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(71) Applicant: **E.K.-D.D.S. LTD** [IL/IL]; Moshav Bet Herut 1/A, 40291 D. N. Kfar Vitkin (IL).

(72) Inventor: **BEN NUN, Joshua**; Moshav Bet Herut 1/A, 40291 D. N. Kfar Vitkin (IL).

(74) Agent: **KAY, Simon**; P.O.Box 2817, Kadima Tzoran 60920 (IL).

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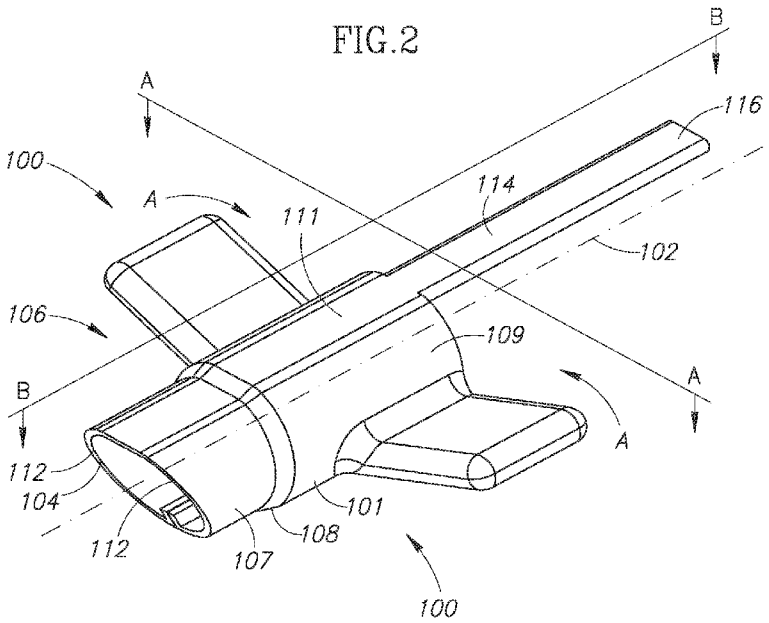
(54) Title: INSERTION APPARATUS FOR USE WITH TISSUE HOLDING FIXTURE



(57) Abstract: Insertion apparatus (100) for use with a tissue holding fixture (10) having a leading resiliently flexible unflexed flat fixation ring (11) holding a Descemet's membrane implant (12). The insertion apparatus includes a shape memory housing (101) bounding a shape memory housing lumen (103) in an unflexed closed configuration and having an opposite pair of wing-like finger grips (121). Initial manual compression force to urge the opposite pair of wing-like finger grips towards one another flexes the shape memory housing into a flexed near-flat open configuration for enabling placement of the unflexed flat fixation ring therein. Subsequent release of the compression force enables the shape memory housing to revert to its unflexed closed configuration for curling the fixation ring inside the shape memory housing.

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INSERTION APPARATUS FOR USE WITH TISSUE HOLDING FIXTURE

Field of the Invention

This invention relates to ophthalmic medical devices in general and in particular to ophthalmic medical devices for assisting in insertion of ophthalmic tools through a corneal or corneo-scleral incision.

Background of the Invention

The cornea is a protective dome-shaped layer of clear tissue covering the front of the eye. The innermost layer of the cornea consists of non-replicating single cells layer known as endothelial cells. In normal healthy membranes, there is a cell density of between about 1500 and 2500 cells per mm^2. Once the population of endothelial cells decreases below a critical number that is about 600 cells per mm^2, the cornea loses its optical qualities and becomes edematous. This condition is known as corneal edema.

In corneal edema, the cornea becomes overly hydrated with accumulated fluid. Corneal edema may result in deteriorated vision. If such corneal edema becomes severe, blisters can appear on the cornea. Corneal edema is a result of a lack of viable cells in the corneal endothelium. In such cases, surgery may be needed to treat corneal edema. In one technique, the cornea is replaced with a transplanted full thickness cornea.

The purpose of a surgical transplant is to replace a section of the corneal endothelium lacking sufficient healthy cells with a section of donor endothelium having a higher density of healthy cells. The full thickness graft of a damaged cornea has been the treatment for corneal edema for many years. However, this approach has some disadvantages including a high degree of post-operative astigmatism, a lack of predictable refractive outcome, and disturbance to the ocular surface.

Recently, the surgical trend has shifted towards removal of only a thin layer of tissue from a diseased eye and replacing it with corresponding donor tissue from a fresh human cadaver eye. The implanted tissue consists of a layer attached to the posterior corneal stroma (the Descemet's membrane) that carries on its surface a monolayer of the endothelial cells known as DMEK. If the implantable tissue consists also a layer of corneal stroma, the procedure is called Descemet Stripping Automated Endothelial Keratoplasty (DSAEK). Both DMEK and DSAEK have dramatically improved the optical outcome of corneal implantation and decreased the rate of transplant rejection. However, during surgical implantation in a recipient eye, endothelial cell damage is massive and it has been documented in various clinical studies that surgical related damage induces 30%-40% endothelial cell death in the first year.

To minimize surgical related corneal astigmatism, a surgical incision made in a patient's cornea for removing his Descemet's membrane and for inserting a donor Descemet's membrane, is preferably as short as possible typically about 5 mm long. To keep the incision short, the diseased Descemet's membrane must be folded to remove it through the short incision. Similarly, the replacement Descemet's membrane must be folded to introduce it through the incision. Manipulating the folded donor Descemet's membrane inside a recipient eye to its unfolded shape attached to the inner corneal surface is a highly skilled task, requiring highly skilled eye surgeons, making the surgical procedure time consuming and limited to a small group of specialists.

In commonly assigned PCT International Application No. PCT/IL2013/050773 published under PCT International Publication No. WO 2014/049591 and PCT International Application No. PCT/IL2015/050049 published under PCT International Application No. WO 2015/111040, incorporated herein by reference, a dedicated apparatus and associated method for sectioning a Descemet's membrane, storing it and manipulating it during a surgical implantation into an eye via a truncated conical inserter is described.

A thin circular implantable tissue that is about 8.0 mm in diameter is attached around its outer edge to a circumferential supporting flat ring of approximately 9.0mm in total diameter that supports the thin tissue and prevents it from folding in on itself and damaging the endothelial cells on that tissue. To enable the insertion of the tissue with its supporting ring into the eye via a short corneal incision, the conical inserter is used. The flat ring is inserted in the wide mouth of the conical inserter which has an inner diameter of about 9.0 mm. As the flat ring is pushed through the conical inserter, it gradually curls along its insertion axis and doubles over so that it exits the narrow round side which is around 4.0mm in diameter as a cylinder with 4 mm diameter that may then be inserted into the eye via corneal incision of about 5.0 mm long.

Summary of the Invention

The present invention relates to an improved insertion apparatus for use with a tissue holding fixture for assisting in insertion of the tissue holding fixture through a corneal or corneo-scleral incision into an eye. The tissue holding fixture has a leading about 9mm diameter resiliently flexible unflexed flat fixation ring with a Descemet's membrane implant.

The insertion apparatus includes a shape memory housing bounding a shape memory housing lumen in an unflexed closed configuration and having an opposite pair of wing-like finger grips. Initial manual compression force to urge the opposite pair of wing-like finger grips towards one another flexes the shape memory housing into a flexed near-flat open configuration for enabling placement of the unflexed flat fixation ring therein. Subsequent release of the compression force enables the shape memory housing to revert to its unflexed closed configuration for curling the fixation ring inside the shape memory housing.

The insertion apparatus is designed such that its shape memory housing is shaped and dimensioned for insertion through an about 5mm long corneal or corneo-scleral incision in its unflexed closed configuration and can be urged into a

flexed near-flat open configuration having a sufficiently wide span to receive an about 9mm unflexed fixation ring with a Descemet's membrane implant. By way of example, a tube with a 3 mm diameter has a 3π mm perimeter corresponding to a shape memory housing in its unflexed closed configuration and its flexed near-flat open configuration.

Brief Description of Drawings

In order to understand the invention and to see how it can be carried out in practice, various embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings in which similar parts are likewise numbered, and in which:

Fig. 1 is a front perspective view of a tissue holding fixture as shown in commonly assigned PCT International Application No. PCT/IL2015/050049 published under PCT International Publication No. WO 2015/111040 Figure 3g;

Fig. 2 is a front perspective view of a first embodiment of an insertion apparatus in accordance with the present invention in an unflexed closed configuration;

Fig. 3 is a transverse cross section of the insertion apparatus in its unflexed closed configuration along line A-A in Figure 2;

Fig. 4 is a front perspective view of the insertion apparatus in a flexed near-flat open configuration;

Fig. 5 is a transverse cross section of the insertion apparatus in its flexed near-flat open configuration along line C-C in Figure 4;

Fig. 6 is a transverse cross section of the insertion apparatus in its unflexed closed configuration along line A-A in Figure 2 accommodating a curled tissue holding fixture;

Fig. 7 is a longitudinal cross section of the insertion apparatus in its unflexed closed configuration along line B-B in Figure 2 accommodating a curled tissue holding fixture;

Fig. 8 is a transverse cross section of a second embodiment of an insertion apparatus in accordance with the present invention; and

Fig. 9 is a front perspective view of a third embodiment of an insertion apparatus in accordance with the present invention.

Detailed Description of Drawings

Figure 1 shows a tissue holding fixture 10 as disclosed in commonly assigned PCT International Application No. PCT/IL2015/050049 published under PCT International Publication No. WO 2015/111040 and in Figure 3g in particular. The tissue holding fixture 10 has a leading resiliently flexible unflexed flat fixation ring 11 holding a Descemet's membrane implant 12 and a trailing pair of elongated electrodes 13. The fixation ring 11 is formed from electrical and thermal insulating material, for example, silicon, and the like. The fixation ring 11 is mounted on a near circular electrode 14 denoted by dashed lines in a similar manner to a car tire. The near circular electrode 14 is in electrical connection with the trailing pair of electrodes 13. The fixation ring 11 has a diameter D of about 9mm.

Figures 2 to 7 show an insertion apparatus 100 for use with the tissue holding fixture 10. The insertion apparatus 100 includes a resiliently flexible shape memory housing 101 having a longitudinal shape memory housing centerline 102 and bounding a shape memory housing lumen 103 in an unflexed closed configuration. The shape memory housing 101 is formed from suitable bio-compatible shape memory materials including metals, polymer material, and the like. The shape memory housing lumen 103 preferably has a uniform cross section along the longitudinal shape memory housing centerline 102. The cross section can be circular, elliptical, oval, and the like. The shape memory housing 101 has a similar length as the fixation ring's diameter D.

The shape memory housing 101 includes a thin walled beveled leading tip 104 for insertion through a corneal or sclero-corneal incision. The shape memory

housing 101 includes a stepped outer surface 106 having a small cross section leading section 107, an intermediate shoulder 108 and a large cross section trailing section 109. The intermediate shoulder 108 limits insertion of the shaped memory housing 101 through a corneal or corneo-scleral incision. The intermediate shoulder 108 also acts to seal a corneal or corneo-scleral incision to prevent leakage therefrom. The stepped outer surface 106 is preferably formed by the large cross section trailing section 109 having a thicker wall than the small cross section leading section 107.

The shape memory housing 101 is constituted from three integral formed parts as follows: a central panel 111 and an opposite pair of lateral curved walls 112 meeting the central support 111 at longitudinally directed fold lines 113. The central panel 111 extends beyond the opposite pair of lateral curved walls 112 as a position rod 114 having an extension rod free end 116. The opposite pair of lateral curved walls 112 terminate at longitudinal directed rim extensions 117 inwardly directed towards the central panel 111. The opposite pair of lateral curved walls 112 meet the rim extensions 117 at longitudinal directed junctures 118. The rim extensions 117 abut in the unflexed closed configuration to define a longitudinal directed slit 119 opposite the central panel 111.

The opposite pair of curved walls 112 has an opposite pair of wing-like finger grips 121 on opposite sides with respect to the longitudinal shape memory housing centerline 102 and equidistanced from the longitudinal slit 119. The wing-like finger grips 121 are preferably an integral part of the shape memory housing 101 but in other embodiments, a separate component can be tightly attached to a shape memory housing 101. The wing-like finger grips 121 are shaped and dimensioned such that a clinical practitioner can readily apply a manual compression force denoted A typically between his thumb and forefinger to urge the wing-like finger grips 121 towards one another such that the shape memory housing 101 assumes a flexed near-flat open configuration.

The manual compression force flexes the opposite pair of lateral curved walls 112 at the longitudinally directed fold lines 113 and substantially flattens the curved walls 112 so as to be near co-planar with the central panel 111 such that the flexed shape memory housing 101 assumes a downward facing concave shape in a front elevation view along the shape memory housing centerline 102 with the central panel 111 being above the previous longitudinal slit 119. The shape memory housing 101 has a span S between the longitudinal directed rim extensions 117 slightly greater than the fixation ring's diameter D. The wing-like finger grips 121 are shaped and dimensioned such that they abut in the flexed near-flat open configuration to prevent over flexing of the shape memory housing 101 from its intended near-flat open configuration.

The position rod free end 116 is intended for positioning in a device for holding the tissue holding fixture 10. The length of the position rod 114 is set such that the shape memory housing 101 is accurately positioned over the fixation ring 11 on inserting the tissue holding fixture 10 and the insertion apparatus 100 into the device.

The use of the insertion apparatus 100 is as follows:

A clinical practitioner inserts the tissue holding fixture 10 into a device employed for transplanting its Descemet's membrane implant 12 into a recipient eye. The clinical practitioner holds the insertion apparatus 100 and applies a manual compression force to flex the insertion apparatus 100 into its maximum flexed near-flat open configuration as stopped by the wing-like finger grips 121. The clinical practitioner inserts the position rod free end 116 into the device with open shape memory housing 101 over the leading unflexed flat fixation ring 11.

The clinical practitioner ensures opposite sides of the unflexed flat fixation ring 11 are deployed at the longitudinal directed junctures 118 and begins to slowly release his manual compression force such that the shape memory housing 101 begins to revert to its unflexed closed configuration. The slow release of the manual compression force traps the opposite sides of the fixation ring 11 at the

junctures 118 and causes the gradual curling of the fixation ring 11 inside the shape memory housing 101 around the shape memory housing centerline 102 to conform to the shape memory housing lumen 103 such that the fixation ring 111 is effectively folded along its diameter extending between the pair of electrodes 13.

The clinical practitioner deploys the device to urge the insertion apparatus 100 together with the tissue holding fixture 10 to through a pre-formed incision until insertion is limited by the intermediate shoulder 108 and the incision is sealed. Once insertion and leak blockage are achieved, the positioning rod free end 116 is bent away from the device while continuously maintaining forward pressure sufficient to keep the intermediate shoulder 108 sealing the corneal incision by means of a hand held pincer. Once the positioning rod free end 116 is bent away, the clinical practitioner can slide the tissue holding fixture 10 forward through the insertion apparatus 100 such that the fixation ring 11 is deployed in the recipient eye. The fixation ring 11 uncurls to its unflexed flat state and the clinical practitioner injects air into the recipient eye to force tissue attachment to the cornea and then actuates the device to release the Descemet's membrane implant 12 in the recipient eye. Once the Descemet's membrane implant 12 is released from the fixation ring 11, the fixation ring 11 is retracted into the insertion apparatus 100 and both the insertion apparatus 100 and the fixation ring 11 are withdrawn from the incision.

Figure 8 shows an insertion apparatus 200 similar in construction and use as the insertion apparatus 100. The latter 200 differs from the former 100 insofar as the latter includes an additional spring-like element 201 for supplementing the inherent ability of the shape memory housing 101 to revert to its unflexed closed configuration. In one embodiment, the spring-like element 201 is molded into the body of the shape memory housing 101 to secure its position. In another preferred embodiment a spring-like element 201 can be attached to the outer surface of the shape memory housing 101 to securely attach the spring like element 201 in

position when the insertion apparatus 200 is forced to assume a flexed near flat open configuration. The spring-like element 201 can be formed from nitinol, and the like.

Figure 9 shows an insertion apparatus 300 similar in construction and use as the insertion apparatus 100. The latter 300 differs from the former 100 insofar as the latter 300 includes a sealing member 301 mounted on the intermediate shoulder 108. The sealing member 301 is formed from suitable bio-compatible materials, for example, silicon, rubber, and the like. The sealing member 301 assists limiting insertion of the insertion apparatus 300 through a corneal or cornea-scleral incision.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims.

Claims:

1. An insertion apparatus for use with a tissue holding fixture for insertion through a corneal or corneo-scleral incision, the tissue holding fixture having a leading resiliently flexible unflexed flat fixation ring holding a Descemet's membrane implant, the insertion apparatus comprising:

(a) a resiliently flexible shape memory housing having a longitudinal shape memory housing centerline, said shape memory housing having an opposite pair of curved walls in an unflexed closed configuration bounding a shape memory housing lumen, said opposite pair of curved walls terminating in an opposite pair of shape memory housing rims extending inwards into said shape memory housing lumen thereby defining a longitudinal slit co-directional with said longitudinal shape memory housing centerline; and

(b) an opposite pair of wing-like finger grips on said opposite sides of said shape memory housing with respect to said longitudinal shape memory housing centerline and correspondingly equidistanced from said opposite pair of shape memory housing rims,

the arrangement being such that

i) on an initial application of a manual compression force to urge said opposite pair of wing-like finger grips towards one another, said compression force substantially flattens said opposite pair of curved walls such that said shape memory housing assumes a flexed near-flat open configuration with said opposite pair of shape memory housing rims spaced apart from one another for enabling placement of the unflexed flat fixation ring therebetween, and

ii) on a subsequent release of said compression force, said shape memory housing reverts from said flexed near-flat open configuration to its unflexed closed configuration for curling the unflexed flat fixation ring inside said shape memory housing around said longitudinal shape memory housing centerline for conforming the fixation ring to said shape memory housing lumen ready for insertion of the fixation ring through the corneal or corneo-scleral incision.

2. The apparatus according to claim 1 wherein said shape memory housing includes a central panel intermediate said opposite pair of curved walls and longitudinally directed fold lines between said central panel and said opposite pair of curved walls.

3. The apparatus according to claim 1 or 2 wherein said opposite pair of wing-like finger grips abut against each other in said flexed near-flat open configuration to prevent over flexing of said shape memory housing.

4. The apparatus according to any one of claims 1 to 3 wherein said shape memory housing includes a thin wall beveled leading tip for insertion through the corneal or corneo-scleral incision.

5. The apparatus according to any one of claims 1 to 4 wherein said shape memory housing includes a stepped outer surface having a small cross section leading section, an intermediate shoulder and a large cross section trailing section wherein said intermediate shoulder limits insertion of said shape memory housing into the corneal or corneo-scleral incision.

6. The apparatus according to claim 5 and further comprising a sealing member mounted on said intermediate shoulder.

7. The apparatus according to any one of claims 1 to 6 wherein said shape memory housing includes a trailing position rod for holding said shape memory housing in said unflexed closed configuration against the corneal or corneo-scleral incision.

8. The apparatus according to any one of claims 1 to 7 and further comprising an additional spring like element for assisting said shape memory housing to revert to said unflexed closed configuration from said flexed near-flat open configuration on release of said compression force.

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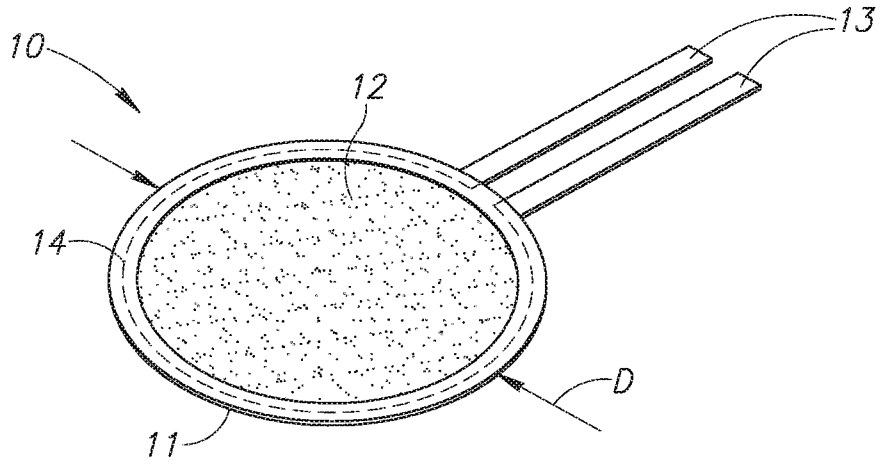

FIG.1
(PRIOR ART)

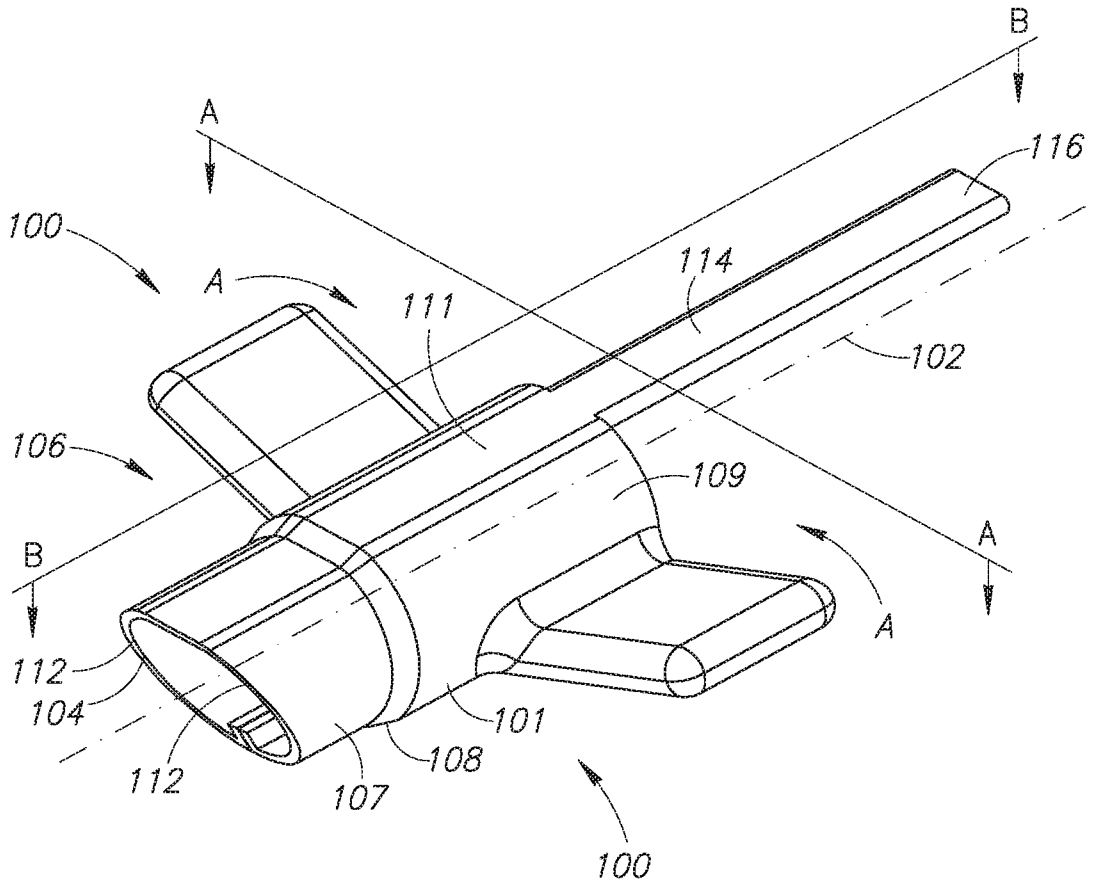

FIG.2

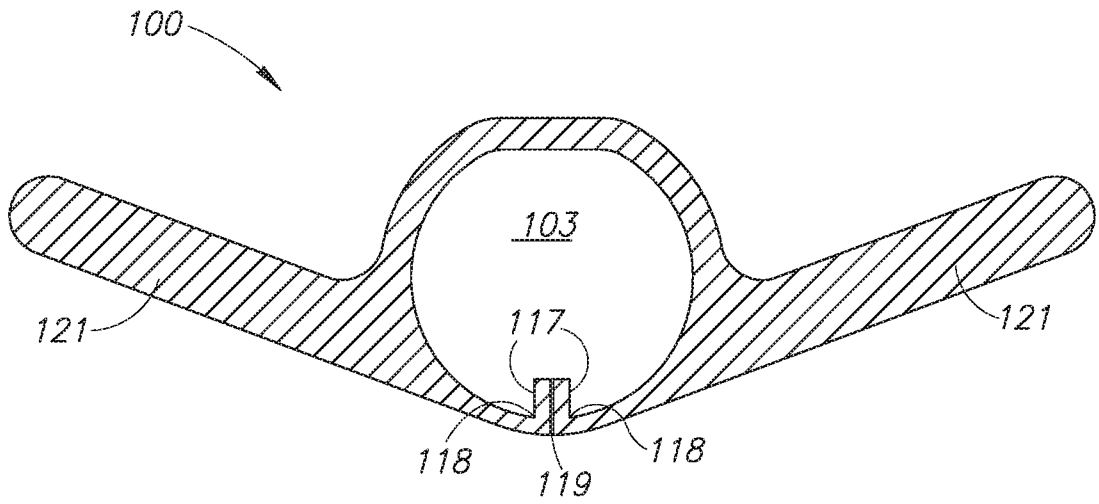

FIG.3

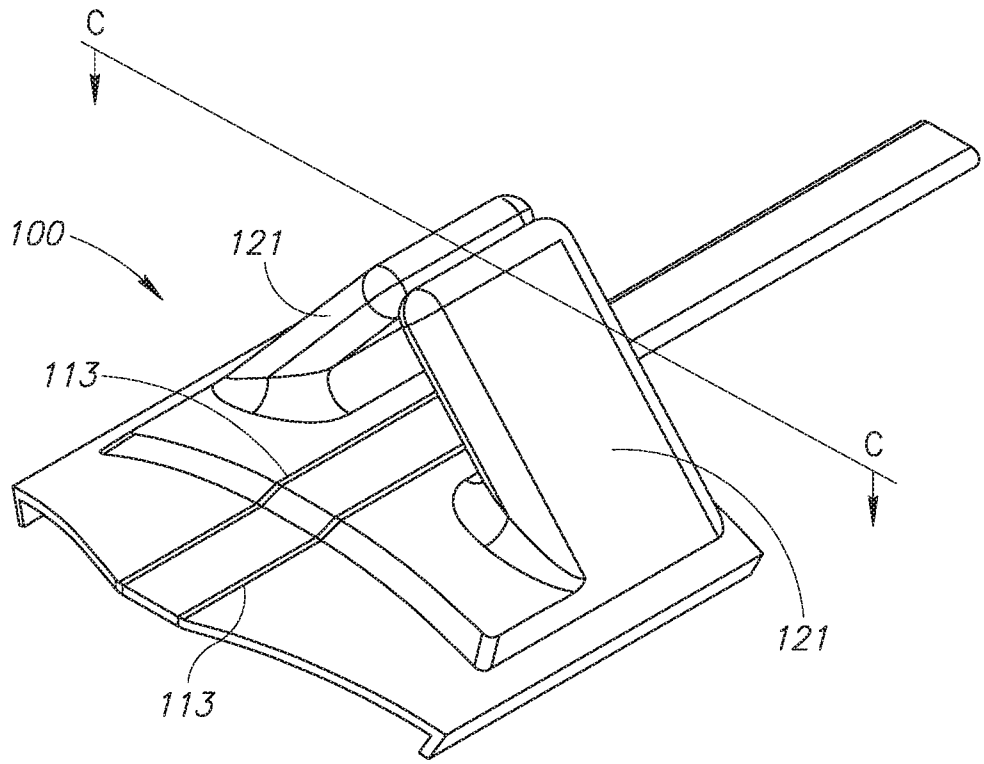

FIG.4

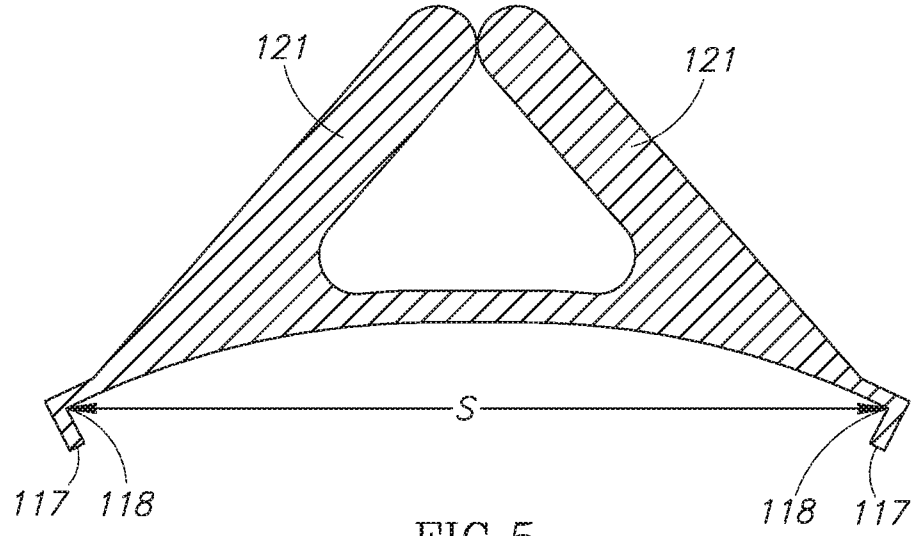

FIG.5

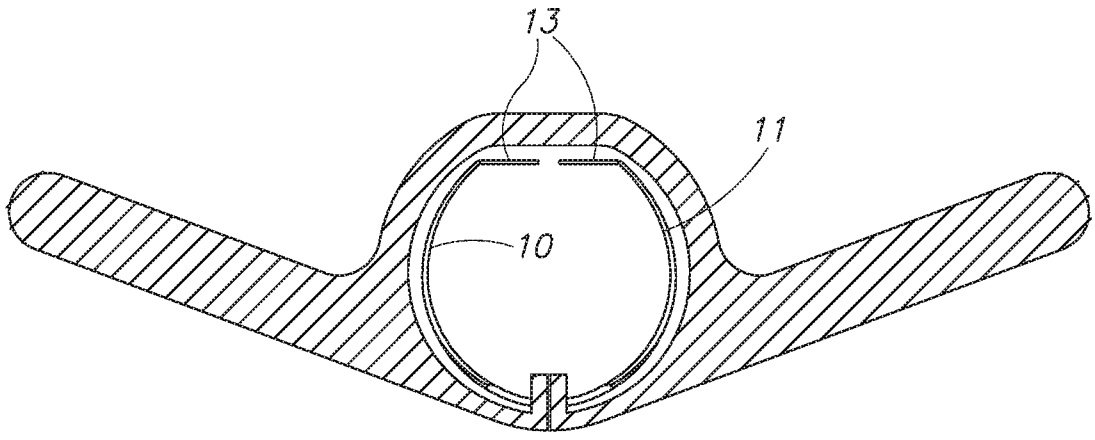

FIG.6

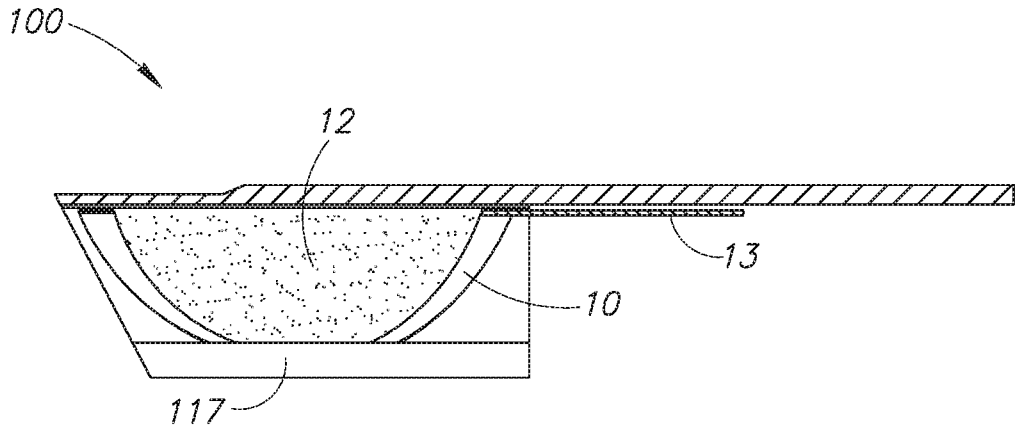

FIG.7

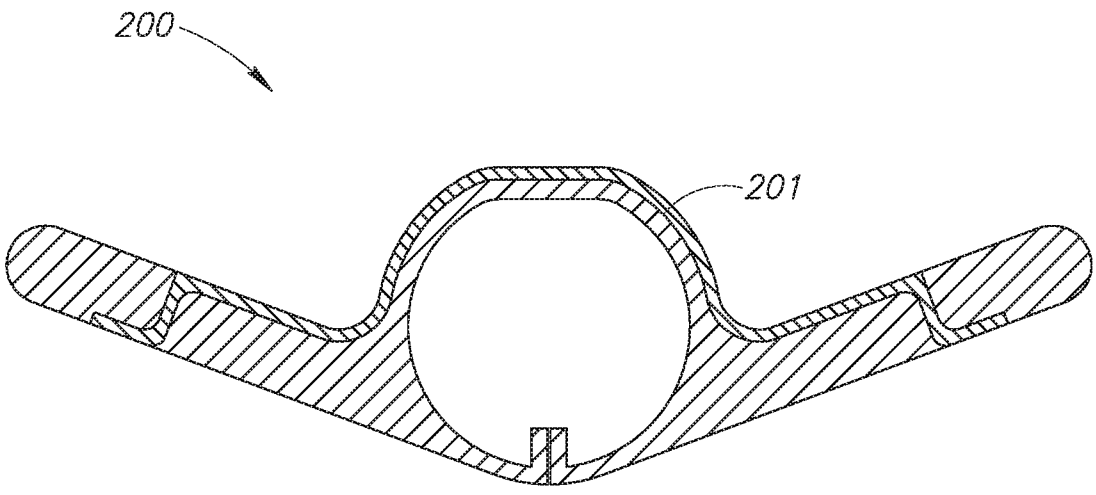

FIG.8

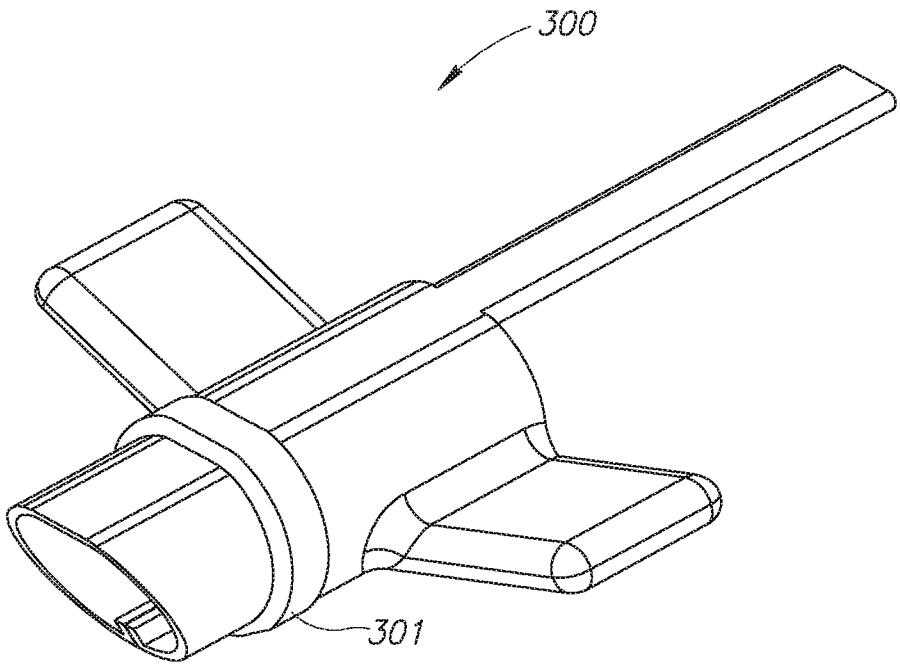

FIG.9

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2016/050641

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/14
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)
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

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/069915 A1 (SHIUEY YICHIEH [US]) 18 March 2010 (2010-03-18) paragraph [0012] - paragraph [0013] paragraph [0074] - paragraph [0075] paragraph [0086] - paragraph [0092]; claims 1,3; figures 6A-7B,12A-15D	1-8
A	US 2007/208422 A1 (WALTER KEITH A [US] ET AL) 6 September 2007 (2007-09-06) paragraph [0081] - paragraph [0111] paragraph [0113] - paragraph [0129] paragraph [0141] - paragraph [0160]; figures 1A-15,17-22,24A-39	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 September 2016	10/10/2016

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

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IL2016/050641

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