

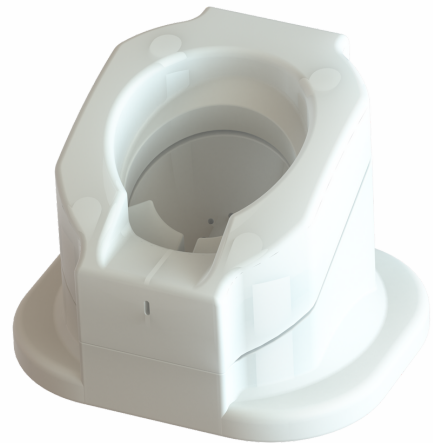
DescePrep[®]

DMEK preparation device

INSTRUCTIONS FOR USE - EYE BANK USE ONLY

DescePrep is a transformative device that enables simple, no-touch preparation of DMEK grafts, helping eye banks maximize operational efficiency, honor more corneal donations, and process high quality non-diabetic and diabetic corneas for corneal surgeons.

- **Enables reliable preparation in high risk corneas**
- **Reduces training and processing time**
- **Provides surgeons with high-quality grafts**



For more information or to order, please contact us at support@eyedeamedical.com or call +1 (443) 650-3848

Instructions for Use for the DescePrep DMEK Processing System

Device Description

The DescePrep DMEK Processing System is a sterile, single-use device intended to aid in preparation of corneal grafts for DMEK procedures. DescePrep utilizes the Bubble Technique to prepare corneal grafts through separation of the Descemet's Membrane from the stroma with a liquid bubble. Each DescePrep system is designated for 'Single Use Only' and should not be reused or re-sterilized by any method.

Intended Use

The DescePrep DMEK Processing System is intended for the preparation of DMEK tissue at eye banks.

Indications For Use

DescePrep is indicated for use in diabetic and non-diabetic donor corneas that have been successfully screened for DMEK use by eye banks.

Contraindications

DescePrep is contraindicated for donor corneas under the following circumstances:

- Endothelial tears or defects

Warnings

High pressures in the bubble can lead to increased cell loss. If experiencing high resistance during injection, stop immediately.



101 W. Dickman St.
Suite 800
Baltimore, MD 21230 USA

443-650-3848
support@eyedeamedical.com
www.eyedeamedical.com

Instructions for Use for the DescePrep DMEK Processing System (cont'd)

INSTRUCTIONS FOR USE

Along with the DescePrep System, you will need a 27-gauge syringe attached to a 1 mL syringe. You will also need 1 mL of corneal tissue media to fill the syringe with prior to injection.

1. REMOVE the cornea from the chamber and stain with Trypan Blue.
2. APPLY 1 to 3 droplets of corneal tissue media onto the concave surface of the base of DescePrep.
3. Once stained, POSITION the cornea on the base such that the cornea is centered on the six drainage holes, **Fig. 1**. REMOVE any air bubbles under the cornea with a surgical spear.
4. Carefully PLACE the top cap onto the base of the device, ensuring the cornea is firmly held in place, **Fig. 2**. The stabilizing arms will hold the cornea 1 - 2 mm from the edge of the trabecular meshwork.
5. APPLY media onto the cornea to ensure it is not drying out.
6. FILL the 1 mL syringe with media.
7. CONNECT the syringe to the 27-gauge needle.
8. PRIME the syringe by ejecting 1 to 3 droplets of media to ensure no air is present in either the syringe or needle.
9. Carefully INSERT the needle into the needle tract of the top cap of the device with the bevel facing upwards.

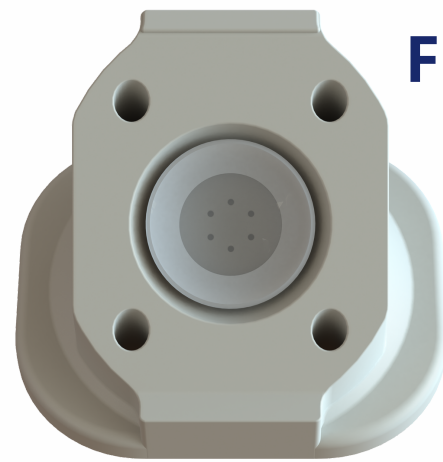


Fig. 1

Top Cap

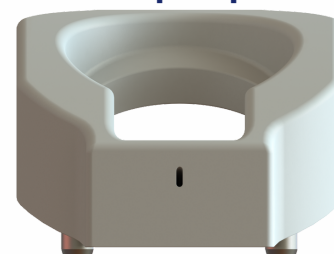


Fig. 2

Cornea



Base



Instructions for Use for the DescePrep DMEK Processing System (cont'd)

INSTRUCTIONS FOR USE

10. Continue to slowly INSERT the needle, **Fig. 3** until it is entering into the trabecular meshwork of the donor cornea, at point **A** on **Fig. 4**.
11. PROGRESS the needle forward while slightly bring the needle upward to ensure that it is as close as possible to the Descemet's layer.
12. STOP when the end of bevel is inside the cornea, no farther than point **B** on **Fig. 4**.
13. INJECT 0.05-0.1 mL of corneal tissue media into the cornea, **Fig. 5**.
 - If experiencing significant pressure or hazing of the cornea, the needle is too deep in the stroma. Gently remove the needle, rotate the cornea 45°, and repeat from step 6.
 - If fluid flow is observed around the cornea, the needle may have perforated the Descemet's Membrane. Gently remove the needle, rotate the cornea 180°, and repeat from step 6.

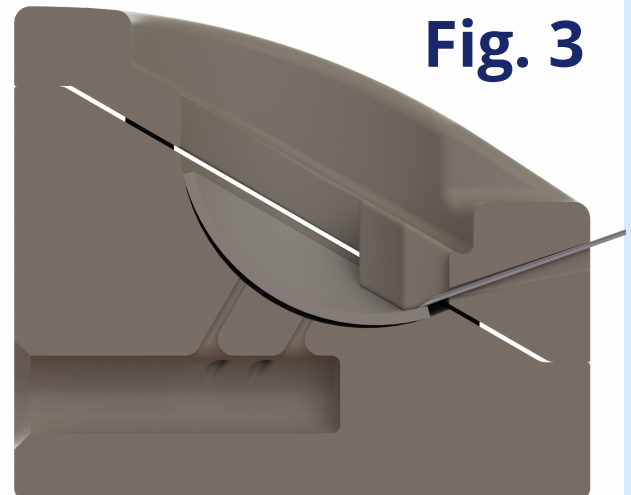


Fig. 3



Fig. 4

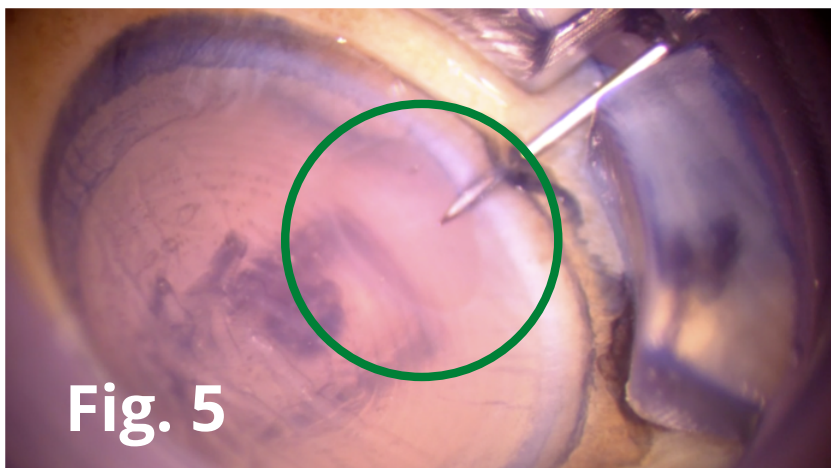
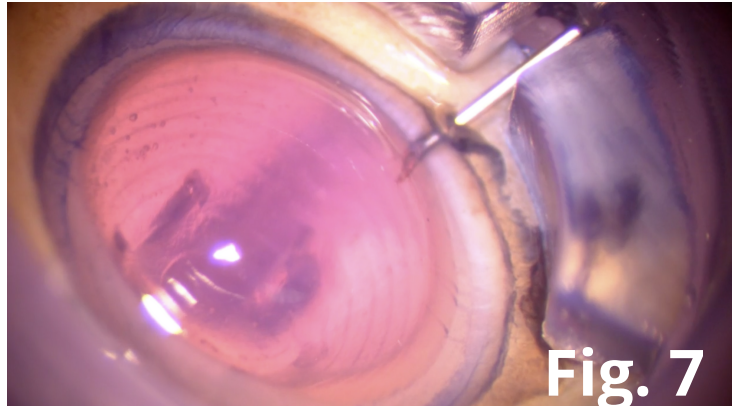
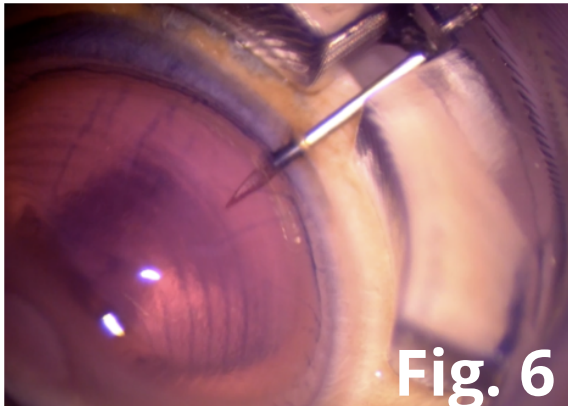


Fig. 5

Instructions for Use for the DescePrep DMEK Processing System (cont'd)

INSTRUCTIONS FOR USE

14. Once a bubble appears to form, continue injecting until the desired size has been reached, **Fig 6 & 7**. High pressures can lead to bubble popping or cell loss - if ever experiencing high resistance, stop immediately.
15. REMOVE the needle from the device, take the top cap off, and drain the fluid from the bubble.
16. SCORE or PUNCH the desired area of the peripheral cornea to create a flap to continue with marking.



Troubleshooting

If a partial bubble is formed, use the following technique:

1. REMOVE the top cap of DescePrep. Insert the needle into the scleral side of the trabecular meshwork.
2. INSERT the needle deep into the stroma, beginning at a downward angle. Once, close to the bubble, tilt the needle upwards so that the needle enters the bubble chamber.
3. CONTINUE bubble injection to the desired diameter has been reached.

Proceed with marking and punching the tissue to surgeon specifications.



101 W. Dickman St.
Suite 800
Baltimore, MD 21230 USA

443-650-3848
support@eyedeamedical.com
www.eyedeamedical.com

Instructions for Use for the DescePrep DMEK Processing System (cont'd)

DescePrep Advantages

Studies have shown that DescePrep has several advantages over traditional DMEK preparation methods such as SCUBA or other manual dissection techniques, including: High-yield preparations in both diabetic and non-diabetic donor corneas

- Reduced DMEK preparation and training times
- Produces high quality grafts for DMEK surgeries
- Achieves large graft diameters (10 mm+)

Packaging & Sterilization

DescePrep is sterilized by Gamma Irradiation according to a validated cycle and the requirements of ISO 11137-2:2013, by an approved sterilization sub-contract, Sterigenics International LLC, a Sotera Health company, Oak Brook, Illinois. DescePrep is packaged according to a validated process and the requirements of ISO 11607-1:2006 by an approved ISO 13485 manufacturing company, Engineered Medical Systems. Devices are designated for Single Use Only.

Symbols



KEEP DRY



KEEP AWAY
FROM SUNLIGHT



DO NOT USE
IF DAMAGED



SINGLE USE



STERILIZED BY
IRRADIATION



101 W. Dickman St.
Suite 800
Baltimore, MD 21230 USA

443-650-3848
support@eyedeamedical.com
www.eyedeamedical.com