









CORONET

'PRODUCT NAME CORONET® SURGICAL TRAINER
'PRODUCT INFORMATION AND INSTRUCTIONS FOR USE

Symbols Used

LOT GB- Lot Number	 GB- Non Sterile	 GB- Do not use if product is opened or damaged and consult instructions for use	 GB – Manufacturer	 GB – Date of Manufacture
REF GB- Catalogue Number	 GB- Caution	 COR 026 GB - Consult Electronic Instructions for Use	 GB – Contains Latex	 GB – Unique Device Identifier

GB - INSTRUCTIONS FOR USE

Description

The **CORONET® Surgical Trainer** is a training aid intended to be used for simulated DMEK wet lab practice only.

The Surgical Trainer is not a medical device.

Note that this device has latex components. Take appropriate precautions if you have a latex allergy.

Preparations

Note: For the simulator to work correctly, it must be watertight. You may need to make adjustments to your usual techniques to accommodate the cadaveric cornea, which will leak more than living human tissue.

If there are leaks in the iris sleeve disassemble and re-assemble the simulator.

Instructions

- Inspect the corneoscleral rim for size and roundness. Asymmetric rims, rims with large notches, and rims smaller than 18mm in diameter may result in a leak from the Surgical Trainer. Any retained conjunctiva on the sclera should be removed entirely from the corneoscleral rim. Retained conjunctiva can cause the rim to slide out from under the tissue retainer when it is tightened and the AAC is pressurized. The iris / uvea must also be completely removed from the scleral rim to prevent the rim from sliding out from under the tissue retainer.
- Keep the corneoscleral rim clear – do not stain the DMEK graft with trypan blue in the cap as this will impede your view into the Surgical Trainer. Edematous corneoscleral rims can be made clear with hospital grade glycerine (not vegetable glycerine).
- Disassemble the Surgical Trainer by unscrewing the Compression Ring and removing the Tissue Retainer from the Pedestal. Attach the supplied silicone tubing to the Tubing Connector. Confirm that the white slide clamp on the tubing is in the open position.
- Place the unit on a stable, flat surface. Apply an Iris Sleeve to the Pedestal. While holding the sleeve between the thumb and forefinger of each hand, stretch the sleeve and place one rolled portion into the Pedestal side groove closest to you. While keeping the sleeve tightly stretched continue the positioning by unrolling the sleeve away from you, over the top opening. Complete the positioning by further unrolling the sleeve down the opposite side of the Pedestal into the Pedestal side groove. The mounted Iris Sleeve should be stretched FLAT across the top of the pedestal like a drum. Ensure the unrolled portion of the sleeve is sufficiently tucked 360° into the Pedestal side groove. Remove and repeat if top of sleeve is not tightly stretched. Note – micro tears in the sleeve will prevent a successful application of the sleeve.
- Draw an x-y axis on the Iris Sleeve with a marker. This X will make it easier for you to see the depth and shape of the iris during practice.
- Pull back the plunger of the supplied 1.0ml syringe to 0.5ml and connect to the luer-lock fitting on the silicone tubing. Ensure that the slide clamp on the tubing is in the open position. **OBSERVE:** Only air is used in the 1.0ml syringe. (Air is compressible, which allows the Iris Sleeve to readily bulge posteriorly when the anterior chamber is filled with fluid. Water, because it is not compressible, does not readily facilitate the same posterior movement of the Iris Sleeve.)
- Pull the attached syringe plunger back 0.5ml (now fully retracted to 1.0ml) and confirm that the iris is now in a concave position. The concave position will give you space to make your first corneal incision.
- Carefully center and place the cornea over the iris.
- Place the Tissue Retainer over the cornea, taking care to place the alignment pin on the Base into the alignment hole on the Tissue Retainer. Firmly press down the Tissue Retainer
- Place the Compression Ring over the Tissue Retainer. While firmly depressing the Tissue Retainer, tighten (turn clockwise) the Compression Ring until it compresses the corneoscleral rim firmly. Wait approximately 30 seconds for the sclera to compact, then further tighten until very tight and the cornea feels firm to digital palpation.
- OBSERVE:** The cornea should be pressurized if the Compression Ring is tightened properly. Failure to tighten the ring sufficiently after pausing for 30 seconds is a common source of leakage when assembling the device.
- Mark the cornea with a marker at the sites of your desired paracentesis incisions and main incision. Depress the plunger of the 1.0ml syringe to 0.5ml. The iris should be flat or concave, but not convex. The AC should now be firm enough for a properly constructed paracentesis incision and the Iris Sleeve should not be bulging anteriorly to prevent puncturing it with your blade.
- Make the first paracentesis incision, taking care to stay relatively parallel to a flat plane to avoid puncturing the iris. **TIP:** Make your paracentesis incisions biplanar, if possible, to avoid leakage during the lab. Remember – you are operating on a cadaveric cornea, not a living cornea. Cadaveric corneas have a much greater tendency to leak than living corneas.
- Once one incision is made, fill the AC with BSS until the chamber is full. Remove any residual bubbles with your cannula. Fill the AC with BSS to pressurize until the iris has been pushed posteriorly by the volume of the BSS into a concave configuration and the chamber feels firm enough for a second clean paracentesis incision. Make the second paracentesis incision. **NOTE:** The AC should hold a firm pressure if your paracentesis incisions are watertight.
- Fill the AC again with BSS as in Step 14. Ensure your paracentesis incisions are not leaking. Make your main incision. **TIP:** Make your main incision tri planar, if possible. Be more meticulous than you would in the O.R. A leaking main incision is a common pitfall when attempting to shallow the AC but not flatten it.
- Pre-placement of a main incision suture without tying is recommended. Note that the syringe remains at the 0.5ml mark, as set in Step 12.
- Insert the graft into the AC, then burp the paracentesis incisions prior to withdrawing the injector. After graft injection is complete, the cornea should be slightly concave in appearance or at least wrinkled. A deformed cornea indicates that the AC volume and pressure are low.
- Fill the AC with BSS until the cornea is almost but not completely reformed. **OBSERVE: The iris should still be flat and the 1.0ml syringe should still be at the 0.5ml mark. There should still be striae apparent on the corneal surface. The pressure should be soft to palpation.**
- Tie the main incision suture closed to ensure that it is watertight.
- Starting at the 0.5ml mark, depress the 1.0ml syringe in 0.1ml increments. Proceed in this incremental fashion until the corneal striae mostly disappear, the cornea has returned to its normal convex shape, and the iris appears slightly convex in shape. **OBSERVE: The AC should now be shallow, and the pressure should be soft, not hard.**

CORONET

PRODUCT NAME CORONET® SURGICAL TRAINER

PRODUCT INFORMATION AND INSTRUCTIONS FOR USE

21. Lock (close) the white slide clamp on the tubing.
22. Begin Training. Deepen the chamber by injecting BSS into a paracentesis – watch the iris bulge posteriorly into a concave shape. Shallow the chamber by burping BSS from a paracentesis – watch the iris bulge anteriorly into a convex shape.

TROUBLESHOOTING

During Step 20, if the 1.0ml syringe is fully depressed to 0.1ml or 0.0ml, check your incisions for leaks and close with suture if necessary. Lock (close) the white slide clamp on the tubing and detach the 1.0ml syringe. Return the plunger to 0.5ml, reattach it to the luer-lock fitting, and unlock (open) the white slide clamp. Repeat Steps 18-22 OBSERVE: Only air is used in the 1.0ml syringe.

CLEANING

All components of the system may be reused in the lab setting, but have a limited life span for expert training. Bleach or alcohol cleaning is recommended

The Surgical Trainer and Refill Kits are available from Network Medical Products Limited

PRODUCT DETAILS	
Cat Ref:	Description
51-3000	Surgical Trainer
51-3010	Surgical Trainer Refill Kit (10pk)

Also available from Network Medical

PRODUCT DETAILS	
Cat Ref:	Description
51-823	EndoGlide™ Ultrathin (DSAEK)
51-826	DMEK EndoGlide™ *
53-951	Tan EndoGlide™ Placement Forceps
53-952	Tan EndoGlide™ Loading Forceps
53-955	EndoGlide™ Placement Forceps, 27G
53-956	EndoGlide™ Loading Forceps, 27G

*The DMEK EndoGlide™ is a device designed particularly to meet the needs of the corneal graft surgeon performing DMEK (Descemet Membrane Endothelial Keratoplasty) procedures.