



DOC: 50 – 850- 006 – IFU-XT.A.01

Effective Date: 27Aug2018

KeraKlear XT Foldable Artificial Cornea Instructions For Use

Introduction:

The KeraKlear XT Foldable Artificial Cornea is a 7 millimeter overall diameter artificial cornea with a 4 millimeter optical zone, designed to create a clear window in an opacified natural cornea. It is made from a foldable biocompatible polymer which contains a UV inhibitor. Its periphery has 12 holes to allow suture fixation to the recipient cornea as well as long term corneal tissue fixation.

The KeraKlear XT Foldable Artificial Cornea is available in a phakic version of 44 Diopter power at the corneal surface which simulates the refractive power of a normal cornea.

The KeraKlear XT Foldable Artificial Cornea is individually packaged and sterilized in a plastic vial with a saline solution. A patient identification card and a set of labels are provided to allow traceability and patient follow up.

Patient Disclosure:

As with any procedure, the use of KeraKlear XT Foldable Artificial Cornea has benefits and risks. Prior to use, always review the benefits, risks and alternatives with your patients.

Indications For Use:

The KeraKlear XT Foldable Artificial Cornea is intended for use as a keratoprosthesis in adult patients with corneal opacity to include the following:

* Eyes with corneal blindness (Best Corrected Snellen visual acuity equal to or worse than 20/200)

*Eyes that are not suitable for standard penetrating keratoplasty with donor tissue.

*Eyes in patients who have declined to have standard penetrating keratoplasty performed with donor tissue,

*Eyes in which the adjunctive measures required to prevent graft rejection are medically contraindicated.



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Contraindications

Severe dry eyes with a Schirmer test score of less than 3 mm at 5 minutes with anesthesia, uncontrolled ocular inflammation, Steven’s Johnson Syndrome, ocular cicatricial pemphigoid, atopic keratoconjunctivitis, active infection, corneal thickness less than 300 microns anywhere on the cornea, inability to receive eyedrop medications on a daily basis, allergy to acrylic materials, inability to protect the operated eye from trauma, continual exposure to cigarette smoke.

Warning

The KeraKlear XT Foldable Artificial Cornea should only be implanted by trained corneal surgeons. As with all surgical procedures, keratoprosthesis implantation presents risks, which the surgeon must evaluate. Some of the potential complications of keratoprosthesis implantation are: infection, need for additional surgery, loss of vision and loss of the eye.

Among those directly linked to keratoprostheses are: corneal melting, extrusion of the keratoprosthesis, retroprosthetic membranes, endophthalmitis occurring months or years after implantation, opaque deposits within the optic, and discoloration of the optic.

The KeraKlear XT Artificial Cornea is single eye use. Do not reuse, reprocess or re-sterilize. Re-Use, reprocessing or re-sterilizing may compromise the structural integrity of the device and lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited, the transmission of infection disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Precautions for use and storage

Store at room temperature, avoid high temperatures above 45°C.



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The KeraKlear XT Foldable Artificial Cornea power and expiration date should be verified before opening.

Do not use after expiration date indicated on the package.

Single use, do not re-sterilize.

Implantation of a KeraKlear XT Foldable Artificial Cornea requires the use of appropriate techniques and instruments. Any KeraKlear XT Foldable Artificial Cornea damaged during handling should not be implanted.

Do not use if the sterile pouch or plastic vial have been compromised.

Sterility of the KeraKlear XT Foldable Artificial Cornea is guaranteed only as long as the individual sterile pouch and plastic vial have not been opened or damaged.

The material may absorb substances that are in contact with the material (e.g. disinfectants such as iodine, cigarette smoke and cooking smoke) therefore do not expose the KeraKlear XT Foldable Artificial Cornea to potential contaminants. The combination of topical beta-blocker and topical steroid has been reported to be associated with deposits in other types of artificial corneas and therefore should not be used in combination for prolonged periods of time. Phosphate buffered topical medications may promote precipitation of calcium.

Instructions for use:

Instrumentation

It is recommended that only stainless steel or titanium surgical instruments be used in the manipulation of the KeraKlear XT artificial cornea. These instruments should be sterilized by autoclave using generally accepted protocols and then rinsed with sterile water before use. If sponges are used on the operative field, the sponges should be particulate free (e.g. Merocel).

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Retrieval of the KeraKlear XT Foldable Artificial Cornea

Check the model number of the KeraKlear XT. The model number will determine the depth of pocket creation for implantation. Open the protective sealed box and remove the pouch containing the plastic vial which contains the KeraKlear XT Artificial Cornea. Remove and open the plastic vial. Gently retrieve the KeraKlear XT Artificial Cornea with a blunt forceps or non-particulate forming sponge (e.g. Merocel).

Note: prior to performing the surgery on the patient, the surgeon should inspect the artificial cornea under a microscope to make sure that the device is completely intact after retrieval with no visible tears or other damage. If there is any sign of damage, the device should not be implanted.

Femtosecond Pocket creation and Trephination

An 8 mm uniform circular corneal pocket is made at a depth corresponding to the model of the KeraKlear XT. For example, a 400 micron depth pocket would be made for a KeraKlear XT 400. It is recommended that there is 100 to 150 microns of corneal tissue posterior to the corneal pocket. For example, if an edematous failed cornea transplant measures 740 microns in thickness, a pocket would be created at a depth of 600 microns to leave a posterior corneal thickness of 140 microns and the KeraKlear XT 600 would be chosen for implantation.

A trephination incision of 3.5 mm diameter should be created with the femtosecond laser. The 3.5 mm diameter trephination incision will allow a snug fit of the recipient cornea around the optic of the KeraKlear. In the case of a femtosecond laser, the trephination depth should be set to 20 microns deeper than the pocket depth to help insure complete trephination.

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Pocket Making Microkeratome and Trephination with 3.5 mm Dermal Punch (To be used when femtosecond trephination is unavailable)

An 8 mm uniform circular corneal pocket is made at a depth corresponding to the model of the KeraKlear XT. For example, a 400 micron depth pocket would be made for a KeraKlear XT 400. It is recommended that there is 100 to 150 microns of corneal tissue posterior to the corneal pocket. For example, if an edematous failed cornea transplant measures 740 microns in thickness, a pocket would be created at a depth of 600 microns to leave a posterior corneal thickness of 140 microns and the KeraKlear XT 600 would be chosen for implantation.

The center of the corneal pocket is marked with a marking pen (e.g. gentian violet). A plastic Sheet's glide or metal spatula is placed through a side incision at the periphery of the pocket to serve as a blocker to prevent trephination of the corneal tissue posterior to the pocket. The 3.5 mm dermal punch is centered on the mark at the center of the corneal pocket and used to punch out the central 3.5 mm of the cornea using gentle turning between the fingers. The anterior cornea is then removed with forceps and the Sheet's glide removed from the pocket.

Warning

It is the responsibility of the surgeon to confirm that there will be at least 100 microns of corneal tissue posterior to the corneal pocket prior to implantation of the KeraKlear XT Artificial Cornea. Failure to confirm at least 100 microns of corneal tissue posterior to the corneal pocket may result in perforation of the cornea and inability to implant the KeraKlear XT Artificial Cornea.

Excision of the Anterior Recipient Cornea and Insertion of the KeraKlear XT Artificial Cornea into the Corneal Pocket with Forceps.

The KeraKlear XT Artificial Cornea is then grasped with smooth forceps (e.g. angled McPherson forceps) and inserted into the pocket. The smooth forceps can then be used to manipulate the rim of the device to fit into the pocket recesses. It is important to confirm that the entire rim is unfolded 360 degrees. The optic is then fit into the anterior cornea opening so that the optic is fit within the rim of the anterior corneal tissue.

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Suturing of the KeraKlear XT Artificial Cornea to the Recipient Cornea

Suturing of the KeraKlear XT to the recipient cornea is optional for most patients, except for patients with keratoconus. It is recommended that all patients with keratoconus who are implanted with the KeraKlear XT have sutures. When suturing is desired, we recommend that a single 10-0 nylon suture be placed in each quadrant through one of the holes in the periphery of the artificial cornea at 90% corneal depth. Each suture is tied and then the knot is buried within the corneal stroma.

Closing of the Peripheral Pocket Entry Incision

When an incision has been made at the periphery of the pocket, we recommend that at least one suture is used to close the pocket entry incision to insure a tight seal.

Bandage Contact Lens

It is recommended that a highly oxygen permeable bandage contact lens (e.g. Bausch and Lomb Purevision) be placed over the cornea at the end of the case. Continual use of a highly oxygen permeable bandage contact lens for at least 1 month after implantation will help promote growth of epithelium over the periphery of the KeraKlear XT Artificial Cornea optic.

Post-Operative Management

A broad spectrum antibiotic eyedrop and a high potency steroid drop (e.g. prednisolone acetate 1%) should be administered to the eye at the end of the case and for 4 times a day for 1 week after the surgery and then stopped.

It is recommended that broad spectrum antibiotic drops be given two times daily for life after KeraKlear XT Artificial Cornea implantation (e.g., ofloxacin or polymyxin/trimethoprim ophthalmic drops).

It is also recommended that a contact lens rewetting drop which contains EDTA (e.g. Alcon Optifree Replenish Contact Lens Rewetting Drops) be given two to four times a day for life

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after KeraKlear XT Artificial Corneal implantation. The contact lens rewetting drop should be given even if a contact lens is not being used as it will help to decrease the likelihood of infection.

Warning

It is known that phosphate buffered topical ophthalmic eye drops can cause calcium precipitation and deposit formation in sick corneas even in eyes without either transplantation or keratoprosthesis. Therefore, we strongly recommend against the use of any phosphate buffered ophthalmic eyedrops after KeraKlear XT Artificial Cornea implantation.

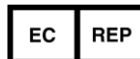
After KeraKlear XT Artificial Cornea implantation, patients should be examined on a regular basis by a corneal specialist to check for any possible complications.

Product Information

Each vial contains one STERILE artificial cornea.



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Explanation of symbols and abbreviations used on product labels:

	Sterile/Steam
	Single Use
<p>Rx Only</p>	Prescription Only
<p>CE 0459</p>	Notified Body European Community registration number
	Expiration Date – YYYY-MM
<p>LOT</p>	Lot or batch number
	See Instructions
<p>EC REP</p>	Authorized Representative
	Manufacturer