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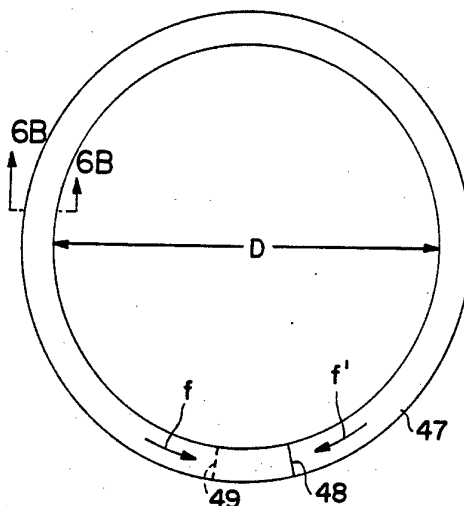
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(54) Title: OVERLAPPING RING DEVICE FOR CORNEAL CURVATURE ADJUSTMENT



(57) Abstract

The intrastromal corneal ring (ICR) (47) of the invention has a flexible, preferably circular body sized and configured such that it can be inserted into a human eye and comprised of a material which is compatible with human ocular tissue. The end portions (48 and 49) of the circular body overlap each other and are formed in several different configurations or embodiments. The end portions (48 and 49) are preferably configured such that when allowed to come together they inter-mesh and provide a ring with a smooth and continuous outer profile.

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5 OVERLAPPING RING DEVICE FOR CORNEAL CURVATURE
ADJUSTMENT

Field of the Invention

10 This invention is in the general field of
medical technology and relates specifically to an
intrastromal corneal ring having overlapping or connected
ends for varying corneal curvature to correct vision.

15 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.

30 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
35 and 4,688,570) and laser corneal ablation (see e.g. U.S.

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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 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 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 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 the ends can be connected. When the correct size ring is inserted the eye will have been caused to assume the correct curvature.

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 such as an iris retaining device are disclosed within 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 have end structures and configurations

which provide certain advantages and improvements as compared to earlier ring structures.

Summary of the Invention

5 The present invention is an intrastromal corneal ring (ICR) comprised of an elongated, flexible, circular body member. The ICR is of a size and shape 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 end portions of the body member may be formed in several different configurations or embodiments. The end portions overlap each other and are preferably configured such that when they are forced toward each other horizontally and/or vertically they intermesh and provide a tight fit against each other. Further, the ends are preferably configured in such a manner that when allowed to come together the resulting ring provides a smooth and continuous outer profile.

A primary object of the invention is to provide an ICR with overlapping end portions.

25 An advantage of the invention is that a closed circuit ring is provided without the need to attach the ends with sutures, additional component fasteners or interconnecting means.

30 A feature of the invention is that when the ring is in place, it provides a continuous, smooth outer profile.

35 Another advantage of the ring is that it can be easily inserted into the corneal tissue of the eye and thereafter released in a manner whereby the ends of the ring will seal themselves together due to the torsional forces provided by the elongated body of the ring.

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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 of the structure and use as more fully set forth below, reference being made to the accompanying drawings forming a part hereof.

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 the cornea.

Figure 3 is a schematic representation showing how light focuses on the retina of a normal eye.

Figure 4 is a schematic representation of how light does not focus on the retina of a myopic eye.

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

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

Figure 7 is a cross sectional view showing split overlapping ring ends while Figures 7A, 7B and 7C are views of the same embodiment with rings having different cross sectional configurations.

Figure 8 is a perspective view showing overlapping ring ends with the details being shown in Figure 8A while Figures 8B, 8C and 8D are cross sectional subembodiments of the embodiment shown in Figure 8 while Figure 8E is a longitudinal cross sectional view showing the overlapping ring ends.

Figure 9 is a perspective view of a plug and socket embodiment with Figures 9A, 9B and 9C showing

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different outer ring configurations and Figures 9D, 9E and 9F show variations of the embodiment.

Figure 10 is a cross sectional view of an overlapping interlocking ring embodiment with Figure 10A and 10B showing how the ends fit together.

Figure 11A, 11B and 11C are cross sectional views of an overlapping notched interlocking embodiment with a blade.

Figure 12 shows notched interlocking embodiments in Figures 12A and 12B.

Figure 13 shows a shrink tube connector embodiment.

Detailed Description of the Invention

Before the intrastromal corneal ring and its various configurations are described, it is to be understood that this invention is not limited to the particular embodiments, configurations and materials 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 claims.

The basic structure function and operation of the intrastromal corneal rings of the invention is shown and discussed in connection with Figures 1-6. Figures 7-13 show seven different embodiments of the invention which show seven basic configurations whereby the ring ends can be connected to each other without the use of 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 7-13 can each include a number of different subembodiments by varying other parameters such as the cross sectional surface dimensions of the ring e.g. forming the ring from cross sections in the form of a circle, square, rectangle, triangle, oval, etc. Although a number of these configurations are shown others are possible and are contemplated by this invention. Further, other possible interconnections are contemplated by this invention with the proviso that preferred interconnections do not include an additional component for interconnecting the end portions of the ring and further provided that the interconnections provide for a substantially smooth and continuous interconnection of the ring ends.

Before discussing these specific embodiments of Figures 7-13 the general structure and method of use of intrastromal corneal rings will be described 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 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 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 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

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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 center by a circular aperture called the pupil 19. The 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.

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 photoreceptors which transform physical energy (light) into nerve impulses.

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.

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

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ciliary body 16 and lens 21 serves to hold the lens 21 in position and enables the ciliary muscle to act on it.

Referring again to the cornea 12, this outermost fibrous transparent coating resembles a watch
5 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 the cornea is called the optical zone with a slight
10 flattening taking place outwardly thereof as the cornea thickens towards its periphery. Most of the refraction of the eye takes place through the cornea.

Referring to Figure 2, a more detailed drawing of the anterior portion of the globe shows the various
15 layers of the cornea 12 comprising an epithelium 31. Epithelial cells on the surface thereof to act as a main protective layer of the cornea 12. These epithelial cells are rich in glycogen, enzymes and acetylcholine and their activity regulates the corneal corpuscles and
20 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
25 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
30 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
35 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. An intrastromal corneal ring 47 is shown inserted between the stroma 32 of the cornea 12.

5 Figure 3 shows the globe of the eye having a cornea 12 with a normal curvature 41. If parallel rays of light pass through the corneal surface of Figure 3, they are refracted by the corneal surfaces to converge eventually near the retina of the eye. The diagram of
10 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 corneal curvature 43 causes the light rays to refract
15 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 of the cornea is flattened. Light rays refracted by the
20 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 possible to adjust the radius of curvature of the cornea without adversely affecting its natural asphericity. By
25 varying parameters of the ICR such as its thickness, shape and circumference the shape of the cornea can be changed in any desired manner. Where there is serious astigmatism, the natural asphericity will not be altered such that the astigmatism will be significantly
30 increased. However, where there is significant astigmatism that results in impaired vision, the ICR of the invention may actually improve the asphericity to reduce such astigmatism and improve vision.

 As shown in Figure 2, an intrastromal corneal
35 ring (ICR) 47, having a cross sectional shape as shown in

Figure 7A is shown implanted in the stromal layer of the cornea. By selecting the thickness of the ring according to the amount of correction necessary, the rays refracted by the cornea and other eye components can be brought to
5 focus directly on the retina 18 (see figures 3 and 4).

Figure 5 shows a perspective view of the ICR 47 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 edge faces outward along the
10 line of sight and away from the eye, whereas the narrower edge faces radically inward toward the center of the eye and the wide and narrow edges are perpendicular to each other. However, it should be noted that other configurations are possible.

15 A planar 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 an elongated, circular, flexible body member. One possible cross sectional configuration is shown in Figure 2 which configuration is
20 basically rectangular with the outer sides being slightly bowed or pointed outward. Other cross sectional configurations are possible, such as rectangular, square, circular, triangular, and variations therebetween (see figures 7A, 7B, 7C, 8B, 9A, 9B and 9C). Because the ring
25 is circular, it has the same diameter in all directions. However, it is possible to configure the body of the ring in other slightly noncircular configurations (not shown), e.g., ovals and elongated ovals. In its preferred circular configuration, the diameter is slightly smaller
30 than 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 which does not cause an immune reaction when brought into continuous contact with ocular tissues such as the
35 corneal tissue. For example, the materials used in the

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construction of various types of contact lens including hard, soft and extended wear contact lens can be used in making ICRs of the invention. It will be understood by those skilled in the art that when the intrastromal rings of the invention are inserted in the cornea of the eye a certain degree of discomfort as well as inflammation and/or other reactions may occur. However, after a given adjustment period the adverse effects should be eliminated. In order to minimize any initial adverse effects the material should be nontoxic, biologically benign, and be relatively flexible as compared with a material such as metal. It is important to use materials which do not create a type of immune reaction or other adverse side effect when inserted into ocular tissue.

The ring in Figure 6A shows one end 48. Because Figure 6A is a planar view, the end 48 is shown as a single line. The other end 49 is shown by a dotted line in that this end is visible only from the other side of the ring 47. The ends 48 and 49 may be structured in several different configurations, as discussed further below. As shown in Figure 6A, the ends 48 and 49 are overlapping each other and are forced toward each other as shown by the arrows f and f' which forces provide sufficient force within the horizontal plane of the ring such that the ends of the ring are in intimate contact with each other, providing a continuous, smooth and uninterrupted connection. The ring may also be configured such that the end portions of the ring force toward each other in vertical upward and downward directions so as to further increase the intimacy of the two ends which feature is described further below.

The thickness of the ring may be between 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

a corrective adjustment to the focal point of light on the retina.

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 is preferably a flexible solid and not a liquid or gel. Suitable materials include those which are used in making contact lens. 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 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) and polyhydroxyethyl methacrylate (polyHEMA)), polyacetals, 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, cross sectional shape of the rings can vary. When a cross section of the ring is circular, it is generally dimensioned to be about 0.05 mm to 1.00 mm in thickness, and about 0.5 to 1.0 cm in diameter.

The cross sectional configuration shown within Figure 2 is schematically shown in Figure 7A. When this configuration is used, the dimension shown from point to point (dimension x) is within the range of approximately

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0.5 mm to 3.25 mm and the thickness (dimension y) is generally 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 on 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 of 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.

Even where the eye is not myopic, the ICRs of the present invention may be useful to alleviate 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 1.0 and 3.0 diopters for the 0.25 mm ICR, between 2.0 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 these values are for ICRs can range from 0.05 to 1.0 mm in thickness and obtain correction of from 0.5 to 18.0. The amount of corrective refraction for the various thicknesses of ICRs of different cross sectional shaped rings may differ from those values depending on the individual patient and variety of factors.

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The ICR is inserted into the corneal stroma of the eye through a 2.5 mm oblique keratotomy incision placed peripherally into the corneal stroma. The size of the insertion will vary somewhat depending on factors
5 such as the size of the ring 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
10 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 the overlapping end portion which may be supplemented by
15 fastening one end to the other. However, such fastening is not generally necessary as the end portions are designed so that further fastening is not required.

Specific Preferred Embodiments

20 Seven different basic preferred embodiments are shown in Figures 7-13. 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
25 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
30 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 whereby the ends of the rings can be interconnected without an additional component and/or can be
35 interconnected so as to provide a substantially smooth

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and continuous interconnection. Although the embodiments of the invention generally do not use any additional components at least one embodiment (see figure 13) includes an overlapping sleeve which covers the connected
5 end portions and results in a substantially smooth and continuous interconnection.

Referring now to Figure 7 which is a cross sectional view of a notched overlapping embodiment which shows the ring end portions 70 and 71 separated from each
10 other. The end portion 70 includes a surface 72 which will be contacted by the surface 73 of the end portion 71. Further, the surface 74 will be brought into intimate contact with the surface 75. In a similar manner the surface 76 will be contacted intimately with
15 the surface 77. The opposing surfaces are forced together as indicated by the horizontal and vertical force arrows. Specifically, the horizontal force arrow hf pointing towards the right and the opposing horizontal force arrow hf' points towards the left. This is
20 accomplished by the structure of the ring itself. The vertical force arrows vf pointing upward and vf' pointing downward force the surfaces 74 and 75 together in the same manner that the horizontal forces bring the surfaces 72 and 73 together as well as the surfaces 77 and 76.

25 The basic embodiment shown within Figure 7 can be configured using different ring structures such as shown by the different cross sectional ring configurations of Figures 7A, 7B and 7C which include a rectangular cross section with points bowing outward from
30 each short side, a rectangular cross section and a circular cross section respectively.

Figure 8 shows a tapered overlapping configuration. The tapered effects of the end portions 80 and 81 is dramatically shown within Figure 8E. One
35 end portion 80 gradually narrows at the same rate and in

the apposite direction that the end portion 81 narrows. The end portions 80 and 81 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 Figure 8A. The cross sectional structure of the ring can be circular as indicated by the different configurations in Figures 8B, 8C and 8D. However, as shown in these figures the manner in which the end portions 80 and 81 fit together along their adjacent surfaces can vary from the planar interconnection of Figure 8B to the curved plane of Figure 8C and the peaked interconnection of Figure 8D. A cross section is shown in Figure 8E.

Figure 9 shows a plug and socket interconnection. The plug end portion 91 fits securely within the socket end portion 90. When the two ends are securely interconnected the surface of the ring provides a substantially smooth and continuous interconnection. The cross sectional configuration of the ring may be triangular, square, or oval as shown in Figures 9A, 9B and 9C or include variations thereof. Further, the socket may be closed on all sides (Figure 9E) or open on two sides (Figure 9D). The socket end can securely hold the plug end in place and prevent the ends from separating. In figure 9F another variation of a plug and socket embodiment is shown. The plug 92 has a tear drop-like shape and fits in the socket 93 when the end portions are forced toward each other.

The configurations of Figures 7, 8 and 9 are preferred due to their simplicity. However, these configurations do not provide constructions whereby the ends of the rings are securely held in place in the event of separational forces. (The embodiment of figure 9F does provide some resistance to separational forces.) The following configurations shown in Figures 10, 11, 12 and 13 do provide some additional complexity in terms of

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their structure. However, these structures do result in holding the ring ends together even if the ring ends are subjected to separational forces.

The configuration shown in Figure 10 provides
5 overlapping ends which are notched in the same manner as shown within Figure 7. However, the overlapping end surfaces include an additional corresponding plug 100 and socket 101 into which the opposing pieces fit and snap the opposing pieces securely into place. Preferably, the
10 plug 100 is slightly larger in diameter than is the diameter of the socket 101. Due to the slight variation in size, the plug 100 will fit securely within the socket 101 and be held securely in place. The ends may further include a protuberance such as the protuberance 102 which
15 fits within the depression 103. In a similar manner, the protuberance 102 may be slightly larger in one dimension than is the depression 103, so that a tight fit is provided for. Figure 10A shows the ends moving towards each other and Figure 10B shows the ends interlocked into
20 each other.

The embodiment shown in Figure 11 provides an additional advantage in that the end of the ring can be used to separate the stroma of the cornea and create an annular channel. The blade or stroma separation endpiece
25 111 is positioned on the end of the ring and is inserted into a socket 112 on the opposing end portion of the ring. The notches 113 and 114 on each ring lock the ends into place and prevent the ring from opening.

Figures 12A and 12B show triangular and
30 rectangular notched ring ends which ends are constructed so that they securely fit one into the other. In accordance with this embodiment the notches on sockets may be designed so that the socket is somewhat smaller than the notch thereby providing for a tight fit.
35 However, such is not necessarily required in that the

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ends of the ring will be forced together vertically and horizontally by force vectors as shown within Figure 7.

Figure 13 shows end portion 130 and 131 which each have a reduced diameter and have their ends forced toward each other. A shrinkable or elastic sleeve 132 fits around the ends 130 and 131 and has a thickness which is equal to the difference in thickness between the body of the ring and the end portions. Thus, when the sleeve is in place the connection is smooth and continuous.

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, from the initial incision, to create an annular subsurface channel in the cornea;
- 10 inserting into the initial incision an end of an intrastromal corneal ring comprised of an elongated, flexible, circular body member having a first and second end portion which end portions overlap each other;
- 15 progressively moving the inserted end of the ring through the initial incision into the annular channel until the ring is fully inserted in the annular channel; and
- 20 allowing the first and second end portions to overlap each other in the channel in a manner so as to provide a ring with a substantially smooth and continuous surface.
2. The method as claimed in claim 1, wherein the first and second end portions have first and second surfaces facing each other and which surfaces have
- 25 notches and protuberances thereon which notches and protuberances are positioned in such a manner that when brought together the protuberances on the first surface fit within the notches on the second surface and the protuberances on the second surface fit within the
- 30 notches on the first surface.

3. The method as claimed in claim 1, wherein the first and second end portions of the ring are tapered toward their respective ends with the first end portion being tapered in a direction opposite to that of the
5 second end portion such that when the end portions fit together they form the substantially smooth and continuous surface.

4. The method as claimed in claim 1, wherein
10 the first end portion of the ring forms a receiving socket and the second end portion forms an insertable plug sized and configured so as to be securely insertable within the socket.

5. The method as claimed in claim 1, wherein
15 the first end portion includes physical configurations which correspond with and allow direct attachment to physical configurations on the second end portion such that when the first and second end portions are
20 overlapped and forced together they become attached by means of directly intermeshing physical configurations.

6. A method for adjusting the shape of the cornea of an eye, comprising the steps of:
25 cutting an initial incision into the cornea of the eye;

continuing, from the initial incision, to create an annular channel in the cornea by means of a corneal stromal separation blade on a first end of an
30 intrastromal corneal ring forced annually into the cornea, the ring being comprised of an elongated, flexible, circular body member having a first end portion which terminates with the stromal separation blade and a second end portion which terminates with a receiving
35 socket for the blade;

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forcing the entire ring into the channel; and placing the blade into the receiving socket.

7. An intrastromal corneal ring for changing
5 the refractive correction of a human eye and thereby improving the vision of the eye, comprising an elongated, flexible, circular body member having a first and a second overlapping end portions which overlap each other in a manner which forms a substantially smooth and
10 continuous ring surface.

8. The intrastromal corneal ring as claimed in claim 7, wherein the end portions include opposing surfaces sized and configured such that when the end
15 portions overlap each other shapes of the opposing surfaces mesh to each other in a manner so as to provide for a smooth and continuous ring surface.

9. The intrastromal corneal ring as claimed
20 in claim 7, wherein shapes are corresponding notches and protuberances shaped and positioned such that when the end portions overlap each other the protuberances fit into opposing notches.

25 10. The intrastromal corneal ring as claimed in claim 8, wherein the end portions of the ring are tapered toward their end, with the first and second end portions being tapered in opposite directions such that when the ends fit together they form the substantially
30 smooth and continuous surface.

11. The intrastromal corneal ring as claimed in claim 7, wherein the first end portion of the ring forms a receiving socket and the second end portion forms an insertable plug and the plug is securely inserted
5 within the socket so as to form a complete circle and thereby provide the substantially smooth and continuous surface.

12. The intrastromal corneal ring as claimed
10 in claim 7, wherein the first end portion is terminated with a blade for stromal separation and the second end portion includes a socket which securely receives the blade so as to form the substantially smooth and continuous surface.

13. The intrastromal corneal ring of claim 7
15 wherein the thickness of the body member is between 0.05 and 1.5 mm.

14. The intrastromal ring of claim 7 wherein
20 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.

15. A mammalian eye, having inserted within
25 its cornea an intrastromal cornea ring which is comprised of an elongated, flexible, circular body member having a first and second overlapping end portions which overlap
30 each other in a manner which forms a substantially smooth and continuous ring surface.

16. The intrastromal ring as claimed in
35 claim 14, wherein the first and second overlapping ends

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have terminal ends and the terminal ends are smooth and blunt in shape.

17. An intrastromal corneal ring for changing
5 the refractive correction of a human eye and thereby improving the vision of the eye, comprising:

an elongated, flexible, circular body
member having a first and a second end portion which end
portions have reduced external circumferences as compared
10 with the body of the ring; and

a tubular interconnecting portion having
an internal diameter which is equal to or slightly
smaller than the external circumferences of the end
portions.

15

18. The intrastromal ring as claimed in
claim 17, wherein the body member and interconnecting
portion are each comprised of a biocompatible, nontoxic,
biologically benign material, and form a ring having a
20 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.

25

30

35

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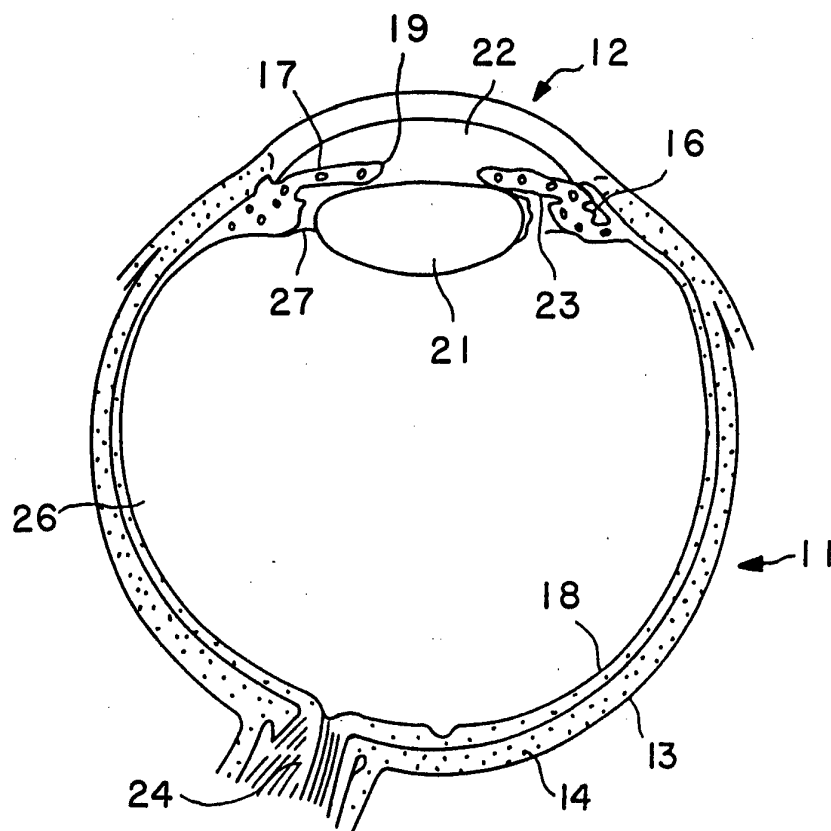


FIG. 1

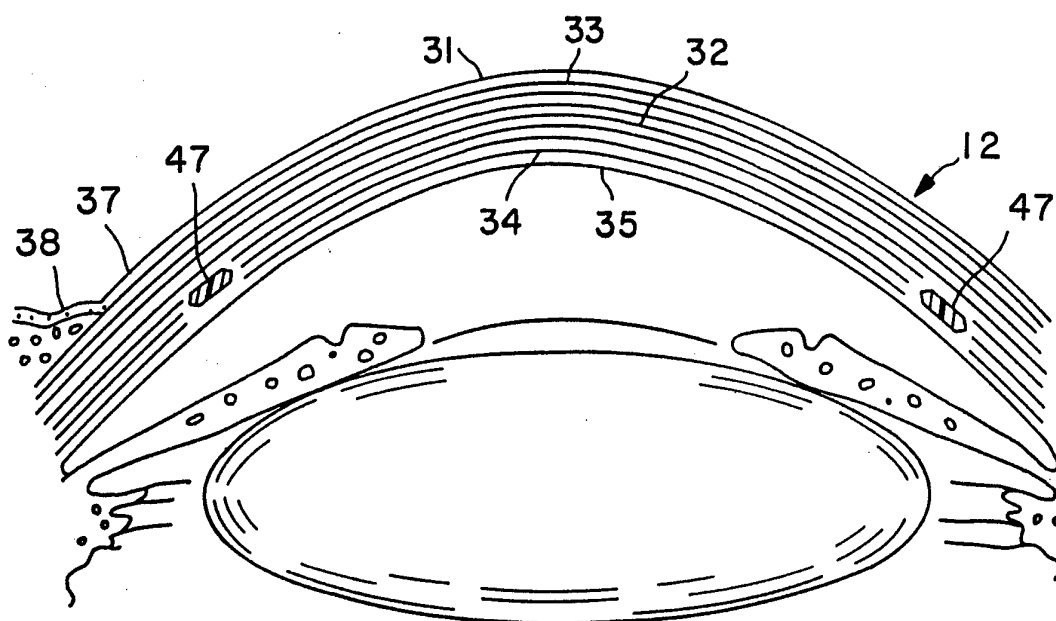


FIG. 2

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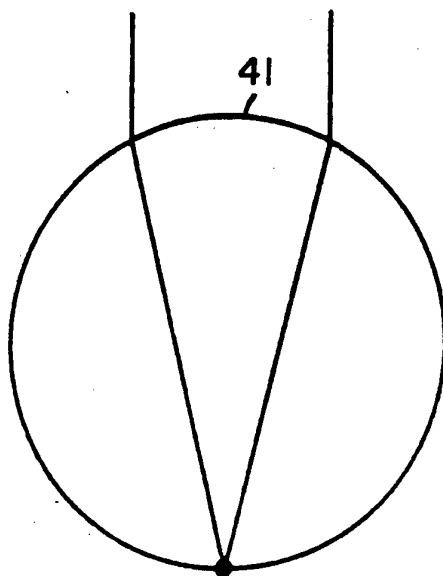


FIG. 3

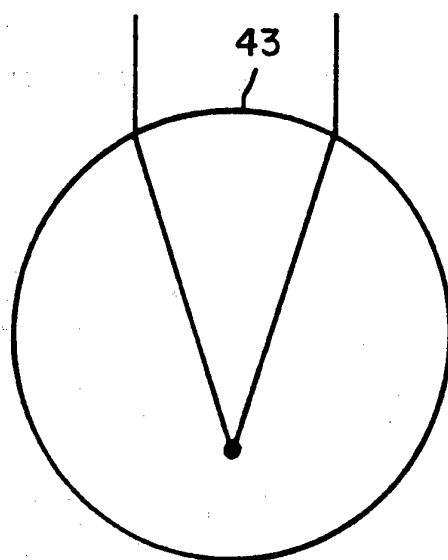


FIG. 4

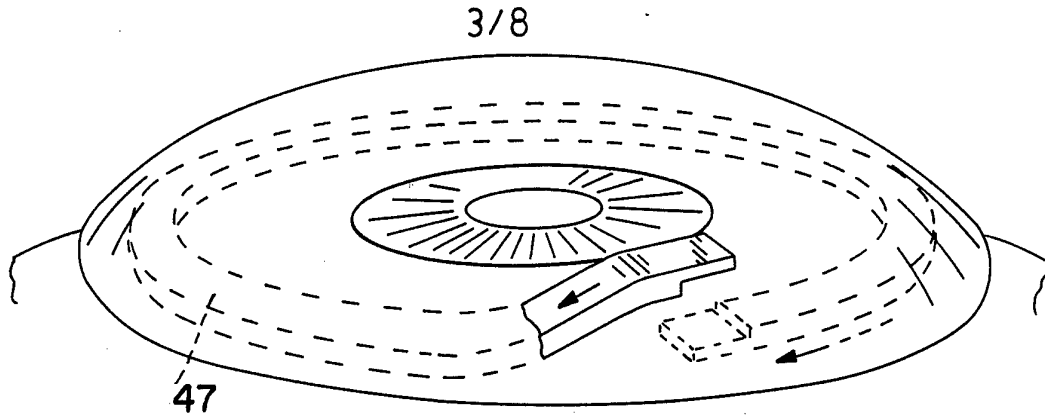


FIG. 5

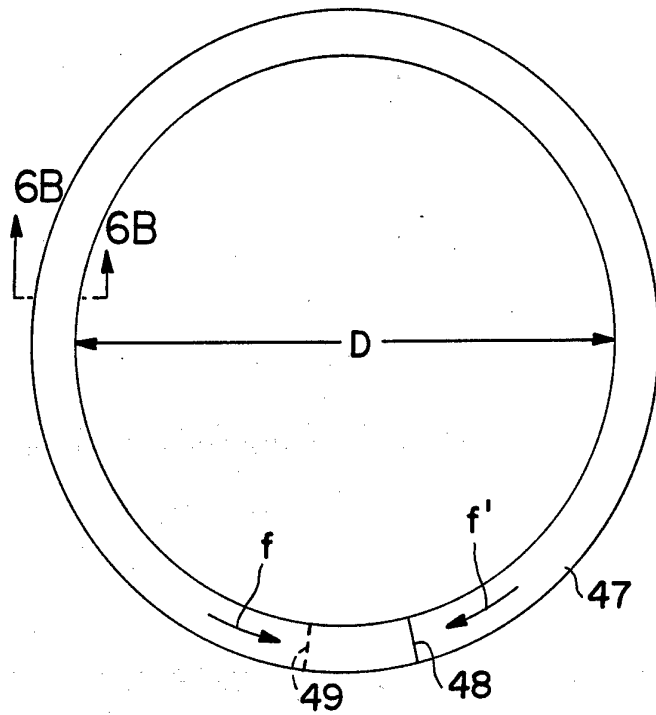


FIG. 6A

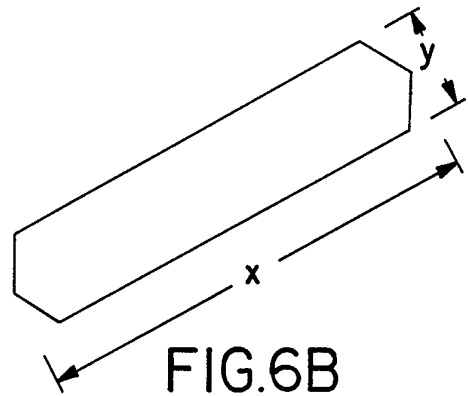


FIG. 6B



FIG. 7A

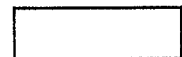


FIG. 7B



FIG. 7C

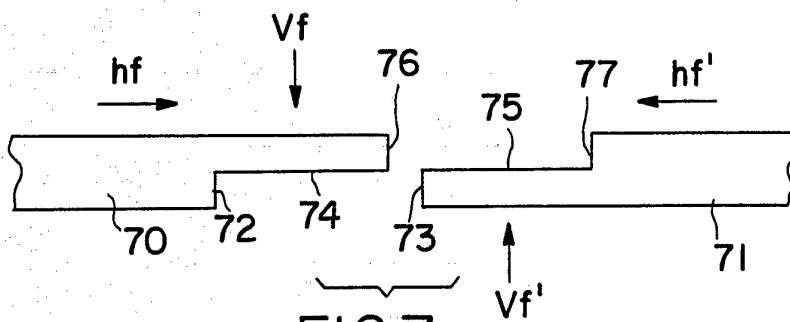


FIG. 7

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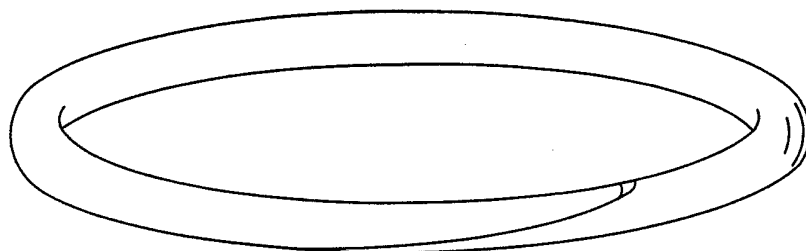


FIG. 8

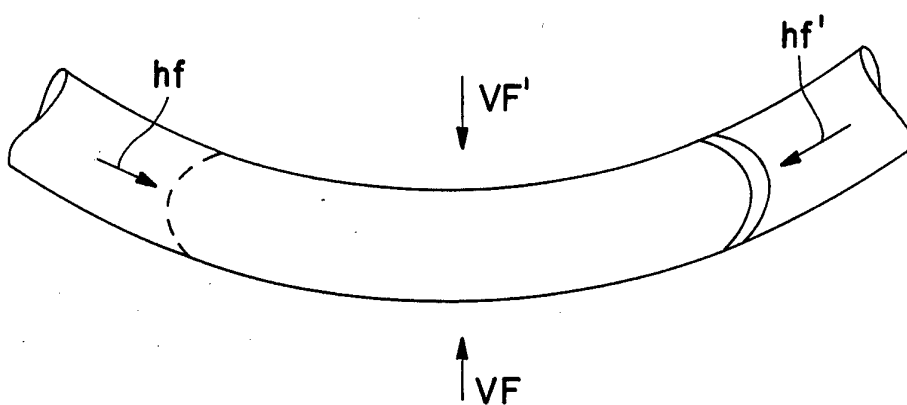


FIG. 8A

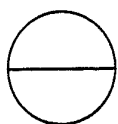


FIG. 8B

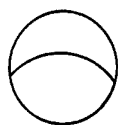


FIG. 8C



FIG. 8D

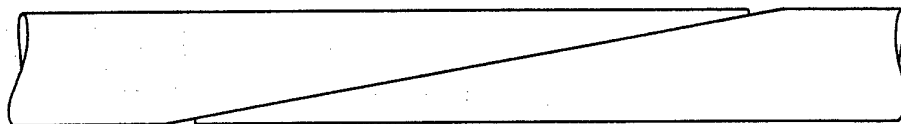


FIG. 8E

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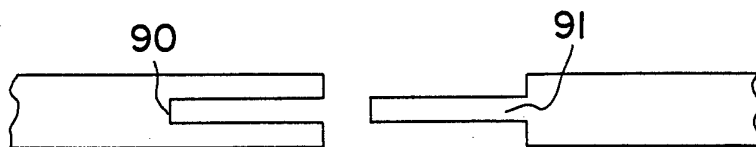


FIG. 9



FIG. 9A



FIG. 9B

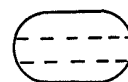


FIG. 9C

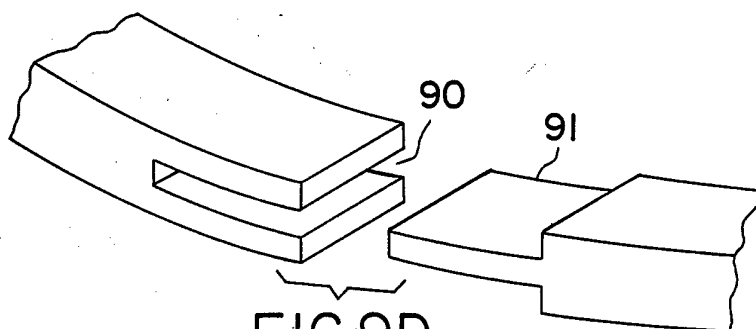


FIG. 9D

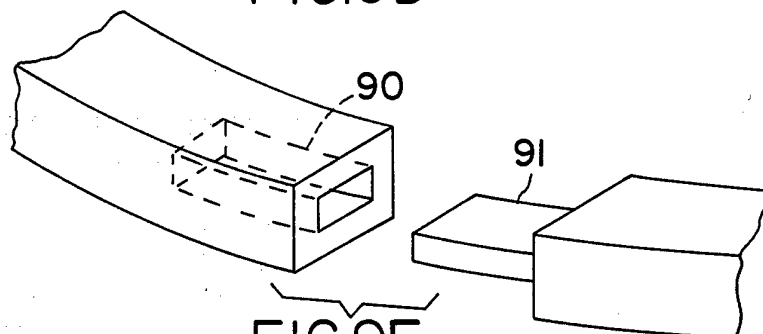


FIG. 9E

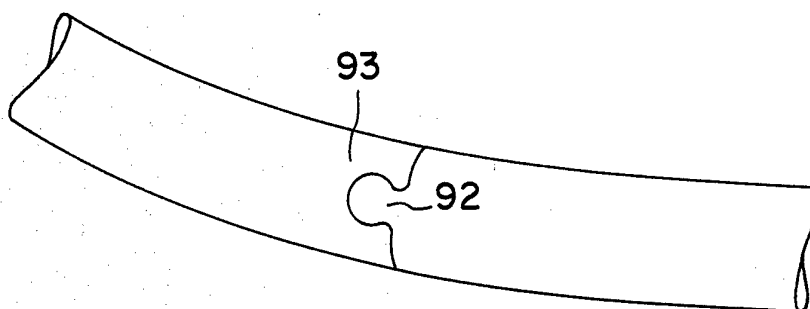


FIG. 9F

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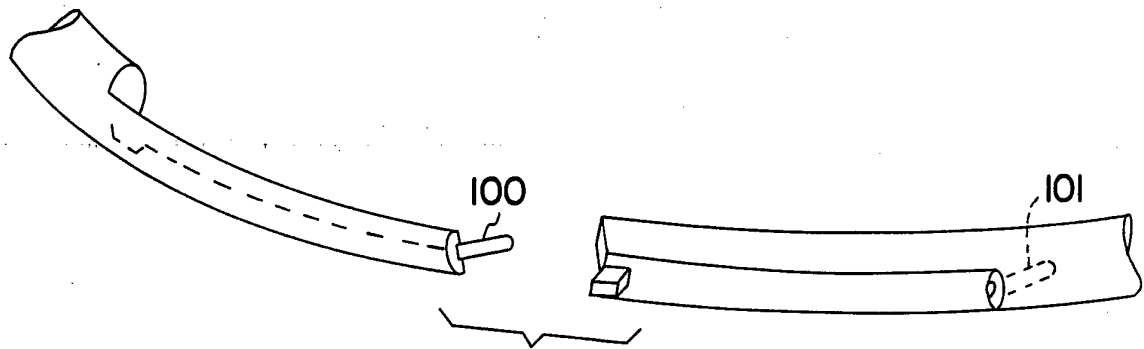


FIG. 10

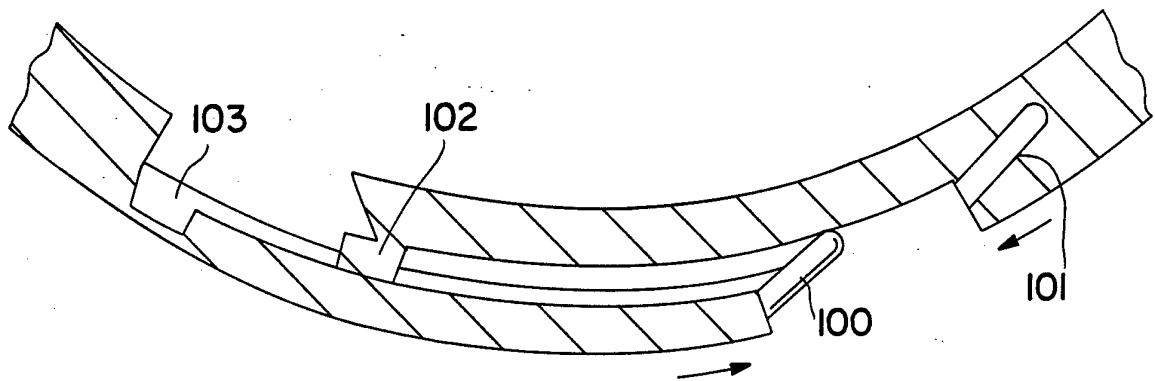


FIG. 10A

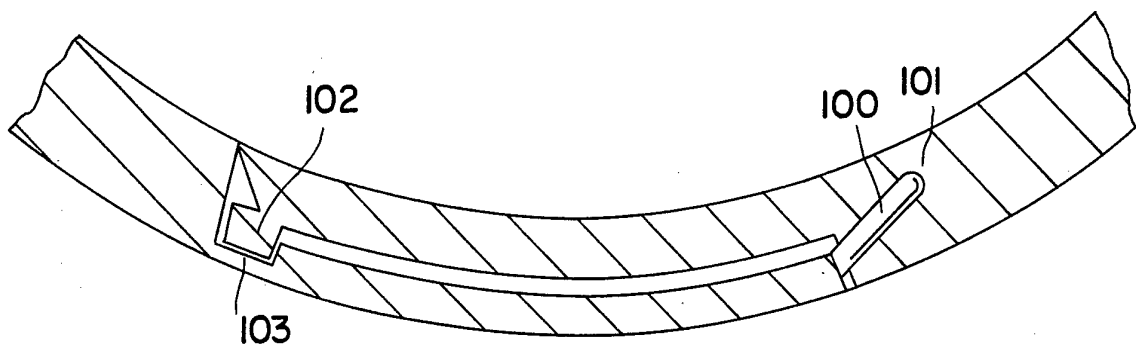


FIG. 10B

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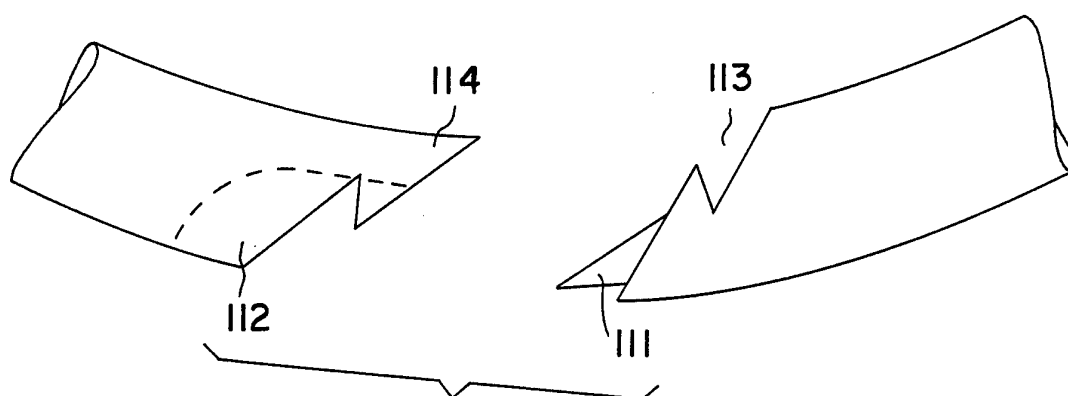


FIG. IIA

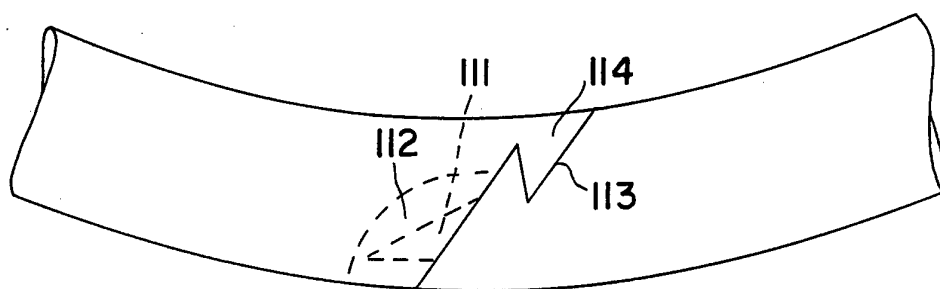


FIG. IIB

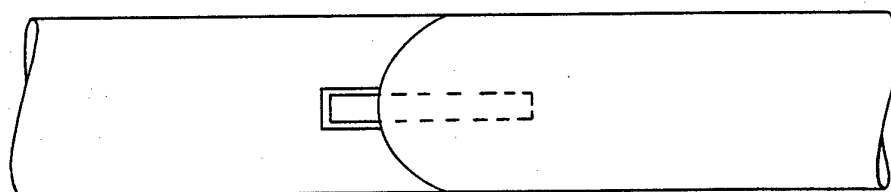


FIG. IIC

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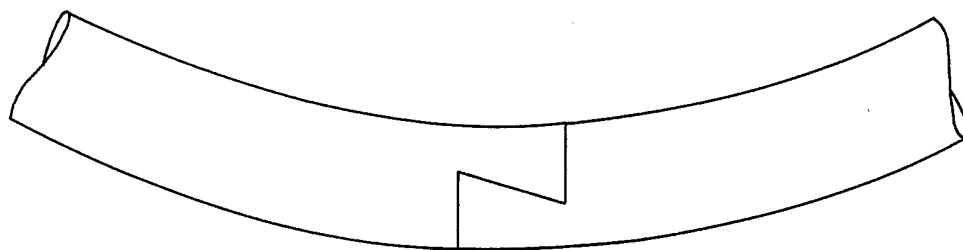


FIG. 12A

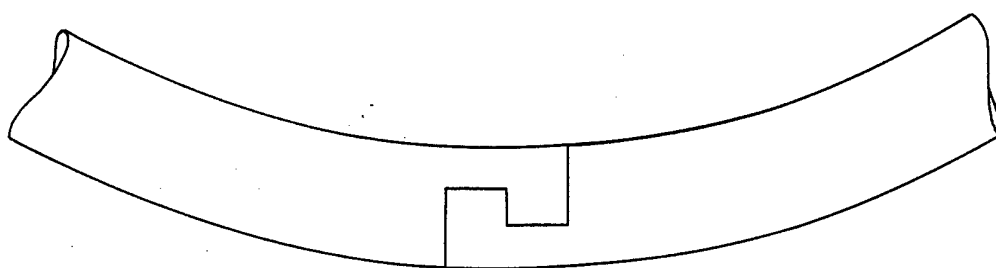


FIG. 12B

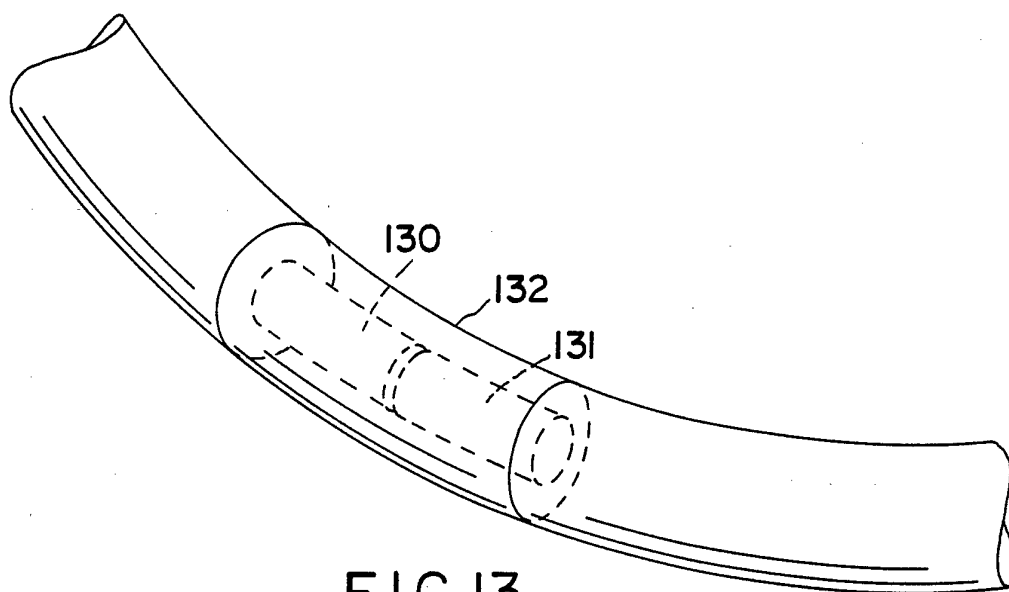


FIG. 13

INTERNATIONAL SEARCH REPORT

I. International application No.

PCT/US93/08770

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 9/00, 2/14

US CL :128/897-99; 623/4-6; 606/4-6

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/897-99; 623/4-6; 606/4-6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NoneElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	U.S., A, 4,655,774 (Choyce) 07 April 1987 (see entire document).	1-18
A	U.S., A, 5,098,443 (Parel et al.) 24 March 1992 (see entire document).	1-18
A	U.S., A, 4,452,235 (Reynolds) 05 June 1984 (see entire document).	1-18
A	U.S., A, 4,671,276 (Reynolds) 09 June 1987 (see entire document).	1-18



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

12 November 1993

Date of mailing of the international search report

25 FEB 1994

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