



- (51) International Patent Classification:
A61F 2/16 (2006.01)
- (21) International Application Number:
PCT/IB2012/000488
- (22) International Filing Date:
12 March 2012 (12.03.2012)
- (25) Filing Language: English
- (26) Publication Language: English
- (71) Applicant (for all designated States except US): **DOCI INNOVATIONS GMBH** [DE/DE]; Am Fahrenkroog 9, Haus B, App.379, 23730 Sieksdorf (DE).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **DOCI, Violeta** [—/DE]; Germany (DE).
- (74) Agent: **SIMANDI, Claus**; Simandi Meinken, Postfach 14 46, 53761 Hennef (DE).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,

DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

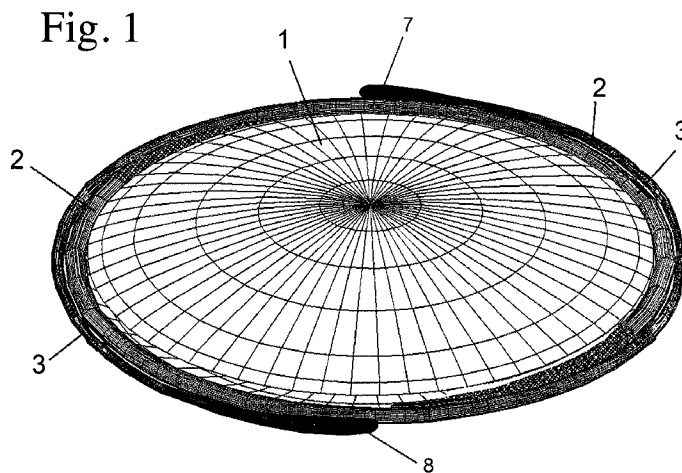
Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

(54) Title: INTRA-OCULAR LENS HAVING HELICAL HAPTICS OF SHAPE MEMORY MATERIALS



(57) Abstract: For easy handling at placement of intra ocular lenses (IOL) for cataract operations, these are equipped with helical haptics of memory materials circumfering the lens. Said haptics adhere to the rim of the lens as long as being cooled down to constriction temperature. On regaining body temperature the haptics expand and fit into the ridges of the eye's capsule sack. Accommodation then is achieved with constriction of the capsule sac by pressure transfer to the rim of the lens to form its shape, in multiplying it with some protrusion towards the pupil.



ABSTRACT:

For easy handling at placement of intra ocular lenses (IOLs) for cataract operations, these are equipped with helical haptics of memory materials circumferring the lens.

- 5 Said haptics adhere to the rim of the lens as long as being cooled down to constriction temperature. On regaining body temperature the haptics expand and fit into the ridges of the eye's capsule sack. Accommodation then is achieved with constriction of the capsule sack by pressure transfer to the rim of the lens to form its shape, in multiplying it with some protrusion towards the pupil.

10

FIELD OF THE INVENTION:

The invention relates to an implantable artificial lens system for replacement in cataract surgery, having accomodative qualities.

15

PROBLEM TO BE SOLVED

- 20 The accommodative capacity of the human eye is lost when the opaque human lens is replaced by a rigid artificial lens in a cataract operation.

A number of implantable artificial lens systems with variable focal length have been developed in view of presbyopia and cataract operation.

- 25 The potentially accommodative intraocular lenses are lenses or lens systems that are inserted into the eye to replace the natural lens after it is removed by surgery, and which are mostly fixed in the capsular sack.

Under the influence of a still present but possibly weakened residual contraction of the ciliary muscle, axial displacement or more spherical deformation of the lens is aimed at through pressure transfer by haptics that are fixed to the IOL rims.

30

This sofar had been only partly feasible in IOL surgery, due to the fact that strong haptics can hardly be inserted through the sklera (and pupil) into a delicate capsule sack –which both must carefully be cut to open a small gap, for not to damage it.

- 35 Soft haptics in return are not capable of transmitting all pressure which would be required to deform or displace the lens adequately, due to internal deformation.

Moreover, hitherto it is not possible to find a method to regularly position the IOL system to the optimum site in the back of the capsule sack, without having to rely on outstanding skills of the operator, or without making bigger cutouts in the cornea or the front part of the capsule sack.

40

For to insert the artificial lens through small openings, it is a common technique to fold and inject it trough a thin cannulae.

When deploying it into the capsule sack it must be unfurling due to its own elasticity and its haptics should align in a way, that they snap into the ridges of the capsule sack or –in case of its decay– into the crease of the ciliaric muscle, for to transfer its contraction to the rim of the lens.

- 5 However, multiple attempts to implement this had not been too successful:
Either the haptics were designed too big and too stiff for injecting it through a cannulae, or they did not provide sufficient pressure transfer to effectuate an adequate focussing.

- 10 Another problem of IOL surgery is, that quite a few patients suffer from post-operational ailments, as irregular definition and dazzling, as well as of effects resulting from astigmatism.
Common reason for this is, that artificial lenses are mostly offered with diametrically positioned haptics. Aside from sometimes deficient positioning, astigmatism here mainly results from irregular deformation of the lens due to unbalanced pressure on its rim, if the haptics are fixed only at a few points on the rim and are straightly outwards orientated –which is as more detrimental to sight, the
15 stiffer the haptics are.

- Moreover, another problem has to be solved: the position of the lens within the capsule sack in conventional systems is not always stable after operation, so that accelerations of the head, particularly in sports or with accidents, can cause lasting defocussing.
20

TASK OF THIS INVENTION

- 25 It is therefore subject of the here disclosed invention to design a lens system, the haptics of which would be foldable to a wide extent, but capable of transmitting the contractional forces from the ridge of the capsule sack or from the sulcus of the ciliary muscle to accommodate the lens to clear sight from close to far.

- It therefore is the task of the here disclosed invention, to solve the problem of these contradictional demands: effective transfer of the ciliar muscle force and small shape of the implant, particularly
30 without haptics, which would obstruct the operation.

- Furthermore the haptics should be designed so that they fit the lens exactly into place and let it effectively accommodate without irregular deformation, even if some fibrosis has hardened the capsule sack.
35

PRIOR ART

- 40 US Patent Application No. 2004/0,181,279 A1 describes a deformable lens that does not require the capsular sack to be deformable. In this case, the axial force operating through the movement of the ciliary muscle between the capsular sack that is rigid but can still be moved by the zonular fibres, and a firmly fixed plate placed outside the capsular sack is supposed to press a transparent deformable body into an orifice in this plate in such a way that the radii of curvature of the transparent deformable body are changed inside this orifice. However, an increased vertex power would only

be expected in the case of a relaxed ciliary muscle if the zonular fibres tensed the capsular sack. A physiological adaptation, i.e. a learning process to tense the ciliary muscle for near vision would therefore be needed here. New designs that eliminate this problem have been promised in the literature.

5

U.S. Pat. No. 6,096,078 describes an intraocular lens that is implanted into the ciliary sulcus to supplement a conventional intraocular lens, and which is supposed to be axially displaceable by the movement of the ciliary muscle. It also has sensors to detect information (data) about the physical state of the lens, especially the mechanical tension in the haptic. This information is transmitted to an external evaluating unit via an electrical connection located on the circumference of the lens or on the haptics. The subject of this U.S. Pat. No. 6,096,078 does not include the concept of a closed control circuit but merely offers the possibility of detecting the activity of the ciliary muscle.

10

U.S. Pat. No. 6,638,304 describes an intraocular lens which is made of an electro-optical material (liquid crystals), is fitted with electrode structures, and alters the imaging behavior of the optical system. The information is obtained either by measuring the distance from the object of fixation (autonomic autofocus) or by using biological signals, which includes the following: registration of the signals that control the accommodation, namely the perception of the mechanical action of the ciliary muscle via a pressure sensor, the detection of the electrical activity of the ciliary muscle by surface electrodes, the detection of the tension in the zonular fibres, and the detection of the deformation of the capsular sack. The inventors suggest that the control signals of the iris contraction can be registered. They also mention the registration of the control signals of vergence, for which the contraction of a single external eye muscle (musculus rectus) is supposed to be detected mechanically, or else its neuronal innervation is to be detected electrically. A closed control circuit is achieved with the aid of a microcontroller. The power can be supplied by a battery or a photocell.

15

20

25

An accommodative intraocular lens for implantation in the human eye is described for example in German Patent No. 94 22 429 U1. This has a monolithic lens body with regulating elements arranged on its circumference, which are directly connected with the ciliary muscle of the eye. For accommodation, the lens body is moved by the ciliary muscle to and fro within the eye via the regulating elements.

30

Implantable monolithic lenses that can be adjusted by the ciliary muscle via the regulating elements have also been described in German Patent Nos. 201 11 320 U1 and No. 100 62 218 A1. In this case, the regulating elements are elastic elevators, which define an initial rest position of the lens when not in operation.

35

German Patent No. 101 39 027 describes an intraocular lens with preferably four haptics that radiate outward and are flexibly connected to the optical system. When the ciliary muscle contracts, the lens is supposed to be displaced forward axially in the light path with the aid of the guide mechanism, thereby increasing the refractivity of the entire system.

40

Such implants have so far produced an axial displacement of the lens by at most 300-500 .mm, restoring an accommodation of 1-2 dioptres. The distance of objects at which the image on the retina

is still in focus is then about 50-70 cm in the case of persons with normal sight (emmetropic subjects). However, this is not sufficient, because an accommodation of more than 3 dioptres is needed for near vision, e.g. for reading. For this, the axial displacement produced under the influence of the ciliary muscle would have to be at least 2 mm, which is not possible for anatomical reasons. See H. Schneider, O. Stachs and R. Guthoff, Evidenzbasierte Betrachtungen zu akkommodativen Kunstlinsen [=Evidence-based considerations about accommodative artificial lenses], lecture delivered at the 102nd Annual Meeting of the German Ophthalmological Society, held in Berlin on 23-26 Sep. 2004. See also J. Kammann and G. Dornbach, Empirical results regarding accommodative lenses, In: Current Aspects of Human Accommodation, ed. by R. Guthoff and K. Ludwig, published by Kaden Verlag, Heidelberg, 2001, see pages 163-170.

Further International Patent WO 02/083033 describes a lens in the case of which the contraction of the ciliary muscle is supposed to displace a number of lens segments over one another via the deformation of the capsular sack, whereas German Patent No. 101 25 829 A1 describes a lens in which the radii of curvature of a sheath filled with a transparent material are supposed to change under the influence of the ciliary muscle on the capsular sack. However, clinical tests have disclosed that the accommodative effects of these methods are still inferior to the adjustment range that could be realized by displacement of the lens.

There are quite a few other propositions, that seek to solve the problem by applying adjustable technical optics, as U.S. Pat. No. 6,638,304, WO 2004/004,605 and WO 2004/004,605. Similar devices for the restoration of the accommodative capacity are also known from German Patent No. 101 55 345 C2, U.S. Pat. No. 6,638,304 B2, International Patent WO 03/017 873 A1, U.S. Pat. No. 4,372,18. and lately in US 8.043.370. However, these solutions rely on accommodation with technical apparatus, the implantation of which into the human eye may be seen questionable. Furthermore it is obvious, that systems of this complexity, having the need of particular sensors, electronic analysis, software and regulator control elements is not only hardly affordable to patients, but requires much space, comprising a yet unassigned power source of adequate capacity, that it seems hardly feasible at this state of the art to be realized as an eye implant.

Some advantage in more conventional systems is realized, if the haptics are of spiral shape, with some contact along to the rim of the lens, as shown in the earlier application DE 2004 029 384 A1. Other helical haptics, as in US 878.501.61.8 / EP 0246 216 B1 to Bisonette or DE 41 100 16 869 C1 to Binder are also state of the art.

However, sofar no design has managed to arrange the haptics in a way, that it would be safe and easy to insert the IOL, as well as effective in transmitting the constrictive momentum of the ciliary muscle.

INVENTIVE STEP

The inventive step to solve these problems is, to realize an adaptive force, that would first keep the haptics densely clinging around the rim of the lens, but to deploy it in a way, that the haptics are

inserted into the rim of the capsule sack with a force pushing the lens forward, when it contracts. This force is realized by application of memory material to the haptics, which contracts when cooled and expands at body temperature.

- 5 This had already been tried in Soviet patents, re-issued e.g. under DE3722732 A1, with poor results, because the haptics were just radially orientated and had a small angle of enlacement.

10 The crucial innovation here is, that the haptics in cold state are pressed to the side of the rim of the IOL for optimal compact shape during operation, while in deployed state they fit into the ridge of the capsule sack. Furthermore, their ending in Slubs allow for a better contact to the rim of said capsule sack and prevent the quite stiff haptics from piercing it. Moreover, the latter inherit a certain twist, so to stabilize the capsule sack and better protrude the lens, if the spiral is contracted.

15 SUMMARY OF THE INVENTION

For to realize sufficient accommodation the two principles –protrusion and changing the curvature of the lens– are combined to apply the multiplicative impact of both together to allow for a wide

20 range of accommodation.

This is mated with haptics, that are flatly contracted at insertion, but expand inside of the eye, thus to provide good transmission of the contraction of the capsule sack or ciliar sulcus.

25 This is further provided by haptics made of change memory materials, such as polymeric or tissue-compatibly coated titan alloys, which in cold state –as provided– are formed so that the haptics cling to the rim of the lens, but when adapting to body temperature extend unto the rim of the capsule sack.

30 In a preferred embodiment these haptics are mounted on half-crescent adaptors to the lens for to provide equal pressure to it and avoid irregular deformation.

In a further embodiment these haptics are circumfering the lens between 280° and 360° to enhance pressure distribution and –when unfolded– they inherit a slight twist backwards, so to make a perfect fit within the rim of the capsule sack.

35 Furthermore the endpieces of said haptics are equipped with a slub, that fits into the capsule sack with enlarged contact surface.

DESCRIPTION OF THE DRAWINGS

40 The here disclosed invention is more closely described by the following drawings:

Fig. 1 shows the intra ocular lens **1** with circumfering haptics **2** and **3** and slubs **7** and **8** in their cold, contracted state, clinging to the edge of the lens **1**.

Fig. 2 shows in top view the same elements lens **1**, and haptics **2** and **3** with slubs **7** and **8**, now in expanded state, fastened to their half-crescent supporting arch **4** and **5**, that connects them to the edge of the lens **1**

5 Fig. 3 demonstrates how the expanded haptics **2** and **3** with their slubs **7** and **8** are fixed to the supporting arches **4** (not seen) and **5** with a slight back offset, so protrude the lens, (here in already constricted shape) when the haptics are embraced with a tightening capsule sack.

Fig. 4 shows the lens **1** with its haptics **2** (not visible) and **3**, as well as its supporting half-crescents **4**
10 and **5** as folded into a cannulae **6** for injection.

15

20

25

30

35

40

What is claimed is:

1. An artificial intraocular lens, consisting of flexible plastic with helical circumferring haptics of memory shape materials, which in cold state are closely adhering to the rim of the lens and at body temperature expand,

wherein

- helical haptics in expanded condition are as stiff as to transmit the pressure of the constricted capsule sack or ciliaric sulcus via a crescent bracing to the rim of the lens, thereby effectuating a change of its surface's curvature

- the central plain of expanded haptics is tilted at 3° to 5° backwards, so to protrude the lens when the capsule sack is constricted

- the multiplicative effect of protrusion and changing the curvature of the lens by compressing its edges is applied for close vision.

2. Intraocular lens as to claim 1, wherein the haptics consist of memory shape polymers.

3. Intraocular lens as to claim 1, wherein the haptics consist of memory shape Titan alloys, coated with tissue-friendly material, as e.g. Tantalum.

4. Intraocular lens as to one of the claims 1 to 3, wherein the lense, the haptics and the injection apparatus, including the lubricant, are pre-cooled to +6 up to +8° Celsius before insertion.

5. Intraocular lens as to one of the claims 1, to 3, comprising haptics that circumfer the lens from the middle of their basis on the rim of the lens unto their peak along an angle of 280° up to 360°.

6. Intraocular lens as to claim 5, wherein the peaks of the expanded haptics are set to a maximum distance of 0.3 mm to the next haptic, thus limiting the protrusion of the lens for not to touch to the iris.

7. Intraocular lens as to claim 5, comprising half-crescent bracings between haptics and the rim of the lens to evenly distribute the pressure on it.

8. Intraocular lens as to one of the preceding claims, comprising slubs at the endpieces of the haptics, that fit into the inner edge of the capsule sack.

* * * * *

Fig. 1

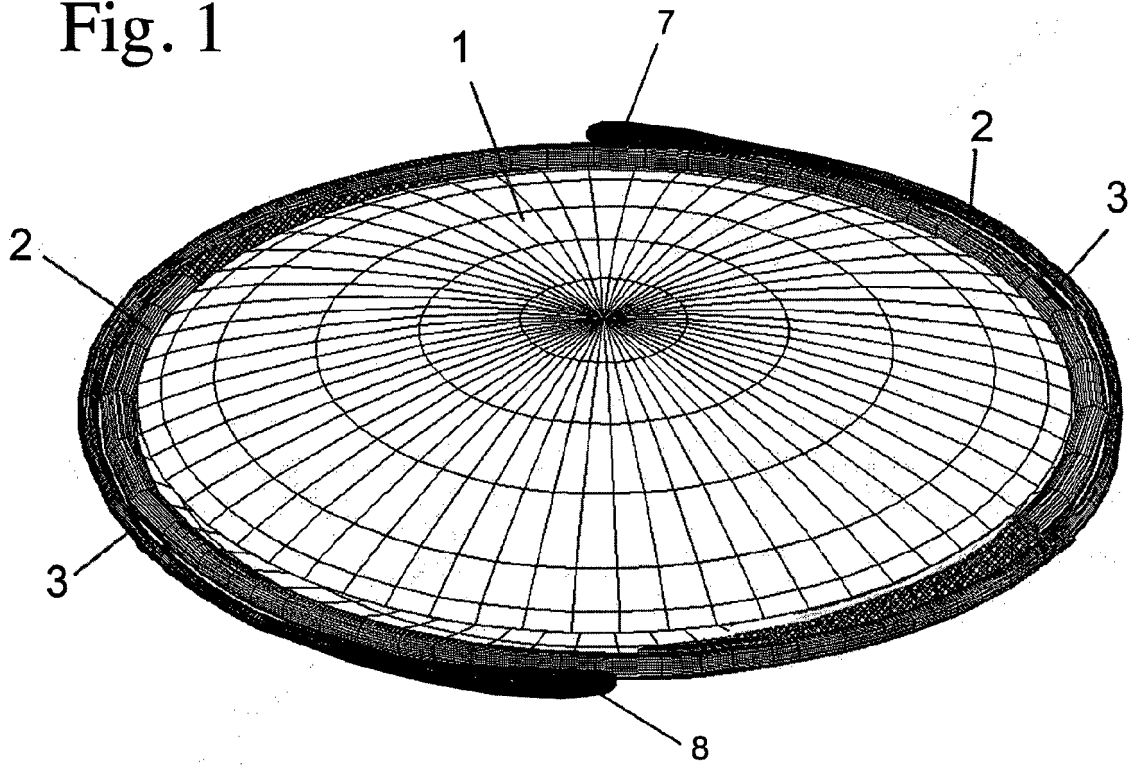


Fig. 3

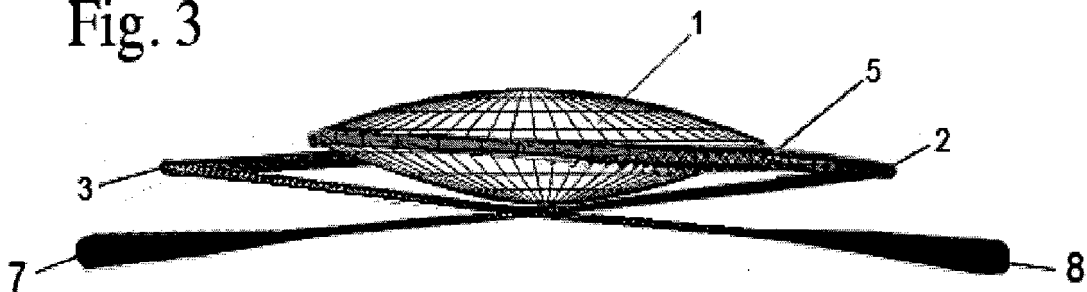


Fig. 2

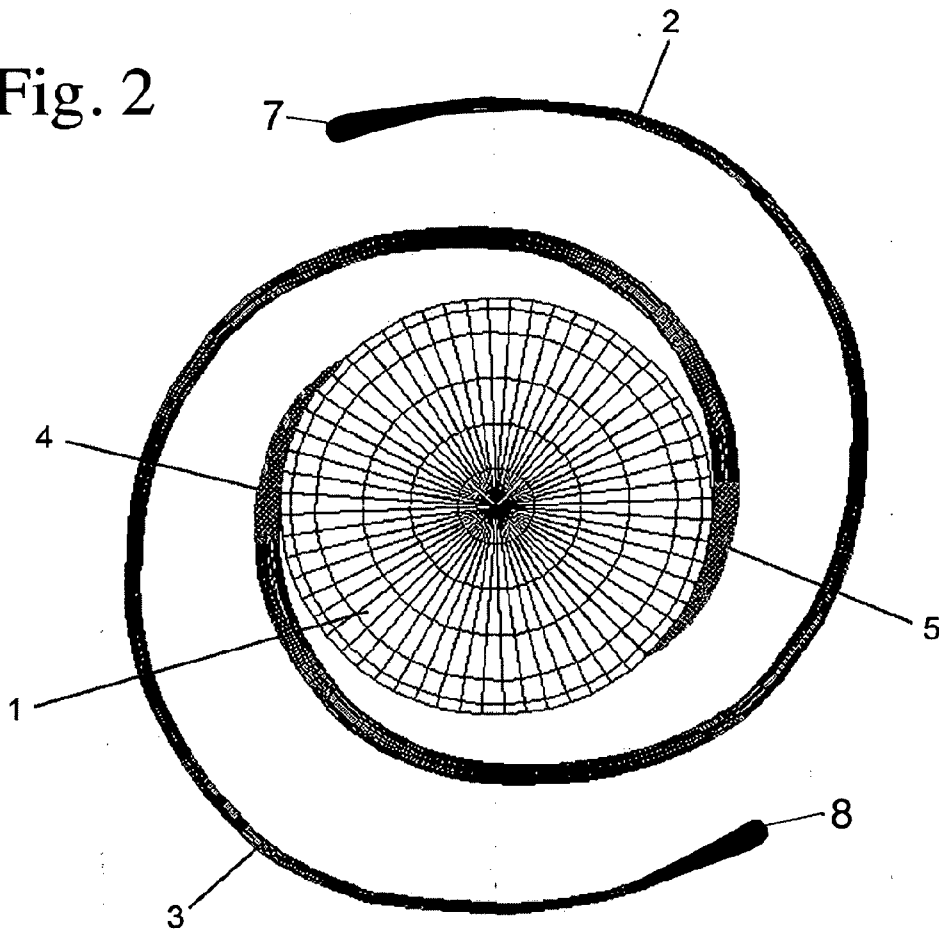
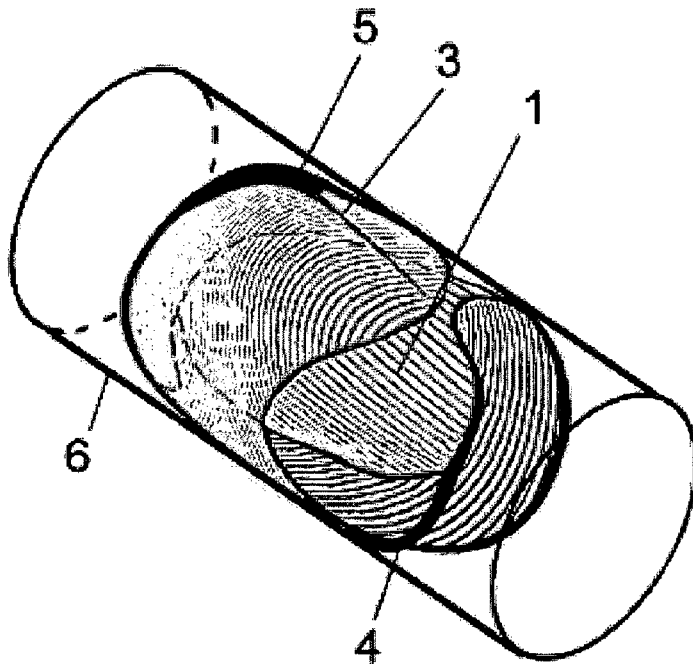


Fig. 4



INTERNATIONAL SEARCH REPORT

International application No PCT/IB2012/000488

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F2/16 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 2004/111152 A1 (KELMAN CHARLES DAVID [US]) 10 June 2004 (2004-06-10) paragraph [0023] - paragraph [0026]; figures -----	1
A	US 2003/149480 A1 (SHADDUCK JOHN H [US]) 7 August 2003 (2003-08-07) paragraphs [0083], [0096]; figures -----	1-4
A	US 6 443 984 B1 (JAHN MARIANNE [DE] ET AL) 3 September 2002 (2002-09-03) column 4, line 5 - line 9; claim 4; figures -----	1
A	US 4 615 701 A (WOODS RANDALL L [US]) 7 October 1986 (1986-10-07) column 1, line 57 - line 66; figures column 2, line 66 - column 3, line 6 column 4, line 59 - column 5, line 2 -----	1
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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 application or patent 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	Date of mailing of the international search report	
1 November 2012	13/11/2012	
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Neumann, Elisabeth	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/IB2012/000488

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004111152 A1	10-06-2004	AU 2003296503 A1 US 2004111152 A1 WO 2004053536 A2	30-06-2004 10-06-2004 24-06-2004

US 2003149480 A1	07-08-2003	US 2003149480 A1 US 2010228344 A1 US 2012078361 A1	07-08-2003 09-09-2010 29-03-2012

US 6443984 B1	03-09-2002	AT 324086 T CA 2315338 A1 DE 19936666 A1 EP 1074228 A1 JP 4190708 B2 JP 2001087287 A US 6443984 B1	15-05-2006 04-02-2001 15-03-2001 07-02-2001 03-12-2008 03-04-2001 03-09-2002

US 4615701 A	07-10-1986	NONE	
