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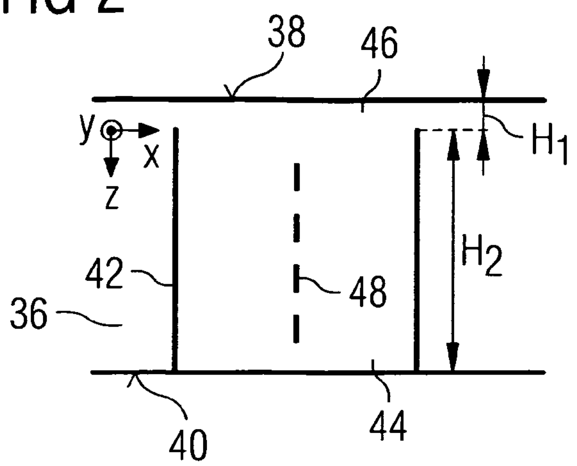
(54) **Title**: DEVICE AND PROCESS FOR IMPLEMENTING A TRANSPLANTATION OF THE CORNEA

FIG 2



(57) **Abstract**: A device for implementing a transplantation of the cornea in respect of the human eye includes instruments for detaching from the eye a corneal segment (44) to be replaced, the instruments including a program-controlled laser apparatus which has been set up to make available focused pulsed laser radiation, the laser apparatus including a control program which provides for such a generation of an incision in the cornea by means of the laser radiation that the corneal segment to be replaced is only partly separated from the remaining corneal tissue of the eye. According to an embodiment, the control program for a penetrating kerato - plasty provides for the generation of a ring incision (42) in the cornea (36), which along its entire periphery severs the corneal tissue as far as the posterior surface (40) of the cornea and along at least a part of its periphery terminates at a distance from the anterior surface (38) of the cornea.

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Device and process for implementing a transplantation of the cornea

The invention is concerned with a device for implementing a transplantation of the cornea (keratoplasty) and also with a process for such a transplantation.

A keratoplasty is indicated, for example, in the case of serious diseases of or injuries to the human cornea. In the course of keratoplasty, a corneal segment is detached from the cornea of the eye to be operated upon, and into the free space that has arisen at this place a corneal donor material is implanted which, for example, is sutured to the cornea being operated upon or is welded thereto by means of laser radiation.

There are various forms of keratoplasty, which differ by virtue of the size and position of the corneal segment to be removed. One form of keratoplasty is designated in specialist circles as so-called penetrating keratoplasty. In this case, from the eye to be operated upon a corneal segment is taken which extends from the anterior surface of the cornea as far as the posterior surface through all the corneal tissue layers, so that as a result of the removal of the corneal segment an uninterrupted hole arises in the cornea. Another form of keratoplasty is epikeratoplasty, which is also designated as epithelial lamellar keratoplasty. In this form of keratoplasty, on the front of the cornea – hence the reference to the epithelium – a lamella is detached which extends over only some of the corneal tissue layers and leaves a recess only on the epithelial side of the cornea, into which a suitably dimensioned piece of tissue of the donor material can then be inserted. The rear analogue of epikeratoplasty is endokeratoplasty (endothelial lamellar keratoplasty), in which a corneal lamella on the rear of the cornea – hence the reference to the endothelium – is taken out and is replaced by a suitable piece of donor material.

In the case of penetrating keratoplasty, the removal of the corneal segment is a critical undertaking, insofar as aqueous humour, or in the worst case even the complete lens, may issue from the anterior chamber of the eye through the hole arising in the cornea. But also in the case of lamellar keratoplasties the removal of the corneal lamella to be removed can result in a structural weakening of the eye, which, depending upon the thickness of the lamella, may not be harmless. In the course of a keratoplastic operation the aim is therefore to keep the state of weakening of the eye by virtue of the absence of the corneal segment to be removed as brief as possible, by the corneal segment being completely detached from the tissue composite of the cornea only when the operating surgeon is ready for the grafting of the donor material.

In order to fulfil this aim, according to one aspect of the invention a device for implementing a transplantation of the cornea in respect of the human eye is provided, including instruments for detaching from the eye a corneal segment to be replaced, the instruments including a program-controlled laser apparatus which has been set up to make available focused pulsed laser radiation, the laser apparatus including a control program which provides for such a generation of an incision in the cornea by means of the laser radiation that the corneal segment to be replaced is only partly separated from the remaining corneal tissue of the eye.

The placement of incisions in human eye tissue, particularly in the cornea, by means of laser radiation has been the subject of intense research for some time and is already utilised in practice. The invention preferentially uses ultra-short-pulse laser radiation with pulse durations within the femtosecond range up to single-digit picoseconds. The wavelength of the laser radiation that is used may, for example, lie within the UV region above about 300 nm. Alternatively, use may be made of a wavelength within the infrared region, for example between about 900 nm and 1300 nm. The effect of interaction of the laser radiation with the corneal tissue that is utilised within the scope of the invention is laser-induced optical breakthrough, which results in a local photodisruption which, in a good approximation, is limited roughly to the region of the radiation focus. By placing several photodisruptions side by side, diverse planar incision figures can be generated. In one configuration the radiation properties of the laser radiation, in particular the pulse energy and the focus size, may have been matched to one another in such a way that each individual pulse results in a photodisruption. In an alternative configuration it is conceivable that in each instance several (at least two) pulses have to be beamed approximately onto the same spot in order to bring about a photodisruption.

In the device according to the invention the control program of the laser apparatus is fashioned in such a way that the corneal segment that is to be removed from the eye is not completely separated from the surrounding corneal tissue but, after the laser machining, this segment is still connected to the surrounding corneal tissue via one or more bridge regions. Although preferentially a predominant part of the corneal segment to be removed is separated from the remaining corneal tissue by means of the laser radiation, after the laser machining the corneal segment nevertheless remains fixed to the cornea via the at least one remaining tissue bridge. This can prevent or at least limit (in the case of a penetrating keratoplasty) an undesirable premature issue of aqueous humour and can maintain the mechanical stability of the eye. The remaining at least one tissue bridge can finally be severed manually by the surgeon with a sharp instrument, for example with a scalpel, with scissors or with a cutting diamond, when he/she is ready for grafting the donor material. Expediently, the thickness of this at least one tissue bridge is so dimensioned that said tissue bridge can be severed without great effort. The aforementioned instrument pertains, together with the laser apparatus, to the instruments with which the corneal segment can be detached from the eye.

According to an embodiment that is designed for a penetrating keratoplasty, the control program may provide for the generation of a ring incision in the cornea, which along its entire periphery severs the corneal tissue as far as the posterior surface of the cornea and along at least a part of its periphery terminates at a distance from the anterior surface of the cornea. In a top view along its ring axis the ring incision may run, for example, approximately in the form of a circle. However, it may alternatively have any other shape that is closed in the manner of a ring, for example depending on the pattern of the diseased/injured corneal regions that are to be replaced in the course of the transplantation.

In an alternative embodiment, which is nevertheless adapted for a penetrating keratoplasty, the control program may provide for the generation of a ring incision in the cornea, which along its entire periphery severs the corneal tissue as far as the anterior surface of the cornea and along at least a part of its periphery terminates at a distance from the posterior surface of the cornea. The same statements made above for the shape of the ring incision when viewed in a plan view along the ring axis apply.

The control program may provide for such a generation of the ring incision that along its entire periphery said ring incision approaches the anterior surface of the cornea at least up to about 110 µm. It is conceivable that along its entire periphery the ring incision even approaches the anterior surface of the cornea up to no more than about 100 µm, 90 µm, 80 µm, 70 µm, 60 µm or 50 µm. It will be understood that these numerical values are not limiting, and in practical applications greater or smaller values may occur.

The numeral values mentioned above can be similarly applied to the distance of the ring incision from the posterior surface of the cornea, in a case where the ring incision along its entire periphery extends all the way to the anterior surface of the cornea and terminates along at least a part of its periphery at a distance from the posterior surface of the cornea.

In one possible configuration, the ring incision may terminate, at least along a part of its periphery, in the stroma of the cornea and in this part may not pass through Bowman's membrane. For example, the ring incision may terminate just ahead of Bowman's membrane.

Furthermore, the control program may provide for such a generation of the ring incision that on a part of its periphery said ring incision passes through as far as the anterior surface of the cornea. In this case the control program may preferentially provide for such a generation of the ring incision that in several regions arranged at a distance from one another in the peripheral direction said ring incision passes through as far as the anterior surface of the cornea. In total, for example, three epithelial tissue bridges distributed in the peripheral direction and preferentially arranged at regular angular distances from one another remain, via which the corneal segment is joined to the remaining corneal regions.

The control program preferably provides for such a generation of the ring incision that at least along a predominant part of its periphery said ring incision terminates at a distance from the anterior surface of the cornea. This ensures a particularly secure fixing of the corneal segment to the cornea.

Generally, the ring incision may have arbitrary contour in the peripheral direction and in the axial direction (relative to its ring axis).

The control program may, for example, provide for such a generation of the ring incision that at least on a part of its axial length said ring incision is cylindrically formed. The axial direction in this connection relates to the ring axis of the ring incision. For example, the ring incision may be cylindrically formed over its entire axial length.

According to a variant, the control program may provide for such a generation of the ring incision that the latter is cylindrically formed in stepped manner. By this expression a design is to be understood in which the ring incision exhibits several (at least two) cylindrical portions of differing diameter which are connected to one another by a step. The step may, for example, run radially in relation to the ring axis of the ring incision, but it may also run obliquely relative to the radial direction. It will be understood that the ring incision may be multiply stepped in the axial direction.

According to a further variant, the control program may provide for such a generation of the ring incision that the latter is realised in stepped conical form. By this expression a configuration is understood in which the ring incision possesses two or more conically extending portions which in each instance are connected to one another in pairs by a step. This step may, in turn, run radially or obliquely relative to the radial direction. The control program may in this case provide for such a generation of the ring incision that the latter exhibits two conical ungulae separated by a step, the cone angles of which are different from one another. It will, however, be understood that the ring incision may also exhibit conical ungulae with the same cone angle.

The above statements on the design of the ring incision are similarly applicable to an embodiment wherein the ring incision along its entire periphery extends all the way to the anterior surface of the cornea and along at least a part of its periphery terminates at a distance from the posterior surface of the cornea.

In the case of a utilisation of the device according to the invention for an epikeratoplasty, in which the corneal segment to be replaced is an epithelial corneal lamella, the control program preferentially provides for the generation of a lamellar incision which along at least a part of the lamellar periphery terminates at a distance from the anterior surface of the cornea and otherwise separates the corneal lamella from the remaining corneal tissue.

The control program may in this case provide for such a generation of the lamellar incision that in several regions arranged at a distance from one another in the peripheral direction of the corneal lamella said lamellar incision passes through as far as the anterior surface of the cornea. Alternatively or additionally, the control program may provide for such a generation of the lamellar incision that at least along a predominant part of the lamellar periphery said lamellar incision terminates at a distance from the anterior surface.

The control program preferentially provides for such a generation of the lamellar incision that along the entire lamellar periphery said lamellar incision approaches the anterior surface of the cornea at least up to about 110 µm. Incidentally, also in respect of the epithelial lamellar incision the same numerical and other statements relating to the extent in the direction of the anterior surface of the cornea apply as in respect of the ring incision in the case of penetrating keratoplasty. This means, in particular, that the epithelial lamellar incision may also terminate, at least on a part of its lamellar periphery, in the stroma and does not extend there as far as the epithelium.

In the case of utilisation of the device according to the invention for an endokeratoplasty, in which the corneal segment to be replaced is an endothelial corneal lamella, according to a preferred embodiment the control program provides for the generation of a lamellar incision which along at least a part of the lamellar periphery terminates at a distance from the posterior surface of the cornea and otherwise separates the corneal lamella from the remaining corneal tissue.

The control program may in this case provide for such a generation of the lamellar incision that in several regions arranged at a distance from one another in the peripheral direction of the corneal lamella said lamellar incision passes through as far as the posterior surface of the cornea. Alternatively or additionally, the control program may provide for such a generation of the lamellar incision that at least along a predominant part of the lamellar periphery said lamellar incision terminates at a distance from the posterior surface of the cornea.

The control program preferentially provides for such a generation of the lamellar incision that along the entire periphery said lamellar incision approaches the posterior surface of the cornea up to about 110 µm. Also in this respect the numerical statements made above relating to the ring incision of the penetrating keratoplasty apply correspondingly but with reference to the posterior surface of the cornea instead of the anterior surface. The endothelial lamellar incision also terminates, for example at least along a part of its lamellar periphery, in the stroma and so does not pass through Descemet's membrane there.

According to a further aspect, the invention provides a process for a transplantation of the cornea in respect of the human eye, comprising:

- making available focused pulsed laser radiation,
- directing the laser radiation onto a human eye, in order by means of the laser radiation to generate in the eye an incision which partly separates a corneal segment to be replaced from the remaining corneal tissue of the eye,
- using a sharp instrument, in order manually to separate completely from the remaining corneal tissue the corneal segment separated partly by the incision,
- removing the corneal segment,
- placing corneal donor material on the eye in the region of the removed corneal segment.

The invention will be elucidated further in the following on the basis of the appended drawings. Represented are:

Fig. 1 in schematic block representation, an embodiment of a laser apparatus for generating intracorneal incisions,

Fig. 2 in schematised manner, an example of an incision pattern generated by laser technology for a penetrating keratoplasty,

Fig. 3 in schematised manner, a variant of an incision pattern generated by laser technology for a penetrating keratoplasty,

Fig. 4 in schematised manner, a further variant of an incision pattern generated by laser technology for a penetrating keratoplasty,

Fig. 5 in schematised manner, an example of an incision pattern generated by laser technology for an epikeratoplasty,

Fig. 6 in schematised manner, an example of an incision pattern generated by laser technology for an endokeratoplasty,

Fig. 7 schematically, a tissue bridge remaining in the incision patterns of Figs. 2 to 6 and passing through all around, according to an embodiment and

Fig. 8 schematically, several tissue bridges remaining in the incision patterns of Figs. 2 to 6 according to a further embodiment.

The laser apparatus shown in Figure 1 – denoted generally by 10 – includes a laser source 12 which generates a laser beam 14 with pulse durations within the femtosecond range. In the beam path of the laser beam 14 a number of optical components are arranged, inter alia a scanner 16, indicated here as a unified functional block, an immovable deflecting mirror 17 and also a focusing objective 18. The scanner 16 serves for transverse and longitudinal control of the location of the focal point of the laser beam 14. 'Transverse' here designates a direction at right angles to the direction of propagation of the laser beam 14; 'longitudinal' corresponds to the direction of beam propagation. In conventional notation the traverse plane in the region of the eye can be designated as the x-y plane, whereas the longitudinal direction can be designated as the z-direction.

For transverse deflection of the laser beam 14 (i.e. in the x–y plane) the scanner 16 may, for example, include a pair of galvanically actuated scanner mirrors which are arranged to be tiltable about mutually perpendicular axes. Alternatively, for example, a transverse deflection by means of an electro-optical crystal is conceivable. For the z-control of the focus position the scanner 16 may, for example, contain a longitudinally adjustable lens or a lens of variable refractive power or a deformable mirror, with which the divergence of the laser beam 14 and consequently the z-position of the beam focus can be influenced. It will be understood that the components of the scanner 16 serving for the transverse focus control and for the longitudinal focus control may be divided up to different structural units. For example, the function of the z-focus control may be fulfilled by a lens which may be arranged in beam-expanding optics (beam expander, e.g. Galilean telescope) not represented here in any detail. The components serving for the transverse focus control may, for example, have been accommodated in a separate structural unit between the aforementioned beam-expanding optics and the focusing objective 18. The representation of the scanner 16 as a unified functional block in Figure 1 therefore serves merely for better clarity of layout.

The focusing objective 18 is preferably an f-theta objective and is preferentially detachably coupled on its beam-exit side with a patient adapter 20 which constitutes an abutment interface for the cornea of an eye 22 to be treated. For this purpose the patient adapter 20 exhibits a contact element 24 that is transparent to the laser radiation and that on its underside facing towards the eye exhibits an abutment surface (contact surface) 26 for the cornea. In the exemplary case that is shown, the abutment surface 26 is realised as a plane surface and serves for levelling the cornea, by the contact element 24 being pressed against the eye 22 with appropriate pressure or by the cornea being aspirated onto the abutment surface 26 by underpressure. The contact element 24 (in the case of plane-parallel design, customarily designated as the applanation plate) is fitted at the narrower end of a conically widening carrier sleeve 28. The connection between the contact element 24 and the carrier sleeve 28 may be permanent, for example by virtue of adhesion bonding, or it may be detachable, for instance by virtue of a screw coupling. The carrier sleeve 28 has at its wider sleeve end, in a manner not represented in any detail, suitable coupling structures for coupling to the focusing objective 18.

The laser source 12 and the scanner 16 are controlled by a control computer 30 which operates in accordance with a control program 34 stored in a memory 32. The control program 34 contains instructions (program code) that bring about, upon execution by the control computer 30, such a control of the location of the beam focus of the laser beam 14 that in the cornea of the eye 22 bearing against the contact element 24 an incision figure arises that partly cuts free from the remaining corneal tissue a corneal segment of the eye 22 that is to be removed within the scope of a keratoplasty (transplantation of the cornea), namely to such an extent that the corneal segment is still joined to the surrounding corneal tissue via one or more comparatively small endothelial or/and epithelial tissue bridges. When 'comparatively small tissue bridges' are mentioned here, by this expression it is understood that the incisions needed for severing the tissue bridges and consequently for completely extracting the corneal segment from the cornea are smaller, preferentially very much smaller, than the size of the incision surfaces that are formed by the incision figure generated by laser technology. The tissue bridges guarantee that the corneal segment already separated for the most part from the surrounding corneal tissue nevertheless remains fixed to the cornea. In this way, after the laser treatment the patient can be taken to another workstation at which the operating surgeon performs the grafting of tissue, without, in the meantime, the issue of aqueous humour (in the case of a penetrating keratoplasty) or/and other complications having to be feared which otherwise might arise in the case of complete removal of the corneal segment. At the new workstation the operating surgeon can then sever the remaining tissue bridges with little effort with a scalpel and can remove the corneal segment completely separated in this way from the remaining corneal tissue. In place of the removed corneal segment he/she then implants a suitably dimensioned piece of donor material which, for example, can be fixed to the cornea of the eye 22 by suturing or welding.

In Figs. 2 to 6 examples of various incision patterns are shown that can be generated in the cornea by means of the laser apparatus 10 within the scope of a keratoplasty treatment. In this connection, the incision patterns of Figs. 2 to 4 are suitable for a penetrating keratoplasty, the incision pattern of Fig. 5 is suitable for an epikeratoplasty, and the incision pattern of Fig. 6 is suitable for an endokeratoplasty. Figs. 7 and 8 show, lastly, two exemplary contours of one or more tissue bridges, via which a corneal segment to be removed after generation of one of the incision patterns of Figs. 2 to 6 can still be connected to the surrounding tissue regions of the cornea.

First of all, reference will now be made to Fig. 2. This shows, in a sectional representation, a human cornea 36 with its anterior surface 38 and its posterior surface 40. By means of a laser apparatus, for instance the laser apparatus 10 shown in Fig. 1, a ring incision 42 has been generated in the cornea 36, which partly separates a corneal segment 44 to be removed, for example by reason of disease or injury, and to be replaced by suitable donor material from the remaining corneal tissue situated outside the ring incision 42. In the exemplary case of Fig. 2 the ring incision 42 is cylindrically formed and extends from the posterior surface 40 over the majority of the thickness of the cornea 36 to close to the anterior surface 38. With the exception of a tissue-bridge arrangement situated in the region of the anterior surface 38 - that is to say, an epithelial tissue-bridge arrangement, indicated at 46 – the ring incision 42 consequently severs all the tissue layers of the cornea 36 as far as the posterior surface 40. Over its entire periphery the ring incision 42 approaches the anterior surface 38, for example, at least up to approx. 50-100 µm, i.e. the thickness dimension H_1 drawn in Fig. 2 for the thickness of the tissue-bridge arrangement 46 in the axial direction ('axial' here refers to a ring axis 48, indicated in dashed manner, of the ring incision 42) amounts, for example, to at most 50-100 µm. In a general approximation the z-direction of the propagation of the radiation of the laser beam 14 in the region of the eye can be equated with the direction of the ring axis 48, in which connection it will be understood that, depending upon the position of the ring incision 42 in the cornea, the ring axis 48 may under certain circumstances also be oriented obliquely relative to the x-direction.

The axial length of the ring incision 42 is represented in Fig. 2 by a length dimension H_2. Together, H_1 and H_2 give the total thickness of the cornea 36. Typical corneal thicknesses are between about 500 µm and 600 µm.

In the other Figures, identical or identically-acting elements or constituents are provided with the same reference symbols as in Fig. 2, but supplemented by a lower-case letter. Unless stated otherwise below, with respect to the elucidation of these elements or constituents reference is made to the elucidations above.

The variant according to Fig. 3 shows a ring incision 42a that is suitable for a penetrating keratoplasty and that, in contrast to the embodiment shown in Fig. 2, is not uniformly cylindrically formed over its entire axial length but is realised in stepped cylindrical form. For this purpose it exhibits several ring-cylindrical incision portions 42a', 42a" which are consecutive in the axial direction and which have differing diameters (alternatively or additionally: differing cross-sectional shapes) and are connected to one another at a step 50a. In the embodiment that is shown, the step 50a runs radially relative to the ring axis 48a, but it will be understood that it may alternatively run obliquely thereto. Even though in the exemplary case shown in Fig. 3 the ring incision 42a is realised with a total of two ring-cylindrical incision portions 42a', 42a", it is conceivable that the ring incision 42a alternatively has more than two such incision portions which in each instance are connected to one another in pairs by a step.

Dimension H_1 has the same significance as in Fig. 2.

The variant shown in Fig. 4 shows a ring incision 42b, with a configuration that is angular in stepped manner, which is likewise suitable for the penetrating keratoplasty. Just as in the variant shown in Fig. 3, the ring incision 42b shown in Fig. 4 is composed of several (here, two) incision portions 42b', 42b" which, however, are realised not in cylindrical form but in conical form. It will be discerned that in the exemplary case shown the two incision portions 42b', 42b" have differing cone angles and are connected to one another at a step 50b running obliquely relative to the radial direction. It will be understood that alternatively the step 50b, just as in the variant shown in Fig. 3, may run radially relative to the ring axis 48b. The peripheral contour of the ring incision 42b may be circular or may have a shape deviating therefrom. To be mentioned, furthermore, is the fact that in the exemplary case shown in Fig. 4 the two incision portions 42b', 42b" have the same cone direction and, in concrete terms, both widen conically in the direction towards the anterior surface 38b of the cornea. In addition, the step 50b connects the narrower axial end of one of the incision portions (here, incision portion 42b') to the wider axial end of the other incision portion (here, 42b"), whereby the one incision portion with its narrower end enters a little into the other incision portion. This results overall in a kind of barb at the transition between the two incision portions 42b', 42b", this barb guaranteeing an additional support so as to counter an undesirable expelling of the corneal segment 44b from the cornea 36b.

Fig. 5 shows an incision figure that is suitable for an epithelial lamellar keratoplasty (epikeratoplasty) and that can be generated with a laser apparatus, for example with the laser apparatus 10 shown in Fig. 1. The incision figure includes a lamellar incision 52c which separates the greater part of a lamellar corneal segment 44c to be removed from the remaining corneal tissue within the scope of the keratoplasty. The lamellar incision 52c is composed, in the exemplary case that is shown, of a ring incision 52c' defining the lamellar periphery and of a base incision 52c" defining an intracorneal lamellar principal surface, which is situated substantially perpendicular to the ring axis 48c of the ring incision 52c'. Even though the base incision 52c" in Fig. 5 is shown as a flat incision, it will be understood that it may alternatively be curved. Similarly, it will be understood that a rounded transition between the base incision 52c" and the ring incision 52c' is possible instead of the angular transition shown in Fig. 5. What is essential is that the lamellar incision 52c terminates along a part of the lamellar periphery at a distance from the anterior surface 38c of the cornea 36c and accordingly, just as in the embodiments shown in Figs. 2 to 4, an epithelial tissue-bridge arrangement 46c remains, via which the corneal segment 44c is still connected to the surrounding tissue region of the cornea 36c. The axial thickness of the tissue-bridge arrangement 46c – denoted by H_1 in Fig 5 – may correspond substantially to that from Figs. 2 to 4. Since in the case of a lamellar keratoplasty an issue of aqueous humour is ordinarily not to be feared, even after removal of the corneal segment 44c, it is conceivable to realise the tissue-bridge arrangement 46c in thinner form than in the case of a penetrating keratoplasty – i.e. the lamellar incision 42c may, under certain circumstances, approach the anterior surface 38c more closely than the incision figures shown in Figs. 2 to 4. The axial extent of the lamellar incision 52c is denoted in Fig. 5 by a thickness dimension H_3. This depends, above all, on the thickness of those tissue regions of the cornea 36c which are diseased or injured and therefore have to be removed.

The embodiment shown in Fig. 6 shows an incision figure generated by laser technology that is suitable for an endothelial lamellar keratoplasty (endokeratoplasty). In the exemplary case that is shown, this incision figure corresponds substantially to the incision figure shown in Fig. 5, apart from the fact that it has, so to speak, been turned upside down and an endothelial tissue-bridge arrangement 46d remains, via which the corneal segment 44d to be removed after placement of the lamellar incision 52d is still connected to the surrounding tissue regions of the cornea 36d. For the thickness of the tissue-bridge arrangement 46d, what was said in connection with Fig. 5 for the tissue-bridge arrangement 46c therein applies. Accordingly, in Fig. 6 the thickness of the tissue-bridge arrangement 46d is indicated by the same thickness dimension H_1. The axial height of the lamellar incision 52d, on the other hand, is indicated by a dimension H_4, whereby here too it again holds that the value of this dimension will be determined, above all, by the thickness of the diseased or injured tissue regions of the cornea 36d. Analogously to the lamellar incision 52c shown in Fig. 5, the lamellar incision 52d shown in Fig. 6 may be composed of a ring incision 52d' defining the lamellar periphery and of a base incision 52d" running transversely, in particular perpendicular, thereto.

Reference will finally be made to Figs. 7 and 8. Indicated in dashed manner therein is the region in which the cornea of the eye to be operated upon bears against the contact element 24 of the laser apparatus 10 shown in Fig. 1 or against an applanation element of another laser apparatus. This region is denoted by 54e and 54f, respectively, and consequently represents the applaned region of the cornea.

Fig. 7 illustrates the case of a single tissue bridge 46e passing through 360°. This corresponds to a scenario in which the incision figure generated by laser technology does not at any point pass through as far as the anterior surface of the cornea (in the case of penetrating keratoplasty and epikeratoplasty) or does not at any point pass through as far as the posterior surface of the cornea (in the case of endokeratoplasty). Fig. 8, on the other hand, illustrates the case of an arrangement of several tissue bridges 46f distributed in the peripheral direction, between which in each instance a region 56f is situated in which the incision figure generated by laser technology passes through as far as the anterior surface of the cornea (in the case of penetrating keratoplasty and epikeratoplasty) or as far as the posterior surface of the cornea (in the case of endokeratoplasty). In the exemplary case of Fig. 8 which is shown, the tissue-bridge arrangement is composed of a total of three tissue bridges 46f, i.e. overall three regions 56f arise at which the incision figure generated by laser technology passes through as far as the anterior surface or posterior surface of the cornea. It will be discerned, however, that the peripheral length of the tissue bridges 46f is considerably longer than the peripheral length of the regions 56f, so that, viewed in the peripheral direction, a greater part of the corneal segment to be removed is still joined to the surrounding tissue regions of the cornea than has been severed.

It will be understood that the number of tissue bridges in the case of a multi-part tissue-bridge arrangement may be variable and is by no means limited to three.

Claims

1. Device for implementing a transplantation of the cornea in respect of the human eye (22), including instruments for detaching from the eye a corneal segment (44) to be replaced, the instruments including a program-controlled laser apparatus (10) which has been set up to make available focused pulsed laser radiation, the laser apparatus including a control program (34) which provides for such a generation of an incision in the cornea (36) by means of the laser radiation that the corneal segment to be replaced is only partly separated from the remaining corneal tissue of the eye.

2. Device according to Claim 1, wherein for a penetrating keratoplasty the control program provides for the generation of a ring incision (42) in the cornea (36) which along its entire periphery severs the corneal tissue as far as the posterior surface (40) of the cornea and along at least a part of its periphery terminates at a distance from the anterior surface (38) of the cornea.

3. Device according to Claim 2, wherein the control program provides for such a generation of the ring incision (42) that along its entire periphery said ring incision approaches the anterior surface (38) of the cornea (36) at least up to about 110 µm.

4. Device according to Claim 2 or 3, wherein the control program provides for such a generation of the ring incision (42) that on a part of its periphery said ring incision passes through as far as the anterior surface (38) of the cornea (36).

5. Device according to Claim 4, wherein the control program provides for such a generation of the ring incision (42) that in several regions arranged at a distance from one another in the peripheral direction said ring incision passes through as far as the anterior surface (38) of the cornea (36).

6. Device according to one of Claims 2 to 5, wherein the control program provides for such a generation of the ring incision (42) that at least along a predominant part of its periphery said ring incision terminates at a distance from the anterior surface (38) of the cornea (36).

7. Device according to one of Claims 2 to 6, wherein the control program provides for such a generation of the ring incision (42) that at least on a part of its axial length said ring incision is cylindrically formed.

8. Device according to one of Claims 2 to 6, wherein the control program provides for such a generation of the ring incision (42a) that the latter is cylindrically formed in stepped manner.

9. Device according to one of Claims 2 to 6, wherein the control program provides for such a generation of the ring incision (42b) that the latter is realised in stepped conical form.

10. Device according to Claim 9, wherein the control program provides for such a generation of the ring incision (42b) that said ring incision exhibits two conical ungulae (50b', 50b") separated by a step (50b), the cone angles of which are different.

11. Device according to Claim 1, wherein for an epikeratoplasty in which the corneal segment (44c) to be replaced is an epithelial corneal lamella the control program provides for the generation of a lamellar incision (52c) which along at least a part of the lamellar periphery terminates at a distance from the anterior surface (38c) of the cornea (36c) and otherwise separates the corneal lamella from the remaining corneal tissue.

12. Device according to Claim 11, wherein the control program provides for such a generation of the lamellar incision (52c) that in several regions arranged at a distance from one another in the peripheral direction of the corneal lamella said lamellar incision passes through as far as the anterior surface (38c) of the cornea (36c).

13. Device according to Claim 11 or 12, wherein the control program provides for such a generation of the lamellar incision (52c) that at least along a predominant part of the lamellar periphery said lamellar incision terminates at a distance from the anterior surface (38c) of the cornea (36c).

14. Device according to one of Claims 11 to 13, wherein the control program provides for such a generation of the lamellar incision (52c) that along the entire lamellar periphery said lamellar incision approaches the anterior surface (38c) of the

cornea (36c) at least up to about 110 µm.

15. Device according to Claim 1, wherein for an endokeratoplasty in which the corneal segment (44d) to be replaced is an endothelial corneal lamella the control program provides for the generation of a lamellar incision (52d) which along at least a part of the lamellar periphery terminates at a distance from the posterior surface (40d) of the cornea (36d) and otherwise separates the corneal lamella from the remaining corneal tissue.

16. Device according to Claim 15, wherein the control program provides for such a generation of the lamellar incision (52d) that in several regions arranged at a distance from one another in the peripheral direction of the corneal lamella said lamellar incision passes through as far as the posterior surface (40d) of the cornea (36d).

17. Device according to Claim 15 or 16, wherein the control program provides for such a generation of the lamellar incision (52d) that at least along a predominant part of the lamellar periphery said lamellar incision terminates at a distance from the posterior surface (40d) of the cornea (36d).

18. Device according to one of Claims 15 to 17, wherein the control program provides for such a generation of the lamellar incision (52d) that along the entire lamellar periphery said lamellar incision approaches the posterior surface (40d) of the cornea (36d) at least up to about 110 µm.

19. Process for a transplantation of the cornea in respect of the human eye, comprising:

- making available focused pulsed laser radiation,
- directing the laser radiation onto a human eye, in order by means of the laser radiation to generate in the eye an incision which partly separates a corneal segment to be replaced from the remaining corneal tissue of the eye,
- using a sharp instrument, in order manually to separate completely from the remaining corneal tissue the corneal segment separated partly by the incision,
- removing the corneal segment,
- placing corneal donor material on the eye in the region of the removed corneal segment.

20. Process according to Claim 19, wherein the transplantation of the cornea is a penetrating keratoplasty and the incision is a ring incision which along its entire periphery severs the corneal tissue as far as the posterior surface of the cornea and along at least a part of its periphery terminates at a distance from the anterior surface of the cornea.

21. Process according to Claim 20, wherein the ring incision is generated in such a way that along its entire periphery it approaches the anterior surface of the cornea at least up to about 110 μm.

22. Process according to Claim 20, wherein the ring incision is generated in such a way that on a part of its periphery it passes through as far as the anterior surface of the cornea.

23. Process according to Claim 22, wherein the ring incision is generated in such a way that in several regions arranged at a distance from one another in the peripheral direction it passes through as far as the anterior surface of the cornea.

24. Process according to Claim 20, wherein the ring incision is generated in such a way that at least along a predominant part of its periphery it terminates at a distance from the anterior surface of the cornea.

25. Process according to Claim 20, wherein at least on a part of its axial length the ring incision is cylindrically formed.

26. Process according to Claim 20, wherein the ring incision is cylindrically formed in stepped manner.

27. Process according to Claim 20, wherein the ring incision is realised in stepped conical form.

28. Process according to Claim 27, wherein the ring incision exhibits two conical ungulae separated by a step, the cone angles of which are different.

29. Process according to Claim 19, wherein the transplantation of the cornea is an epikeratoplasty in which the corneal segment to be replaced is an epithelial corneal lamella, wherein the incision is generated in such a way that along at least a part of

the lamellar periphery it terminates at a distance from the anterior surface of the cornea and otherwise separates the corneal lamella from the remaining corneal tissue.

30. Process according to Claim 29, wherein the incision is generated in such a way that in several regions arranged at a distance from one another in the peripheral direction of the corneal lamella it passes through as far as the anterior surface of the cornea.

31. Process according to Claim 29, wherein the incision is generated in such a way that at least along a predominant part of the lamellar periphery it terminates at a distance from the anterior surface of the cornea .

32. Process according to Claim 29, wherein the incision is generated in such a way that along the entire lamellar periphery it approaches the anterior surface of the cornea at least up to about 110 μm.

33. Process according to Claim 19, wherein the transplantation of the cornea is an endokeratoplasty in which the corneal segment to be replaced is an endothelial corneal lamella, wherein the incision is generated in such a way that along at least a part of the lamellar periphery it terminates at a distance from the posterior surface of the cornea and otherwise separates the corneal lamella from the remaining corneal tissue.

34. Process according to Claim 33, wherein the incision is generated in such a way that in several regions arranged at a distance from one another in the peripheral direction of the corneal lamella it passes through as far as the posterior surface of the cornea.

35. Process according to Claim 33, wherein the incision is generated in such a way that at least along a predominant part of the lamellar periphery it terminates at a distance from the posterior surface of the cornea.

36. Process according to Claim 33, wherein the incision is generated in such a way that along the entire lamellar periphery it approaches the posterior surface of the cornea at least up to about 110 μm.

FIG 1

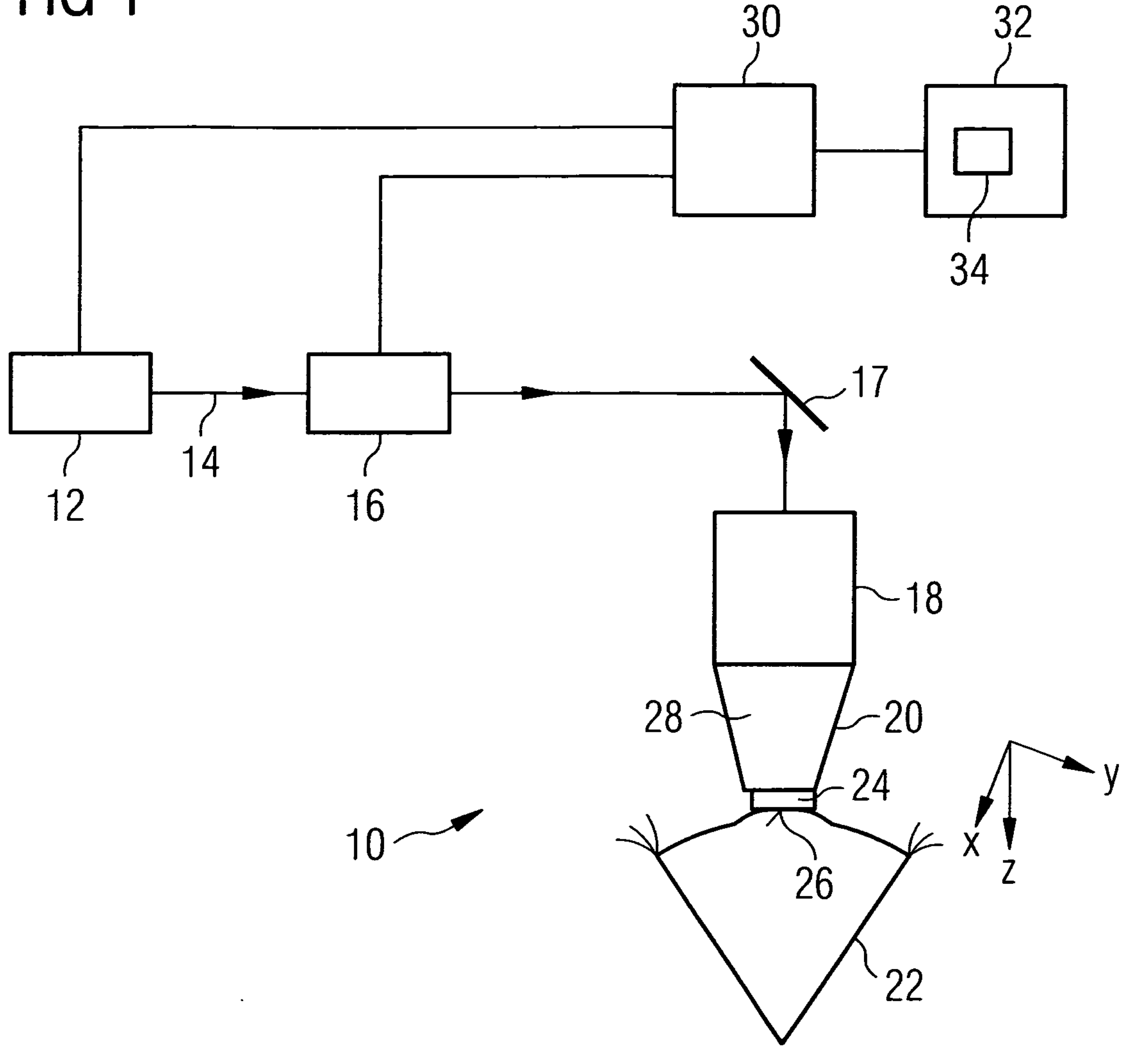


FIG 2

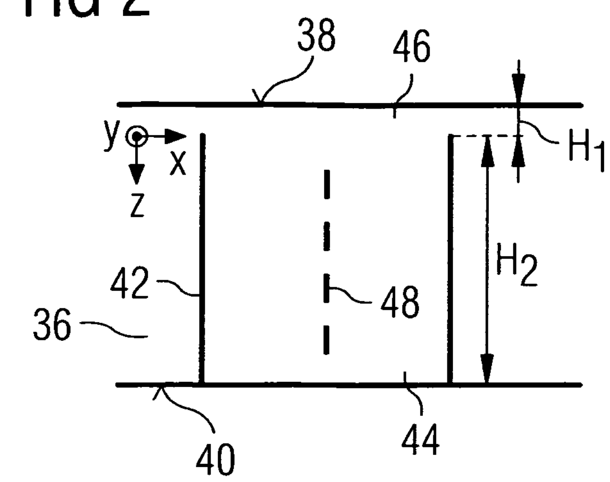


FIG 3

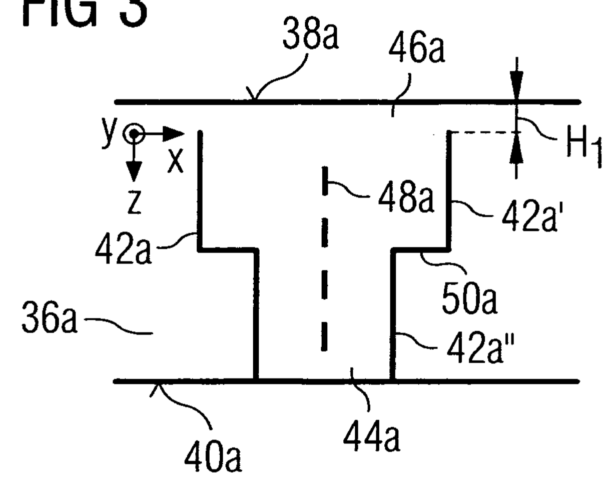


FIG 4

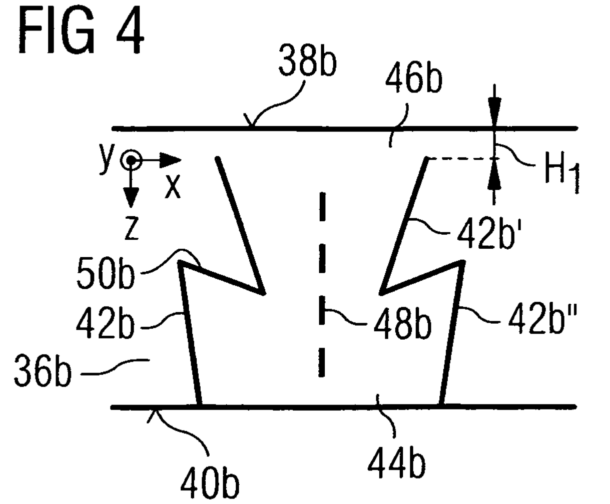


FIG 5

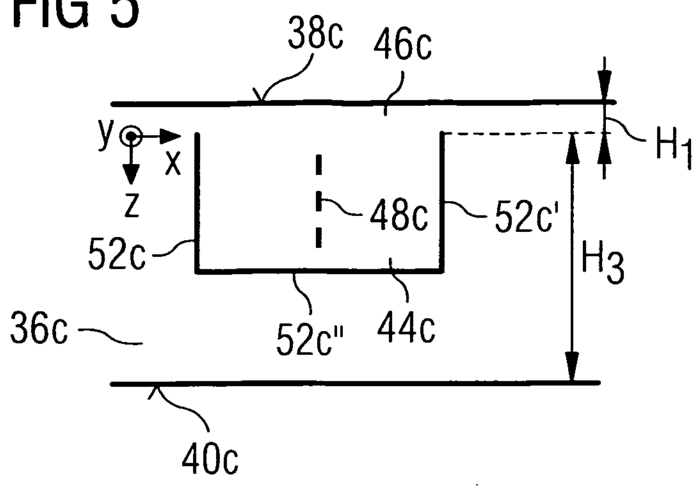


FIG 6

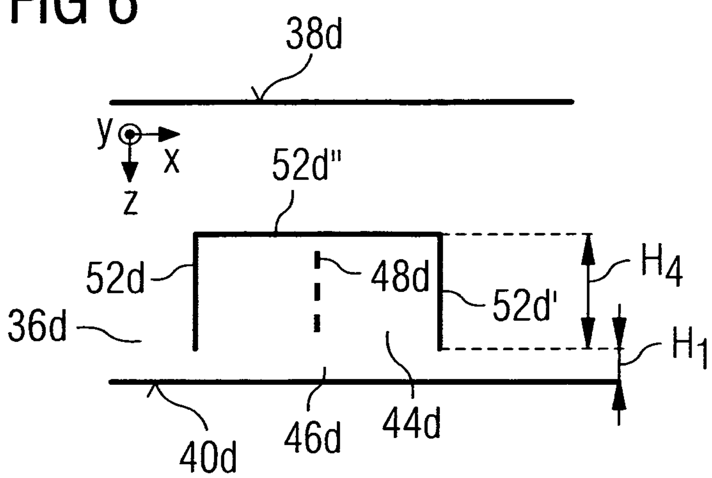


FIG 7

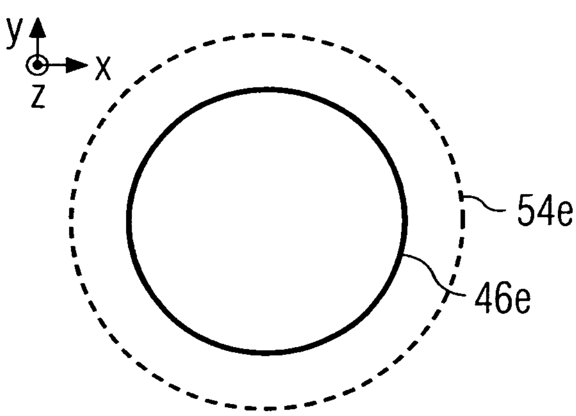
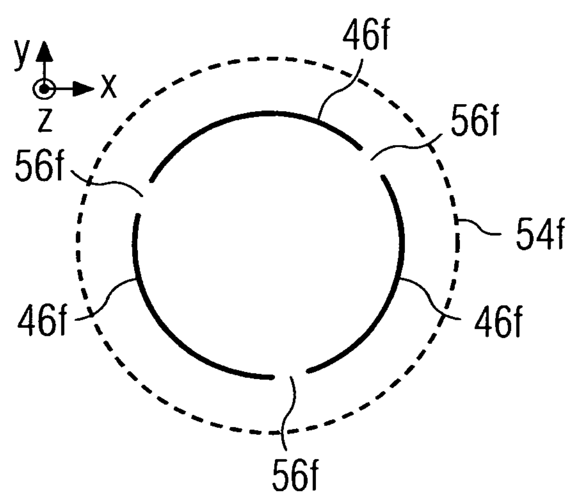


FIG 8



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/000709

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F9/01
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 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 2008/030719 A2 (INTRALASE CORP [US]; KURTZ RONALD M [US]; PRICE FRANCIS W [US]; SARAYB) 13 March 2008 (2008-03-13) abstract paragraphs [0005], [0006], [0011], [0016], [0020] figures 1A,1B,1C,1D,1E,1F,1H,2 -----	1-18
X	EP 1 719 483 A1 (CARRIAZO CESAR C DR [CO] SCHWIND EYE TECH SOLUTIONS GMBH & CO KG [DE]) 8 November 2006 (2006-11-08) abstract paragraphs [0014], [0016], [0018], [0025] figure 1 -----	1-7, 11-18

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[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
10 November 2011	24/11/2011

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	Jansen, Birte

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/000709

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. [X] Claims Nos.: 19-36
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 19-36

The process for a transplantation of the cornea comprising the steps of directing laser radiation onto a human eye to generate in the eye an incision using a sharp instrument to separate completely the corneal segment removing the corneal segment
placing corneal donor material on the eye
as defined in claims 19-36 is regarded to be a method for surgical treatment of the human or animal body, since it intervenes in the structure of an organism. Said methods are excluded from patentability according to Rule 39.1(iv) PCT.

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HEISTERKAMP A ET AL: "[Optimizing laser parameters for intrastromal incision with ultra-short laser pulses] OPTIMIERUNG DER LASERPARAMETER FUER DIE INTRASTROMALE SCHNITTFUEHRUNG MITTELS ULTRAKURZER LASERPULSE", OPHTHALMOLOGE, SPRINGER, BERLIN, DE, vol. 98, no. 7, 1 July 2001 (2001-07-01), pages 623-628, XP002368976, ISSN: 0941-293X, DOI: 10.1007/S003470170097 the whole document -----	1,11,12
X	WO 92/03187 A1 (PHOENIX LASER SYSTEMS INC [US]) 5 March 1992 (1992-03-05) abstract page 10, line 34 - page 11, line 15 figures 7,7A,8, 8A,9,9A,10,10A -----	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2011/000709

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