

EndoGlide™ Ultrathin Pre-Loaded Graft for DSAEK • Handling & In-Service

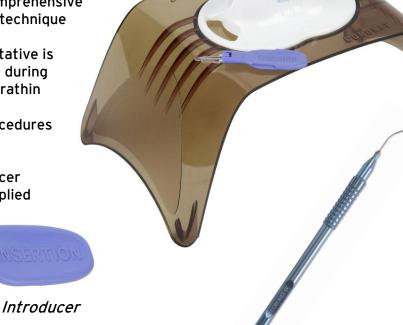
Attention:

Refer to the EndoGlide[™] Ultrathin Instructions For Use for comprehensive device protocol for surgical technique

A Coronet Medical representative is recommended to be present during initial use of EndoGlide™ Ultrathin

Combined cataract / EK procedures are not recommended

Only the Cartridge / Introducer containing the graft are supplied by the eye bank



PRE - OPERATIVE

Cartridge

- A. 23g EndoGlide Placement Titanium Forceps (Ref # 53-951) are required for the procedure. Insure that the forceps have been cleaned / sterilized for the surgery.
- B. An Anterior Chamber Maintainer is required for the procedure. A disposable 23g AC Maintainer is recommended.
- C. For transport safety, the graft is pre-loaded in a position inside the anterior bevel of the EndoGlide™ Ultrathin cartridge. The graft / device is then placed in a storage media vial for transit from the eye bank. The graft should be transplanted within 24 hours after eye bank processing / loading.
- D. Remove the storage media vial from the shipping container. The vial remains sealed and must be allowed to reach ambient room temperature (1 to 2 hour wait time).



Graft / Device remains in sealed vial until performing operative step 1



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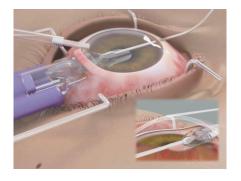
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OPERATIVE

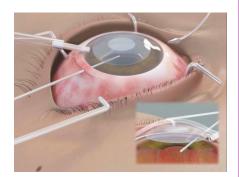
- 1. After the eye is draped and prepped, remove the graft/device from the storage media vial and fully immerse in BSS+ irrigating solution to dilute the hypertonic storage media. Graft / device should remain in BSS+ for a minimum of 10 minutes.
- 2. A temporal 4.5mm (scleral tunnel) or 4.9mm (clear corneal) primary incision is required. A 1.0mm nasal paracentesis is required for the 23g forceps. A paracentesis positioned adjacent (superior or inferior) to the primary incision is required for the AC Maintainer. BSS+ flow should be directed away from the incision.
- 3. Inspect the graft position within the EndoGlide[™] cartridge under the microscope prior to use. If necessary, manually adjust the graft to a position adjacent to the cartridge opening.



- 4. A deep AC is best for unfolding the graft with minimal or no manipulation. Recommended bottle height is 40cm. Careful attention is required to adjust the bottle height as needed to avoid shallowing of AC.
- 5. Maintain control of the graft with the placement forceps throughout the graft insertion process and inject a small (2mm) air bubble. Insure that the AC is stabilized (AC Maintainer on low or off and no wound leakage) prior to releasing the donor from the forceps.
- 6. Full wound closure, donor positioning with air tamponade and completion of the procedure should then be performed in the usual manner.







POST - OPERATIVE

- 1. At end of operative procedure, drops are recommended instead of ointment. Do not patch eye during recovery. Following surgery, patient should remain supine for one hour in the post-operative care unit before being discharged. Patch eye at discharge.
- 2. Recommended use of sodium chloride 5%, 4 times daily for 2 to 4 weeks.



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