XENIA® Corneal Implant
Custom-Made Device

1. Indications for Use
The XENIA Lenticule is intended for ophthalmic lenticular intracorneal keratoplasty (e.g., LIKE). Thereby, it is intended to be implanted in a patient's cornea in order to change its thickness and / or to change the cornea's anterior curvature and / or to replace defective, compromised or vacant stromal tissue.

2. Contra Indications
The following contraindications must be observed:

- Previous penetrating keratoplasty
- Herpes simplex or Herpes zoster involving the eye area
- Glaucoma, suspected glaucoma or ocular hypertension
- Acute eye diseases including – but not limited to – uveitis/iritis or blepharitis
- Diseases or medications that may affect wound healing
- The XENIA Lenticule must not be used in patients suffering from allergy against porcine proteins
- Deep stromal opacities, when used in procedures for ametropia treatment
- If the XENIA Lenticule is used in LIKE procedures for keratoconus treatment:
    - Corneal endothelial dysfunction
    - Poor attachment of epithelial cells to Bowman's membrane (relative contraindication)
- Post-LASIK / Post-Refractive Ectasia
- Corneal thickness ≤ 400 µm
- Corneal scars

3. Complications and Warnings
Since the XENIA Lenticule is manufactured from porcine corneal tissue, there is a residual risk that particularly predisposed patients may develop an immunological tissue rejection. Therefore, in order to protect the patient against immunological complications and graft rejection, a local immuno-suppressive corticoid treatment is recommended for a period of approximately 6 months after the implantation. High-risk patients may require additional systemic immunosuppressive and / or antibiotic treatments.

In the unlikely event that the XENIA Lenticule should be damaged or not be transparent (in re-hydrated state) when the primary packaging is opened, this nontransparent lenticule must not be implanted.

The responsible ophthalmic surgeon or ophthalmologist is requested to instruct the patient receiving a XENIA Lenticule not to vigorously rub his/her treated eye. Excessive rubbing may open or even destroy the corneal pocket containing the implanted XENIA Lenticule, which would require immediate medical intervention.

The responsible surgeon may use a bandage contact lens immediately after surgery in order to support the healing process of the treated corneal tissue.

Furthermore, the surgeon-in-charge is responsible to inform patients implanted with the XENIA Lenticule about possible risks associated with the use of commercially available contact lenses, to avoid compromising the corneal surface after surgery, respectively, to avoid a detachment of the corneal pocket from the corneal stroma.

Depending on the patient's condition to be treated, the following particular complications may occur:

- When the XENIA Lenticule is used in procedures for ametropia treatment:
  - Transient light sensitivity syndrome - glare or halos at night
  - Dry eye syndrome in the first 3 months following surgery
  - Infections: Probability of occurrence is 1 in 2.000 patients
  - Retinal detachment, which, however, can also occur in myopic patients without any surgical intervention
  - Inappropriate pocket creation: in 1 patient out of 1.000, the pocket is too small, too shallow / deep, off center or incomplete
  - Postoperative interface inflammation
  - Cellular ingrowth
  - Postoperative ametropia – over/under correction
- When the XENIA Lenticule is used in LIKE procedures for keratoconus treatment
  - Early postoperative complications:
    - Wound leak / suture track leak
    - Persistent epithelial defects
    - Intraocular pressure rise / glaucoma
    - Suture infiltrates
    - Primary (early) graft failure
    - Inflammation, edema, infection, iris ischaemia or loose / broken sutures
  - Late postoperative complications:
    - Late graft failure
    - Astigmatism
    - Glaucoma
    - Retrocorneal membranes
    - Interface opacification
    - Intra-operative Descemet's membrane tear or perforation requiring penetrating keratoplasty surgery
    - Pseudo double anterior chamber created by the presence of aqueous humor between the donor button and the recipient posterior stroma
    - Late epithelial / corneal edema, followed by corneal melting
    - Late opacification of the implant and/ or the adjacent patient corneal tissue

It shall be noted that the most aforementioned contraindications and complications are not specific for the XENIA Lenticule, but rather may be related to the respective surgical intervention – such as keratoplasty and LIKE procedures – by which the lenticule is transplanted into the patient's cornea, and may also occur with any lenticules or grafts obtained from human donors.

CAUTION
Patients must be instructed to critically observe their treated eye after implantation and to immediately notify the ophthalmic surgeon or responsible ophthalmologist of any potential irritation or immunological reactions, and to avoid any vigorous rubbing or mechanical manipulations of the treated eye. In any doubtful observations, the patient must be instructed to consult his/her ophthalmic surgeon or responsible ophthalmologist without delay.

4. Precautions and Safety Instructions

Gebauer Medizintechnik GmbH does not guarantee a specific refractive and/or surgical result if patients are treated for ametropia. It is the sole responsibility of the ophthalmic surgeon or responsible ophthalmologist to determine and prescribe the most appropriate lenticular geometry and optical profile for the particular medical condition of the patient on an individual basis. In the case that the initial lenticule implantation should not result in the optimal visual correction, it is the responsibility of the ophthalmic surgeon to initiate any necessary action, which may include replacement of the ineffectual XENIA Lenticule by one of newly specified lenticular geometry.

NOTICE
It is the sole responsibility of the attending ophthalmic surgeon or ophthalmologist to individually select and prescribe the most appropriate lenticular geometry and optical profile, as required for the respective patient and the particular medical condition.

5. Liability

The manufacturer is not liable for the implantation method and surgical techniques used by the responsible ophthalmic surgeon performing the implantation procedure of the XENIA Lenticule. Furthermore, it is the sole responsibility of the ophthalmic surgeon to select an appropriate XENIA Lenticule geometry and optical profile, that is best suited to the specific medical needs of a particular patient. Therefore, any descriptions of surgical procedures provided by Gebauer Medizintechnik GmbH can only provide a general orientation, which never is intended to overrule the medical and surgical competence and experience of the responsible ophthalmic surgeon.

Gebauer Medizintechnik GmbH
Monbachstraße 7/1
75242 Neuhausen, Germany
www.xenia-implant.com