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(54) Title: SCLERAL BUCKLES FOR SUTURELESS RETINAL DETACHMENT SURGERY

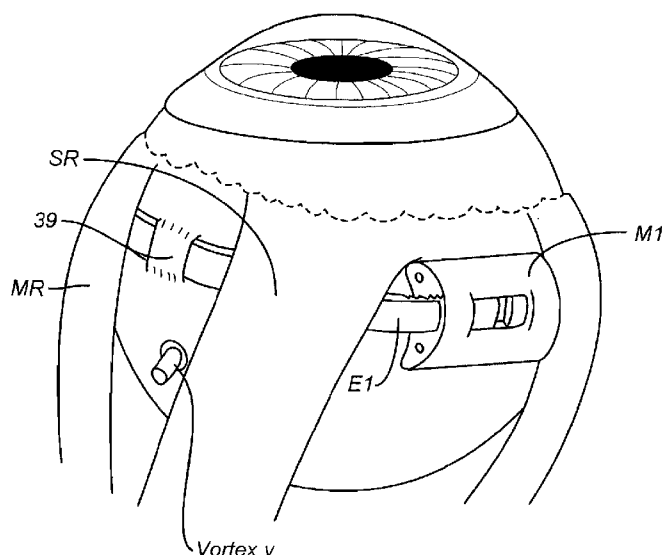


FIG. 12

(57) Abstract: A set formed by a scleral buckle (M1, M2, S1, S2) and an encircling band (E1, E2, E3) is provided for use in retinal detachment surgery to enable the implantation of both the scleral buckle (M1, M2, S1, S2) and encircling band (E1, E2, E3) free of any suture. A self-assembling scleral buckle-encircling band combination is secured in place by surface scleral tunnels (39) operating as belt loops to enable the securing of a scleral buckle (M1, M2, S1, S2) and encircling band (E1, E2, E3) on the eyeball to exert an intended indentation effect for treatment of retinal detachment.



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SCLERAL BUCKLES FOR SUTURELESS RETINAL DETACHMENT SURGERY

BACKGROUND OF THE INVENTION

[0001] This invention relates to eye surgery and more particularly to aids for retinal detachment surgery.

[0002] The retina is a thin sheet of light sensitive nerve tissue lining the inner posterior of the eye and which functions to capture focused images like the film of a camera. Retinal detachment (RD) occurs when the retina separates from the posterior wall of the eye. It is usually caused by a break in the retina. Retinal detachment is one of the major human eye diseases which can lead to severe visual impairment or even blindness unless it is treated surgically.

[0003] Scleral buckling surgery is one of the most commonly performed surgical operations to treat retinal detachment. In the surgery as conventionally practiced, silicone rubber explants are sewed externally onto the scleral tissue (eye walls) overlying the retinal tear. The explants indent the sclera against the retina and close retinal tear by relieving the force tracking on the tear. These explants are known as scleral buckles. Scleral buckles are provided in a variety of sizes and shapes to treat different sizes of retinal breaks. Usually, a long silicone strip known as encircling band is also sutured and tightened onto the globe of the eye to further relieve forces pulling up the retina from the posterior wall. To complete the surgery, cryotherapy is applied externally to achieve a permanent adhesion between the retina and underlying tissue, to prevent the retina from re-detachment.

[0004] Commercially available buckle and encircling bands are still used according to a method based on an invention by Custodis in the early 1950s (Custodis E. "Treatment of retinal detachment by circumscribed diathermal coagulation and by scleral depression in the area of tear caused by imbedding of a plastic implant," *Klin Monatsbl Augenheilkd* 1956;129:476–495). The major differences from the original invention are the material used and the configurations of the buckles. The material used is either a silicone sponge which was pioneered by Lincoff et al. (Lincoff HA, Baras I, McLean J., "Modifications to the Custodis Procedure for Retinal Detachment," *Arch. Ophthalmol.* 1965;73:160–163) or a solid silicone element which was pioneered by Schepens (Schepens CL, Okamura ID, Brockhurst RJ, Regan CD, "Scleral buckling procedures v. Synthetic sutures and silicone implants," *Arch. Ophthalmol.* 1960;64:868–881). The method of securing the scleral buckle and encircling

band onto the scleral wall by suturing has remained virtually unchanged for more than 50 years.

[0005] Although scleral buckling surgery is effective, it is also a highly demanding surgical procedure with potential major complications. For example, the buckle and encircling band are conventionally sutured onto the sclera with a fine needle, and the suture depth is aimed at the half thickness of the very thin sclera (0.5 - 1 mm). If the placement of needle is too deep, the sclera will be accidentally perforated. Perforation of sclera may damage the underlying tissue, leading to bleeding or retinal hole formation, surgical failure and permanent damage. However, if the placement of the needle is too shallow, the buckle or encircling band could be loosened or even exposed out from the eye after the surgery. A loosened or exposed buckle also leads to surgical failure, infection and unwanted pain.

[0006] Apart from perforation of the globe, suturing poses at least one more disadvantage. For securing one suture, there are two bites: the anterior anchor and the posterior anchor. The anterior anchor site is relatively easy to reach. However, the posterior anchor is usually located posterior to the equator of the globe, and this location is relatively difficult to reach. The working space for making the posterior anchor is usually very limited because of the funnel shape of the bony orbit and the posterior location of the anchor site. Sometimes the surgeon must pull the extra-ocular muscle with a bridle suture in order to rotate the eye ball to yield more working space for applying the suture. The patient may experience great pain during this step and sometimes patient's heart rate may be decreased because of oculo-cardiac reflex. Moreover, the posterior anchor can be located close to the exit of the vortex vein. If the vortex vein is accidentally perforated, profound bleeding can lead to failure of the whole surgery.

[0007] U.S. Patent No. 4,299,227 – Ophthalmologic appliance of Lincoff describes a method of treating retinal detachments through a small conjunctival incision wherein an expandable balloon like device is inserted into Tenon's space of the eye. The balloon is then expanded, to form a temporary indentation in the eye, and the balloon is deflated and removed from the eye after the retina has re-attached. There is no permanent indentation effect onto the retina because the balloon is removed from the eye once the retina is re-attached in the early postoperatively period. The retinal detachment has higher chances of re-detaching when the indentation is removed, especially when there is proliferative vitreo-retinopathy during mid or late postoperative period.

[0008] U.S. Patent No. 4,452,776 - Hydrogel implant article and method of Refojo describes a hydrogel buckle of significant softness, pliability and elasticity when dry as well as when wet. It is sutured onto the scleral wall to produce the indentation effect. It claimed to be better than silicone in that it will swell up post-operatively to give a greater indentation effect. However, it can swell unexpectedly up to four fold of its original size years after the surgery because of hydrolytic degradation, thus potentially causing serious complications such as buckle extrusion, intrusion, squint and subcutaneous mass, etc. Production of this device was halted in mid 90's.

[0009] U.S. Patent No. 6,547,714 - Magnetized scleral buckle for use with silicone magnetic fluids in the treatment of retinal diseases, and U.S. Patent No. 6,135,118 - Treatment with magnetic fluids, both by Dailey describe a method to treat retinal detachment by the combined usage of a magnetic fluid tamponade inside the eye with a magnetized flexible scleral buckle placed outside the eye. The magnetic fluid is injected into the eye using a syringe, and the magnetic scleral buckle is positioned and immobilized in place, generally by suture or adhesive. The scleral buckle needs to be fixed in place by sutures or adhesives, which inevitably pose the same hazards as conventional scleral buckling surgery.

[0010] U.S. Patent Publication US2006/06167422 A1-Heat shrink scleral band with custom-made buckle for retinal detachment surgery of Mohsen Shahinpoor et al. discloses a scleral band of polymeric material that is capable of shrinking when it is stimulated by heat (hot-tip), laser, radio-frequency or other conventional means. In the Shahinpoor system, a progressively increasing indentation effect is created by the progressive tightening of the scleral band. It is noted that the system requires a number of stages of follow-up procedures to produce the progressively increasing indentation effect. The scleral band is inserted into the Tenon's space, but there is no mechanism described to stabilize the scleral band onto the eyeball. There is no external drainage of subretinal fluid. It aims at internal self-absorption of subretinal fluid. The ends of the scleral band are joined together by self-locking serrated ends. The scleral band can be combined with one snap-on custom-made buckle by an insertion peg to achieve scleral indentation over the retinal tear region. The invention aims at merely a temporary indentation (at least three days) and the whole implant is designed to be removed from the eye when the retina is re-attached.

[0011] If scleral buckling surgery can be improved, the risk is much reduced and the success rate is increased.

SUMMARY OF THE INVENTION

[0012] According to the invention, a combination of a scleral buckle and an encircling band is provided for use in connection with retinal detachment surgery to enable the implantation of both the scleral buckle and encircling band free of any suture. A self-assembling scleral buckle-encircling band combination is secured in place by surface scleral tunnels operative as belt loops to enable the securing of scleral buckle and encircling band on the eyeball to exert an intended indentation effect for treatment of retinal detachment.

[0013] The device and associated procedure reduce intraoperative risk of globe perforation during the procedure, thus reducing the chance of disastrous complications such as bleeding, retinal hole formation and softening of the globe. In addition, the device simplifies the procedure, so the length of time of surgery is reduced and patient comfort is increased.

[0014] A device according to the invention could be easily combined with other options of retinal detachment treatment including pars plana vitrectomy, increasing surgical effects synergistically.

[0015] The buckle and encircling band according to the invention can be more securely implanted onto the globe. Therefore the postoperative risk of a loosened buckle can be reduced, enhancing the surgical success rate and minimizing the need for repeated surgery.

[0016] For a complete understanding of the present invention, reference is made to the following detailed description taken in conjunction with the accompanying drawing figures wherein like reference characters denote corresponding parts throughout the several views.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1A is a perspective view of a main circumferential scleral buckle for implantation according to a first embodiment of the present invention.

[0018] FIG. 1B is a side cross sectional view according to the first embodiment of the invention.

[0019] FIG. 1C is a top view according to the first embodiment of the invention.

[0020] FIG. 2 is a perspective view of a main radial scleral buckle for implantation according to the first embodiment of the present invention.

[0021] FIG. 3A is a perspective view of a supplementary circumferential scleral buckle for implantation according to the first embodiment of the present invention.

[0022] FIG. 3B is a side cross sectional view of the supplementary buckle according to the first embodiment of the invention.

[0023] FIG. 3C is a top view according to the first embodiment of the invention showing section line 3B.

[0024] FIG. 4 is a perspective view of a supplementary radial scleral buckle for implantation according to the first embodiment of the present invention.

[0025] FIG. 5 is a perspective view of an encircling band according to the first embodiment of the present invention showing the interior of the band.

[0026] FIG. 6A is a perspective view of a circumferential scleral buckle for according to a second embodiment of the present invention.

[0027] FIG. 6B is a side cross sectional view according to the second embodiment of the invention.

[0028] FIG. 6C is a top view according to the second embodiment of the invention.

[0029] FIG. 7 is a perspective view of a radial scleral buckle for implantation according to the second embodiment of the present invention.

[0030] FIG. 8A is a perspective view of an encircling band according to the second embodiment of the present invention showing the exterior of the band.

[0031] FIG. 8B is a perspective view of an encircling band according to the second embodiment of the present invention showing the interior of the band.

[0032] FIG. 9A is a perspective view of a circumferential scleral buckle for implantation according to a third embodiment of the present invention.

[0033] FIG. 9B is a side cross sectional view according to the second embodiment of the invention.

[0034] FIG. 9C is a top view according to the second embodiment of the invention.

[0035] FIG. 10 is a perspective view of a main radial scleral buckle for implantation according to the third embodiment of the present invention.

[0036] FIG. 11A is a perspective view of an encircling band according to the third embodiment of the present invention showing the exterior of the band.

[0037] FIG. 11B is a perspective view of an encircling band according to the third embodiment of the present invention showing the interior of the band.

[0038] FIG. 12 is a perspective view of an eye illustrating circumferential scleral buckling without sutures.

[0039] FIG. 13 is a perspective view of an eye illustrating radial scleral buckling without sutures.

[0040] FIG. 14 is a perspective view of a further embodiment of the invention.

DETAILED DESCRIPTION SPECIFIC EMBODIMENTS

[0041] According to the invention, a combination of a scleral buckle and an encircling band are provided to enable the implantation of a scleral buckle and encircling band to repair retinal detachment without the need of suturing. Instead of performing multiple suturing, only four sets of surface incisions are made to produce scleral tunnels on the scleral wall for implantation of the sutureless scleral buckling system.

[0042] To this end, a set of sutureless scleral buckles and encircling band are provided for use in connection with retinal detachment surgery. These explants are particularly configured so as to allow anchoring on eye globe without suturing. An important feature is the ability of self assembly between the scleral buckle and encircling band, forming a united unit of a scleral buckle-encircling band complex, for implantation onto the globe as a unit. Four partial thickness scleral tunnels are created on the scleral wall for implantation of the scleral buckle-encircling band complex. The making of scleral tunnels is relatively easy compared with making sutures. First, the site of the scleral tunnel is usually made at the relatively accessible equator of the globe, where the sclera at equator is relatively thicker than that at the extraocular muscle insertion. Second, a crescent knife may be used to make the scleral tunnel, a knife that is wider than the conventional needle used in suturing, thus reducing the risk of globe perforation by the conventional spatula needle and cheese wiring used in a suture. Moreover, since the total area of anchor is increased, the buckle and the encircling band are less likely to be loosened postoperatively.

[0043] According to the invention, the scleral buckle is self assembled with the encircling band and hence it is secured onto the eyeball indirectly by locking with the encircling band. Three embodiments for the sutureless scleral buckling system are described herein. The embodiments differ in the manner of assembly between the scleral buckle and encircling band.

*Embodiment I**Main scleral buckle*

[0044] Figure 12 depicts a perspective view of a main circumferential scleral buckle in a first embodiment of the invention in use, and Figure 13 depicts an additional perspective view of a main radial scleral buckle in the first embodiment in use. In the first embodiment, there are two types of scleral buckles: the main scleral buckle and the optional supplementary scleral buckle. All use an encircling band E1. All are made with medical grade silicone rubber. Other embodiments of the scleral buckles are mounted in a similar fashion and are therefore not shown as mounted.

[0045] The structure features a main or major scleral buckle and an optional supplementary scleral buckle and an encircling band. The main scleral buckle has two configurations, circumferential M1 (Figures 1A-1C and Figures 12) and radial M2 (Figure 2 and Figure 13). The main scleral buckle M1 or M2 directly locks and tightens the two ends of the encircling band E1 (Figures 12, 13) with locks 1, 6 and forms the most important indentation effect onto the eyeball directly over the site where there is a retinal break inside the eyeball. The two locks on the main scleral buckle of the first embodiment have asymmetric castellations with a sawtooth profile that serves to lock with the complementary castellations with a sawtooth profile 17 at both ends of the encircling band E1. There is a lateral snap fit joint 3, 4, 7 (not shown), 9 to allow assembling with a supplementary scleral buckle S1 (Figures 3A-3C) or S2 (Figure 4) having mating snap fit joints 10, 13, 14 (not shown), 16. A main buckle M1 or M2 is used in all cases.

Supplementary scleral buckle

[0046] The supplementary scleral buckle has two configurations: circumferential S1 (Figures 3A-3C) and radial S2 (Figure 4). These optional buckles are to be assembled with the encircling band E1 away from or side by side to the major scleral buckle M1 or M2. A supplementary buckle is medically indicated in the occasional cases where the lesion is wider than the length of the major buckle or where there are multiple retinal lesions located in more than one quadrant of the retina. There are lateral snap fit joints 10, 13, 14 (not shown), 16 on both front and back sides to allow stacked assembly by attachment to the main scleral buckle or additional supplementary scleral buckles. The common feature of the main and supplementary scleral buckles is the snap fit groove 5, 8, 12, 15, 105 on the external surface of the scleral buckle to accommodate the encircling band E1.

The encircling band

[0047] The encircling band E1 has one fixed size (typically 2.5 mm wide by 0.8 mm high and 120 mm long) with a typical 25 mm length of sawtooth profiles 21 at each end of the encircling band as shown in Figure 5 for use to lock with the main scleral buckles M1, M2. The encircling band E1 can also assemble with supplementary buckles S1, S2. The encircling band itself is affixed to the globe by passing through four scleral tunnels 39 made on the scleral wall at or near the level of the globe equator, which resemble belt loops. After the band is passed through the scleral tunnels 39, the two ends of the encircling band are inserted into the locks 1, 6 at each side of the main scleral buckle M1, M2. The castellations with a sawtooth profile 17 on both ends of the encircling band E1 are complementary to the castellations with a sawtooth profile of the two locks 1, 6 on the main scleral buckle M1, M2 to lock both of them together. The two ends of the encircling band E1 are pulled towards each other until both the buckle and encircling band have exerted appropriate indentation effect on the eyeball and they lock against the vertical walls of the castellations. Redundant ends of the encircling band are trimmed off. Moreover, there is a step element 18 on either side and along the whole length of the band for snap fit into the groove 5, 8, 12, 15 of all types of buckles (main or supplementary). Thus, this is the method for assembling between a supplementary buckle and an encircling band.

[0048] In the above mentioned embodiment, the whole set comprising scleral buckles and encircling band can be secured onto the eyeball and exert appropriate indentation effect onto the eyeball without any need of sutures.

Choosing type and combination of buckle

[0049] There are two types of major scleral buckles M1, M2 and supplementary scleral buckles S1, S2 respectively to treat different shapes and distributions of the retinal lesions which cause retinal detachment. The different combinations of scleral buckles and encircling band can be tailored to treat an individual's retinal detachment, and the assembly of scleral buckle with the encircling band E1 is simple. To be more specific, the circumferential scleral buckle M1 is chosen in case of retinal breaks orientated in a circumferential manner such as lattice degeneration or rows of retinal holes/tears. The radial scleral buckle M2 is chosen in case of retinal breaks orientated in a radial manner such as horse shoe tear. When there are retinal breaks located primarily in one quadrant on the retina, only the main scleral buckle M1 or M2 plus the encircling band E1 are needed. When there are retinal breaks located in more than one quadrant on the retina, a combination of a supplementary scleral buckle of either or both S1 and/or S2 plus the main scleral buckle M1 or M2 and the encircling band E1 is used.

When to use the tongue of the scleral buckle

[0050] In some embodiments of buckle, a central tongue structure 2, 11 is provided at the base of the groove 5, 12 in the scleral buckle. In the process of scleral tunnel-making, the 4 scleral tunnels 39 are made in-between the scleral muscle, since the scleral tunnel cannot be made underneath the rectus muscle of the eyeball. When the retinal break is located in between the rectus muscle, the scleral buckle should be also implanted in between the rectus muscle, right on top of the location of the retinal breaks. In this circumstance, the tongue 2 of the main scleral buckle is useful: The tongue is inserted through the scleral tunnel 39 in the quadrant of the retinal break, and the encircling band E1 needs to pass through the rest of the 3 scleral tunnels only. Antero-posterior movement of the main scleral buckle M1 is prevented by the union between the tongue 2 and the scleral tunnel 39.

[0051] When the retinal break is located underneath the rectus muscle, the scleral buckle should be implanted underneath the rectus muscle. In this circumstance, the tongue 2 of the main scleral buckle is not used. The encircling band E1 will pass through all the 4 scleral tunnels 39 only. Antero-posterior movement of the main scleral buckle is prevented by rectus muscle insertion and the two scleral tunnels for the encircling band close to the ends of the buckle.

Assembly of the scleral buckles and the encircling band.

[0052] Three different types of locking systems are used for fixation between the scleral buckles and encircling band.

[0053] 1. Lock between the main scleral buckle and the encircling band – the interlocking joint 1, 6 with sawtooth profile 17.

[0054] 2. Lock between the main scleral buckle with the supplementary buckle – 3, 4, (7 not shown), 9, 10, 13, (14 not shown), 16 the snap-fit joint (frictional form-fitting joint).

[0055] 3. Encircling band with a supplementary buckle – the snap-fit joint 12, 15, 18 (frictional joint).

Embodiment II:

[0056] In a second embodiment, there is only one type of scleral buckle (with 2 configurations: radial (Figure 6A-6C) and circumferential (Figure 7) to assemble with an encircling band E2. The basic principle, material and rationale for choice of configuration of scleral buckle are the same as that of embodiment I. The difference between embodiment I &

II lies in the method of locking between the scleral buckle and encircling band. In this embodiment, both ends of the encircling band are locked together directly by a silicone sleeve (not shown) after the encircling band E2 has passed through the four scleral tunnels. The scleral buckle does not function as the main lock to hold and tighten the two ends of the encircling band. The buckle is assembled with the encircling band to exert indentation effect onto the eyeball. (Figure 8).

The scleral buckle

[0057] The scleral buckle of a second embodiment has two configurations: circumferential II1 (Figure 6A-6C) and radial II2 (Figure 7). The scleral buckle is assembled with the encircling band E2 to exert indentation effect onto the eyeball, directly on the site where there is retinal break inside the eyeball. There is no lock on the scleral buckle as in the main scleral buckle of Embodiment I. However, there are snap-fit longitudinal grooves 23, 25, 25a along the long axis of the scleral buckle to assemble with the side step 28 of encircling band E2. Moreover, at the base of the groove, there are multiple castellations having a symmetric longitudinal frictional profiles 20, 25 to fit with the complementary symmetric castellations having frictional profiles 27 on the whole length of the encircling band E2 to prevent lateral movement of the scleral buckle from the encircling band when the silicone sleeve is in place. There are lateral snap fit joints 19, 22, 24 (not shown), 26 to assemble with any additional scleral buckle when needed.

The encircling band

[0058] The length and dimension of the encircling band E2 are the same as in embodiment I E1, but there is no sawtooth profile on each end of the encircling band. Instead, there are multiple castellations with frictional profiles 27 along the whole length of the encircling band E2 to fit with the frictional profiles 20, 25 on the groove 23, 25a of the scleral buckle II1, II2 to prevent lateral movement of the scleral buckle from the encircling band E2.

[0059] Resembling embodiment I, the encircling band E2 itself is affixed to the globe by passing through four scleral tunnels 39 made on the eyeball scleral wall (Figures 12 and 13). The two ends of the encircling band E2 are then inserted into a short silicone sleeve (not shown) to hold the two ends together and to tighten the encircling band. The two ends of the encircling band E2 are pulled towards each other until both the buckle and encircling band have exerted appropriate indentation effect on the eyeball. Redundant ends of the encircling band E2 after passing through the sleeve are trimmed off.

[0060] Moreover, there is a step 28 on either side and along the whole length of the band for snap fit into the groove 23, 25a of the scleral buckle. This is the fastening mechanism for assembly between scleral buckles and encircling band.

Embodiment III:

[0061] Embodiment III is similar to embodiment II where there is only one type of scleral buckle (with 2 configurations: circumferential (Figure 9) and radial (Figure 10) to assemble with an encircling band E3. The basic principles, materials and rationale for choice of configuration of the scleral buckle are the same as that of embodiments I and II. The difference between embodiment II and embodiment III lies in the method of locking between the scleral buckle and the encircling band. In this embodiment, like embodiment II, a sleeve is used to lock and tighten the two ends of the encircling band together after it has passed through the four scleral tunnels 39. The buckles III1, III2 are assembled with the encircling band E3 to exert an indentation effect onto the eyeball by a different mechanism from embodiment II.

The scleral buckle

[0062] The scleral buckle has two configurations: circumferential III1 and radial III2. The scleral buckles III1, III2 are assembled with the encircling band E3 to exert an indentation effect onto the eyeball directly on the site where there is retinal break inside the eyeball. There is no lock on the scleral buckle. However, there are form fitting spikes 32, 34 (Figures 9A-9C and 10) at the base of the groove along the long axis of the scleral buckle to assemble with the row of complementary form fitting holes 37 (Figures 11A-11B) along the whole length of encircling band. There are lateral snap fit joints 29, 31, 33 (not shown), 36 to join with any additional scleral buckle when needed.

The encircling band

[0063] The length and dimension of the encircling band E3 are the same as embodiments I and II. There is a row of complementary form fitting holes 37 along the length of encircling band E3 to fit with the snap fit frictional form fitting spikes 32, 34 at the base of the groove 30, 35 of the scleral buckle III1, III2 to prevent lateral movement of the scleral buckle from the encircling band E3. Resembling embodiment I, the encircling band E3 38 itself is affixed to the globe by passing through four scleral tunnels 39 (Figures 12, 13) made on the eyeball scleral wall. The two ends of the encircling band E3 are then inserted into a short silicone sleeve to hold the two ends together and to tighten the encircling band E3. The two ends of the encircling band E3 are pulled towards each other until both the encircling band E3 has

exerted appropriate indentation effect on the eyeball. Redundant ends of the encircling band E3 after passing through the sleeve are trimmed off.

Embodiment IV:

[0064] In a fourth embodiment, as shown in Figure 14, the main scleral buckle is combined with the encircling band 118 to form an integrated scleral buckle M4. One end of the encircling band is permanently affixed to and serves as an extension of the main scleral buckle. The other end of the encircling band has asymmetric castellations 117 with a sawtooth profile that serve to lock with the complementary castellations with a sawtooth profile within the snap fit slot 105 of the scleral buckle, resembling embodiment I. There is only one lock in the scleral buckle. The basic principles, material and rationale for choice of configuration of scleral buckle M4 are the same as that of embodiment I. After the free end of the encircling band has passed through the four scleral tunnels, as in Figure 12, the free end is inserted into the lock of the scleral buckle and the encircling band 118 is tightened by pulling the free end until both the scleral buckle and encircling band have exerted appropriate indentation effect onto the eyeball.

The scleral buckle

[0065] The main scleral buckle-encircling band combination M4 of the fourth embodiment has two configurations: circumferential IV1 as shown and radial IV2 like Figure 2, which only varies in the scleral buckle part. The main scleral buckle-encircling band combination M4 is implanted by aligning the buckle portion directly on the site where there is a retinal break inside the eyeball. There is a central tongue structure provided at the base of the groove, and the function is identical to that of embodiment I. Moreover, there are lateral snap fit joints 105 to assemble with any additional supplementary scleral buckle when needed. The supplementary buckle resembles that in embodiment I.

The encircling band

[0066] The length and dimension of the encircling band 118 are the same as in embodiment I, but there is a sawtooth profile 117 on only one end of the encircling band, which is the free end of the encircling band. Resembling embodiment I, there is a step on either side and along the whole length of the encircling band for snap fit into the groove of any supplemental scleral buckle.

Market potential

[0067] The incidence of rhegmatogenous retinal detachment is 1 per 10,000 population per year, and the incidence could be higher in area with population of high prevalence of myopia such as Hong Kong and Singapore. Scleral buckling surgery is one of two commonly performed operations to treat this type of disease. Scleral buckling (external surgery) is sometimes indicated to combine with pars plana vitrectomy (internal surgery) to treat advance RD. Therefore the application of this invention could be of great help in this field.

[0068] This invention has been explained with reference to specific embodiments. Other embodiments may be suggested by this disclosure to those of skill in the art. Therefore it is not intended that this invention be limited, except as indicated by the appended claims.

WHAT IS CLAIMED IS:

1. A device for treatment of retinal detachment in an eye, the eye having a scleral wall, the device comprising:
 - a main scleral buckle configured to be implanted over a retinal break at a retinal detachment repair site; and
 - a band for encircling the eye and configured to fit through a plurality of slits around a scleral wall forming shallow tunnels in the scleral wall;
 - the main scleral buckle and the encircling band having a fastening mechanism to secure the main scleral buckle with the encircling band with pressure on the scleral wall without sutures.
2. The device of claim 1 wherein one end of the main scleral buckle is permanently affixed to and connected with one end the encircling band.
3. The device of claim 1 wherein the main scleral buckle has a .circumferential configuration whereby it extends along the encircling band.
4. The device of claim 2 wherein the main scleral buckle has a radial configuration whereby it extends across the band.
5. The device of claim 1 wherein the main scleral buckle has a radial configuration whereby it extends across the band.
6. The device of claim 1 wherein the scleral buckle has a central groove along its length and the band and the main scleral buckle are configured to engage along the central groove.
7. The device in claim 6, wherein the base of the central groove in the main scleral buckle comprises a plurality of asymmetric castellations in the form of a sawtooth configured to fit complementary sawtooth castellations adjacent the two ends of the encircling band, in order to tighten the encircling band to prevent movement of the scleral buckle from the encircling band.
8. The device in claim 1, wherein the main scleral buckle has a lateral snap fit joint to enable self-assembly with supplementary scleral buckle side by side at either end of the buckle to lengthen the whole area of indentation by the main and supplementary buckles.

9. The device of claim 1 further including a supplementary scleral buckle, the supplementary scleral buckle being configured to fit to the encircling band.

10. The device of claim 1, wherein the fastening mechanism of the main scleral buckle comprises two locks along a central groove with a sawtooth profile to lock with a complementary sawtooth profile at both ends of the encircling band.

11. The device of claim 1, wherein the encircling band comprises a step on either side and along the whole length of the band for snap fit into a central groove of the scleral buckle.

12. The device in claim 1, wherein the main scleral buckle and a plurality of the supplementary scleral buckles are configured to self-assemble side by side at either end of the main scleral buckle anywhere along the encircling band to extend areas of indentation by the main and supplementary scleral buckles.

13. The device in claim 1, further comprising a supplementary buckle, wherein the supplementary buckle has no lock to lock with the two ends of the encircling band.

14. The device in claim 1, wherein the main scleral buckle has a central tongue like structure at the base of the groove for use where a retinal tear is located in between rectus muscles and where the main scleral buckle is implanted between the rectus muscles on top of the retinal tear, the tongue of the scleral buckle being configured to be inserted through the scleral tunnel in the quadrant of the retinal break to prevent antero-posterior movement of the scleral tunnel.

15. The device in claim 1, wherein the both ends of the encircling band are configured to be locked together directly by a silicone sleeve, to exert substantial indentation by the scleral buckle and the encircling band onto the eyeball.

16. The device in claim 1, the fastening mechanism comprising:
in the scleral buckle, a central groove, a plurality of spikes at the base of the central groove along the long axis of the scleral buckle, and
in the encircling band, a plurality of holes configured to receive the spikes along the encircling band to self-assemble, such that the groove accommodates the encircling band and the spikes prevent lateral movement of the scleral buckle from the encircling band.

17. The device in claim 16, wherein the encircling band comprises a plurality of form fitting full thickness holes on its undersurface along the length of the encircling band to fit with the complementary spikes.

18. The device in claim 16, wherein each end of the encircling band is locked together directly by a silicone sleeve, to exert substantial indentation by the scleral buckle and the encircling band onto the eyeball.

19. The device in claim 1, the fastening mechanism comprising:
in the scleral buckle, a central groove, a plurality of symmetric castellations across the central grove at the base of the central groove and arranged along the long axis of the scleral buckle, and

in the encircling band, a plurality of symmetric castellations configured to complement the scleral buckle such that the groove accommodates the encircling band and the castellations prevent movement of the scleral buckle from the encircling band when the encircling band is tightened by a sleeve around the ends of the encircling band.

20. A method of treating retinal detachment, comprising:
causing surface incisions in the outer surface of the scleral wall of a subject's eye to create nonpenetrating slits forming tunnels for receiving an encircling band;
implanting upon the subject's eye at least one main scleral buckle over a retinal detachment repair site on the scleral wall;
attaching the encircling band to the main scleral buckle;
threading the encircling band through the slits; and
securing the encircling band and the main scleral buckle together to apply pressure to repair retinal detachment without suturing.

21. The method according to claim 20, the attaching step comprising inserting the encircling band into a central groove of the main scleral buckle to accommodate and self-assemble with the encircling band.

22. The method in claim 20, the securing step comprising exerting pressure on the retinal detachment repair site forming an indentation effect solely via the main scleral buckle and the encircling band as tightened by the encircling band.

23. The method in claim 20, wherein the implanting of the main scleral buckle is performed after 360 degree peritomy, tagging of four rectus muscles with suture,

indentation of retinal breaks under visualization with indirect ophthalmoscopy, visible marking of the location of posterior margin of the retinal breaks externally on the eyeball surface and cryotherapy around the retinal break, and where the causing step comprises making four half-scleral-thickness scleral tunnels for implantation of encircling band.

24. The method in claim 20, wherein the threading step comprises passing the encircling band underneath the rectus muscle and while being inserted through the four scleral tunnels, thereafter inserting opposing ends of the encircling band into locks at each side of the major scleral buckle, pulling each end through the corresponding until both the main scleral buckle and encircling band have exerted appropriate indentation effect on the eyeball.

25. The method in claim 20, including implanting a supplementary scleral buckle on the eyeball via the encircling band, the supplementary scleral buckle being displaced from the main scleral buckle at a position to optimize retinal repair relative to the retinal breaks inside the eye.

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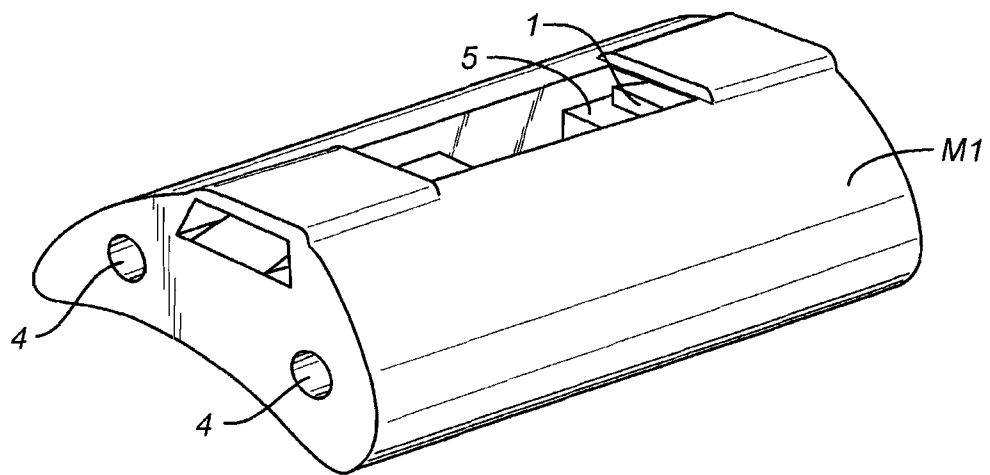


FIG. 1A

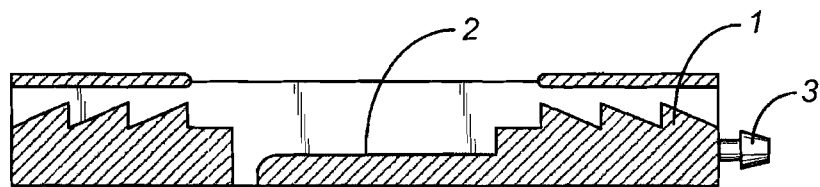


FIG. 1B

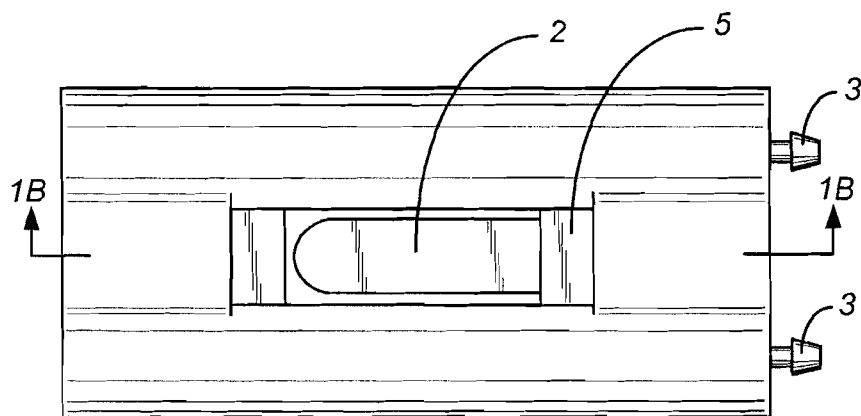
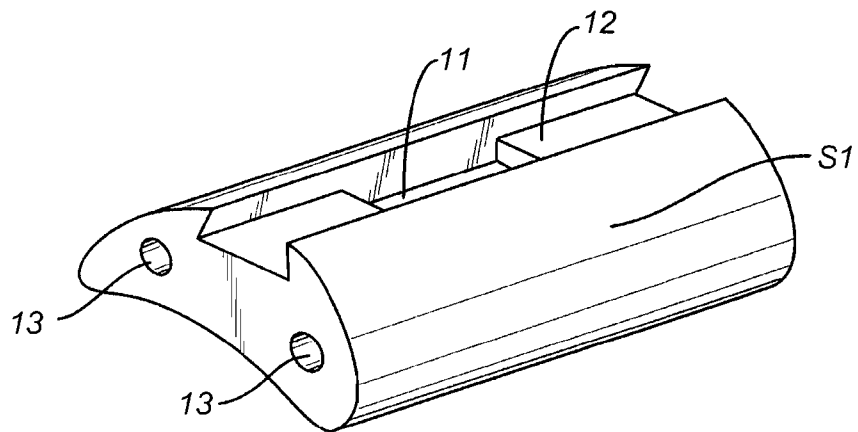
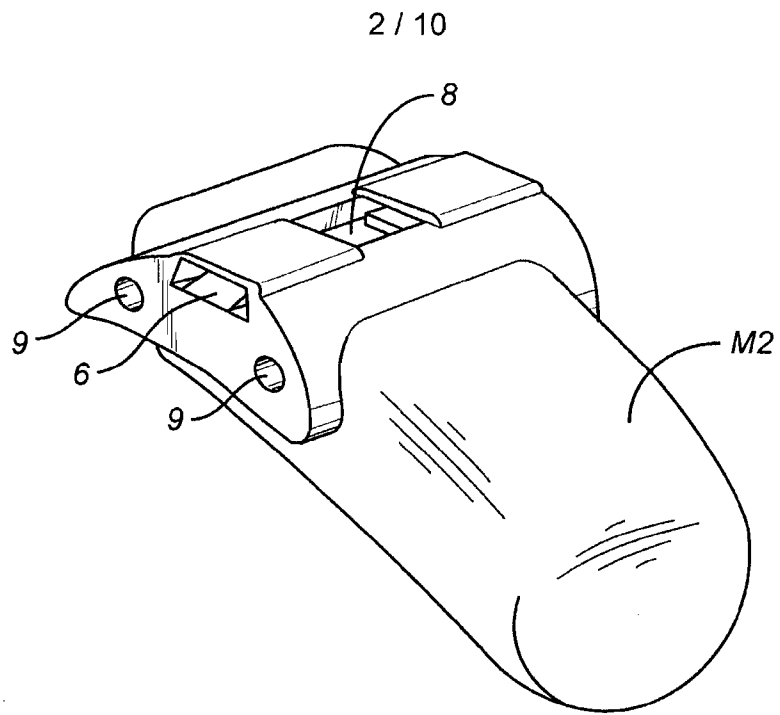


FIG. 1C



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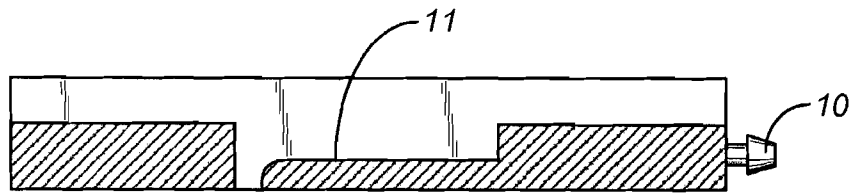


FIG. 3B

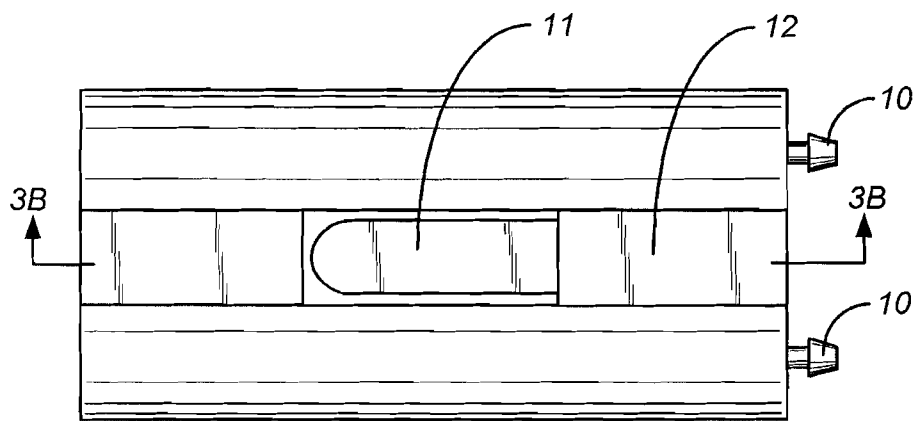


FIG. 3C

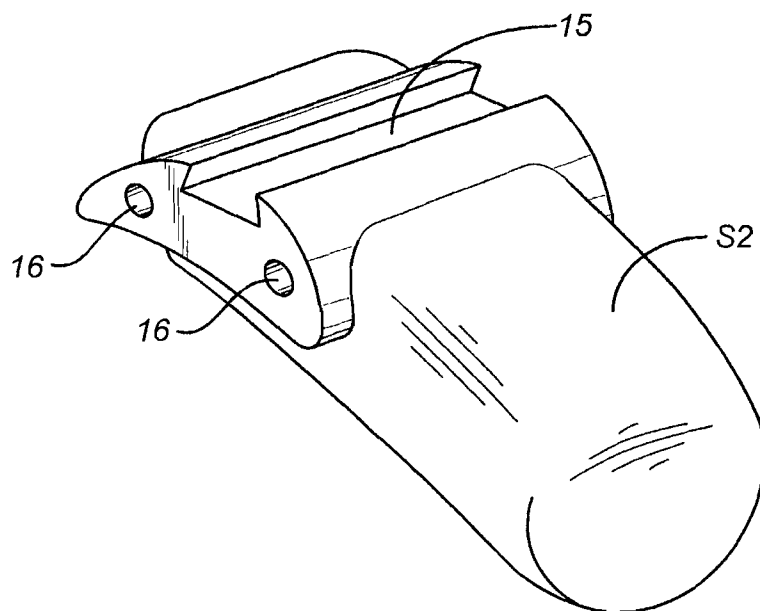


FIG. 4

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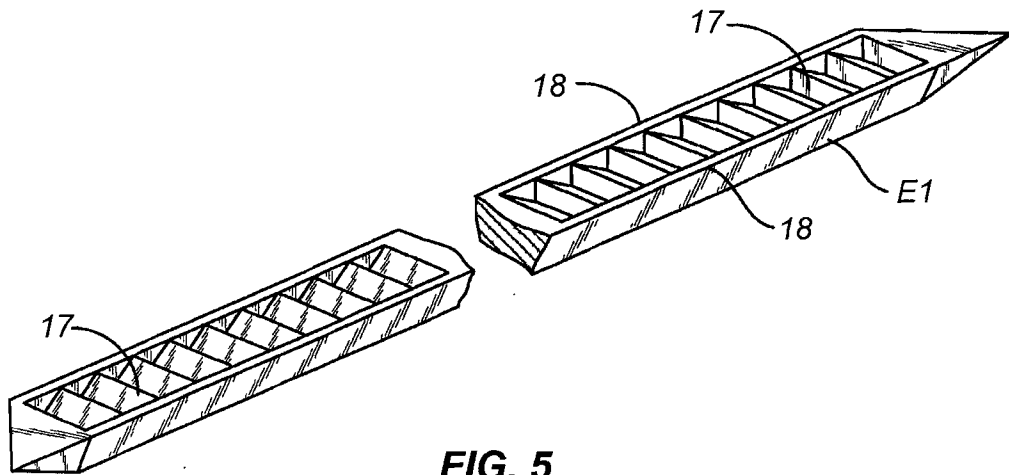


FIG. 5

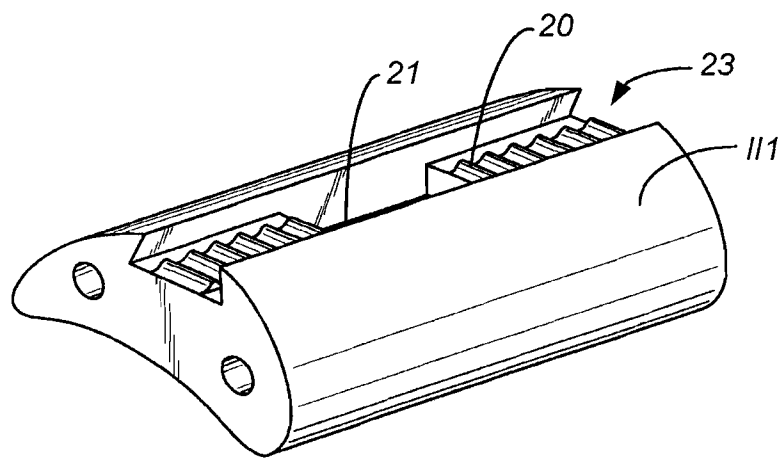


FIG. 6A

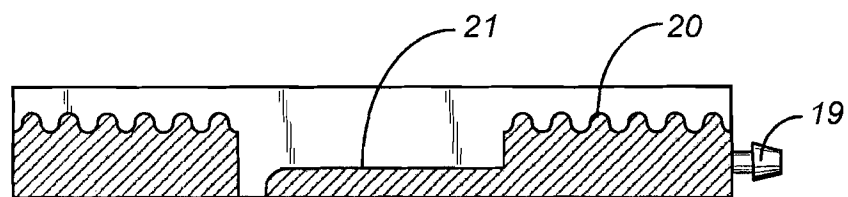


FIG. 6B

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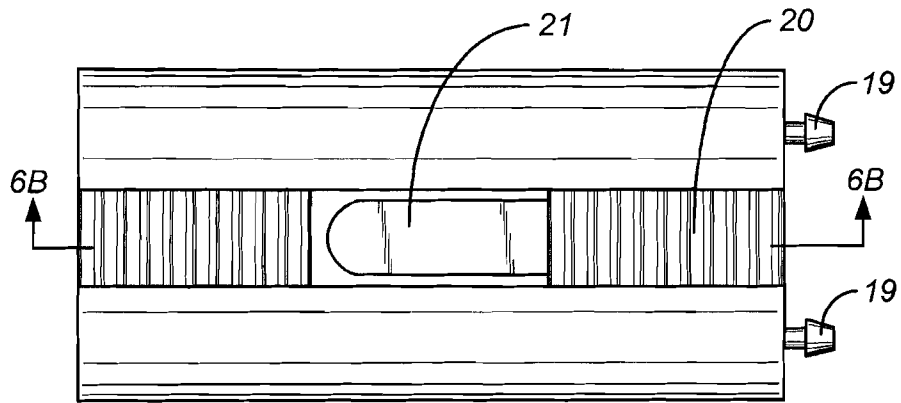


FIG. 6C

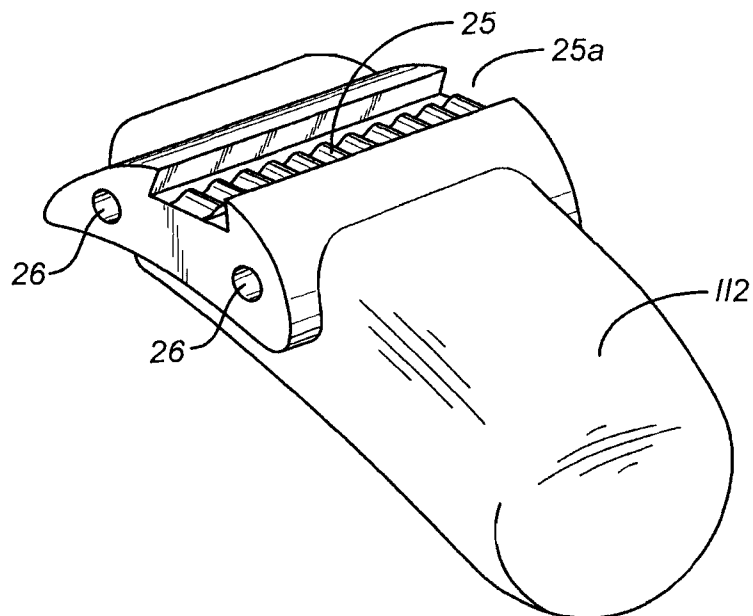


FIG. 7

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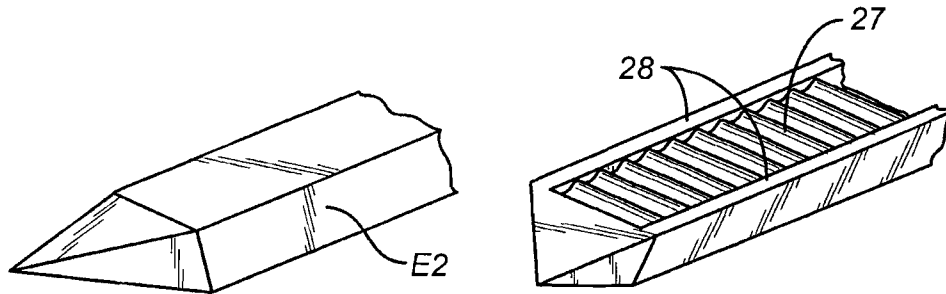


FIG. 8A

FIG. 8B

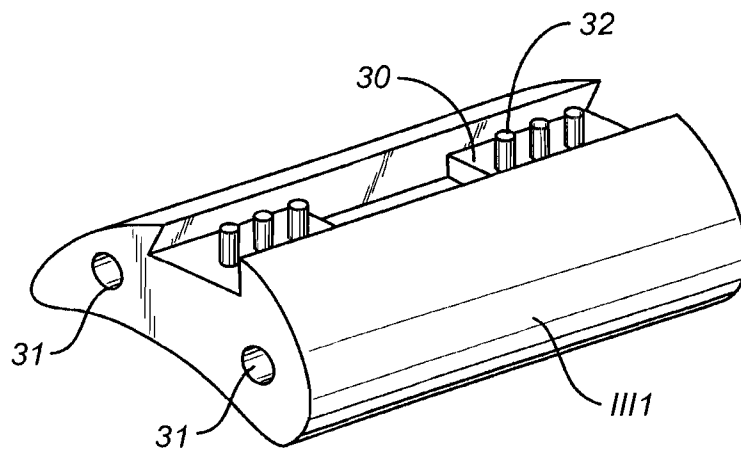


FIG. 9A

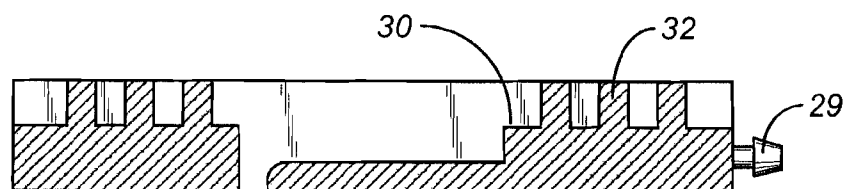


FIG. 9B

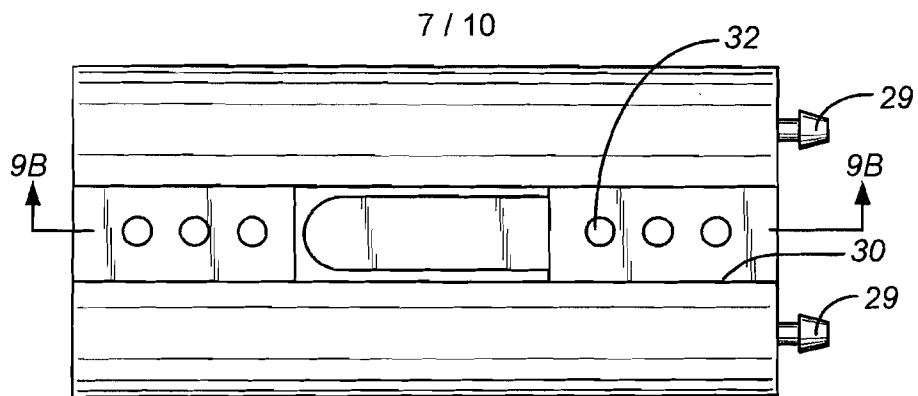


FIG. 9C

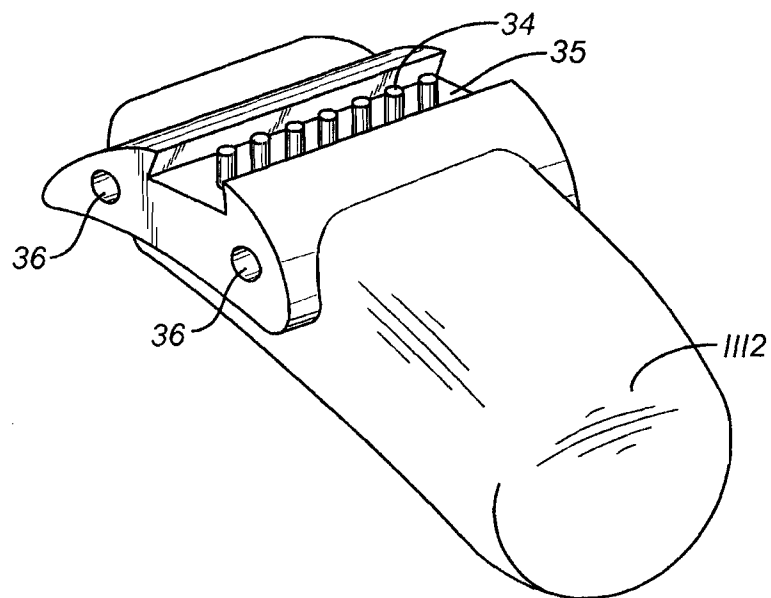


FIG. 10

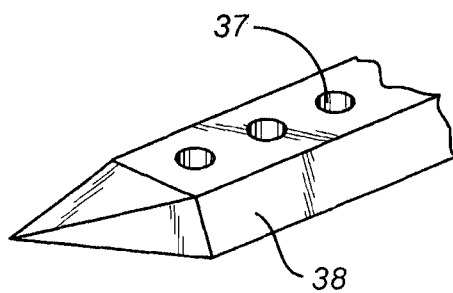


FIG. 11A

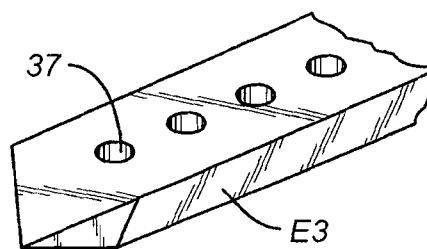


FIG. 11B

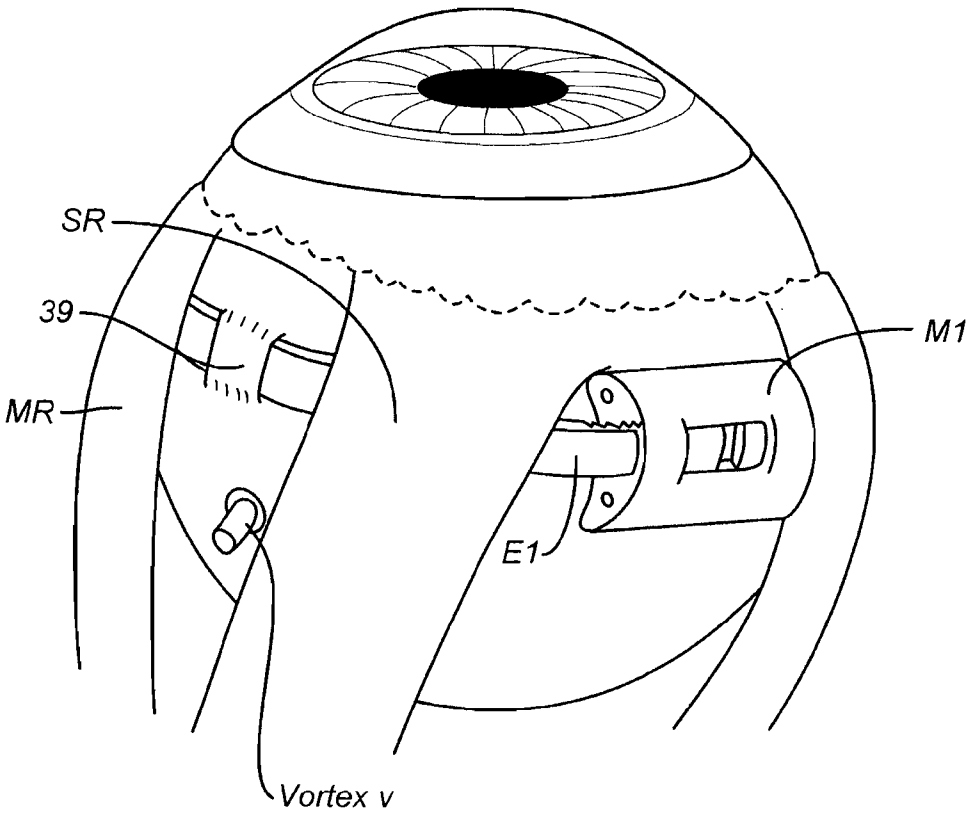


FIG. 12

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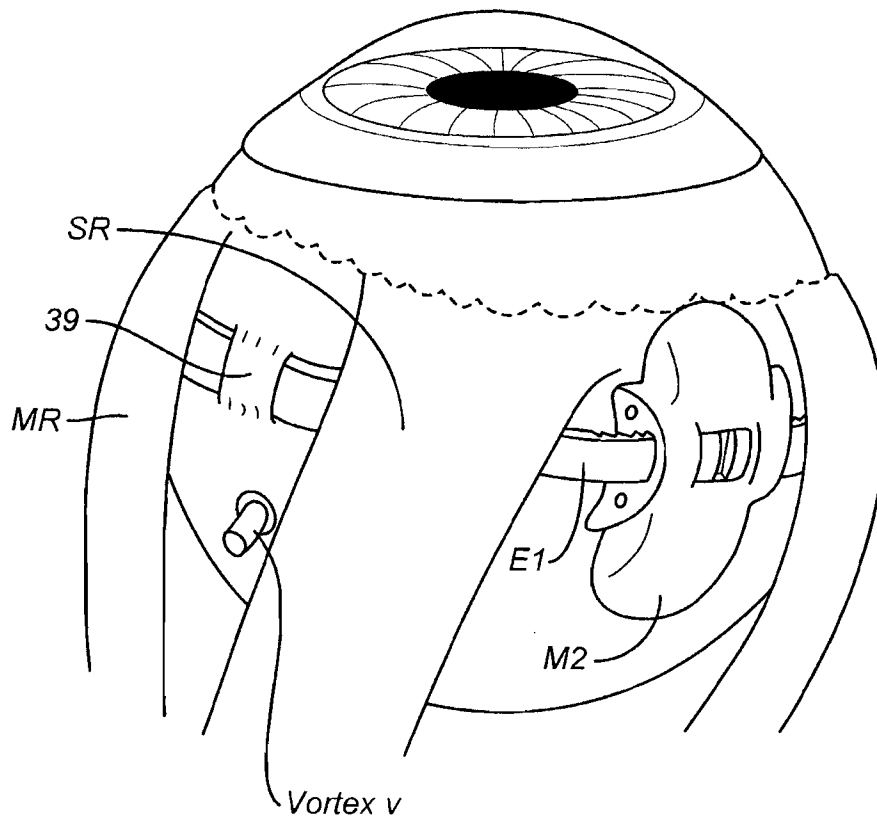


FIG. 13

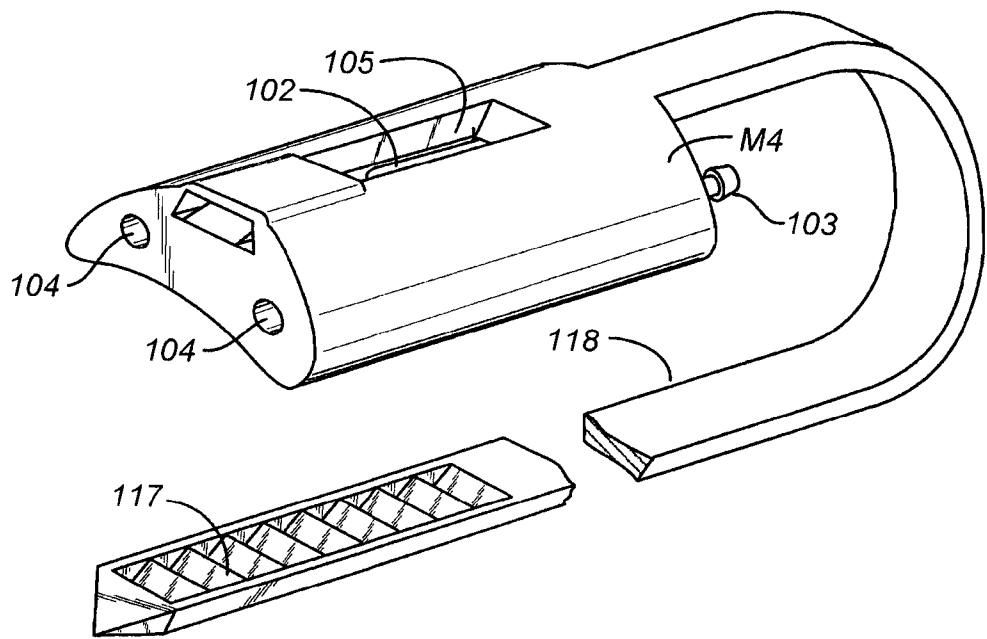


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2010/072990

A. CLASSIFICATION OF SUBJECT MATTER

See extra sheet

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)

A61F9/007, A61F9/008, A61F9/013, A61F9/00, A61F2/16, A61F2/14; EC: A61F9/007N, A61F9/007+, A61F2/14+, A61F2/16+

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)

CNPAT, CNKI, WPI, EPODOC: scleral sclera buckle? band retina retinal detach+ attach+ reattach+ groove slot trough sutur+

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US2006/0167422A1(SHAHINPOOR, Mohsen et al.) 27 July 2006 (27.07.2006) para.[0023]-[0034], figs.1-7	1-5,9,12,13,15
A	WO2007/065149A2(INNFOCUS LLC) 7 June 2007(07.06.2007) the whole document	1-19
A	US2005/020333A1(DAILEY, James P. et al.) 15 Sep. 2005(15.09.2005) the whole document	1-19
A	WO02/11648A1(ENVIRONMENTAL ROBOTS INC.) 14 Feb. 2002(14.02.2002) the whole document	1-19
A	US6117170A (BATDORF, SR, David B.) 12 Sep. 2000(12.09.2000) the whole document	1-19
A	TW275387B (LIFE SPRING BIOTECH CO., LTD.)11 Mar. 2007(11.03.2007) the whole document	1-19

☐ 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 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 application or patent but 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)	“&”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 28 Jul. 2010 (28.07.2010)	Date of mailing of the international search report 26 Aug. 2010 (26.08.2010)
Name and mailing address of the ISA/CN The State Intellectual Property Office, the P.R.China 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451	Authorized officer TANG Lirong Telephone No. (86-10)62413840

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2010/072990

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20-25
because they relate to the subject matter not required to be searched by this Authority, namely: they relate to methods for treatment of the human or animal body by surgery or therapy.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

International application No.
PCT/CN2010/072990

Form PCT/ISA /210 (patent family annex) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2010/072990

A. CLASSIFICATION OF SUBJECT MATTER

A61F 9/007 (2006.01) i

A61F 2/14 (2006.01) i

A61F 2/16 (2006.01) i