KeraKlear XT / XTA Artificial Cornea
Instructions For Use

Device Description:

This IFU covers KeraKlear XT (for phakic eyes) and KeraKlear XTA (for aphakic eyes) configurations. Throughout the rest of this document, both configurations are generically referred to KeraKlear XT.

The KeraKlear XT 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 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 XTA Artificial Cornea is also available in an aphakic version of 60 Diopter power at the corneal surface which compensates for the absence of an intraocular lens.

The KeraKlear XT Artificial Cornea is individually packaged and sterilized by steam in a glass vial containing 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 Artificial Cornea has benefits and risks. Prior to use, always review the benefits, risks and alternatives with your patients.

Caution: Federal law restricts this device to sale by or on the order of a Physician.

Indications For Use:

The KeraKlear XT 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.

Warnings

The KeraKlear XT Artificial Cornea should only be implanted by trained corneal surgeons. As with all surgical procedures, XT Artificial Cornea implantation presents risks, which the surgeon must evaluate. Some of the potential complications of XT Artificial Cornea 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 artificial cornea, retroprosthetic opacity, infection occurring months or years after implantation, opaque deposits within the optic, and discoloration of the optic.

The KeraKlear XT Artificial Cornea is for single patient eye use. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilizing may compromise the structural integrity of the device and or 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.

The KeraKlear XT Artificial Cornea has not been evaluated for Magnetic Resonance Imaging (MRI) procedures or MRI safety.

Additional warnings are listed throughout this document.

Visual Packaging Inspection

Inspect the packaging to ensure the sterile barrier is intact and there is no evidence of leakage.

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Precautions for use and storage

Store at room temperature.

The KeraKlear XT Artificial Cornea dioptric power (phakic or aphakic) 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 Artificial Cornea requires the use of appropriate techniques and instruments. Any KeraKlear XT Artificial Cornea damaged during handling should not be implanted.

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

Only sterile surgical instruments should be used during the implantation surgery. Instrumentation is not in the scope of this IFU.

After implantation, the implant 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 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 onto the device.

Disposal Instructions:

Dispose as standard biohazardous material.

Instructions for use:

1) 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).

2) Patient Prep

The patient should be prepped and draped for corneal lamellar surgery using povidone-iodine to the peri-ocular skin with care to avoid the ocular surface.

Two drops of topical anesthetic (e.g. proparacaine 0.5% ophthalmic solution) will be instilled into the operative eye for anesthesia. Additional drops of topical anesthetic may be used as needed to maintain patient comfort.

Two drops of a broad-spectrum topical antibiotic medication (e.g. gatifloxacin ophthalmic solution or equivalent) should be instilled into the operative eye for antibiotic prophylaxis.

3) Retrieval of the KeraKlear XT Artificial Cornea from Packaging

Check the model number of the KeraKlear XT Artificial Cornea. The model number will determine the depth of pocket creation for implantation. Open the protective sealed box and remove the pouch containing the glass vial which contains the KeraKlear XT Artificial Cornea. Inspect the pouch for damage or indications the sterile barrier has been compromised. Open the pouch and remove the glass vial. Open the glass vial and 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.

4) Femtosecond Pocket Creation, Trephination and Removal of Diseased Corneal Disc

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. An 8 mm uniform circular corneal pocket is made at a depth corresponding to the model of the KeraKlear XT Artificial Cornea. For example, a 600 micron depth pocket would be made for a KeraKlear XT 600.

A trephination incision of 3.5 to 3.7 mm diameter should be created with the femtosecond laser. The 3.5 to 3.7 mm diameter trephination incision will allow a snug fit of the recipient cornea around the 4 mm diameter optic of the KeraKlear. The trephination depth of the femtosecond laser should be set to 20 microns deeper than the pocket depth to help insure complete trephination. After completion of the laser trephination, a 0.12 mm toothed forcep is used to grasp the edge of the trephination disc and is gently peeled away from the stroma using slow steady pressure.

4a) Pocket Making Microkeratome and Trephination with 3.5 mm Dermal Punch (To be used when a femtosecond laser is unavailable)

It is recommended that there is 100 to 150 microns of corneal tissue posterior to the corneal pocket. For example, if a cornea with an anterior corneal scar measures 520 microns in thickness, a pocket would be created at a depth of 400 microns to leave a posterior corneal thickness of 120 microns and the KeraKlear XT 400 would be chosen for implantation. An 8 mm uniform circular corneal pocket is made with a pocket making microkeratome (e.g. Dioptex) at a depth corresponding to the model of the KeraKlear XT Artificial Cornea. For example, a 400 micron depth pocket would be made for a KeraKlear XT 400.

After creation of the pocket, 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 the side incision at the periphery of the pocket to serve as a blocker to prevent trephination of the corneal tissue posterior to the pocket. A 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 corneal tissue is then removed with .12 forceps and the Sheet's glide removed from the pocket.

Warning

Manual dissection of the lamellar pocket should never be used for implantation of the KeraKlear. The human hand cannot create a uniform corneal pocket with the strict tolerances (+/- 20 microns) needed for safe and reproducible surgery. Manual dissection is expected to result in shallow pockets which lead to extrusion or corneal perforation which will prevent safe implantation of the KeraKlear.

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.

Implantation of the KeraKlear XT Artificial Cornea into the Cornea

5) **KeraKlear XT Artificial Cornea Insertion and Unfolding**

The KeraKlear XT Artificial Cornea is then grasped with smooth forceps (e.g. angled McPherson forceps) and inserted into the pocket. A smooth broad spatula (e.g. Maloney PRK spatula) 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 the anterior corneal tissue is at the same level as the KeraKlear for 360 degrees.

6) Suturing of the KeraKlear XT Artificial Cornea to the Recipient Cornea

Suturing of the KeraKlear XT Artificial Cornea 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 Artificial Cornea have sutures. This is because many keratoconic patients habitually rub their eyes. 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.

7) 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.

8) Bandage Contact Lens

It is recommended that a highly oxygen permeable bandage contact lens stored in borate buffered solution (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 after KeraKlear XT Artificial Cornea implantation. The contact lens rewetting drop should be given even if a contact lens is not being worn 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 an artificial cornea. 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.

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Subject to modification

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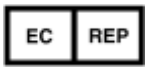
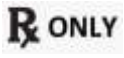
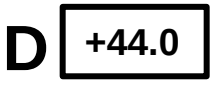
Explanation of symbols and abbreviations used on product labels:

Symbol	Description	Symbol	Description
	Manufacturer		Consult Electronic Instructions for Use
	Catalogue Number		Medical device
	Serial Number		Caution
	Lot or batch number		Notified Body European Community registration number
	Keep Dry		Authorized Representative in the European Community
	Do not freeze		Expiration Date
	Sterile/Sterilized by Steam		No direct laser light
	Do Not Reuse		Keep out of direct sunlight
	Do not reserialize		Date of Manufacture
	Prescription only		Do not use if package is damaged
	44 Diopter Power		60 Diopter Power