A device providing enlargement and preventing collapse of the pupil of the eye during an ophthalmic surgical procedure. The device configured as a continuous or discontinuous ring (47) comprises plurality of notches (55, 56, 57, 58) at corners and flanges (48, 49, 50, 51) at sides. The ring is formed from a strand of resiliently flexible material and is disposed entirely within a single plane. The notches engage the pupillary margin at different parts, pushing them apart, resulting in sustained enlargement of the pupil. In addition, the device causes bending of the pupillary margin and iris at the notches and above and below the flanges, resulting in a secure engagement. The enlarged pupil created by the ring, allows a wide view of the structures deeper to the pupillary plane, previously obscured due to a small pupil.
TITLE OF THE INVENTION

Device Providing Enlargement & Preventing Collapse of the Pupil of the Eye

CROSS REFERENCE TO RELATED APPLICATION

This application claims priority to Application 225/KOL/2013 filed at Patent Office, India (IN), on February 27, 2013.

DESCRIPTION

BACKGROUND OF THE INVENTION:

The present invention is in the field of ophthalmic surgery and relates to an improvement in the device for mechanical enlargement or dilation of the pupil of the eye during surgery.

During phacoemulsification surgery and vitreo-retinal surgery, when the pupil does not dilate with medicated drops, a device is required for mechanical enlargement of the pupil. Such a device has to maintain the pupil in the enlarged state and prevent it from collapsing for the entire duration of the surgery. Removal of the device returns the pupil to an unenlarged state to preserve its function and cosmesis. Eyes with non-dilating pupils are often also associated with floppiness of the iris, which poses additional difficulty during surgery.

In phacoemulsification surgery for cataract, a 1.6 to 2.8 mm incision in the side of the cornea is required to insert a phaco probe. Smaller incisions result in secure and astigmatically neutral wounds translating into better visual outcomes.

Vitreo-retinal surgery requires 0.6 mm or smaller incisions in the sclera to insert instruments into the eye. Since a corneal incision is not required, such an incision, only to insert a pupil-dilating device, should be as small as possible.

Current devices in use for pupillary dilation require a 2.2 to 2.5 mm incision for insertion into the eye. They snag the incision because of gaps or pockets at the corners, which have a biplanar structure with a top and bottom part. Such
snagging makes removal of the device difficult and causes damage to the cornea. They require precise alignment to engage the pupillary margin into the small narrow wedge shaped gaps or pockets at the corners. This is particularly difficult because the surgeon has a top view and the device itself obscures view of the narrow gap, which is at the side of the device. The gaps or pockets have two structural planes having an upper and lower part making the corners thick and bulky. The gaps or pockets hold the pupillary margin and iris tissue passively and the pupillary margin can easily disengage during surgical manipulations.


OBJECTS OF THE INVENTION:

The principal object of the present invention is to provide a device to enlarge the pupil of the eye, which requires a very small incision for insertion into the eye. Another object of the invention is to provide a device with a mechanism to engage the pupillary margin that will not snag the incision during insertion or removal. A further object of the invention is to provide a device, with an easier mechanism to engage the pupillary margin that does not require precise alignment of the pupillary margin into the narrow wedge shaped gaps or pockets at the sides of the device. A further object of the invention is to provide a device, with corners that can engage the pupillary margin but are slim and strictly in the same plane of the device. A further object of the invention is to provide a device, which not only enlarges the pupil, but also remains securely, yet reversibly fastened to iris tissue
so that surgical manipulations do not lead to its disengagement. A further object of the invention is to provide a device that reduces floppiness of the Iris, which is often associated with non-dilating pupils.

SUMMARY OF THE INVENTION:

The present invention is a device to enlarge and prevent collapse, of the pupil of the eye, during surgery. The notches and flanges, on the same plane of a continuous or discontinuous ring, used to engage the pupillary margin, is the novelty of the present invention. The notches are at corners and alternate with side elements or flanges along the perimeter of the ring. The notches are open outwards with a blind receptacle inwards. Notches engage different parts of the pupillary margin and push them apart, resulting in sustained enlargement of the pupil. The flanges are formed from broad loops of the strand and are directed outwards.

The device is made of a strand of any resiliently flexible material. Thermally treated 4-0 nylon suture (0.15 to 0.17 mm) is such. Notches temporarily straighten as they pass through the incision allowing the device to be inserted through a very small incision. The device, having no gaps or pockets, being entirely disposed in a single plane, passes through the incision without snagging. The device bends the pupillary margin and iris at the notches and flanges, somewhat like a paper clip, creating a secure engagement. The iris being flexible, can tolerate such bending without any damage. The flanges lying in front of the iris reduce its floppiness by restricting the billowing effect.

Within the scope of the same inventive concept, variations in design are necessary, to allow the surgeon choices depending on the nature of the surgery, size of the eye, depth of the anterior chamber, associated co morbidity, size of incision, initial pupil size, desired pupil size etc. Variations in design are also necessary to suit different manufacturing capabilities.

The continuous form of the ring is in the form of a polygon with at least three sides and can be with or without a joint. The ends are joined by knotting or tying
of the ends, or by chemical, thermal or ultrasonic bonding of the ends or by any
other method. When made by molding, stamping or other methods there is no
joint. The discontinuous form of the ring has at least three sides, two corners and
four notches. This form requires a much smaller incision for insertion.

In one of the form of the invention, the ring has alternate side elements or flanges
gently tilted backwards, enabling easy tucking of the flange under the iris.

Notches are formed by an inward loop of the strand at the corners or by an inward
loop of the strand between two outward digit shaped protruded loops of the strand.
In one form of the invention, the corners of the ring have two adjacent notches.

Positioning holes on the device help in manipulations of the device. When the
device is made of expansible material, it enlarges to a larger size after insertion.

The ring device is configured to adapt one or more selected configurations from a
folded, extended or deformed configuration, allowing insertion through small
incisions.

BRIEF DESCRIPTION OF THE DRAWINGS:

Fig. 1 is an enlarged diagrammatic top perspective of the ring of the type

Fig. 2 is an enlarged diagrammatic side view of ring of the type disclosed in
Malyugin US Patent 8323296, showing iris tissue within the wedge shaped gaps
of the loops.

Fig. 3 is an enlarged diagrammatic top plan of the modified ring of the type

Fig. 4 is a perspective view of the ring of the type disclosed in Christensen &

Fig. 5 is an enlarged diagrammatic top view of one form of the device of the
present invention, showing a square shaped continuous ring with a joint.
**Fig. 6** is an illustration of the pupil maintained in an enlarged position by the device of Fig. 5.

**Fig. 7** is an enlarged diagrammatic side view showing the relation of iris tissue to the notches.

**Fig. 8** is an illustration of the insertion of the ring device into the eye and engagement of the pupillary margin with the first notch of the device of Fig. 5.

**Fig. 9** is an illustration of the stretched pupillary margin after engagement by the second notch of the device of Fig. 5.

**Fig. 10** is an illustration of the pupil fully enlarged after engagement by all four notches of the device of Fig. 5.

**Fig. 11** is an enlarged diagrammatic top view of one form of the device of the present invention, showing a discontinuous ring with five sides, four corners and six notches.

**Fig. 12** is an illustration of the pupil maintained in an enlarged position by the device of Fig. 11.

**Fig. 13** is an enlarged diagrammatic top perspective of one form of the device of the present invention, showing alternate flanges of the device of Fig. 11, gently tilted backwards.

**Fig. 14** is an enlarged diagrammatic top view of one form of the device of the present invention, showing plurality of positioning holes on a hexagon shaped continuous ring with no joint.

**Fig. 15** is an enlarged diagrammatic top view of one form of the device of the present invention, showing engagement of the pupillary margin by notches formed by an inward loop of the strand between two outward digit shaped protruding loops of the strand of a square shaped continuous ring with no joint.
**Fig. 16** is an enlarged diagrammatic top view of one form of the device of the present invention, showing engagement of the pupillary margin by two adjacent notches at the corners of a square shaped continuous ring with no joint.

**DETAILED DESCRIPTION OF DRAWINGS**

The relevant features of existing devices and the novelty of the present invention, is illustrated in the accompanying drawings, throughout which, like reference numerals indicate corresponding parts in the various figures.

**Fig. 1** shows an enlarged diagrammatic top perspective of the ring of the type disclosed in Malyugin US Patent 8323296, Dec 4, 2012. The Malyugin ring 1 has a square configuration with four helical loops 2, 3, 4 and 5 formed by one complete turn of the strand and separated by sides 6, 7, 8 and 9. The two ends 10 and 11, of the ring have indented portions and are butt attached to each other by adhesive at the joint 12. Each loop has a wedge shaped gap 13 and 14, which faces the periphery of the ring, to receive and capture the iris tissue. The ring 1 maintains the pupil in an extended position while the central opening 15 provides a wide viewing area during surgery.

**Fig. 2** shows an enlarged diagrammatic side view of ring of the type disclosed in Malyugin US Patent 8323296, showing iris tissue 16 within the wedge shaped gaps 13 and 14 of the loops. The side 9 connects the bottom part of gap 13, which is at one plane, to the top part of gap 14, which is at another plane.

**Fig. 3** shows an enlarged diagrammatic top plan of the modified ring of the type disclosed in Dusek US Patent Publication 2012/0269786. The Dusek ring 17 has four sides 18, 19, 20 and 21. Side 20 has the end butt joint 22 where a drop of adhesive secures the ends 23 and 24. Side 19 is perpendicular to side 20. The sides are joined by a corner portion 25 which has three distinct bends, namely, a first obtuse bend 26 (essentially 135° inward and to the left as viewed in Fig. 3), second return bend 27 (essentially 180° inward and then down away from the viewer and then toward the right as viewed in Fig. 3), and a third obtuse bend 28
(essentially 135° up and to the left as viewed in Fig. 3). Corner portions 29, 30 and 31 are identical to corner portion 25.

Fig. 4 shows a perspective view of the ring of the type disclosed in Christensen & Colvard US Patent Publication 2013/0096386. In the described embodiment of this disclosure, ring 32 has a square formation with rounded corners 33, 34, 35 and 36. At each corner, there is a top plate 37, which forms generally one plane of the ring and there is a bottom plate 38, which forms generally a second plane of the ring. These planes are generally above and below the primary plane of the ring formed by connecting limbs 39, 40, 41 and 42. Together, the outer periphery of the top plate and the bottom plate at each corner form a lip feature, which is the entrance of the pockets 43, 44, 45, and 46 that contain a portion of the iris, which is supported in an open configuration.

Fig. 5 shows an enlarged diagrammatic top view of the ring of the present invention used for enlargement and prevention of collapse of the pupil. The ring 47 is made of any resiliently flexible strand, for example, thermally treated 4-0 nylon suture. It is a continuous ring, has a square configuration and has four sides 48, 49, 50 and 51, joined by corner portions. Side 50 has ends 52 and 53 joined at the butt joint 54 with adhesive. Each one of the corner portions 55, 56, 57 and 58, forms a notch, same numerals representing the notches. Corner portion 56 joins side 49 to side 50, which are perpendicular to each other. At the corner portion 56, the strand loops inwards to form a notch. Three distinct bends of the strand in the same plane form the notch. A first acute bend 59, second rounded return bend 60, and a third acute bend 61. The notch has a narrow outward opening 62, which allows iris tissue to enter the notch. Inwards, the notch has a blind, bulbous receptacle 63, which engages the pupillary margin and iris tissue gently. Corner portions 55, 57 and 58 are identical to corner portion 56. Parts 64 and 65 of corner portions 57 and 58 respectively, along with side 51, form an outward flange. Sides 48, 49 and 50, form similar flanges. The ring comprises alternate notches and flanges, all being in the same plane and enclosing a space 66.
Fig. 6 shows an illustration of the pupil maintained in an enlarged position by the ring 47 of Fig. 5. The notches at corners 55, 56, 57 and 58, engage the pupillary margin 67 at different parts and push them apart, causing enlargement of the pupil. The flanges at sides 48 and 50 remain in front of the Iris 68. The flanges at sides 49 and 51 remain behind the Iris and are not visible. The alternate notches and flanges cause bending of the pupillary margin and iris tissue somewhat like a paper clip. This results in a secure yet reversible engagement. The central opening 66, allows wide view of the structures deeper to the pupillary plane.

Fig. 7 shows an enlarged diagrammatic side view of the relation of iris tissue to the notches. This side view is at a vertical plane passing through the middle of any two adjacent notches of Fig. 6. The device distinctly bends the iris tissue 68, four times, as it passes through the two notches. From the left as viewed in Fig. 7, the iris 68 passes above the side element 69 and outer limb 70 of the notch 71. The first bend is at an obtuse angle as it passes downwards around the outer limb 70 of the notch 71 and through the notch. The second bend is at an obtuse angle to pass under the inner limb 72 of the notch 71. Iris 68 then makes a third bend at an obtuse angle as it passes upwards around the inner limb 73 of the notch 74 and through the notch. The final fourth bend is at an obtuse angle to pass above the outer limb 75 of the notch 74 and side element 76. As viewed in Fig. 7, side element 69, outer limb 70 of the notch 71, the notch 71, inner limb 72 of the notch 71, inner limb 73 of the notch 74, the notch 74, outer limb 75 of the notch 74 and side element 76, all lie in the same plane.

Fig. 8 refers to the usage of the invention, is an illustration of the insertion of the ring 47 of Fig. 5, into the eye and engagement of the pupillary margin 67 with the first notch 55 of the ring. A forceps (not shown here) carries the device or an injector (not shown here) delivers the device through the incision 77, into the anterior chamber of the eye. The flexible square ring 47 adopts a rhomboid configuration as it negotiates through a much smaller incision 77. The notches 56 and 58 open up and temporarily straighten out as the device passes through the incision. The leading first notch 55 hooks and engages the pupillary margin 67.
pushing it in an outward direction. The pupillary margin 67 is lifted with a Hirschman hook (not shown here) to tuck the flange 49 under the pupillary margin 67 and iris 68.

Fig. 9 refers to the usage of the invention in further detail, is an illustration of the stretched pupillary margin after engagement by the second notch 56 of the device 47 of Fig. 5. The resiliently flexible ring 47 has now returned to its square configuration. Notches 55 and 56 have engaged the pupillary margin 67 at two different points and pushed them apart. Flange 49 (not visible here), remains tucked under the pupillary margin 67, while flanges 48, 50 and 51, remain in front of the iris 68. As the pupillary margin is hooked again with an iris or hirschman hook, introduced through a side port (not shown here), a forceps introduced through another side port (not shown here), holds the flange 51 and tucks it under the pupillary margin 67 and iris 68.

Fig. 10 refers to the usage of the invention in further detail, is an illustration of the pupillary margin 67, fully enlarged and adopting a square configuration after engagement by all four notches 45, 56, 57 and 58 of the device 47 of Fig. 5. The flanges 48 and 50 remain in front of the Iris 68. The flanges at sides 49 and 51 remain behind the iris and are not visible. The central opening 66, allows wide view of the structures deeper to the pupillary plane. On completion of surgery, the device is easily disengaged from the pupillary margin and pulled out with a forceps. The device exits the eye without snagging the incision because notches are in the same plane as the flanges and are capable of straightening temporarily.

Fig. 11 is an enlarged diagrammatic top view of another form of the device of the present invention, showing a discontinuous ring 78 with ends 79 and 80, which are blunt or olive shaped to prevent damage to delicate structures of the eye. The discontinuous ring 78 has five sides 81, 82, 83, 84 and 85, which are shaped like flanges. Corner portions joining these sides are internally obtuse angled. The four corner portions 87, 88, 89 and 90, form four notches, same numerals representing the notches. Notch 86 is at the first end and notch 91 is at the second end of the
ring. In the device of Fig. 11, the angles at corner 87 and 90 are equal to each other and the angles at corner 89 and 90 are equal to each other. The first side 81 and the fifth side 85 are parallel to each other, giving the device a flat top house shape. The central space 92, is closed on five sides by the device, and open on one side. In another form of the device of Fig. 11 (not shown here), the first side 81 and the fifth side 85, are unparaUel, such that the distance between the ends 79 and 80, is more than that between the first comer 87 and fourth comer 90, giving the device the shape of a flat top tower.

Fig. 12 is an illustration of the pupil maintained in an enlarged position by the device of Fig. 11. The notches 86, 87, 88, 89, 90 and 91, engage the pupillary margin 67 at different parts and push them apart, causing enlargement of the pupil. Ends 79 and 80, and flanges 82 and 84 remain in front of the Iris 68. The flanges 81, 83 and 85 remain behind the Iris and are not visible. The constricting force of the pupil draws the notches at the ends 79 and 80 of the discontinuous ring closer and the resultant shape of the central space 92 of the device and that of the pupil is a hexagon. The central space 92, allows wide view of the structures deeper to the pupillary plane. While the device of Fig. 11 may be inserted into the eye, in the manner described above for the device of Fig. 5, the device may alternatively be inserted end first, into the eye, through a much smaller side port incision. The entire device is inserted into the anterior chamber and placed on the iris. The pupillary margin is hooked with an iris or hirschman hook, introduced through one side port incision, while a forceps introduced through another side port, holds flange 83 and tucks it under the pupillary margin 67. Similarly, flanges 81 and 85 are tucked under the pupillary margin.

Fig. 13 is an enlarged diagrammatic top perspective of one form of the device of the present invention, showing alternate flanges of the device of Fig. 11, gently tilted backwards. Device 93 allows easier tucking of the flanges under the pupillary margin. Flanges 81, 83 and 85, shown in dotted lines, represent the previous straight position of flanges. Flanges 94, 95 and 96 represent the backward tilted flanges, respectively. The flanges are tilted all the way up to the
centre of the notch or only at the peripheral edge. The position of flanges 82 and 84, which remain in front of the pupillary margin, is unaltered. Although tilted flanges are shown on the device of the present invention of Fig. 11, it is understood that such flanges may be present on all the forms of the device.

**Fig. 14** is an enlarged diagrammatic top view of one form of the device of the present invention, showing plurality of positioning holes on a hexagon shaped continuous ring with no joint. Holes 98 and 99 are shown on a flange and notch respectively on the device 97. These holes are partial thickness or full thickness. These holes allow easy manipulation of the device inside the eye with the help of a pointed instrument called dialler. Although positioning holes or eyelets are shown on the device of the present invention of Fig. 14, it is understood that such positioning holes or eyelets may be present on all the forms of the device.

**Fig. 15** is an enlarged diagrammatic top view of one form of the device of the present invention, showing engagement of the pupillary margin 67 by notches formed by an inward loop of the strand between two outward digit shaped protruding loops of the strand of a square shaped continuous ring with no joint. The ring 100 has four side elements 101, 102, 103 and 104. Corner portions 105, 106, 107 and 108, join the side elements. Corner portion 108 joins side 101 to side 104, which are perpendicular to each other. At the corner portion 108, the strand makes three distinct loops in the same plane to form a notch. Loops 115 and 116 are outward digit like protrusions. Notch 117, is formed by an inward loop between these two outwardlooped protrusions. Corner portions 105, 106 and 107 are identical to corner portion 108 and form notches 118, 119 and 120 respectively. The pupillary margin 67 has a square configuration as it is engaged by the notches 117, 118, 119 and 120, as it passes behind the elements 110, 111, 114 and 115, and in front of elements 112, 113, 116 and 109. The enclosed space 121, allows wide view of the structures deeper to the pupillary plane.

**Fig. 16** is an enlarged diagrammatic top view of one form of the device of the present invention, showing engagement of the pupillary margin 67 by two
adjacent notches at the corners of a square shaped continuous ring with no joint. The ring 122 has four side elements 123, 124, 125 and 126. Comer portions 127, 128, 129 and 130, join the side elements. Comer portion 127 joins side 123 to side 124, which are perpendicular to each other. At the comer portion 127, the strand makes three distinct loops in the same plane to form two adjacent paired notches or a double notch. Paired notches 131 and 132 are formed by two loops directed inwards. A digit like structure 139, is formed between these two notches by a loop directed outwards. Comer portions 128, 129 and 130, are identical to comor portion 127 and form paired notches 133, 134 and 135, 136 and 137, 138 respectively. The pupillary margin 67 has a square configuration, engaged by the notches 131, 132, 133, 134, 135, 136, 137 and 138. The pupillary margin 67 passes behind side elements 123, 124, 125 and 126, and in front of elements 139, 140, 141 and 142. The enclosed space 143, allows wide view of the structures deeper to the pupillary plane. The pupillary margin 67 could alternately pass (not shown here) in front of side elements 123, 124, 125 and 126, and behind elements 139, 140, 141 and 142.

Those ordinarily skilled in the art can make changes in the embodiments described and illustrated, without altering the concepts of the present invention. Hence, it is to be understood that the invention is not limited to the descriptions, illustrations and examples, but includes all modifications within the scope of this invention.
CLAIMS:

1. A device configured as a ring, used to enlarge and prevent collapse, of the pupil of the eye, during an ophthalmic procedure, comprising at least three notches and two side elements, formed from a strand of resiliently flexible material, being disposed entirely within a single plane, notches being open outwards with a blind receptacle inwards, notches engaging different parts of the pupillary margin and pushing them apart, resulting in sustained enlargement of the pupil.

2. The device of claim 1, wherein said ring has side elements shaped like flanges, said flanges being formed by a loop of the strand, flanges being directed outwards, the pupillary margin and iris and remaining above or below alternate flanges.

3. The device of claim 1, wherein said notches being formed by inward looping of the strand.

4. The device of claims 1, 2 and 3, wherein said ring is continuous, formed by joining the two ends of a discontinuous ring.

5. The device of claims 1, 2 and 3, wherein said ring is continuous, with no joints.

6. The device of any one of claims 4 and 5, wherein said continuous ring has a polygonal shape, having at least three sides and three corners.

7. The device of claim 6, wherein said ring is shaped as a rectangle, with a notch being at each of the four corners.

8. The device of claim 6, wherein said ring is shaped as a square, with a notch being at each of the four corners.

9. The device of claim 6, wherein said ring is shaped as a hexagon, with a notch being at each of the six corners.

10. The device of claim 1, wherein said ring is discontinuous, having at least three sides and two corners, ends of the ring being blunted or olive shaped.

11. The device of claims 1, 2, 3 and 10, wherein said discontinuous ring has three sides, two corners and four notches, notches being at the two ends and at the two corners, comers being internally obtuse angled.
12. The device of claim 1, 2, 3 and 10, wherein said discontinuous ring has five sides, four corners and six notches, notches being at the two ends and four corners, corners being internally obtuse angled, the first and the fifth sides either being parallel to each other or being unparallel, such that the distance between the two ends of the ring is more than that between the first and fourth corners.

13. The device of any one of claims 6 to 12, wherein said ring has alternate side elements gently tilted backwards, in its entirety or only at the edges, to enable easy tucking under the pupillary margin.

14. The device of any one of claims 6 to 13, wherein said ring has one or more positioning holes or eyelets on the notches, side elements or ends.

15. The device of any one of claims 6 to 14, wherein the notch of the said ring is shaped like a bulb, flask, Keyhole, hockey stick, omega, U, V, L, S, incomplete rectangle or incomplete polygon, all notches on a given device being similar or dissimilar.

16. The device of any one of claims 6 to 15, wherein said notches being formed by an inward loop of the strand between two outward digit shaped protruding loops of the strand.

17. The device of any one of claims 6 to 15, wherein said notches being formed between two outward digit shaped protrusions of the strand, said protrusions being continuation of the strand itself or elements joined to the strand.

18. The device of any one of claims 6 to 17, wherein at least one of the corners of the ring has two adjacent notches.

19. The device of any one of claims 6 to 18, wherein said ring is expansible, being capable of enlarging or being enlarged to a size larger than its original size.

20. The device of any one of claims 6 to 19, wherein said ring is configured to adapt one or more selected configurations from a folded, extended or deformed configuration.
CLAIMS:

1. A device to expand the pupil of the eye comprising a strand of resilient material having multiple pupil margin engaging portions, said strand being formed as a continuous ring with straight sides joined by corner portions, said corner portions constituting the pupil margin engaging portions (55, 56, 57 and 58) are formed by a first acute bend (59), second return bend (60), and a third acute bend (61) of the strand, and are characterised in that all three bends are in a single plane and form a notch (56) in the same plane having an outward opening (62), and the sides constituting the support elements (48, 49, 50 and 51) are characterised in that they form outward flanges that are entirely in a single plane, alternate notches (55, 56, 57 and 58) and flanges (48, 49, 50 and 51) are in the same plane as the entire device and enclose a space (66), and are characterised in that the pupil margin (67) and adjacent iris pass through the plane of the device and straddle across this plane at the notches (Fig. 6, 71 and 74).

2. The device of claim 1 wherein said continuous ring has a joint (54).

3. The device of claim 1 wherein said continuous ring has no joint (Fig. 14).

4. The device of any one of claims 2 and 3, wherein said continuous ring has a polygonal shape, having at least four sides and four corners.

5. The device of claim 4, wherein said ring is shaped as a rectangle.

6. The device of claim 4, wherein said ring is shaped as a square (47, Fig 5).

7. The device of claim 4, wherein said ring is shaped as a hexagon (Fig 14).

8. A device to expand the pupil of the eye comprising a strand of resilient material having multiple pupil margin engaging portions characterised in that the said strand being formed as a discontinuous ring (78) with two blunt ends (79 and 80) and five straight sides (81, 82, 83, 84 and 85), sides being joined by corner portions which are internally obtuse angled, the corner portions (87, 88, 89 and 90) and end portions (86 and 91) constituting the pupil margin engaging portions are formed by a first acute bend, second return bend, and a third acute bend of the strand, and are characterised in that all three bends are in a single plane and form a notch in the same plane having an outward opening (84) and (85).
opening and characterised in that the said sides constituting the support elements form outward flanges (81, 82, 83, 84 and 85) that are entirely in a single plane, alternate notches (86, 87, 88, 89, 90 and 91) and flanges (81, 82, 83, 84 and 85) are in the same plane as the entire device and enclose a space (92) closed on five sides by the device and open on one side, and are characterised in that the pupil margin (67) and adjacent iris pass through the plane of the device and straddle across this plane at the notches (Fig. 12).

9. The device of claim 8 wherein the angle at the first corner (87) and the fourth corner (90) are equal to each other, the angles at the second corner (88) and third corner (89) are equal to each other, and the first side (81) and the fifth side (85) are parallel to each other, the distance between first pupil margin engaging portion (86) and sixth pupil margin engaging portion (91) is equal to the distance between second pupil margin engaging portion (87) and fifth pupil margin engaging portion (90), both distances being 120 percent of the length of the third side (83) (Fig. 11).

10. The device of claim 8 wherein the angle at the first corner (87) and the fourth corner (90) are equal to each other, the angles at the second corner (88) and third corner (89) are equal to each other, and the first side (81) and the fifth side (85) are unparallel to each other in a manner that the distance between first pupil margin engaging portion (86) and sixth pupil margin engaging portion (91) is 110 percent of the distance between second pupil margin engaging portion (87) and fifth pupil margin engaging portion (90), the distance between second pupil margin engaging portion (87) and fifth pupil margin engaging portion (90) is 120 percent of length of the third side (83).

11. The device of any one of claims 5, 6, 7, 9 and 10 wherein the pupil margin engaging corner portions (105, 106, 107 and 108) are formed by three loops of the strand in the same plane as the device and a notch is formed in the same plane by an inward loop (117) between two outward protruding closed loops (115 and 116), limbs of each outward loop being in contact with each other.

12. The device of any one of claims 5, 6, 7, 9 and 10, wherein the pupil margin engaging corner portions (127, 128, 129, and 130) are formed by three loops
of the strand in the same plane as the device and a pair of adjacent notches are formed in the same plane by a first inward loop followed by a second outward closed loop and a third inward loop of the strand (127, 128, 129, and 130), limbs of the second outward loop being in contact with each other.

13. The device of any one of claims 5, 6, 7, 9, 10, 11 and 12, wherein said ring has one or more positioning holes or eyelets on the notches (99), side elements (98) or ends.

14. The device of any one of claims 5, 6, 7, 9, 10, 11, 12 and 13, wherein said ring is configured to adapt one or more selected configurations from a folded, extended or deformed configuration (figures 8, 9 and 10).
Referring to amended claim 1:

Though the characterization portion referring to the bends may appear to be a modification of D2 as has been pointed out in item 4.4 of the written opinion, the device of the present invention actually uses a radically different concept to engage the pupil margin. Bringing all the bends at the corner to a single plane in turn brings the supporting elements also to a single plane, and effectively brings the entire device to a single plane and reduces the vertical profile.

The different way in which the pupil margin engaging part of the device engages the pupil margin, is the inventive step. This solves the problems of snagging of the self-sealing slit corneal incision by the device, large incision size required for insertion and removal of the device, and limitation of use in eyes with shallow anterior chambers due to large vertical profile of the device.

In all prior art, the pupil margin engaging part or gap straddles across the pupil margin either obliquely or perpendicularly and has an upper part and a lower part making this part actually a biplanar structure. The space or gap that receives the pupil margin (between the upper part and lower parts of the helical coil or the bends of the strand, or between the upper and lower lips or flanges of the groove or pocket) is oriented either perpendicular or oblique to the principal plane of the device. The device does not bend the pupil margin and the adjacent iris at the area of engagement and they remain undisturbed in their own plane (Fig. 2).

In the present invention, since the pupil margin engaging part is in the same plane as the device, it bends the pupil margin and the adjacent iris at the area of engagement (Fig. 7). In the present invention, the pupil margin straddles across the plane of the device whereas in all prior art a part of the device straddles across the plane of the pupil margin.

The last sentence of paragraph 0033 of D2 refers to two corners of the device not being directly opposed and being offset lengthwise for compact nesting in the
insertion tube. Which implies that one corner portion would be opposed to a side portion and not another corner portion thus reducing the horizontal or vertical space required within the insertion tube. There is no suggestion of a change in any bend to change the manner in which the pupil margin is engaged or any suggestion to reduce the vertical profile of the device itself.
**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61B17/02

ADD.

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)

A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>US 5 163 419 A (GOLDMAN KENNETH N [US]) 17 November 1992 (1992-11-17) cited in the application on the whole document</td>
<td>1, 10-12, 14, 15, 17, 19, 20</td>
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**X** Further documents are listed in the continuation of Box C.  

**X** See patent family annex.

* Special categories of cited documents:

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  * **Z** document member of the same patent family

Date of the actual completion of the international search: 19 December 2013

Date of mailing of the international search report: 09/01/2014

Name and mailing address of the ISA:
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040
Fax: (+31-70) 340-3016

Authorized officer: Ebbi Nghaus, M
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