



HU000030889T2

(19) **HU****MAGYARORSZÁG****Szellemi Tulajdon Nemzeti Hivatala**(11) Lajstromszám: **E 030 889**(13) **T2**

EURÓPAI SZABADALOM SZÖVEGÉNEK FORDÍTÁSA

(21) Magyar ügyszám: **E 13 706159**(22) A bejelentés napja: **2013. 01. 09.**

(96) Az európai bejelentés bejelentési száma:

EP 20130706159

(97) Az európai bejelentés közzétételi adatai:

EP 2802301 A1 **2013. 07. 18.**

(97) Az európai szabadalom megadásának meghirdetési adatai:

EP 2802301 B1 **2016. 08. 03.**(51) Int. Cl.: **A61F 90/07** (2006.01)

(86) A nemzetközi (PCT) bejelentési szám:

PCT/DE 13/200001

(87) A nemzetközi közzétételi szám:

WO 13104360

(30) Elsőbbségi adatok:

102012200411**2012. 01. 12.****DE**

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Berendezés glaukómasebészeti alkalmazásra

Az európai szabadalom ellen, megadásának az Európai Szabadalmi Közlönyben való meghirdetésétől számított kilenc hónapon belül, felszólalást lehet benyújtani az Európai Szabadalmi Hivatalnál. (Európai Szabadalmi Egyezmény 99. cikk(1))

A fordítást a szabadalmas az 1995. évi XXXIII. törvény 84/H. §-a szerint nyújtotta be. A fordítás tartalmi helyességét a Szellemi Tulajdon Nemzeti Hivatala nem vizsgálta.



- [1] The invention relates to a device for use in glaucoma surgery, in particular for implantation in the eye, for the purpose of lowering an abnormally high intraocular pressure.
- [2] The device is for use in glaucoma surgery, in particular for the surgical treatment of glaucoma. The term "green star" includes a plurality of ocular diseases of varying aetiology that can all lead to the loss of nerve fibres. A disease of this type leads typically to the loss of the field of vision and, in extreme cases, blindness of the eye. An abnormally high intraocular pressure is considered to be the most important risk factor.
- [3] Many people suffer from an elevated intraocular pressure. Correspondingly, many people suffer from glaucoma: about one million people in Germany alone.
- [4] Besides pharmacological treatment of glaucoma, a number of different surgical procedures are available for treating glaucoma. Depending on the specific type of disease, the often preferred method of treatment is to drain the aqueous humour, which makes it possible to lower intraocular pressure. Besides other types of filtering surgical intervention, trabeculectomy (TE) is deemed to be the standard method in penetrating glaucoma surgery. First, an artificial opening is made in the white of the eye (sclera). This opening is then loosely closed and covered with conjunctiva. Different shunt systems are used to drain the aqueous humour.
- [5] Based on the principle of trabeculectomy, subconjunctival drainage is known, according to which a channel system is formed between the anterior chamber of the eye and a scleral pocket or a subconjunctival filtering bleb. In order to achieve corresponding drainage, the Ahmed valve is known from practice.
- [6] Another surgical approach is the trabecular meshwork bypass, according to which the shunt forms an open channel in the trabecular meshwork through the implantation of a micro-tube. The iStant is known from practice for this purpose.
- [7] An additional method uses drainage into the suprachoroidal space. The SOLX shunt is known from practice for this purpose.
- [8] All of the glaucoma shunts known from practice are based on draining fluid from the anterior chamber of the eye (see for example publication US5626559). Another publication US 2005/119737 A1 discloses a glaucoma shunt which can be fitted between the posterior chamber and a space between the conjunctiva and the sclera. The implant comprises a flat, convex head part and a relief channel for draining the eye.
- [9] The devices known from practice for lowering an abnormally high intraocular pressure are difficult to handle, in particular during the process of implantation. In addition, there is also the risk of misplacement and/or "wandering."
- [10] Therefore, the object of the present invention is to provide a device for use in glaucoma surgery, for implantation in the eye, and which, for the purpose of lowering an abnormally high intraocular pressure, is as easy and at the same time safe as possible to handle and to implant. Furthermore, it should be ensured that the device is securely fitted when in its implanted state, i.e. in the eye. Finally, the device should be inexpensive to manufacture.
- [11] The above object is achieved by means of the features of claim 1. According to said claim, the device according to the invention for use in glaucoma surgery, in particular for implantation in the eye, comprises a flat head region, a probe that adjoins the head region, and a relief channel, which extends through the head region and the probe and is open on both sides.

[12] The head region is an extremely flat region, which is constructed in the manner of a flat nail head or the head of a drawing pin. The bottom side of the head region thus forms a resting surface and therefore makes it possible to precisely position the probe.

[13] The relief channel is formed by a tube that is open on both sides, the tube ending in the head region in such a way that the relief channel extends through the head region and opens to the exterior. The relief channel is thus open at both ends.

[14] The head region and the probe are dimensioned and configured in such a way that, when the conjunctiva is open, the free end of the probe can be inserted through the white of the eye or the sclera as far as the posterior chamber of the eye for the purpose of lowering an abnormally high intraocular pressure. The dimensions or the length of the probe are therefore predefined, the bottom side of the head region resting against the sclera when in the inserted position.

[15] Therefore, the device according to the invention is based on the idea of not draining fluid from the anterior chamber of the eye as is routine in the prior art. On the contrary, according to the invention, the glaucoma shunt is placed where the intraocular pressure is abnormally high, in particular in the posterior chamber of the eye. Accordingly, the device having the probe is dimensioned in such a way that it can be inserted through the sclera as far as the posterior chamber of the eye, in such a way that fluid communication is established between the posterior chamber of the eye and the exterior. Once the device has been inserted, the special function of the head region is important, the conjunctiva being closed again over the head region and being routinely sutured. Consequently, the originally opened conjunctival flap covers the upper side of the head region in such a way that drainage from the posterior chamber into a space between the conjunctiva and the sclera is achieved.

[16] At this point it should be noted that the device according to the invention is a type of trocar tube, which is used, in the form of an implant, for draining from the posterior chamber into the region between the conjunctiva and the sclera.

[17] To prevent the retina from becoming detached, the pars plana region is appropriate for implantation. After the conjunctiva has been prepared or opened, it is possible to place one or more shunts in the form of the device according to the invention, i.e. in the form of very small and flat trocars, under the conjunctiva with a minimum of effort. Once the trocars have been placed, the conjunctival flap formed for opening said conjunctiva can be closed again over the trocar head(s) and sutured, and so, by using the device according to the invention, drainage takes place into the space between the conjunctiva and the sclera.

[18] Advantageously, the head region is concavely curved at least on the bottom side, i.e. on the side facing the probe, in conformity with the geometry of the eye. It is thus possible for the device to be securely fitted directly at or on the sclera. It is also advantageous for the head region to be configured so as to be at least slightly convex on the upper side, i.e. on the side facing away from the probe. This facilitates the head region being covered by the conjunctiva or the conjunctival flap.

[19] The head region has radial grooves or notches on the upper side facilitating drainage, in order to guide fluid emerging from the relief channel of the probe, preferably by using capillary forces, into the space between the sclera and the conjunctiva. Again this facilitates the drainage action.

[20] Advantageously the device is made of a biocompatible material, or is at least coated with a biocompatible material. According to a specific embodiment, the device can be made of ceramic, glass ceramic or glass. The material can be permeable or semi-permeable, which again facilitates the drainage action.

[21] As already stated above, the device according to the invention is for use in glaucoma surgery, or more specifically for implantation in the eye for the purpose of lowering an abnormally high intraocular pressure. Accordingly, a method is also described for using a device according to the invention, i.e. in glaucoma surgery for implantation in the eye, and in particular for the purpose of lowering an abnormally high intraocular pressure. Here, it is essential that, when the conjunctiva is open, the free end of the probe is inserted through the sclera as far as the posterior chamber of the eye. In the process, when the head region is resting against the sclera, it is covered by closing the conjunctiva or the conjunctival flap formed upon opening the conjunctiva, and so drainage from the posterior chamber into the space between the conjunctiva and the sclera is achieved.

[22] At this point, there are a number of possibilities for advantageously designing and developing the teaching of the present invention. To this end, reference is made to both the claims dependent on claim 1 and the following description of a preferred embodiment of the invention with reference to the drawings. Generally preferred embodiments and developments of the teaching are also described, in conjunction with the description of the preferred embodiment of the invention with reference to the drawings, in which:

Fig. 1 is a schematic view of a part of the human eye in the pars plana region when the conjunctiva is opened and the device according to the invention already inserted, and

Fig. 2 is a schematic view of a part of the eye according to Fig. 1, the conjunctiva having already been closed again over the trocar head by means of the conjunctival flap formed when said conjunctiva was opened.

[23] Fig. 1 and Fig. 2 are schematic views of a part of the human eye, cropped and represented in a simplified manner, the lens 1, the cornea 2, the conjunctiva 3 and the sclera 4 being identified as essential components.

[24] In the representation in Fig. 1, the device 5 according to the invention is inserted in the form of an implant and the conjunctiva 3 opened, the probe 6 extending completely through the sclera 4. The relief channel 7, which is open on both sides, extends through the probe 6.

[25] The insertion of the device 5 or of the probe 6 is limited by the head region 8. More precisely, the bottom side of the head region 8 rests closely against the sclera 4.

[26] According to the representation in Fig. 2, the flap 9 formed for opening the conjunctiva 3 is laid over the head region 8 of the device 5, and the conjunctiva 3 is sutured. The device 5 is thus implanted in its entirety, with the result of achieving drainage between the posterior chamber 10 and a space 11 between the sclera 4 and the conjunctiva 3. Finally, pressure is released from the posterior chamber 10 by using the device according to the invention.

[27] With regard to further advantageous embodiments of the device according to the invention, reference is made to the general part of the description and to the claims so as to avoid repetitions.

[28] Finally, it should be explicitly noted that the purpose of the above-described embodiment of the device according to the invention is merely to discuss the claimed teaching, but said claimed teaching is not restricted to said embodiment.

List of reference numerals

{0029}

- 1 lens
- 2 cornea
- 3 conjunctiva
- 4 sclera, white of the eye
- 5 device (comprising the probe 6, the relief channel 7 and the head region 8)
- 6 probe
- 7 relief channel
- 8 head region
- 9 flap (of the conjunctiva)
- 10 posterior chamber (of the eye)
- 11 space (between the sclera and the conjunctiva)

Berendezés glauklómasebészeti alkalmazásra

SZABADALMI IGÉNYPONTOK



1. Berendezés glauklómasebészeti alkalmazásra, nevezetesen szembe történő beültetésre, ami tartalmaz egy fejrészt (8) és egy ahhoz csatlakozó szondát (6),
azzal jellemezve, hogy a fejrészen (8) és a szondán (6) keresztül egy mindkét végén nyitott tehermentesítő csatorna (7) nyúlik át, ahol a fejrész (8) és a szonda (6) úgy van kialakítva és méretezve, hogy a szonda (6) felnyitott kötőhártyánál (3) a túlságosan nagy intraokuláris nyomást szabad végével az inhártyán (4) keresztül a szemszarnokba (10) vezethető, és bevezetett helyzetben a fejrész (8) alsó oldalával az inhártyán (4) felfekszik, és a kötőhártya (3) visszazárva a fejrész (8) felső oldalát úgy tudja lefedni, hogy a szemszarnok (10) lecsapolása a kötőhártya (3) és az inhártya (4) közötti résben (11) elvégezhető, és hogy a fejrész (8) lapos kialakítású, és a felső oldalán a lecsapolást segítő barázdák vagy bordák vannak.
2. Az 1. igénypont szerinti berendezés, azzal jellemezve, hogy a fejrész (8) legalább alul, a szonda (6) felé néző oldala a szem geometriájának megfelelően homorú ívelt felülettel van kialakítva.
3. Az 1. vagy 2. igénypont szerinti berendezés, azzal jellemezve, hogy a fejrész (8) felső, a szondával (6) ellenkező oldala legalább enyhén domború felülettel van kialakítva.
4. Az 1. – 3. igénypontok bármelyike szerinti berendezés, azzal jellemezve, hogy biokompatibilis anyagból van kialakítva vagy ilyen bevonattal van ellátva.
5. Az 1. – 4. igénypontok bármelyike szerinti berendezés, azzal jellemezve, hogy kerámiából, üvegkerámiából vagy üvegből van kialakítva.
6. Az 1. vagy 5. igénypont szerinti berendezés, azzal jellemezve, hogy anyaga permeábilis vagy szemipermeábilis.

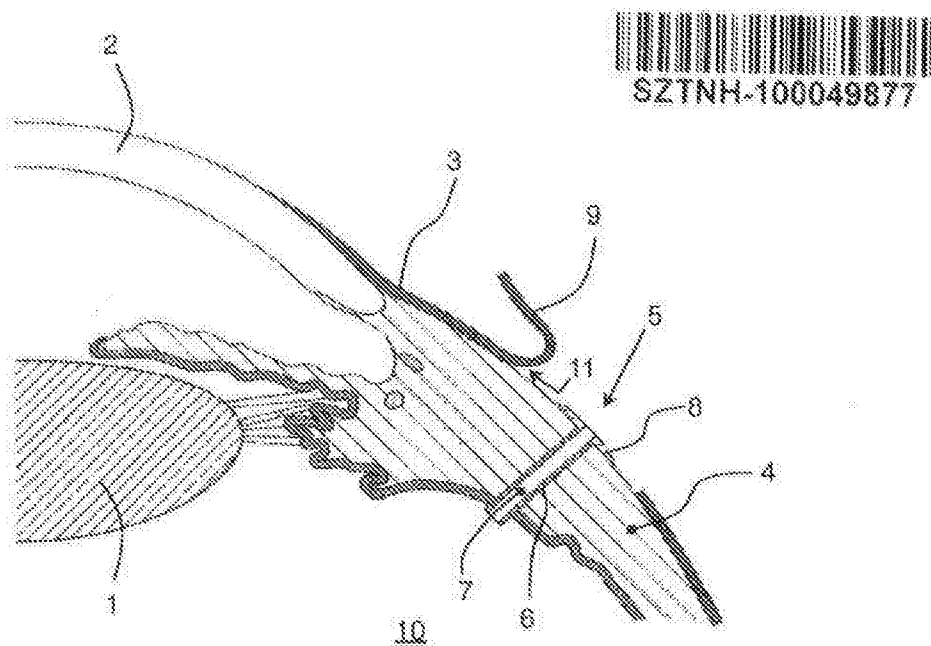


Fig. 1

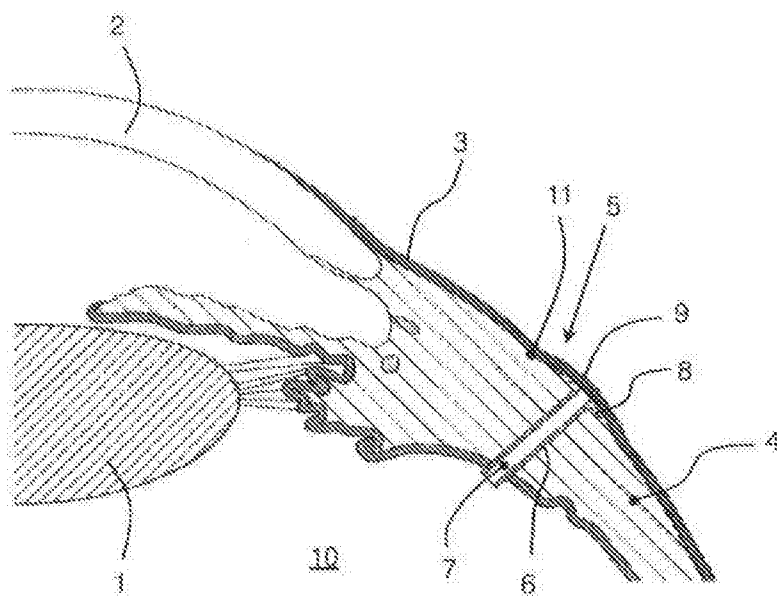


Fig. 2