indentations on said surfaces configured so that protuberances of one surface may seat with the indentations of the other.

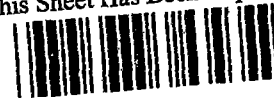
18. The insert of claim 14 wherein said insert comprises top and bottom members, said top member having a bottom surface and said bottom member having a top surface, said members having smooth and continuous peaks and valleys on said surfaces configured so that peaks of one surface may seat with the valleys of the other.

19. The insert of claim 14 wherein said insert comprises a coil having multiple turns and insert thickness is determined by selecting the number of turns to be implanted in the cornea.

20. The insert of claim 14 wherein said insert comprises a plurality of members and insert thickness is determined by selecting the number of members to be implanted in the cornea.

21. The insert of claim 14 wherein said insert comprises a plurality of members, one of said members being an inner member provided between other members, insert thickness being determined by selecting the size of said inner member.

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22. The insert of claim 21 wherein said member has a transverse cross-section with a circular periphery.

23. The insert of claim 22 wherein said inner member comprises a tube.

24. The insert of claim 21 wherein said inner member has a transverse cross-section with a rectilinear periphery.

25. The insert of claim 21 wherein said inner member and said outer members are provided in a substantially parallel arrangement.

26. The insert of claim 10, wherein said insert is adapted to accept a variable amount of material between surfaces of said insert.

27. The insert of claim 26 wherein said material is selected from the group consisting of solids, liquids and gels.

28. The insert of claim 26 wherein said insert comprises a fillable tube.

29. The insert of claim 26 wherein said insert comprises a coil having multiple turns and insert thickness is determined by selecting the number of turns to be implanted in the cornea.



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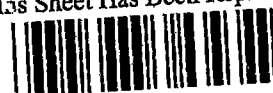
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30. The insert of claim 26 wherein said insert comprises a plurality of members and insert thickness is determined by selecting the number of members to be implanted in the cornea.

31. The insert of claim 26 wherein said insert comprises a plurality of members, one of said members being an inner member provided between other members, insert thickness being determined by selecting the size of said inner member.

32. The insert of claim 10 wherein said implant comprises at least one tapered end portion adapted to overlap with a complementarily tapered end portion to form a substantially smooth and continuous surface.

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1. An intrastromal corneal ring for refractive correction of a human eye to improve the vision of the eye, comprising:

a first elongated, flexible body member in the form of an open circle; and

a second elongated, flexible body member in the form of an open circle wherein the first and second bodies are adjustably interconnected in a manner such that the thickness dimension of the two bodies when interconnected can be changed.

2. The intrastromal corneal ring as claimed in claim 1, wherein the ends of the first body member and second body member each have ends which ends overlap and mesh to each other in a manner so as to provide for a smooth and continuous surface.

3. The intrastromal corneal ring as claimed in claim 1, wherein the first and second body members are adjustably interconnected by including a plurality of protuberances on an outer circumference of the first body member and a plurality of protuberances on an inner circumference of the second body wherein the protuberances and circumferences of the first and second body members are designed such that the first and second bodies fit within each other by the intermeshing of the protuberances.

4. The intrastromal corneal ring as claimed in claim 1, wherein the first body member and second body member are adjustably interconnected by providing threads on an outer circumference of the first body member and corresponding threads on an inner circumference of the second body member wherein the threads and diameters of the first and second body

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members are designed such that the threads interlock each other and when the first body member is moved circularly in a direction opposite to the second body member the thickness dimension is changed.

5. The intrastromal corneal ring as claimed in claim 1, wherein the first body member includes a first surface which faces a second surface of the second body member wherein the first surface and the second surface have corresponding notches and protuberances thereon and the first surface and the second surface are forced together by an attachment means the protuberances and notches being designed such that when the first body member is moved circularly relative to the second body member the notches and protuberances cause the thickness dimension to be changed.

6. The intrastromal corneal ring of claim 1, wherein the thickness of the ICR is adjustable between 0.05 and 1.5 mm.

7. The intrastromal ring of claim 1, wherein the body of the ring has a width in the range of 0.25 mm to 3.25 mm.

8. The intrastromal ring as claimed in claim 1, wherein the ring is comprised of a biocompatible, nontoxic, biologically benign material, has a diameter in the range of 0.5 mm to 10 mm and a thickness in the range of 0.05 mm to 1.5 mm.

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9. An intrastromal corneal ring for refractive correction of a human eye to improve the vision of the eye, comprising:

5 an elongated, flexible, inflatable, annular body member, the inflatable body member having an inflation stem positioned thereon wherein the inflation stem is designed such that fluid can be injected into the inflatable body so that the thickness dimension of the body is changed.

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10. A substantially ring-shaped insert adapted for implantation within a human cornea and effecting refractive correction, said insert having a width dimension and a thickness dimension wherein at least one of said dimensions is variable.

11. The insert of claim 10 wherein said insert is variable in width.

12. The insert of claim 11 wherein said insert comprises a fillable tube.

13. The insert of claim 12 wherein said insert is variable in thickness.

14. The insert of claim 10 wherein said insert is variable in thickness.

15. The insert of claim 14, wherein said insert comprises first and second body members threadably engaged with each other, insert thickness being variable by rotating said members relative to each other.

16. The insert of claim 14 wherein said insert comprises inner and outer members, said outer member having an inner surface and said inner member having an outer surface, said members having protuberances and indentations on said surfaces configured so that protuberances of one surface may seat with the indentations of the other.



17. The insert of claim 14 wherein said insert comprises top and bottom members, said top member having a bottom surface and said bottom member having a top surface, said members having protuberances and indentations on said surfaces configured so that protuberances of one surface may seat with the indentations of the other.

18. The insert of claim 14 wherein said insert comprises top and bottom members, said top member having a bottom surface and said bottom member having a top surface, said members having smooth and continuous peaks and valleys on said surfaces configured so that peaks of one surface may seat with the valleys of the other.

19. The insert of claim 14 wherein said insert comprises a coil having multiple turns and insert thickness is determined by selecting the number of turns to be implanted in the cornea.

20. The insert of claim 14 wherein said insert comprises a plurality of members and insert thickness is determined by selecting the number of members to be implanted in the cornea.

21. The insert of claim 14 wherein said insert comprises a plurality of members, one of said members being an inner member provided between other members, insert thickness being determined by selecting the size of said inner member.

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22. The insert of claim 21 wherein said member has a transverse cross-section with a circular periphery.

23. The insert of claim 22 wherein said inner member comprises a tube.

24. The insert of claim 21 wherein said inner member has a transverse cross-section with a rectilinear periphery.

25. The insert of claim 21 wherein said inner member and said outer members are provided in a substantially parallel arrangement.

26. The insert of claim 10, wherein said insert is adapted to accept a variable amount of material between surfaces of said insert.

27. The insert of claim 26 wherein said material is selected from the group consisting of solids, liquids and gels.

28. The insert of claim 26 wherein said insert comprises a fillable tube.

29. The insert of claim 26 wherein said insert comprises a coil having multiple turns and insert thickness is determined by selecting the number of turns to be implanted in the cornea.



30. The insert of claim 26 wherein said insert comprises a plurality of members and insert thickness is determined by selecting the number of members to be implanted in the cornea.

31. The insert of claim 26 wherein said insert comprises a plurality of members, one of said members being an inner member provided between other members, insert thickness being determined by selecting the size of said inner-member.

32. The insert of claim 10 wherein said implant comprises at least one tapered end portion adapted to overlap with a complementarily tapered end portion to form a substantially smooth and continuous surface.

