THE BOSTON KERATOPROSTHESIS TYPE I

CLICK-ON
Instructions for Use (US)

1. Description of the device

The Boston Keratoprosthesis is designed as an "artificial cornea" that can be used in patients with severe corneal opacity.

The Boston KPro is used after standard penetrating keratoplasty has failed or when such a transplant would be unlikely to succeed. Thus, keratoprosthesis implantation is a procedure designed to help patients whose corneal diseases are the most difficult to treat.

The Boston KPro Click-On design* consists of only two components: a front plate made of clear polymethyl methacrylate (PMMA) plastic, and a back plate made of titanium that locks the device in place around a corneal donor graft, The Boston keratoprosthesis when fully assembled has the shape of a collar-button. The front plate acts as a lens and is provided in aphakic version compatible with a variety of axial lengths (16.0 mm to 31.00mm) or in pseudophakic version when an intraocular lens is present and assumed to target emmetropia.

The device is assembled within a corneal graft, which is then sutured into the patient's cornea as in standard transplantation. If the natural crystalline lens is in place, it is also removed. After implantation of a type I device, a soft contact lens is applied to the surface, and is worn continuously.

2. INTENDED USE

The Boston KPro Type I is indicated to provide a transparent optical pathway through an opacified cornea in an eye that is not a reasonable candidate for any form of corneal transplant.

The benefit of this device to patients who do not tolerate a standard corneal transplant is the restoration of sight in the treated eye, including anatomic retention. No other option is available to these patients to restore sight resulting from corneal damage.

3. INTENDED USERS

The intended user for Boston KPro device is a licensed ophthalmologist.

4. PATIENT SELECTION CRITERIA

- Patients with at least one failed corneal transplant, with poor prognosis for further grafting, or severe corneal opacity and vascularization with poor prognosis for corneal transplantation.
- Patients with vision worse than 20/200 (and opposite eye with vision less than 20/40).
- Patients with no retinal detachment or extreme optic nerve cupping.
- Patients with intact nasal light projection to exclude end stage glaucoma.
- If patient has severe glaucoma, consider simultaneous Ahmed shunt.
- If patient's eye is pseudophakic, plan to keep IOL in place and use Boston KPro for pseudophakia.
- If patient's eye is phakic, do simultaneous open-sky cataract extraction and use KPro indicated for aphakia (chosen according to axial length of the eye).
- Consider the following parameters in your patient selection and evaluation:
  - History
  - Visual acuity, also with hard contact lens when necessary. Accuracy of light projection (lack of central fixation, lack of nasal projection- end-stage glaucoma?)
  - Intraocular pressure
  - Evaluation of blink mechanism, tear secretion
  - Signs of chronic inflammation

- Phakic, pseudophakic or aphakic
- Optic nerve cupping, macula
- Ultrasound B-scan (retinal detachment?)
- A-scan (for KPro optical power in aphakic eyes)
- External photo

5. CONTRAINDICTIONS

- Patients with longstanding severe intraocular inflammation and/or phthisis bulbi.
- Patients with retinal detachment or extreme optic nerve cupping.
- Patients without intact nasal light projection (suggest end stage glaucoma).
- Patients with vision better than 20/200 (or opposite eye has vision of 20/40 or better)

6. WARNINGS AND PRECAUTIONS

- Patients with autoimmune diseases (pemphigoid, Stevens-Johnson syndrome, uveitis, Sjögren's syndrome, etc.), severe chemical burns, or other severe inflammations may experience a higher rate of post-operative complications.
- This is an artificial corneal device requiring special training to properly assemble and implant. Any surgeon wishing to implant the device should have participated previously in the procedure with a qualified physician.
- Use Boston KPro only by the expiration date given on the label. Do not reuse device. Do not resterilize. Resterilization may damage the device and lead to patient complications.
- Do not use Boston KPro if the sterile packaging is damaged or has been unintentionally opened before ready for use.
- It is required that Boston KPro packaging is only to be opened in a surgical environment.An assistant nurse should open the outer packaging and thereafter product in inner layer can be placed on sterile surfaces for further use.

- Safe dispose of assembly tool and the adhesive according to local regulations.
- Glare is a manageable visual phenomenon that could only occur in patients lacking an iris.

6. POTENTIAL COMPLICATIONS

- Persistent Epithelial Defect
- Sterile Keratolysis
- Microbial Keratitis
- Retroprosthetic Membrane
- Glaucoma
- Sterile Vitritis
- Microbial Endophthalmitis
- Retinal Detachment

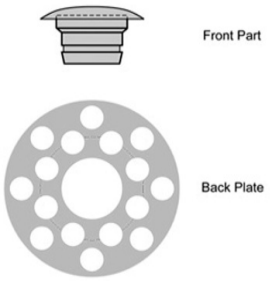
See User Manual for further details of each complication.

Notes:

- The device is visible in the patient's eye following implantation.
- Any serious incident in relation to the device should be reported to the Massachusetts Eye and Ear Infirmary.
- Please provide International patient card and BK-IFU-080 (Information for Patients) to the patients.
- MEEI Boston Keratoprosthesis has established a lifetime of 20 years for the Boston Keratoprosthesis.

- Photographs of the component parts of the Boston Keratoprosthesis, Click-On Type I.

7. Schematic illustration of the components:

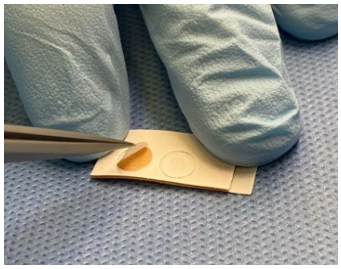


- The front plate consists of a front plate (5.0 mm in diameter) and the stem (3.35 mm)
- The back plate (8.5 mm diameter) with a central hole, and 16 holes (1.2 mm each)

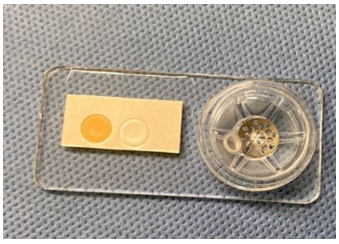
8. Photo-Montage: Assembly of Boston KPro Click-On type I

- White assembly tool with a hollow bore will assist in the assembly

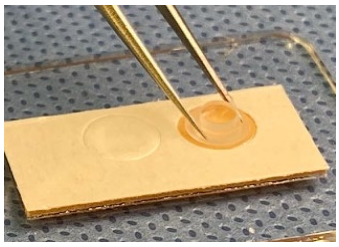
- After an 8.5 mm corneal graft is punched out from a donor cornea, a 3.0 mm hole is punched in the center of the graft. Central position of the hole is important.



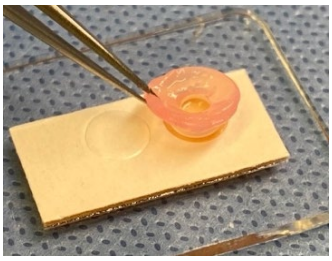
- An adhesive patch is used to stabilize the **Boston Keratoprosthesis** assembly. Scotch tape is peeled off.



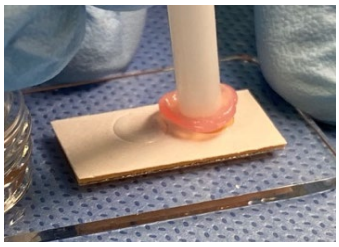
- The bared adhesive is pressed down onto a stable surface. The cover of one of the top windows is peeled off, baring the adhesive.



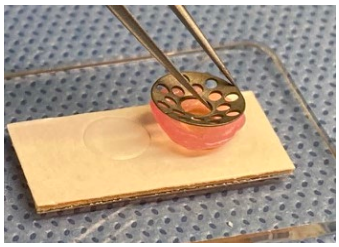
- The KPro front plate is pressed down onto the adhesive (plate down, stem up) where it sticks.



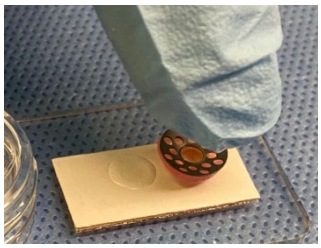
- The corneal graft is placed on the stem of the KPro front plate.



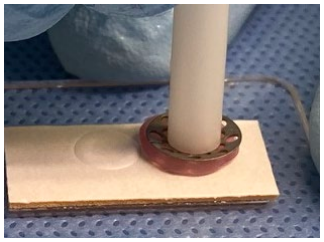
- The hollow bore end of the white pin is used to gently push the graft down over the stem.



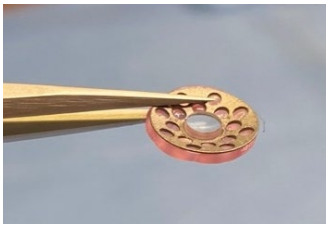
- The back plate is placed on the stem of the front plate.



- The back plate is gently pushed down with a finger onto the stem.



- Finally, the wider end of the assembly tool is used to press the back plate firmly down into the groove, usually with an audible sound. The assembly tool must be perpendicular to the front plate when pressing down.



- **The position of the back plate should be inspected prior to implantation.**

- The assembly should be temporarily placed back in the storage solution while the patient's eye is being prepared.
- The graft-prosthesis combination is sutured into the patient's cornea like a standard corneal graft. Twelve 9-0 nylon sutures are placed, and the knots are buried. DO NOT SUTURE THROUGH THE BACK PLATE HOLES OR OTHERWISE INCORPORATE THE BACKPLATE IN THE SUTURES.
    - During surgery protect the macula from light damage by covering the center of the KPro with a wet cellulose sponge, or similar.
    - Finally, a large soft contact lens is applied (Kontur lens, plano, 16.0 mm diameter, 9.8 base curve.

9. MRI COMPATIBILITY

MR Conditional

The **Boston Keratoprosthesis, back plate and locking ring made from titanium** was determined to be **MR-conditional.**

Non-clinical testing demonstrated that the Boston Keratoprosthesis back plate and locking ring made from titanium is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the Boston Keratoprosthesis, back plate and locking ring made from titanium produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.5°C

Therefore, the MRI-related heating experiments for the Boston Keratoprosthesis, back plate

and locking ring made from titanium at 3-Tesla using a transmit/receive RF body coil at an MR

system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.5°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Boston Keratoprosthesis, back plate and locking ring made from titanium. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of the Boston Keratoprosthesis,
back plate and locking ring made from titanium.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	97-mm2	35-mm2	290-mm2	296-mm2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

This information is based on the latest information from the Food and Drug Administration and the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

The Boston Keratoprosthesis is included in the Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2013 Edition (page 603), Frank G. Shellock, Ph.D., Biomedical Research Publishing Group (Los Angeles, CA (2013)

10. EXPLANATION OF SYMBOLS

	Manufacturer
	Use-by Date
	Serial Number
	Batch code
	Do not re-use
	Sterilized using ethylene oxide
	MR Conditional
	Caution
	Date of Manufacture
	Do not use if package is damaged
	Medical Device
	Consult instructions for use
	Unique Device Identifier
	Single sterile barrier system with protective packaging inside.