1. **Description of the device**

The Boston Keratoprosthesis Type I device is designed as an “artificial cornea” that can be used in patients with severe corneal opacity.

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

The Boston KPro Type I consists of three ethylene oxide sterilized components: a front plate made of clear polymethyl methacrylate (PMMA) plastic, a 8.5 mm titanium back plate, and a locking ring of titanium, with excellent tissue tolerance and optical properties. When fully assembled, it 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 (16mm – 31mm) 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. Finally, a soft contact lens is applied to the surface and worn continuously.

An assembly tool, used to secure the locking ring onto the stem of the front plate, and an adhesive patch, used as an aid to hold the front plate steady during the assembly process, are pouches with the device. The Acuderm 3mm punch is packaged separately, but supplied with the device.

The device should be stored at room temperature.

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.

3. Indications

- Patients with at least one failed graft, with poor prognosis for further grafting
- Patients whose blink and tear mechanisms are reasonably intact
- 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 glaucoma, consider simultaneous Ahmed shunt
- If patient’s eye is pseudophakic, plan to keep IOL in place and use Boston Keratoprosthesis for pseudophakia
- If patient’s eye is phakic, do simultaneous open-sky cataract extraction and use Boston Keratoprosthesis 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 Boston Keratoprosthesis optical power in aphakic eyes)
  - External photo

4. Contraindications
Patients with autoimmune diseases (pemphigoid, Stevens-Johnson syndrome, uveitis, Sjögren’s syndrome, etc.) and after severe chemical burns, or other severe inflammations.

Patients with longstanding severe intraocular inflammation and 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 (and opposite eye has 20/40 vision or better)

5. **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.

- 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.

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.

7. **Boston Keratoprosthesis Type I Assembly Instructions**

- **Note:** the device should not be used if the sterile packaging is damaged.

- A corneal graft (usually 8.5 mm diameter) is prepared and a central 3 mm hole is trephined with a dermatological punch.

- For stability, the front part of the Keratoprosthesis Type I can be placed upside down on the adhesive patch, which is provided with the device.

- The graft with the central hole is then slid over the Keratoprosthesis Type I stem. The assembly tool provided, hollow on one end, is used to gently push the graft down over the stem of the front plate.

- Viscoelastic is applied to the posterior surface of the graft.

- The back plate is placed over the stem without any rotating movement.
• Then the locking ring is pressed onto the stem with a finger and the hollow end of the assembly tool is used to press the locking ring firmly into the groove, usually with an audible snap. The assembly tool should be held at 90 degrees to the front plate when pressing down.

• The assembled Keratoprosthesis Type I should be inspected under the operating microscope for correct position of the locking ring.

• The graft-prosthesis combination is removed from the adhesive patch and stored in the eye bank solution while the patient’s eye is prepared for implantation of the device.
8.0 MRI Information

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.
<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
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9.0 Explanation of Symbols

Manufacturer

Use by Date

Serial Number

Batch code

Authorised Representative in the European Community

Do not re-use

Sterilised using ethylene oxide

MR Conditional

Consult instructions for use