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CORNEAT KPRO IMPLANTATION KIT
INSTRUCTIONS FOR USE

CorNeat Vision Ltd.

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	**Warning: do not attempt to use this device without completing training and certification**
	Consult instructions for use – read carefully and entirely prior to use
	Do Not Reuse – single patient use only

Investigational device
To be used by qualified investigator only
Instrument de recherche
Réservé uniquement à l'usage de chercheurs compétents

Product Intended Use

The CorNeat KPro is intended to provide a transparent optical pathway through an opacified cornea, in an eye which is not a reasonable candidate for a corneal transplant. The CorNeat KPro is permanently implanted.

Contraindications

The following list outlines the contraindications for the CorNeat KPro:

- Keratoconus, no prior keratoplasty
- Corneal scar without vascularization, no prior keratoplasty
- Uncontrolled glaucoma
- Orbital inflammation
- Active scleral inflammation
- Active inflammation of the cornea
- Ocular ischemic syndrome
- Relative contraindication – scarred conjunctiva

Product Description

The CorNeat KPro is a patented synthetic corneal implant (keratoprosthesis) developed to provide a long-lasting medical solution for corneal blindness, pathology and injury. The CorNeat KPro is designed to provide an accessible, efficient, effective and reliable remedy for people with cornea-related visual impairments.

The CorNeat KPro utilizes a novel polymeric bio-integrating skirt to assimilate synthetic optics within resident ocular tissue. Other currently available solutions rely either on donor tissue (keratoplasty), or on synthetic implants mounted on biological carrier tissues and then attached to the native corneal tissue – a tissue lacking blood vessels and healing capacity. In contrast, the CorNeat KPro integrates seamlessly with the eyewall, underneath the conjunctiva and over the sclera where scarring potential is maximal.

The CorNeat KPro (Figure 1) consists of two main components: a lens made of polymethyl methacrylate (PMMA) and a porous integrating skirt surrounding it, made of non-woven and non-degradable medical grade polyurethane mesh.

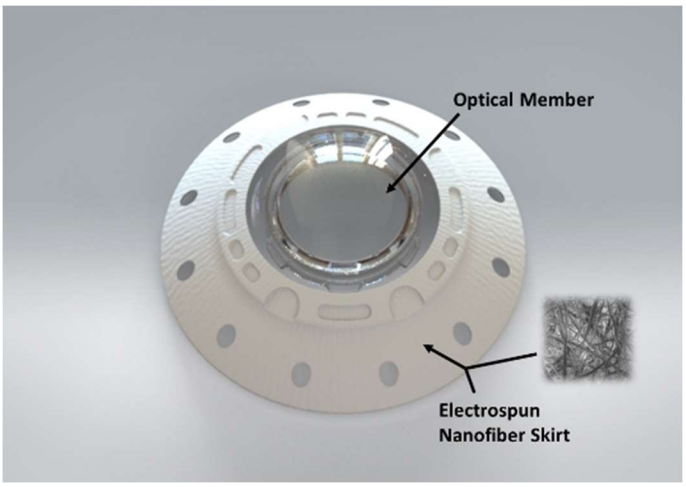


Figure 1: CorNeat KPro – main components

The CorNeat KPro Implantation Kit ("the device") is comprised of the **CorNeat KPro** and a tool set. The tool set includes a **Snapper Tool**, that assists in the positioning/insertion of the implant into the trephined cornea and a **Marker Tool** that ensures alignment and assists in visualization during the surgical procedure.

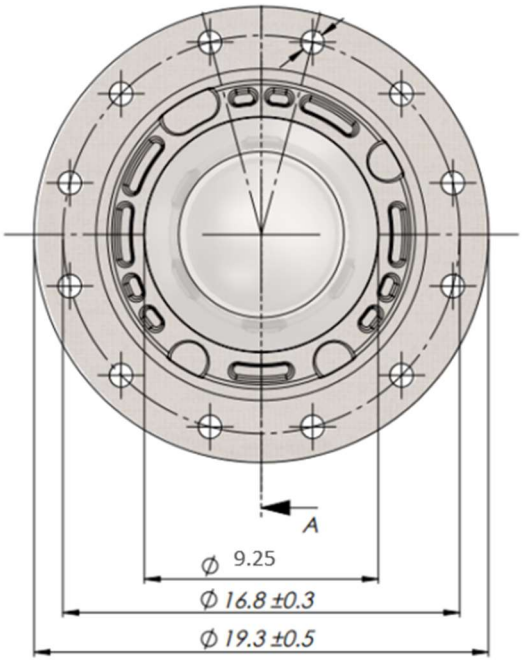


Figure 2a: CorNeat KPro top view

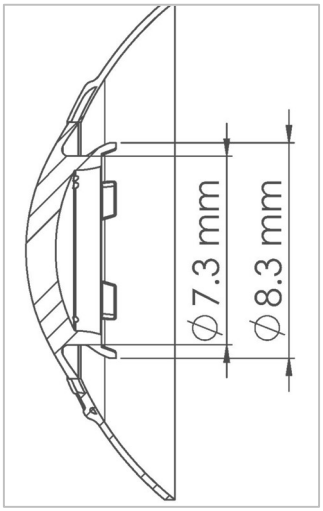


Figure 2b: CorNeat KPro side view

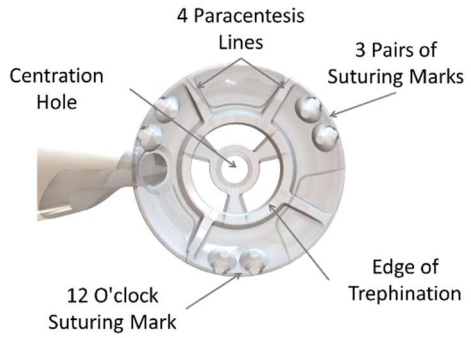


Figure 3a: Marker head

Figure 3b: Snapper & Marker

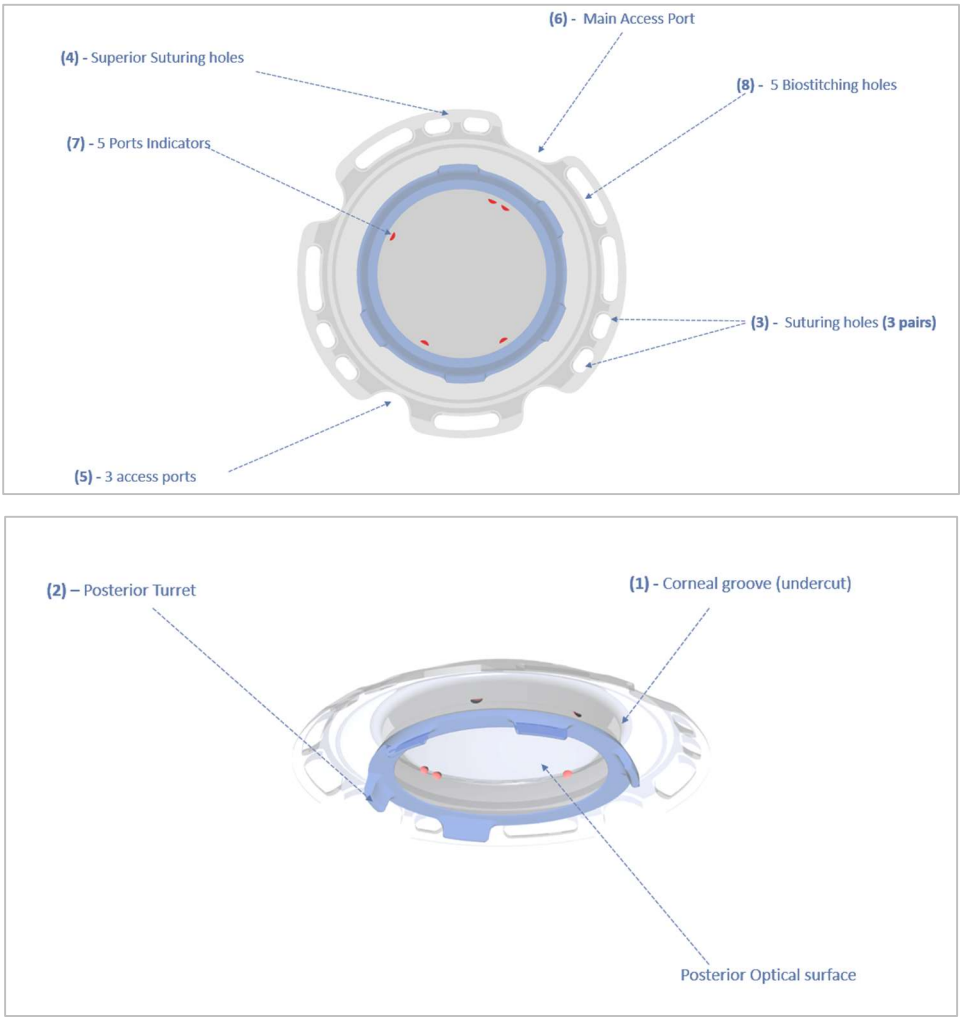


Figure 4: CorNeat KPro Lens with features (integrating skirt not shown)

Feature		Relevance to Clinical Function
(1) Corneal Groove (undercut)		The lip on the posterior side of the lens hosts the patient's corneal stump. It has a wide opening that can accommodate thick or edematous corneas (up to 1.5mm think). This wide opening also allows for aqueous humor to reach the edge of the cornea, maintain its health and avoid or minimize thinning or melting. In order to keep the eye watertight immediately post-implantation, the undercut wall diameter is slightly larger than the trephination diameter.
(2) Posterior Turret		A set of flanges on the posterior side of the lens assists the surgeon with the implant fitting process and secures the remnant cornea in place. The flanges enable a methodological fitting process as they reduce the chances of the cornea slipping out of the undercut after being placed into it.
Integration Rim	(3) Suturing Holes	Three pairs of suturing holes are positioned on the lens rim, 120 degrees apart. These holes enable suturing the lens to the eye wall at the area of the limbus using non-degradable sutures. The suturing of the device to the eye ensures its centration, retention and bio integration. It also facilitates the process of fitting the patient's cornea into the KPro corneal undercut.
	(4) Superior Suturing Holes	The superior suturing holes are placed at the 12 o'clock position assisting in correct alignment of the device.
	(5) Access Ports	Four access ports (openings) on the rim of the PMMA lens, positioned around the limbus, enable penetrating the anterior chamber with surgical tools. Insertion of surgical instruments into the anterior chamber or vitreous cavity allows intraocular surgical procedures to be performed after CorNeat KPro implantation, if necessary. Ports are positioned in locations consistent with current best practices for cataract and retinal surgery for both right and left eyes.
	(6) Main Access Port	The main access port, which should be positioned at 11 o'clock, is 2.6mm wide. This port is designed to enable IOL injection following KPro implantation.
	(7) Port Indicators	Following implantation, the integration rim - including the access ports - is expected to be covered by conjunctiva. A set of indicators on the optic's edge, that are visible under a

		microscope, assist the surgeon in locating the access ports post implantation. The port indicators are essentially tiny “bumps” on the edge of the central optical zone; one opposite each access port, two opposite the main access port.
	(8) Bio-stitching Holes	The bio-stitching holes on the rim of the lens are filled with the skirt material. Connective tissue is expected to grow through these holes, practically “bio stitching” the PMMA lens onto the sclera. This mechanism further ensures device attachment, mitigating risks of detachment in case the skirt fibers weaken or detach from the lens.

Labeled power (K-factor)

Label Power	42D

Packaging

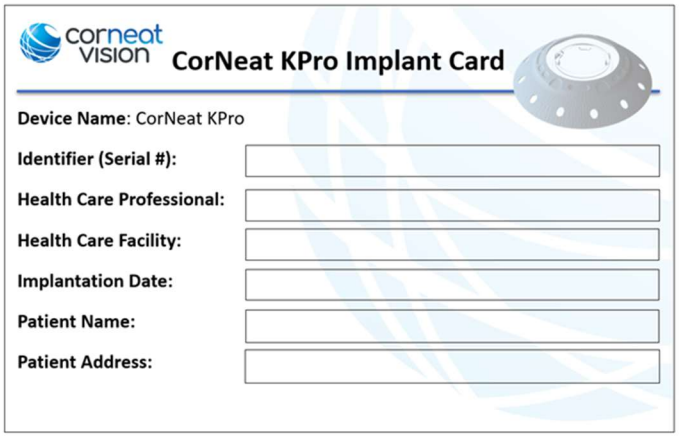
The CorNeat KPro Implantation Kit is comprised of:

- The CorNeat KPro: contained in a protective holder and sealed in a sterile double blister.
- The tool set: sealed in a sterile single blister.

Both blisters are packed in a labeled carton. The packaging is designed to prevent damage to the device.

Patient card information

The Patient Implant Card included in the package is to be completed and given to the patient, together with instructions to keep this card as a permanent record of the implant and to show the card to any eye care professional seen in the future.



Sterilization

The device is sterilized with EtO – Ethylene Oxide.

Storage

The device should be stored in a clean and dry environment at room temperature.

Patient Warnings

- The surgeon should inform the patient of potential medical/surgical risks of the implantation.
- In the three months following implantation the patient should refrain from hazardous activities and extreme sports and should wear protective goggles at all times.
- The surgeon should inform the patient not to bathe in saunas and beware of extreme heat directed at the facial area.
- The surgeon should inform the patient to continue follow-up throughout his/her lifetime, specifying that keratoprostheses have the propensity to be complicated with a retroprosthetic membrane and in case of symptoms, specifically visual degradation, the patient should seek medical consultation.
- The surgeon should instruct the patient to undergo periodic glaucoma screening including routine optic nerve analysis (Optical Coherence Tomography (OCT)), visual field exam and complete ophthalmological checkup.
- The surgeon should inform the patient that eyeglasses/spectacles may be needed post-surgery to achieve full vision potential.
- The surgeon should instruct the patient to wear sunglasses or UV-blocking contact lenses to protect against UV light and undergo regular eye exams for tracking UV-induced eye damage.

Precautions

- The surgeon must study the device and its corresponding surgical procedure and must undergo training prior to performing any surgical procedure.
- The surgeon must inspect the device’s integrity before using the device.
- Poor health, or any local ophthalmic pathology that might limit blood supply or compromise healing, should be considered as a relative contraindication when selecting patients for implantation.

Instructions for Use

It is mandatory to read and understand the following instructions prior to clinical use:

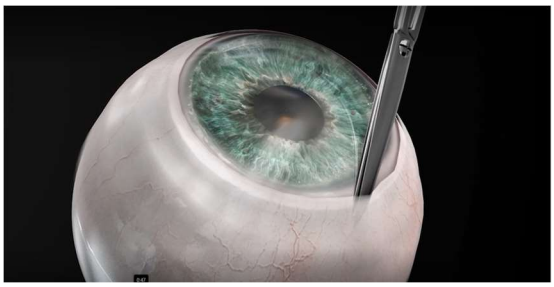
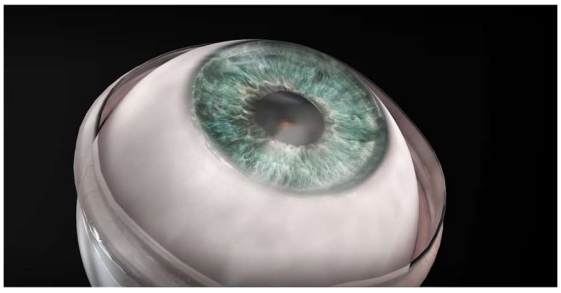
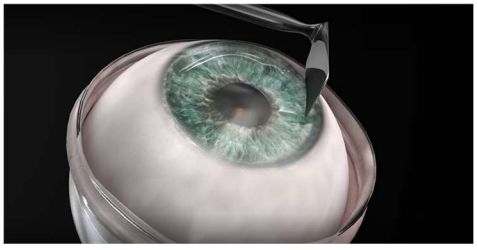
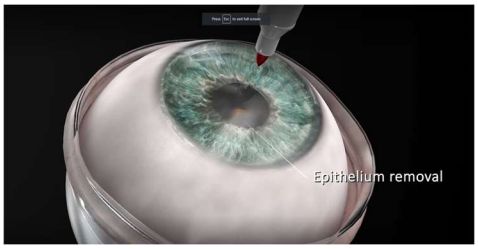
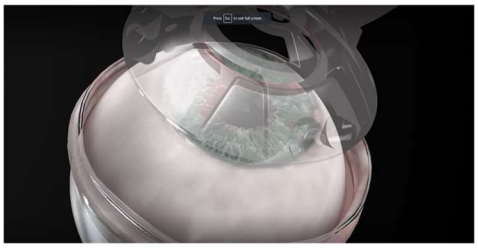
Recommended consumables for the surgical procedure

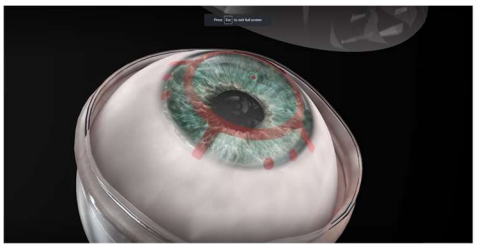
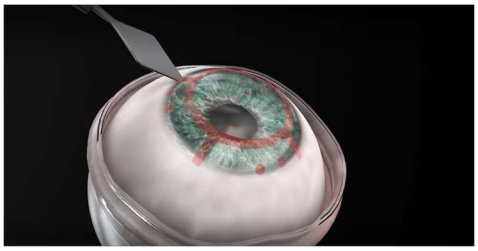
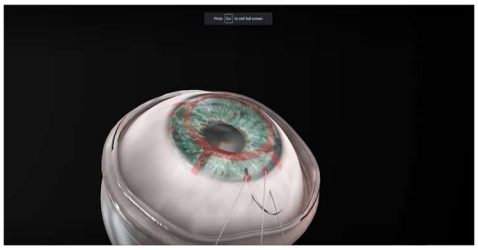
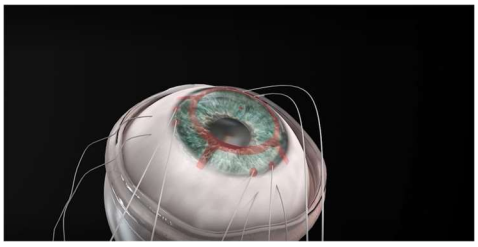
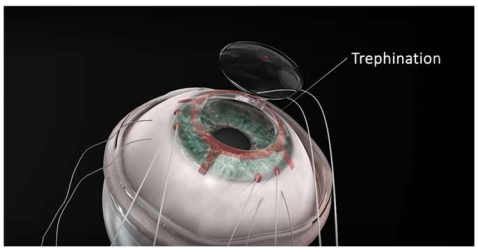
- 3 non-degradable, double-armed sutures (recommended spatulated needles)
- 7.5 mm trephine
- 2.2mm corneal blade
- Cohesive OVD, preferably high molecular weight
- Anterior chamber maintainer (optional)
- Corneal transplantation tool-set
- Tissue adhesive (optional)

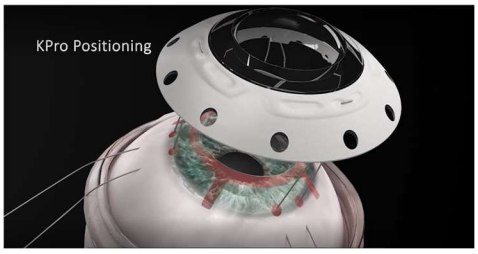
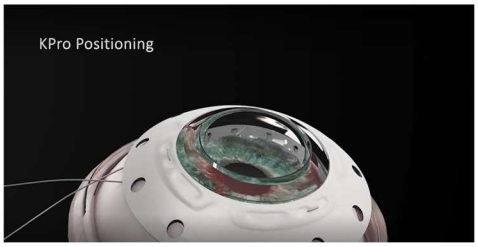
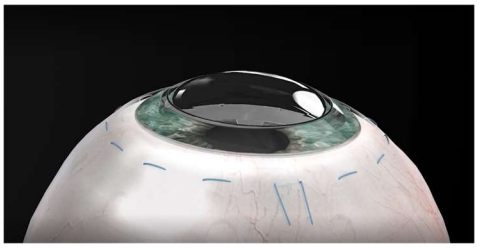
General instructions for device handling

- The CorNeat KPro Implantation Kit is for single use only. It is to be used on a single occasion, for a single patient. Once the sterile packaging is breached the kit must be used for the current procedure or discarded.
- Medical professional inspection of the package and labelling is mandatory prior to use.
- Do not use if package is opened or damaged.
- Do not use past the expiration date printed on the label.
- Do not use if any information is missing, or if there are any discrepancies on the label.
- Do not use other tools for this procedure, the Snapper and Marker tools provided with this CorNeat KPro Implantation Kit are the optimal surgical tools for this procedure.
- Do not apply excessive force to the KPro Lens rim during implantation.
- Inspect the rim of the KPro Lens for integrity before and after the implantation.
- Apply aseptic product handling technique for device preparation and implantation.
- An additional device (CorNeat KPro) and/or donor tissue (where available) should be available in the operating room during the procedure.
- Do not re-sterilize.
- Promptly report all product defects and adverse events according to the clinical trial procedures

Implantation Procedure Stages

Description	Illustration
Peritomy. The conjunctiva is dissected limbaly from the sclera 360°, creating a deep pocket at least 5 mm posterior to the limbus while releasing bands of tissue that might apply tension to the conjunctival leading edge. If required, relaxing conjunctival incisions should be performed superiorly and/or inferiorly, but not laterally. To avoid losing the conjunctiva's edge the surgeon may leave a temporary conjunctival suture to allow localization of that edge at the end of the procedure. Cautery should be avoided as much as possible to allow better adhesion of the device's skirt.	 
Epithelial debridement. The corneal epithelium is completely removed using a blade & a surgical spear. Limbal stem cells should also be removed.	
Cornea central mark. The center of the cornea is marked with a surgical marker. This ensures proper centration of the implant.	
Cornea marking. Using the dedicated Marker tool, the cornea surface is marked. The marked pattern includes 3 pairs of suturing marks, 4 potential paracenteses lines, and a trephination edge mark. The marker head is transparent and includes a rounded hole centered on the cornea by aligning it with the central mark. The marker and implant are not symmetrical, and care should be taken to align	

Description	Illustration
the superior suturing marks with the corneal 12 o'clock position. Paracentesis lines should be extended sclerally to improve the surgeon's ability to locate the paracentesis once the device is approximated to the eye.	
Paracenteses + OVD injection. Two clear corneal incisions are created using a 2.2mm corneal blade where indicated by the paracentesis lines, and the eye is filled with cohesive viscoelastic (OVD). Partial-thickness trephination may be performed prior to suturing of the device to the eye wall to prevent cutting the sutures with the trephine blade.	
Preplacing sutures. 3 pairs of double armed non-degradable sutures are preplaced, passing first through dedicated holes on the rim of the KPro's optics, and then through the cornea – entering at the suture hole marks, passing radially through the sclera. Surgeons should ensure that the 12 o'clock suturing holes are located superiorly. To avoid entanglement, each suture pair should be clamped**.**	 
Trephination. Once all preparatory steps are completed, the central cornea is trephined using a 7.5 mm trephine. Centration is achieved by aligning the trephine cross hairs with the central corneal mark. Trephination should be completed with curved scissors.	

Description	Illustration
KPro positioning. The device is fastened to the eye wall by tightening the 3 sutures, and then tying temporary knots between the device skirt and the sclera to create a formed anterior chamber which eases the insertion of the corneal remnant into the posterior undercut.	 
KPro fitting using the Snapper. The trephined corneal edge, which is stained for better visualization, is inserted into the KPro's posterior (corneal) undercut using the Snapper tool. The trephination edge should be visible in the posterior undercut. Upon verification of the device's position, the sutures' temporary knots are replaced with permanent ones.	
Conjunctiva repositioning and suturing. The OVD can be exchanged with Balanced Salt Solution (BSS) either with an irrigation aspiration hand piece or with a cannula inserted through the paracentesis ports. Intracameral injection of cefuroxime or an alternative intracameral antibiotic for endophthalmitis prophylaxis is recommended. An air bubble may be injected into the AC for initial closure of the paracentesis. The conjunctiva is repositioned and sutured into place using degradable anchoring sutures placed mid-way through the skirt and sclera to relieve tension on the conjunctival leading edge. The conjunctiva is pulled over the KPro skirt and completely covering it preferably over-hanging the PMMA optic. Then, the limbal edge of the conjunctiva is closed by a non-degradable suture using a purse string technique.	

Recommended Post-operative Supportive Care

Systemic therapy

- Acetazolamide 500 mg (or equivalent) should be administered once at the end of the surgery and again after 12 hours.
- During the first week, systemic prophylactic antibiotic treatment should be prescribed. The regimen should cover both gram negative and gram positive (Levaquin, Cefuroxime, Ofloxacin or similar).
- During the initial follow-up period, systemic steroids can be prescribed in case of significant AC inflammation.

Local therapy

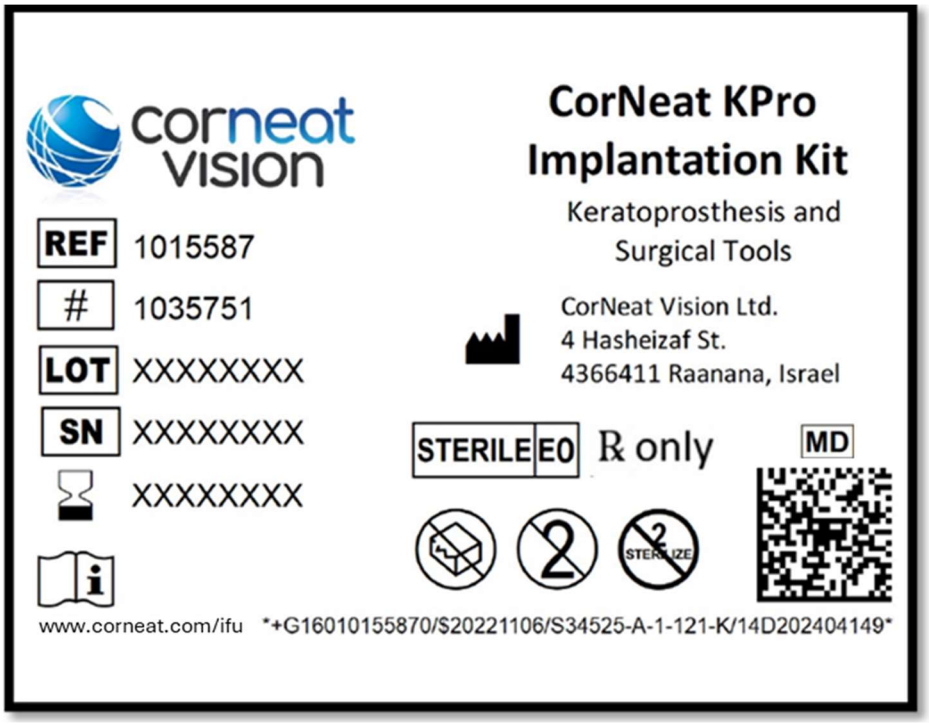
- A fluoroquinolone, preferably 4th generation, should be applied for the first month QID (4Xd)
- Povidone iodine twice weekly.
- To control inflammation after KPro implantation, prednisolone 1% drops 2-4x per day for the first month are recommended either with or without additional non-steroidal anti-inflammatory drugs (NSAID) such as Tromethamine.
- Glaucoma (hypotensive) medications that penetrate the sclera such aminoclonidine, clonidine and bimatoprost should be administered locally.

Potential Complications – adverse events and side effects

- Postoperative Corneal Melt
- Lack of graft retention
- Post-operative Glaucoma
- Poor post-operative visual quality
- Intra-operative suprachoroidal hemorrhage and vitreous prolapse
- Retro-KPro membranes (RPM) formation
- Endophthalmitis
- Conjunctival retraction over the skirt
- Transient inflammatory reaction around the eye
- Vitreous hemorrhage- bleeding inside the eye

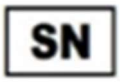
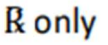
- Vitritis - sterile inflammation inside the eye
- Retinal Detachment- separation of the retina from the wall of the eye necessitating surgical intervention
- Ptosis - a droopy eyelid
- Foreign body sensation
- Secondary surgical intervention and/or device explantation leading to loss of vision
- Iris adhesions
- Device dislocation from the corneal stump in host eye, this could lead to angle closure glaucoma, hypotony and/or infection
- Choroidal hemorrhage/effusion
- Intraocular lens (IOL) damage and/or IOL dislocation (due to surgical manipulation implanting a large KPro) resulting in additional surgery for IOL implantation
- Intraocular inflammation requiring hospitalization
- Infectious keratitis
- Scleritis (either infectious or inflammatory)
- Conjunctival mucous discharge
- Device Decentration
- Injury to extraocular muscles, which can lead to diplopia, limited extraocular movement
- Infection on the external part of the eye – conjunctivitis which may lead to explantation of the device
- Eye and/or head pain requiring hospitalization and treatment by medications
- Conjunctivitis leading to explantation
- Fungal growth leading to explantation
- Any of the above-mentioned complications in their severe form may result in transient or permanent loss of visual function

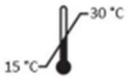
Device Label



List of Definitions

Symbol	Title	Description	Standard	Reference Number
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.1.6
#	Model number	Indicates the model number or type number of a product	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.1.10
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.1.5

Symbol	Title	Description	Standard	Reference Number
	Serial Number	Indicates the manufacturer's serial number so that the specific unit can be identified	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.1.5
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.1.4
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.4.3
	Prescription only	Federal law restricts this device to sale by or on the order of a physician	Guidance for Industry and FDA on Alternative to certain Prescription Device Labeling Requirements	N/A
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.1.1
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.4.2
	Sterilized using Ethylene Oxide	Indicates a medical device that has been sterilized using Ethylene Oxide	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.2.10
	Do not use if package is damaged and consult	Indicates that a medical device that should not be used if the package has been damaged or opened	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by	5.2.8

Symbol	Title	Description	Standard	Reference Number
	instructions for use	and that the user should consult the instructions for use for additional information	the manufacturer - Part 1: General requirements	
	Double sterile barrier system	Indicates two sterile barrier systems	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.2.12
	Do not resterilize	Indicates a medical device that is not to be resterilized	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.2.6
	Keep away from sunlight	Indicates a medical device that needs protection from light sources	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.3.2
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.3.7