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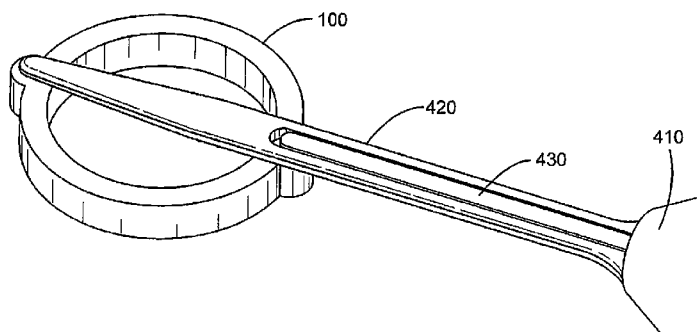


FIG. 6

(57) **Abstract:** A capsulorhexis electrode device and corresponding insertion tool are disclosed. A flexible capsulorhexis electrode device comprises an elastomeric ring, first and second electrically conductive traces disposed at a first face of the elastomeric ring and extending concentrically around the elastomeric ring, and first and second electrically conductive connectors. The first and second electrically conductive connectors are electrically connected to the first and second traces, respectively, and are disposed at opposing points across the elastomeric ring from one another. An insertion tool includes first and second stretcher bars with connectors for mating to the electrode device. One of the stretcher bars translates relative to the other to elongate the flexible electrode device for insertion into the anterior chamber of the eye through a small incision.



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FLEXIBLE, AUTOMATED CAPSULORHEXIS DEVICE

TECHNICAL FIELD

5 The present invention relates generally to the field of cataract surgery and more particularly to methods and apparatus for performing a capsulorhexis.

BACKGROUND

10 An accepted treatment for the treatment of cataracts is surgical removal of the lens and replacement of the lens function by an artificial intraocular lens (IOL). In the United States, the majority of cataractous lenses are removed by a surgical technique called phacoemulsification. Prior to removing the cataractous lens, an opening, or rhexis, must be made in the anterior capsule. During
15 phacoemulsification, there is a great deal of tension on the cut edges of the anterior capsulorhexis while the lens nucleus is emulsified. Accordingly, a continuous cut or tear (rhexis), without "tags," is a critical step in a safe and effective phacoemulsification procedure.

20 If the capsule is opened with numerous small capsular tears, the small tags that remain can lead to radial capsular tears which may extend into the posterior capsule. Such a radial tear constitutes a complication since it destabilizes the lens for further cataract removal and safe intraocular lens placement within the lens capsule later in the operation. Further, if the posterior capsule is punctured then the vitreous
25 may gain access to the anterior chamber of the eye. If this happens, the vitreous must be removed by an additional procedure with special instruments. The loss of vitreous is also associated with an increased rate of subsequent retinal detachment and/or infection within the eye. Importantly, these complications are potentially blinding.

30 Conventional equipment used for phacoemulsification includes an ultrasonically driven handpiece with an attached cutting tip. In some of these handpieces, the operative part is a centrally located, hollow resonating bar or horn directly attached to a set of piezoelectric crystals. The crystals supply ultrasonic
35 vibration for driving both the horn and the attached cutting tip during phacoemulsification.

Prior art devices and methods used for the capsulorhexis procedure require a great deal of skill on the part of the surgeon to produce a continuous curvilinear capsular opening. This is due to the extreme difficulty in controlling the path of the cutting tip of the device. For example, a typical procedure begins with a capsular incision made with a cystotome, e.g., a cutting tip as described above. This incision is then coaxed into a circular or oval shape by pushing the leading edge of the incision in the capsule, using the cystotome as a wedge rather than in a cutting fashion. Alternatively, the initial capsular incision may be torn into a circular shape by grasping the leading edge with fine caliber forceps and advancing the cut. Either of these approaches involves a very challenging maneuver and the tearing motion can sometimes lead to an undesirable tear of the capsule toward the back of the lens, even in the most experienced hands.

Moreover, even if a smooth capsular opening without tags is ultimately produced, the size and/or position of the capsular opening may present a problem. For instance, a capsular opening that is too small can impede the safe removal of the lens nucleus and cortex and prevent proper intraocular lens insertion into the lens capsule. The additional stresses necessary to accomplish the operation with a small or misplaced capsular opening put the eye at risk for zonular and capsular breakage. Either of these complications will likely increase the length and complexity of the operation and may result in vitreous loss.

A continuous, properly positioned, and circular opening is thus highly desirable because it results in: (1) a significant reduction in radial tears and tags within the anterior capsule, (2) capsule integrity necessary for proper centering of a lens prosthesis; (3) safe and effective hydrodissection; and (4) safe use of capsular procedures on patients having poorly visualized capsules and/or small pupil openings. In addition, the capsulorhexis should be properly dimensioned relative to the diameter of the IOL being implanted in order to reduce the chances of a secondary cataract, also called posterior capsule opacification ("PCO") and for use with proposed accommodative IOLs designs. Therefore, there is a continuing need for an improved device for performing an anterior chamber capsulorhexis.

SUMMARY

As described more fully below, embodiments of the present invention include a flexible capsulorhexis electrode device comprising an elastomeric ring with bipolar electrodes disposed upon the ring's front surface. The flexible electrode device is removably attachable to an insertion tool via mating connectors on the electrode device and on stretcher bars of the insertion tool. The stretcher bars are configured so that one of the stretcher bars may be translated relative to the other, stretching the flexible electrode device into an elongated configuration. In its elongated configuration, the flexible electrode device may be inserted into the anterior chamber of an eye through a small incision. After insertion into the eye, the flexible electrode device is permitted to relax into its normal, generally circular, shape, and applied to the lens capsule. The electrodes are energized, using a high-frequency power source, to cauterize a circular section of the anterior lens capsule, thus weakening the capsule tissue and defining a portion of the lens capsule that can be easily removed with forceps. After the cauterization process, the electrode device is stretched into its elongated position before removal from the eye.

Aspects of the present invention include the flexible capsularhexis electrode device and insertion tool described above, and variants thereof, as well as corresponding methods for using an autocapsularhexis system. Accordingly, embodiments of the present invention include a capsularhexis electrode device, comprising an elastomeric ring, first and second electrically conductive traces disposed at a first face of the elastomeric ring and extending concentrically around the elastomeric ring, and first and second electrically conductive connectors. The first and second electrically conductive connectors are electrically connected to the first and second traces, respectively, and are disposed at opposing points across the elastomeric ring from one another. In some embodiments, at least one of the first and second electrically conductive connectors comprises a socket disposed in the elastomeric ring; said socket is accessible to a mating connector from a direction opposite the first face in some of these embodiments. In other embodiments, at least one of the first and second electrically conductive connectors comprises a pin attached to and extending from the elastomeric ring; said pin extends from the elastomeric ring in a direction substantially opposite the first face in some of these embodiments. In various embodiments, one or both of the first and second electrically conductive traces comprises electrically conductive ink applied to the first face of the elastomeric ring or adhesive strips applied to the first face of the elastomeric ring. In several embodiments, the first trace extends completely around

the elastomeric ring; in some of these embodiments the second trace extends completely around the elastomeric ring except for a discontinuity adjacent to an electrical connection between the first trace and the first electrically conductive connector.

5

Other embodiments of the invention include an autcapsulorhexis system, comprising a handpiece, a first stretcher bar fixed to the handpiece and extending from a distal end of the handpiece, and a second stretcher bar extending from the distal end of the handpiece and attached to the handpiece so as to allow the second
10 stretcher bar to reciprocate relative to the first stretcher bar. In these embodiments, each of the first and second stretcher bars comprises an electrically conductive connector configured to mate with a corresponding connector on a removable, flexible, capsulorhexis electrode device.

15 In some of these embodiments, at least one of the electrically conductive connectors comprises a pin configured to mate with a corresponding socket on the capsulorhexis electrode device. In others, at least one of the electrically conductive connectors comprises a socket configured to mate with a corresponding pin on the capsulorhexis electrode device. In a few embodiments, the second stretcher bar
20 may be mounted to a thumb slide on the handpiece device, for manual operation by the system's user, while other systems may include an electric drive system for translating the second stretcher bar. Other embodiments of the present invention include any of the autcapsulorhexis systems described herein, with a removable, flexible, capsulorhexis electrode device installed thereupon, so that the electrically
25 conductive connectors on the first and second bars are engaged with the corresponding connectors on the capsulorhexis electrode device.

Of course, those skilled in the art will appreciate that the present invention is not limited to the above features, advantages, contexts or examples, and will
30 recognize additional features and advantages upon reading the following detailed description and upon viewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a first view of an exemplary capsulorhexis electrode device according to some embodiments of the present invention.

5 Figure 1B is a second view of the capsulorhexis electrode device of Figure 1A, illustrating the reverse face of the device.

10 Figure 2 illustrates an alternative embodiment of the capsularhexis electrode device of Figures 1A and 1B.

Figure 3 illustrates still another alternative embodiment of a capsularhexis electrode device.

15 Figure 4 illustrates a capsulorhexis insertion device according to some embodiments of the present invention.

Figure 5 illustrates the capsulorhexis insertion device of Figure 4 in a stretching configuration.

20 Figure 6 illustrates the capsulorhexis insertion device of Figure 4 with an exemplary capsulorhexis electrode device installed thereupon.

25 Figure 7 illustrates the capsulorhexis insertion system of Figure 6 in a stretching configuration.

Figure 8 is a process flow diagram illustrating an exemplary method for using an autocapsulorhexis system.

DETAILED DESCRIPTION

30

Various embodiments of the present invention provide apparatus and corresponding methods of use for performing capsulorhexis. In particular, the present invention relates to a surgical instrument, a flexible capsulorhexis electrode device, which may be positioned within the anterior chamber of an eye through a small
35 incision to perform capsulorhexis, or capsulotomy. This procedure facilitates phacoemulsification of a cataractous lens and insertion of an artificial intraocular lens (IOL).

Various methods and devices for automating the capsularhexis process have been proposed. United States Patent Application Publication No. 2006/0100617, the entire contents of which are incorporated herein by reference, describes an "autocapsularhexis" device comprising a circular, flexible ring made of an elastomer or an acrylic or thermoplastic material. Embedded within each of various
5 embodiments of this flexible ring is either a resistance-heating element or a pair of bipolar electrodes, which are energized according to known techniques to produce localized heating on the anterior capsule, so as to define a weakened boundary for an easy detachment of the portion of the capsule within the circular ring. Various
10 other devices have been proposed, many of which depend on resistive-heating cautery elements, such as U.S. Patent No. 6,066,138, issued May 23, 2000; U.S. Patent 4,481,948, issued Nov. 13, 1984; and WIPO Publication No. WO 2006/109290 A2, published October 19, 2006. The entire contents of each of the previous references are incorporated by reference herein, for the purpose of
15 providing background and context for the present invention.

Although those skilled in the art will appreciate the broader applicability of several of the inventive techniques and apparatus disclosed herein, the present invention is generally directed to methods and apparatus for performing
20 capsularhexis using high-frequency electrical current applied to the anterior lens capsule through a pair of bipolar electrodes. One approach to fabricate such types of electrodes is to form the electrodes by depositing electrically conductive ink onto an elastomeric ring to form conductive traces, e.g., by insert molding the elastomeric substrate and then screen-printing conductive traces to the desired dimensions.
25 Alternatively, an adhesive trace can be applied to a pre-fabricated elastomeric ring, or conductive traces can be combined with the elastomeric ring 110 through an insert molding process. Figure 1 thus illustrates an exemplary capsularhexis electrode device 100, according to some embodiments of the present invention, comprising a flexible, elastomeric ring 110 with bipolar electrodes 120 and 130 formed on a front
30 face 115 of the ring.

The elastomeric ring 110 and the electrodes 120 and 130 are dimensioned according to the desired size of the capsulotomy, e.g., with a diameter of approximately 5 millimeters. Those skilled in the art will appreciate that a circular
35 opening is preferred, to avoid tearing when the portion of the lens capsule within the opening is removed. Accordingly, the elastomeric ring 110 of Figure 1 and the electrodes 120 and 130 thereupon are illustrated as circular. Of course, those skilled in the art will appreciate that some variation from a circular shape may be acceptable

in some applications. Thus, the term "ring" as used herein will be understood to include generally circular, oval, or elliptical structures.

5 The electrodes 120 and 130 define the boundaries of the portion of the lens capsule that is cauterized by the high-frequency current when the electrodes are energized. When applied against the anterior lens capsule, the spacing between the electrodes 120 and 130 defines a gap across which the high-frequency current flows when the electrodes are energized. The basic principles of such electro-surgery, which may involve, for example, frequencies of greater than 100 kHz, are well known to those skilled to the art. Accordingly, the details of such procedures, which are not necessary to a complete understanding of the present invention, are not provided herein.

15 In the exemplary configuration illustrated in Figures 1A, the inner electrode 130 forms a complete circle around the face of the elastomeric ring 110. The outer electrode 120 is concentric to electrode 130, and forms a circle except for a small gap. In the pictured configuration, this discontinuity, which is near a connection point to electrode 130, is necessary to maintain electrical isolation between the electrodes.

20 Figure 1B illustrates the reverse side of the capsulorhexis electrode device 100. As will be explained in more detail below, connectors 150 provide mechanical attachment points between the flexible capsulorhexis electrode device 100 and an insertion tool. Connectors 150 also provide electrical connections between the electrodes 120 and 130 and corresponding electrodes on the insertion tool. In Figure 25 1B, connectors 150 are illustrated as sockets, extending all the way through the elastomeric ring 110. In some embodiments, these sockets may simply comprise electrically conductive ink applied on the inner surface of a hole formed through the elastomeric ring 110. In others, the sockets may be formed from electrically conductive grommets inserted into the holes, or as rigid sockets insert molded into the elastomeric ring 110. In any case, each of the two connectors 150 is electrically connected to corresponding ones of the electrodes 120 and 130 via, e.g., electrically conductive ink, adhesive electrical traces, solder, or the like, and also provides an electrically conductive contact surface for a corresponding connector on an insertion tool.

35

In an alternate embodiment, such as the embodiment pictured in Figure 2, each of the connectors comprises a pin 170 extending from the rear face 145 of the elastomeric ring. The outer surface of pins 170 comprises an electrically conductive

material, for making contact with a corresponding socket on an insertion tool, and each pin is connected to a corresponding one of electrodes 120 and 130 via, e.g., any of the means described above.

5 However, those skilled in the art will appreciate that other configurations are possible. For instance, in the configuration pictured in Figures 1 and 2, the connectors 150 are disposed at directly opposing points across the elastomeric ring 110 from one another, and are both outside the concentric circles formed by electrodes 120 and 130, necessitating the small discontinuity in electrode 120
10 adjacent to the point where electrode 130 connects to one of the connectors 150. In other configurations, one or both of the connectors may instead be positioned inside the concentric circles formed by electrodes 120 and 130. If one connector is disposed towards the interior of the ring and the other towards the exterior, both of the electrodes 120 and 130 may form a complete loop. An exemplary capsulorhexis
15 device according to this configuration is shown in Figure 3. Those skilled in the art will recognize, however, that the embodiment pictured in Figure 3 will have a somewhat larger insertion profile than the embodiments pictured in Figures 1 and 2, assuming that the devices are similarly dimensioned.

20 Those skilled in the art will also appreciate that designations herein of a “front face” and a “rear face” are arbitrary, and adopted only for the sake of convenience. Unless specified otherwise, the term “front face” refers to the surface upon which the electrodes 120 and 130 are formed, while “rear face” refers to the opposite surface. Those skilled in the art will also appreciate that either or both of front face 115 and
25 145, or any of the flat surfaces, may be curved. In some embodiments, for example, the front face 115 may have a slightly convex curve, rather than a flat surface. On the other hand, the reverse side of electrode device 100 might have a concave curve, in some cases to the extent that the inner, outer, and reverse surfaces of the device 100 form a single curved contour.

30 The female connectors 150 or the male connectors 170 may be used to facilitate “folding” of the elastomeric capsulorhexis electrode device 100 by stretching it into a shape that can be inserted into an eye through a very small incision, e.g., through a 2 millimeter incision. This mechanical stretching of the capsulorhexis
35 electrode device 100 can be achieved with an insertion tool such as the one pictured in Figures 4, 5, 6, and 7. Insertion tool 400 includes a handpiece 410, a first stretcher bar 420, and a second stretcher bar 430. The first and second stretcher bars 420 and 430 have electrically conductive connectors 425 and 435, respectively,

which are configured for mechanical and electrical connection to corresponding connectors on a flexible capsulorhexis electrode device. In the pictured embodiment, the first stretcher bar 420 is rigidly fastened to the handpiece 420, while the second stretcher bar 430 can be translated from an extended position, as shown in Figure 4, to a retracted position, as shown in Figure 5. This translation may be under the manual control of an operator, such as via a thumb slide (not shown) disposed on the handpiece 410, in some embodiments. In other embodiments, the second stretcher bar 430 may be translated using a motorized drive system, using any of a variety of miniature linear actuators.

As shown in Figure 6, a flexible capsulorhexis electrode device 100 may be installed onto the connectors 425 and 435, with the second stretcher bar 430 in its extended position. The electrode device 100 is installed onto the connectors 425 and 435 so that the electrodes 120 and 130 are facing away from the tool.

Linear translation of the second stretcher bar 430 to its retracted position stretches the electrode device 100 so that it may be inserted into the eye through an incision that is considerably smaller than the maximum dimension of the electrode device in its "relaxed" configuration. Figure 7 illustrates the flexible electrode device 100 in its stretched configuration. After insertion into the eye, the second stretcher bar 430 may be translated into its extended position again, permitting the flexible electrode device 100 to return to its generally circular shape for the capsulorhexis procedure.

The particular insertion tool 400 pictured in Figures 4-7 comprises mating connectors 425 and 435 in the form of pins, suitable for mechanical and electrical mating with the female (socket) connectors 150 of Figures 1A and 1B. Those skilled in the art will appreciate, however, that different mating connectors 425 and 435 suitable for mating with male connectors 170 (as shown in Figure 2) may be used in alternate embodiments. Thus, for example, connectors 425 and 435 may each comprise a post, in some embodiments, extending from respective stretcher bars, with a socket disposed in each for mechanical and electrical engagement with the male connectors 170. Other embodiments may employ one female connector and one male connector, for mating with a suitably designed electrode device. In any case, the connectors 425 and 435 comprise an electrically conductive surface that contacts the corresponding connector on the electrode device. This electrically conductive surface provides an electrical attachment to supply wires or leads, which may extend through the respective stretcher bars 420 and 430, through the

handpiece 410, and to an appropriate power source. As noted above, this power source provides a high-frequency current to the anterior lens capsule when the device is positioned within the eye and energized.

5 With the above-described device configurations in mind, those skilled in the art will appreciate that Figure 8 illustrates an exemplary method for utilizing an autocapsulorhexis system according to some embodiments of the present invention. The illustrated method begins, as shown at block 810, with the attachment of a removable, flexible electrode device to first and second stretcher bars of an insertion
10 tool, e.g., as shown in Figure 6. The electrode device is readily assembled to and removed from the tool and may in some embodiments be disposable. Those skilled in the art will appreciate that this approach allows the insertion tool (which includes the stretcher bars and the mating connectors) to be sterilized and reused multiple
15 times.

In any event, the illustrated procedure continues, as shown at block 820, with translation of one stretcher bar, relative to the other, so that the flexible electrode device is stretched into an elongated configuration for insertion into the anterior chamber of a patient's eye. After insertion into the eye, as shown at block 830, the
20 stretcher bar is returned to the extended position, as shown at block 840, thus allowing the flexible electrode device to relax to its normal shape. The front face of the electrode device is placed against the anterior lens capsule, so that the bipolar electrodes are in contact with or in close proximity to the capsule, and the device energized, as shown at block 850. After energizing the device, the capsule area
25 defined by the electrodes is weakened and subject to easy removal using conventional forceps.

After the device is energized, the stretcher bar is translated once more, as shown at block 860, to once again stretch the flexible electrode device into its
30 elongated position. The device may then be easily removed from the anterior chamber of the eye, as shown at block 870.

The preceding descriptions of various embodiments of a flexible capsulorhexis electrode device, an autocapsulorhexis insertion tool, and methods for
35 utilizing these devices, were given for purposes of illustration and example. Those skilled in the art will appreciate, of course, that the present invention may be carried out in other ways than those specifically set forth herein without departing from essential characteristics of the invention. The present embodiments are thus to be

considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

CLAIMS

What is claimed is:

1. A capsulorhexis electrode device, comprising:
5 an elastomeric ring;
first and second electrically conductive traces disposed at a first face of the elastomeric ring and extending concentrically around the elastomeric ring;
a first electrically conductive connector, electrically connected to the first trace; and
10 a second electrically conductive connector electrically connected to the second trace and disposed at an opposing point across the elastomeric ring from the first electrically conductive connector.
2. The capsulorhexis electrode device of claim 1, wherein at least one of the
15 first and second electrically conductive connectors comprises a socket disposed in the elastomeric ring.
3. The capsulorhexis electrode device of claim 2, wherein said socket is accessible to a mating connector from a direction opposite the first face.
20
4. The capsulorhexis electrode device of claim 1, wherein at least one of the first and second electrically conductive connectors comprises a pin attached to and extending from the elastomeric ring.
- 25 5. The capsulorhexis electrode device of claim 4, wherein the pin extends from the elastomeric ring in a direction substantially opposite the first face.
6. The capsulorhexis electrode device of claim 1, wherein at least one of the first and second electrically conductive traces comprises electrically conductive ink
30 applied to the first face of the elastomeric ring.
7. The capsulorhexis electrode device of claim 1, wherein at least one of the first and second electrically conductive traces comprises adhesive strips applied to the first face of the elastomeric ring.
35
8. The capsulorhexis electrode device of claim 1, wherein the first trace extends completely around the elastomeric ring.

9. The capsulorhexis electrode device of claim 8, wherein the second trace extends completely around the elastomeric ring except for a discontinuity adjacent to an electrical connection between the first trace and the first electrically conductive connector.

10. An autocapsulorhexis system, comprising:
a handpiece;
a first stretcher bar fixed to the handpiece and extending from a distal end of
the handpiece; and
5 a second stretcher bar extending from the distal end of the handpiece and
attached to the handpiece so as to allow the second stretcher bar to reciprocate
relative to the first stretcher bar;
wherein each of the first and second stretcher bars comprises an electrically
conductive connector configured to mate with a corresponding connector on a
10 removable, flexible, capsulorhexis electrode device.

11. The autocapsulorhexis system of claim 10, wherein at least one of the
electrically conductive connectors comprises a pin configured to mate with a
corresponding socket on the capsulorhexis electrode device.
15

12. The autocapsulorhexis system of claim 10, wherein at least one of the
electrically conductive connectors comprises a socket configured to mate with a
corresponding pin on the capsulorhexis electrode device.

13. The autocapsulorhexis system of claim 10, wherein the second stretcher
bar is mounted to a thumb slide on the handpiece device.
20

14. The autocapsulorhexis system of claim 10, further comprising the
removable, flexible, capsulorhexis electrode device, wherein the electrically
25 conductive connectors on the first and second bars are engaged with the
corresponding connectors on the capsulorhexis electrode device.

15. The autocapsulorhexis system of claim 10, further comprising a high-
frequency power source electrically connected to the electrically conductive
30 connectors.

16. A method of using an autocapsulorhexis system, the method comprising:
attaching a removable, flexible, electrode device to first and second stretcher
bars of a handheld insertion tool;

5 translating the second stretcher bar relative to the first stretcher bar so as to
stretch the flexible electrode device to an elongated configuration for insertion into
the anterior chamber of an eye through an incision;

after insertion of the elongated electrode device into the eye, translating the
second stretcher bar relative to the first stretcher bar so as to permit the flexible
electrode device to return to a generally circular configuration within the eye;

10 applying the flexible electrode device to the lens capsule of the eye and
energizing the electrode device; and

translating the second stretcher bar relative to the first stretcher bar so as to
stretch the flexible electrode device to an elongated configuration for removal from
the eye.

15

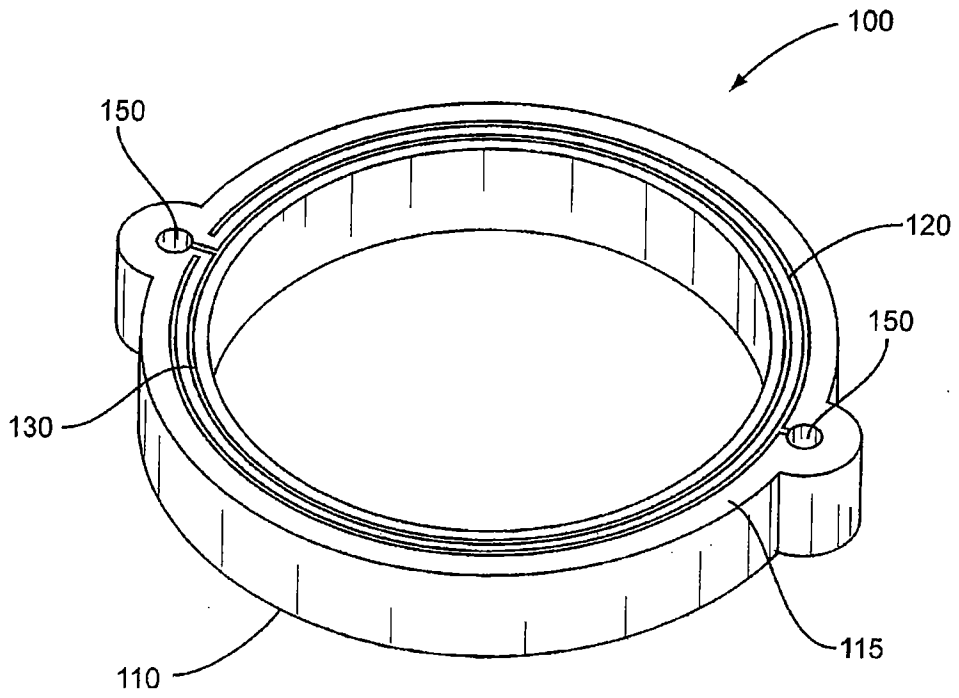


FIG. 1A

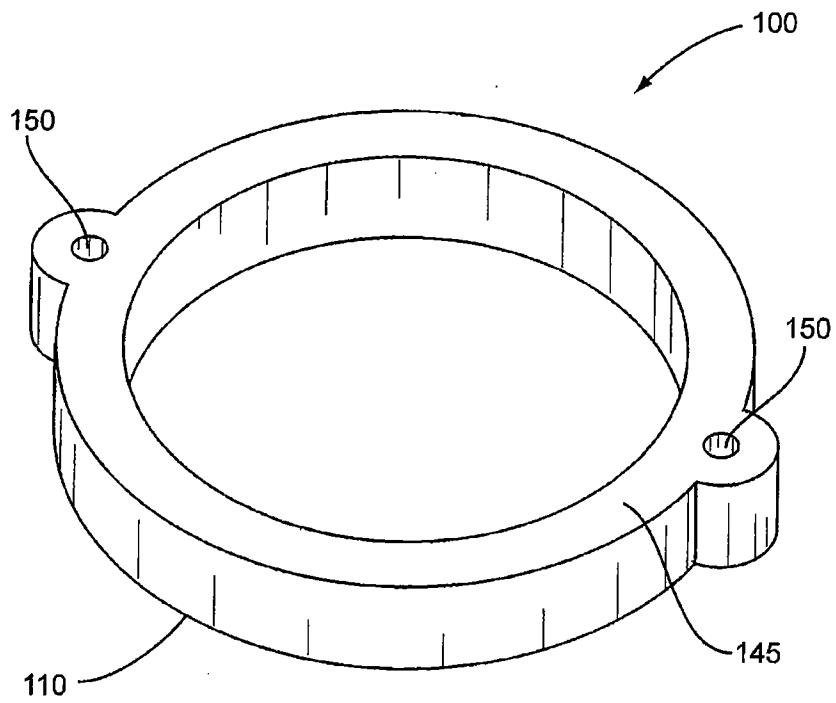


FIG. 1B

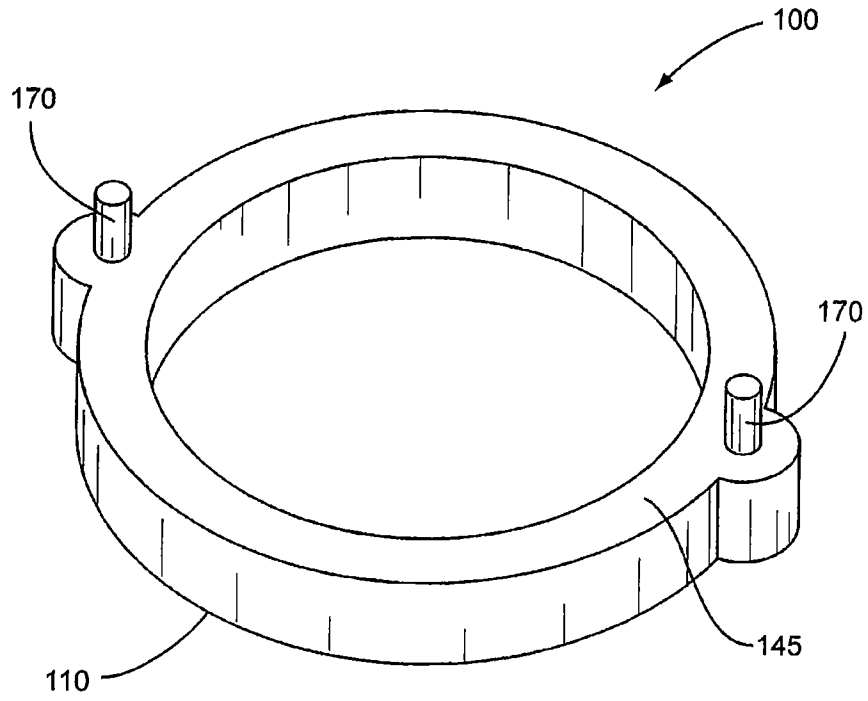


FIG. 2

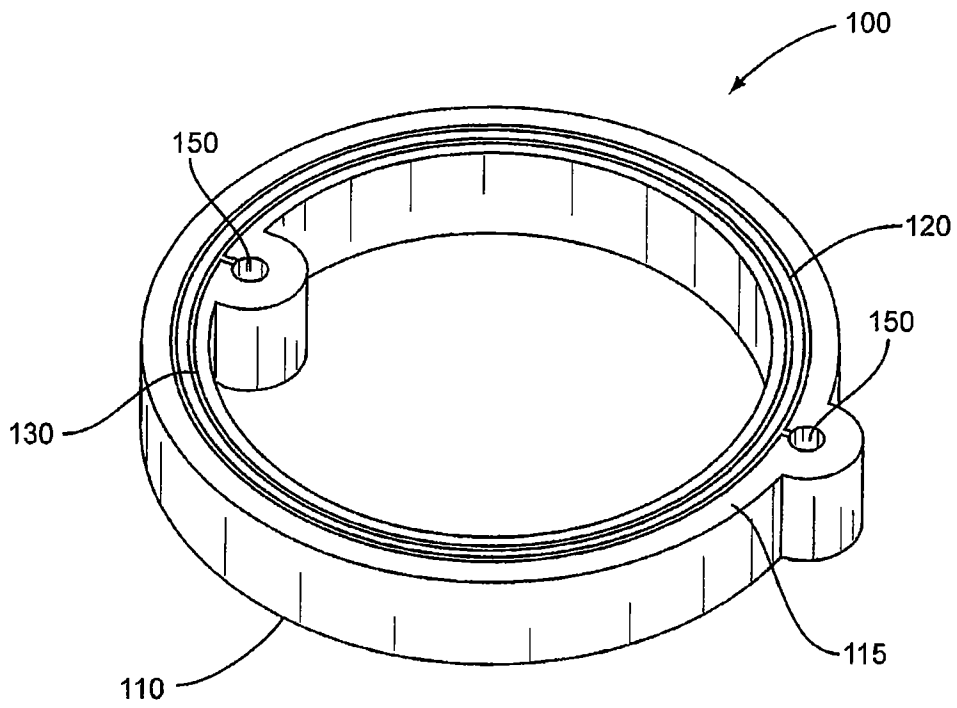


FIG. 3

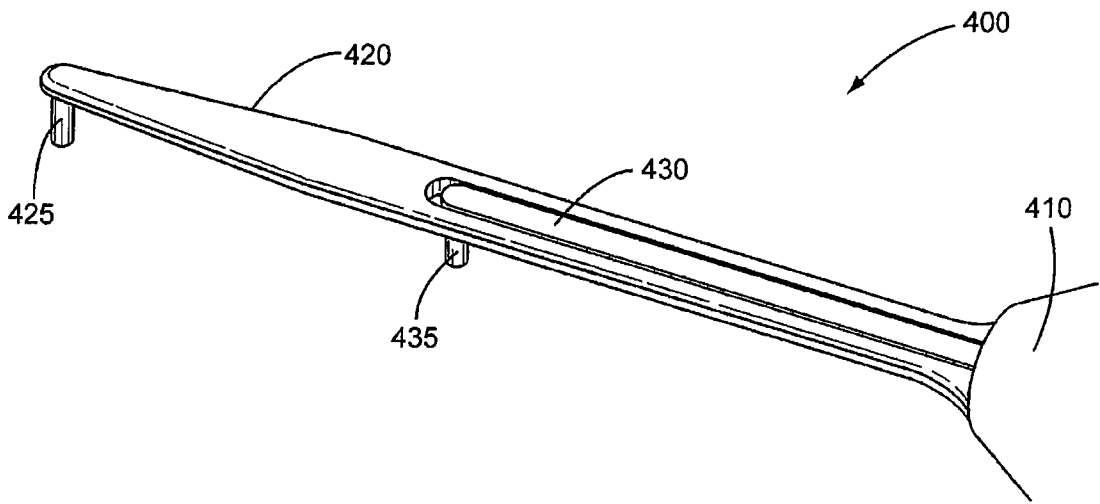


FIG. 4

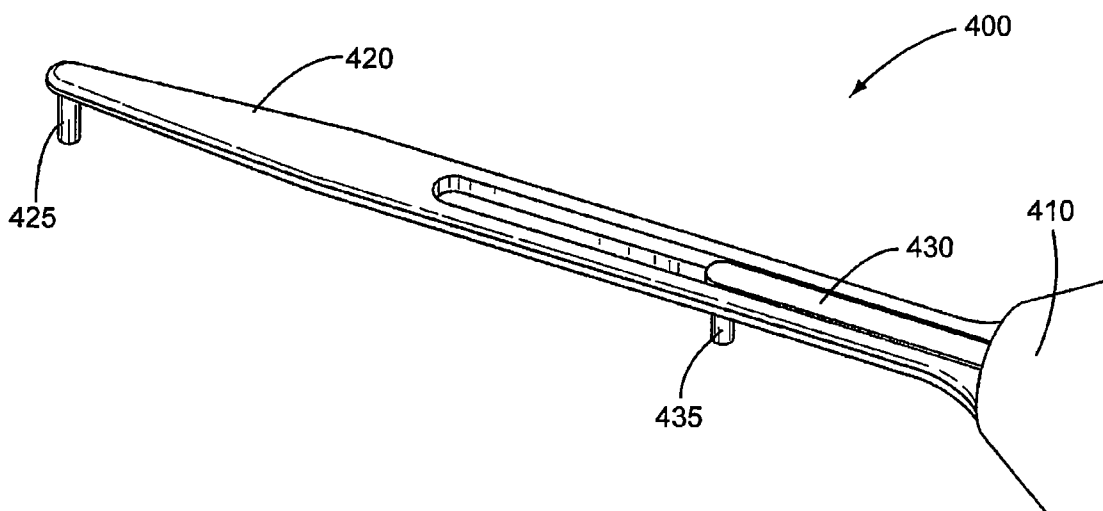


FIG. 5

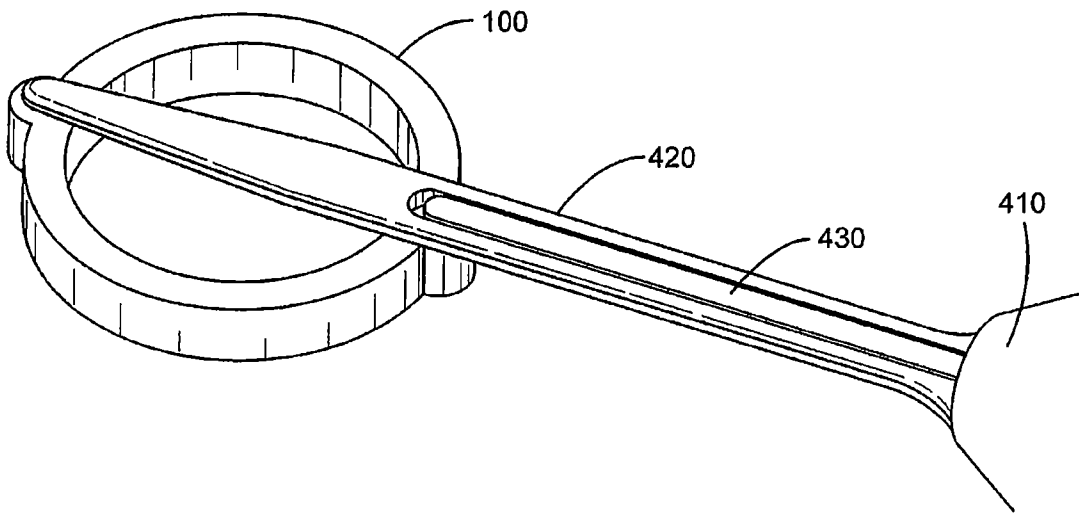


FIG. 6

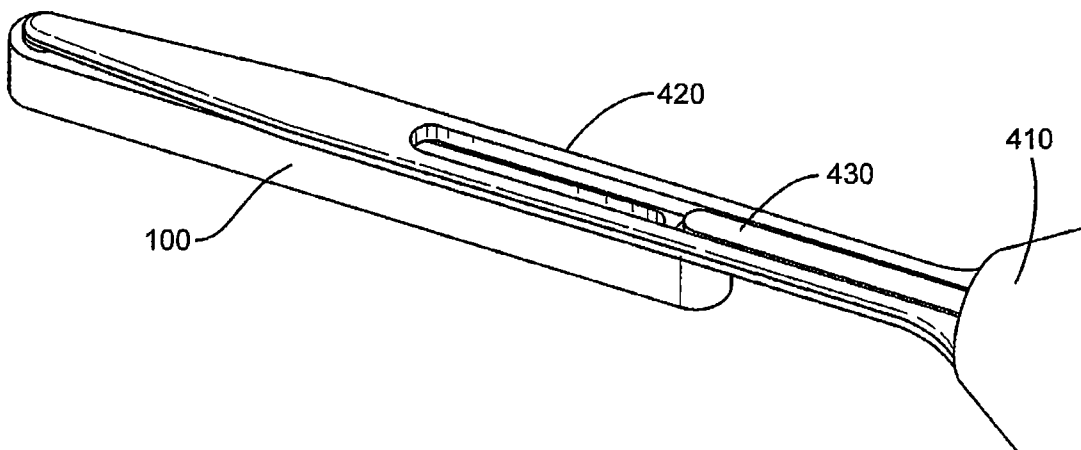
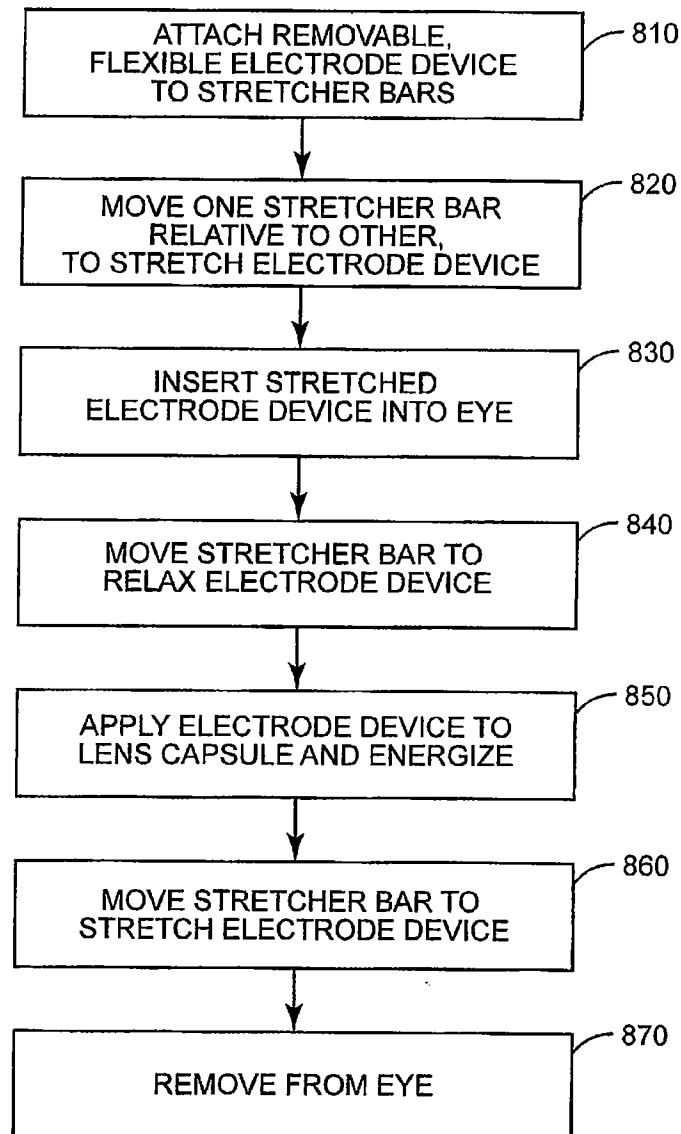


FIG. 7

**FIG. 8**

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/067305

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14 A61F9/007
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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/109290 A2 (VALENS ASSOCIATED INC [PA]; BEN-NUN JOSHUA [IL]) 19 October 2006 (2006-10-19) cited in the application page 9, line 22 - line 32; figures 5,6	10-15
A	US 2006/100617 A1 (BOUKHNY MIKHAIL [US]) 11 May 2006 (2006-05-11) cited in the application paragraphs [0020] - [0022]; figures 1,2	1
A	US 4 481 948 A (SOLE GARY M [US]) 13 November 1984 (1984-11-13) abstract; figures 1,2	1
A	US 5 135 530 A (LEHMER LARA [US]) 4 August 1992 (1992-08-04) figures 8-11	10

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "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)
- "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

- "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
- "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
- "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.
- "&" document member of the same patent family

Date of the actual completion of the international search

1 April 2010

Date of mailing of the international search report

13/04/2010

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/067305

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.: 16
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 fees.
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 SEARCH REPORT

Information on patent family members

International application No PCT/US2009/067305

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006109290 A2	19-10-2006	CN 101557769 A EP 1871216 A2 JP 2008538306 T	14-10-2009 02-01-2008 23-10-2008
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US 4481948 A	13-11-1984	NONE	
US 5135530 A	04-08-1992	NONE	