 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11

**THE BOSTON KERATOPROSTHESIS TYPE I
SNAP-ON
Instructions for Use
(First issued: April 2014)**

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 Snap-On 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 corneal 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 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 EU market.

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.

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11


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. 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 (excludes 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, macular disease

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11

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

5. 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 (suggests end stage glaucoma)
- Patients with vision better than 20/200 (and opposite eye has 20/40 vision or better)

6. Warnings and Precautions (With the surgeons experience and knowledge, below points can be discussed with the patient)

- 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

 MEEI Boston Keratoprosthesis
243 Charles St. Boston, MA 02114 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 170	Effective Date: 10/02/23	Rev. 11

- Glaucoma
- Sterile Vitritis
- Microbial Endophthalmitis
- Retinal Detachment

See User Manual for further details of each complication.

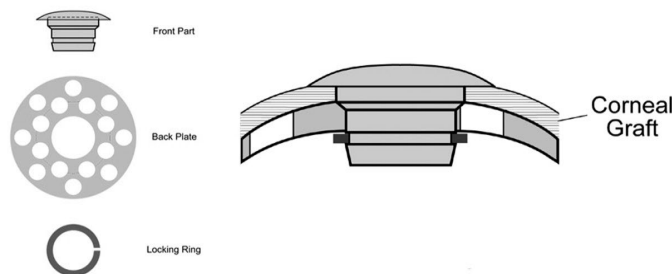
Notes:

- Any serious incident in relation to the device should be reported to the Massachusettes Eye and Ear Infirmary and the competent authority of the Member State in which the user and/or patient is established.
- SSCP can be accessible through European database on medical devices(EUDAMED), where it is linked to the Basic UDI-DI. Please refer table below:


Basic UDI-DI	00862394000215 Snap On Type I Pseudophakia 00862394000208 Snap On Type I Aphakia
--------------	---

- You can visit: <https://ec.europa.eu/tools/eudamed/eudamed> for any further information.
- Please provide International patient card and BK-IFU-080 (Patients information) to the patients.
- MEEI Boston Keratoprosthesis has established a lifetime of 20 years for the Boston Keratoprosthesis.

8. Schematic illustration of the components:




- The front plate (5.0 mm)
- The back plate (8.5 mm diameter) with a central hole, and 16 holes (1.2 mm each), Titanium locking ring
- Assembled device with the corneal graft

 MEEI Boston Keratoprosthesis
243 Charles St. Boston, MA 02114 USA

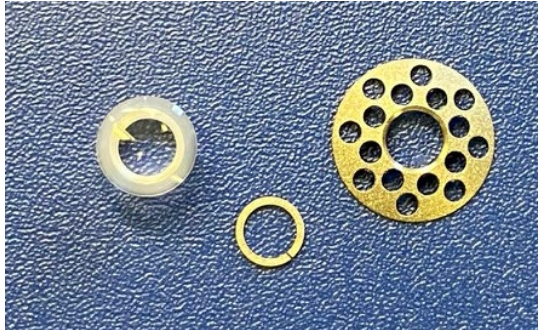
EC REP

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

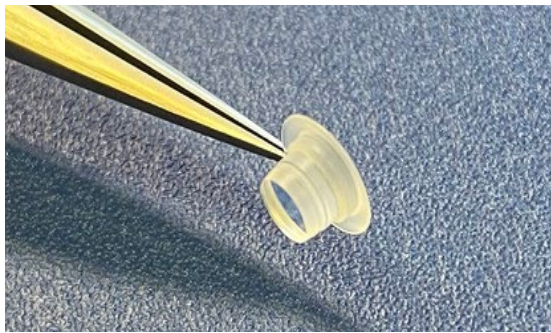
CE 0459

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11

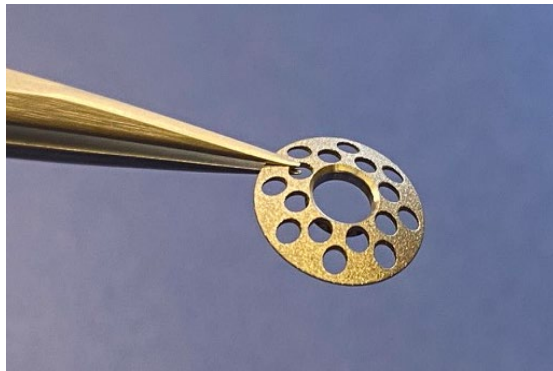
9. PHOTO-MONTAGE: ASSEMBLY OF BOSTON KPRO SNAP-ON




- Photographs of the components of the Boston Keratoprosthesis, Snap-On.

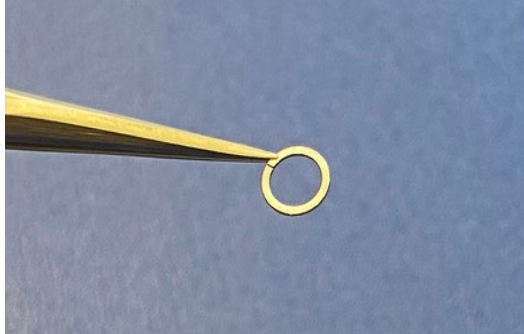


- The front plate is a solid piece of PMMA with a mushroom shape, with an anterior lip (5 mm in diameter), and stem (3.35 mm in diameter). (one/pouch)



- The titanium back plate (8.5 mm Diameter with a central hole and 16 holes (1.2 mm each) (one/pouch)

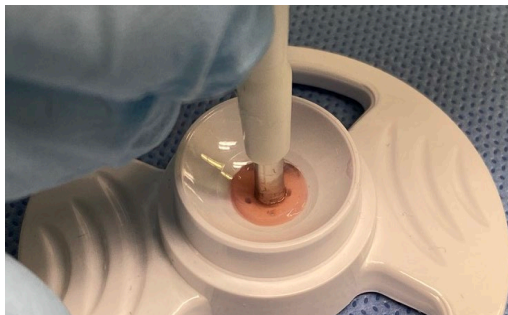
 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11




- Titanium locking ring (one/pouch)



- White assembly tool will assist in the assembly. (one/pouch)

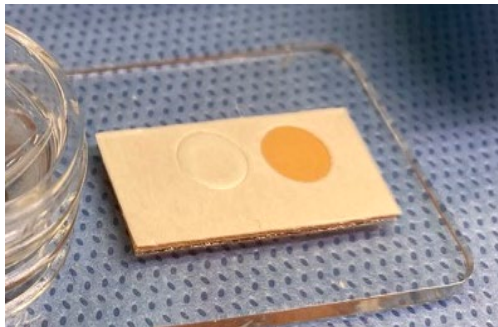


- An 3.0 mm hole is punched in the center of an 8.5 mm corneal graft. Central position of the hole is important.

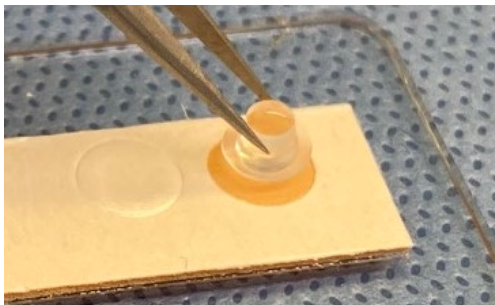
 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11




- An adhesive patch is used to stabilize the Boston Keratoprosthesis assembly. The paper cover is peeled off. (one/pouch)

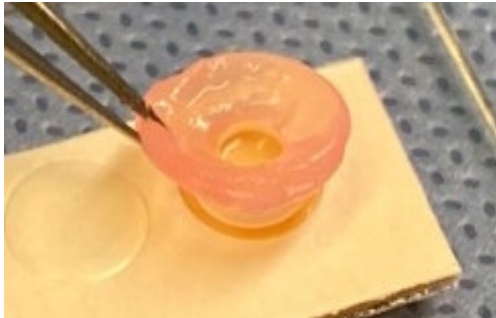


- The bared adhesive is pressed down onto a stable surface.



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

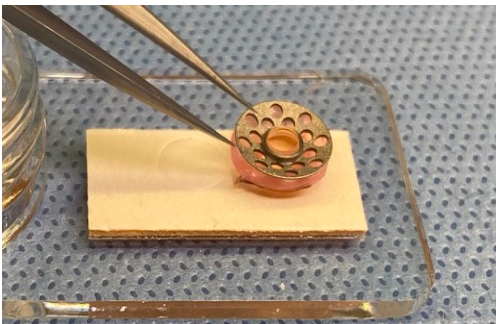
 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11




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

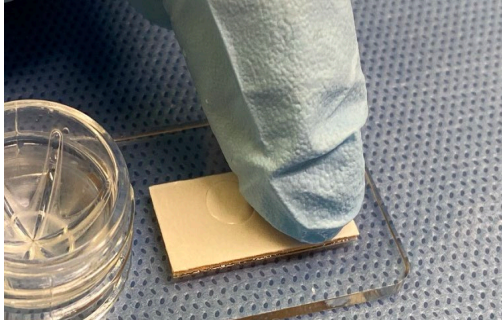


- The hollow bore end of the white pin is used to gently push the graft down over the stem.



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

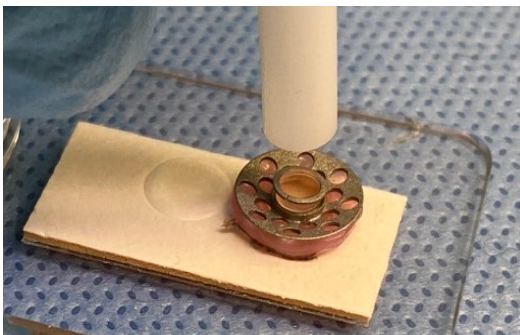
 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11




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

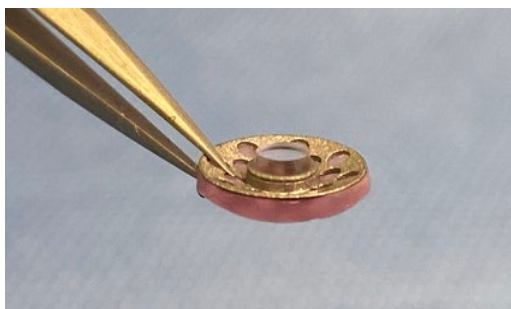


- The locking ring is placed on stem of the front plate and properly aligned parallel to the front plate prior to final assembly.




- The hollow end of the assembly tool is used to press the locking ring firmly down into the groove, usually with an audible snap. The assembly tool must be at 90 degrees from the front plate when pressing down.

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11



- **The position of the back plate and locking ring should be inspected prior to implantation to be certain it is properly positioned.**

- The assembled keratoprosthesis/donor graft should be temporarily placed back in the storage solution while the patient's eye is being prepared.
- The assembled keratoprosthesis/donor graft is then sutured into the patient's cornea like a standard penetrating keratoplasty. Twelve 9-0 nylon sutures are placed and the knots are buried. Do not suture through the back plate holes or otherwise incorporate the back plate 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.
- A large soft contact lens is applied (Kontur lens, plano, 16.0 mm diameter, 9.8 mm base curve, available on the EU market).
- Antibiotic drops, e.g. a fluoroquinolone are applied. Avoid ointments.

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11

10. 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.

 MEEI Boston Keratoprosthesis
243 Charles St. Boston, MA 02114 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 170	Effective Date: 10/02/23	Rev. 11


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.





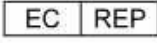










Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	97-mm ²	35-mm ²	290-mm ²	296-mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular


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.

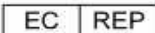
The Boston Keratoprosthesis is included in the Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2013 Edition (page 603), Frank G. Shellock, Ph.D., Biomedical Research Publishing Group (Los Angeles, CA (2013)

 MEEI Boston Keratoprosthesis	INSTRUCTIONS FOR USE Snap-On (EU)	BK-IFU-004
DCR 170	Effective Date: 10/02/23	Rev. 11

11. Explanation of Symbols

	Manufacturer
	Use-by Date
	Serial Number
	Batch code
	Authorized Representative in the European Union
	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

 MEEI Boston Keratoprosthesis
243 Charles St. Boston, MA 02114 USA



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

 0459