Proposed Amendments

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I CLAIM AS MY INVENTION: Replaced by new claims.

1. An intrastromal corneal insert for inserting into an intrastromal intracorneal channel, comprising a pliable polymeric insert subtending less than 360° of the cornea's circumference.

2. The insert of claim 1 that is hollow.

3. The insert of claim 1 that is tubular.

4. The insert of claims 1 or 3 that further contains a settable polymer, a gel, a drug or a biologically active material.

5. The insert of claim 1 that has a hexagonal or circular cross section.

6. The insert of claim 1 that encircles less than about 320° of the cornea's circumference.

7. The insert of claim 6 that encircles less than about 270° of the cornea's circumference.

8. The insert of claim 1 that is at least partially coated with an ocular lubricant.

9. The insert of claim 8 where the ocular lubricant is selected from hyaluronic acid, methylethylcellulose, dextran solutions, glycerine solutions, polysaccharides, or oligosaccharides and which optionally contains a drug, biologic or other biologically active material.

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10. The insert of claim 1 that is bonded to a biologically active material.

11. The insert of claim 1 that comprises a low modulus physiologically compatible polymer.

12. The insert of claim 11 where the low modulus physiologically compatible polymer is selected from polyhydroxyethylmethyacrylate (Poly-HEMA), polyvinylpyrrolidone (PVP), polyethylene oxide, or polyacrylates, polyacrylic acid and its derivatives, their copolymers and interpolymers, silicones, crosslinked dextran, crosslinked heparin, or hyaluronic acid.

13. The insert of claim 11 where the low modulus physiologically compatible polymer is selected from hydratable polymers which swell upon hydration, hydratable polymer systems which do not swell upon hydration, and elastomers.

14. The insert of claim 4 where the gel is selected from polyHEMA hydrogel, cross-linked collagen, cross-linked hyaluronic acid, siloxane gels, polyvinyl pyrrolidone, and organic-siloxane gels.

15. The insert of claims 4 or 8 where the drug is selected from dexamethasone, heparin, corticosteroids, antimitotics, antifibrotics, antiinflammatory, anti-scar-forming, anti-adhesion, antithrombogenic, and antiangiogenesis factors.

16. The insert of claim 1 in which the intrastromal intracorneal channel subtends the corneal circumference

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and the pliable polymeric insert subtends less than 360° of the cornea's circumference.

17. The insert of claim 16 in which more than one pliable polymeric insert segments is inserted into the intrastromal channel.

18. The insert of claim 17 in which the more than one pliable polymeric insert segments inserted into the intrastromal channel subtend a total of 360° or more of the cornea's circumference.

19. The insert of claim 17 in which the more than one pliable polymeric insert segments inserted into the intrastromal channel are of different sizes.

20. The insert of claim 17 in which more than one pliable polymeric insert segments are inserted into more than one intrastromal channel.

21. An insert suitable for introduction into the corneal stroma comprising a pliable, physiologically compatible polymeric insert having two ends and an axis between those ends, containing a reinforcement comprising at least one filament within said polymer and of a size suitable for insertion into an intrastromal channel.

22. The insert of claim 21 where the reinforcement comprises a filament or a woven or matte fabric.

ABSTRACT

SEGMENTED PLIABLE INTRASTROMAL CORNEAL INSERT

This invention is a pliable intrastromal corneal insert (10) designed to be inserted into an inter-lamellar channel made within the cornea of a mammalian eye. It is made of a physiologically compatible polymer and may be used to adjust corneal curvature and thereby correct vision abnormalities. The insert (10) or segment may also be used to deliver therapeutic or diagnostic agents to the corneal interior or to the interior of the eye. The insert (10) subtends at least a portion of a ring, or "arc", encircling the anterior cornea (33) outside of the cornea's field of view but within the cornea's frontal diameter. The invention also includes both a minimally invasive procedure for inserting one or more of the devices into the cornea (12) as well as the thus corrected eye.

Figure 2