

 <b>MEEI Boston Keratoprosthesis</b>	<b>INSTRUCTION FOR USE CLICK-ON US</b>	<b>BK- IFU-033</b>
<b>DCR 109</b>	<b>Effective Date: 03/01/19</b>	<b>Rev. 02</b>

**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 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.



MEEI Boston Keratoprosthesis

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## 2. INTENDED USE

The Boston KPro 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, including penetrating keratoplasty.

## 3. INDICATIONS

- 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

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- Ultrasound B-scan (retinal detachment?)
- A-scan (for KPro optical power in aphakic eyes)
- External photo

#### 4. CONTRAINDICATIONS

- Patients with autoimmune diseases (e.g, mucous membrane pemphigoid, Stevens-Johnson syndrome, uveitis, Sjögren’s syndrome) and after severe chemical burns, or other severe inflammations (these patients if operable, require the type II device).
- 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)

#### 5. WARNINGS AND PRECAUTIONS

- Patients with autoimmune diseases (pemphigoid, Stevens-Johnson syndrome, uveitis, Sjogren’s syndrome, etc.), severe chemical burns, or other severe inflammations may experience a higher rate of post-operative complications.
- **Do not reuse the Boston KPro. Reuse of the Boston KPro exposes the patient to the risk of infection.**
- **Use Boston KPro only by the expiration date given on the label.**
- **Do not resterilize. Resterilization may damage the device and lead to patient complications.**
- **Note: the device should not be used if the sterile packaging is damaged.**

#### 6. POTENTIAL COMPLICATIONS

- Persistent Epithelial Defect
- Sterile Keratolysis
- Microbial Keratitis

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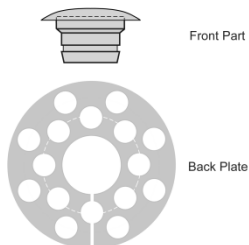
- Retroprosthetic Membrane
- Glaucoma
- Sterile Vitritis
- Microbial Endophthalmitis
- Retinal Detachment

**See User Manual for further details of each complication**

## 7. PHOTO-MONTAGE: ASSEMBLY OF BOSTON KPRO



- Photographs of the component parts of the Boston keratoprosthesis, type I (top) and type II (bottom)



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)

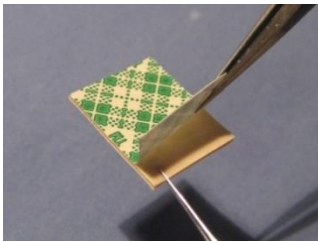
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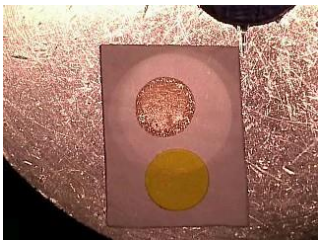
- White assembly tool with a hollow bore will assist in the assembly.



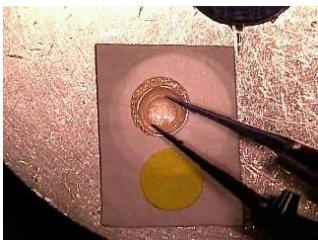
- After an 8.5 mm corneal graft is punched out from a donor cornea, a 3.0 mm hole is punched in the center of the graft. Central position of the hole is important.



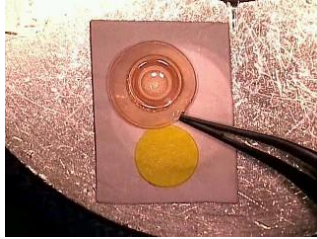
- An adhesive patch is used to stabilize the **Boston Keratoprosthesis** assembly. Scotch tape is peeled off.



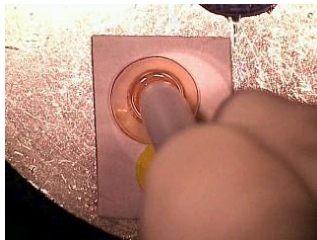
- The bared adhesive is pressed down onto a stable surface. The cover of one of the top windows is peeled off, baring the adhesive.



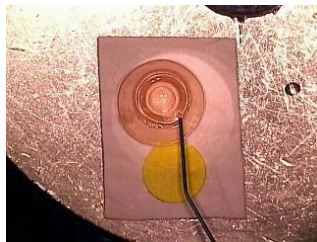
- The KPro front plate is pressed down onto the adhesive (plate down, stem up) where it sticks.



- Viscoelastic is applied around the stem. The corneal graft is slid over the stem.



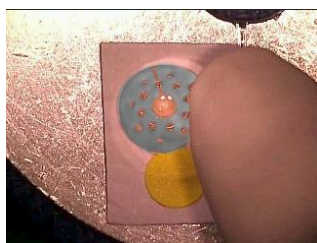
- The hollow bore end of the white pin is used to gently push the graft down over the stem.



- More viscoelastic is applied on the endothelial surface. **Important!**

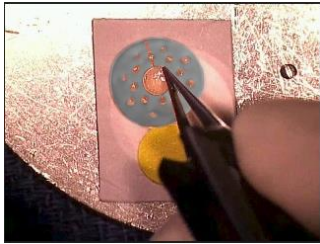


- The back plate is placed on the stem.



- The back plate is gently pushed down with a finger onto the stem. Finally, with the white assembly pin, give final push to have back plate click into the groove on the stem.

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- **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

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## 8. 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



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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 <sup>2</sup>	35-mm <sup>2</sup>	290-mm <sup>2</sup>	296-mm <sup>2</sup>
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)

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## 9. EXPLANATION OF SYMBOLS



Manufacturer



Use by Date



Serial Number



Batch code



Do not re-use



Sterilised using ethylene oxide



MR Conditional



Consult instructions for use