

 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08

**THE BOSTON KERATOPROSTHESIS TYPE I
CLICK-ON
Instructions for Use (CANADA)**

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 are 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.

The device should be stored at room temperature.

Boston KPro has discontinued supplying the Acuderm 3mm punch for trephining a central 3mm hole in the graft and advises users to utilize a 3mm biopsy punch available on the Canadian market.



 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08

2. INTENDED USE

The Boston Keratoprosthesis 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



 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08

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

5. CONTRAINDICATIONS

- 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.

7. POTENTIAL COMPLICATIONS

- Persistent Epithelial Defect
- Sterile Keratolysis
- Microbial Keratitis
- Retroprosthetic Membrane
- Glaucoma



 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08

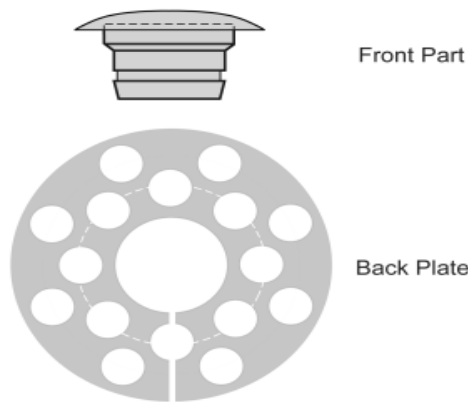
- Sterile Vitritis
- Microbial Endophthalmitis
- Retinal Detachment

See User Manual for further details of each complication

Notes:

- The device is visible in the patient’s eye following implantation.
- Any serious deterioration in the state of health of a patient should be reported to the Massachusetts Eye and Ear Infirmary and to the minister in which the user and/or patient is established.
- MEEI Boston Keratoprosthesis has established a lifetime of 20 years for the Boston Keratoprosthesis.

8. 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)



 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08

9. PHOTO-MONTAGE: ASSEMBLY OF BOSTON KPRO Click-On Type I



- Photographs depicting the individual components of Boston Keratoprosthesis Click-On Type I



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



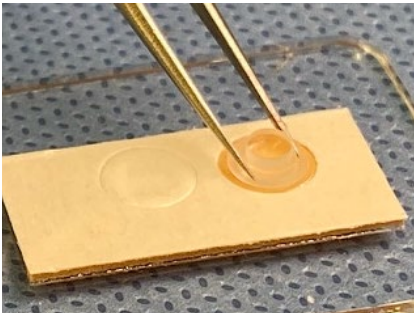
- After an 8.5 mm corneal graft is punched out from a donor cornea, a 3.0 mm hole is punched in the center of the graft. Central position of the hole is important.



 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08



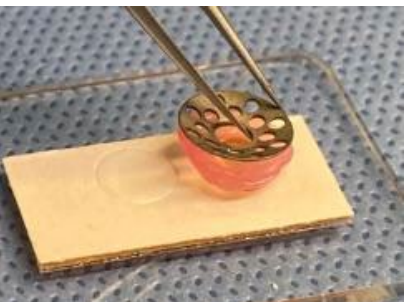
- An adhesive patch is used to stabilize the **Boston Keratoprosthesis** assembly. Scotch tape is peeled off.



- 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.

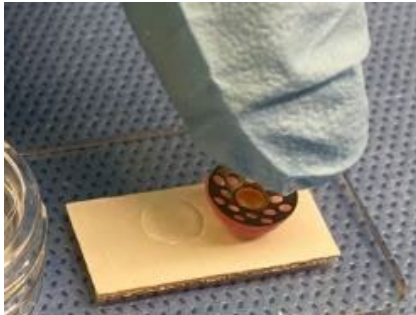


- The corneal graft is placed on the stem of the KPro front plate. The hollow bore end of the white pin is used to gently push the graft down over the stem.

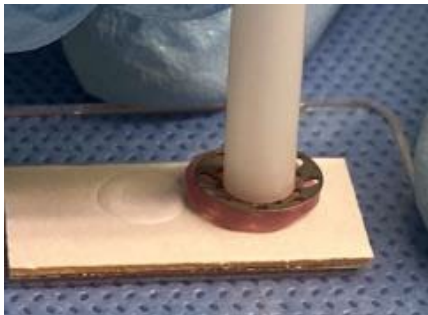


- The back plate is placed on the stem of the front plate.

 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08



- 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 (for example: Kontur lens), plano, 16.0 mm diameter, base curve.



 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08

10. 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



 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08

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-mm ²	35-mm ²	290-mm ²	296-mm ²
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)



 MEEI Boston Keratoprosthesis	INSTRUCTION FOR USE CLICK-ON CANADA	BK- IFU-039
DCR 175	Effective Date: 01/10/24	Rev. 08

9. EXPLANATION OF SYMBOLS

	Manufacturer
	Date of Manufacture
	Use by Date
	Serial Number
	Batch code
	Do not re-use
	Sterilised using ethylene oxide
	Caution
	Medical Device
	Consult instructions for use
	Single sterile barrier system with protective packaging inside.

