 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On EU	BK-IFU-004
DCR 124	Effective Date: 02/18/20	Rev. 07

**THE BOSTON KERATOPROSTHESIS TYPE I
SNAP-ON
Instructions for Use**

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 pouched with the device. The Acuderm 3mm punch is packaged separately, but supplied with the device.


The device should be stored at room temperature.

 Massachusetts Eye and Ear Infirmary
243 Charles St. Boston, MA 02144 USA

EC REP

Winckels Medical Devices Expertise (WMDE B.V.),
Bergerweg 18 6085 AT

CE 0459

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 124	Effective Date: 02/18/20	Rev. 07


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. No other option is available to these patients to restore sight resulting from corneal damage.

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

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 124	Effective Date: 02/18/20	Rev. 07

- 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

 Massachusetts Eye and Ear Infirmary
243 Charles St. Boston, MA 02144 USA

EC REP

Winckels Medical Devices Expertise (WMDE B.V.),
Bergerweg 18 6085 AT
Horn, The Netherlands

 0459


 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 124	Effective Date: 02/18/20	Rev. 07

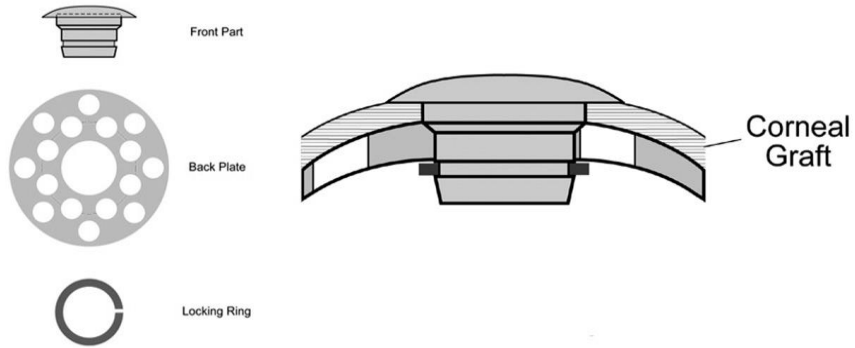
See User Manual for further details of each complication.


Note: Any serious incident in relation to the device should be reported to the Massachusetts Eye and Ear Infirmary Boston Keratoprosthesis and the competent authority of the Member State in which the user and/or patient is established.

7. Boston Keratoprosthesis Type I Assembly Instructions

- **Note:** Do not use Boston KPro if the sterile packaging is damaged or has been unintentionally opened before ready for use.
- 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 place 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.

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 124	Effective Date: 02/18/20	Rev. 07




 Massachusetts Eye and Ear Infirmery
243 Charles St. Boston, MA 02144 USA

EC REP

Winckels Medical Devices Expertise (WMDE B.V.),
Bergerweg 18 6085 AT
Horn, The Netherlands

CE 0459

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 124	Effective Date: 02/18/20	Rev. 07

8.0 MRI Information



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.

 Massachusetts Eye and Ear Infirmary
243 Charles St. Boston, MA 02144 USA

EC REP

Winckels Medical Devices Expertise (WMDE B.V.),
Bergerweg 18 6085 AT
Horn, The Netherlands

 0459

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 124	Effective Date: 02/18/20	Rev. 07


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	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 124	Effective Date: 02/18/20	Rev. 07

9.0 Explanation of Symbols



Manufacturer



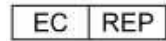
Use by Date



Serial Number



Batch code



Authorised Representative in the European Community



Do not re-use



Sterilised using ethylene oxide




MR Conditional

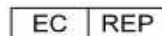


Caution



Date of Manufacture


 Massachusetts Eye and Ear Infirmary
 243 Charles St. Boston, MA 02144 USA



Winckels Medical Devices Expertise (WMDE B.V.),
 Bergerweg 18 6085 AT
 Horn, The Netherlands

