

# EndoSarter®

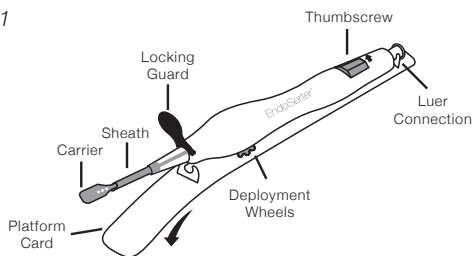
## Corneal Endothelium Delivery Instrument

CAUTION: Federal (USA) Law restricts this device to sale by, or on the order of, a physician.

### Description

The EndoSarter® Corneal Endothelium Delivery Instrument is a device used for delivering a corneal endothelial allograft into the eye. The EndoSarter® consists of the instrument's body and its internal mechanism and carrier shown in Fig. 1. The EndoSarter® is a sterile, disposable, single use only device. When loaded with allograft tissue, rotated, and inserted into the eye the allograft can be deployed in the anterior chamber.

Fig. 1



### Indications

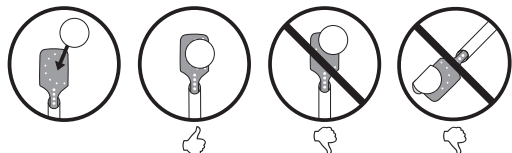
The EndoSarter® is used to insert corneal endothelial allograft tissue measuring less than or equal to 8.5mm in diameter and 175 micron in central thickness into the anterior chamber through a minimum 4mm incision during endothelial keratoplasty procedures.

**WARNINGS: DO NOT remove black locking guard from the EndoSarter® until ready to insert tissue into anterior chamber. Loading tissue should be performed immediately prior to insertion and deployment. Once loaded, do not flush the device unless the sheath is inserted in the anterior chamber. Failure to follow the Instructions for Use may result in patient injury or damage to donor tissue.**

### Instructions for Use

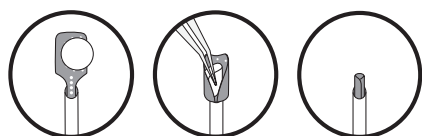
1. Refer to Fig. 1 to acquaint yourself with the device.
2. Open the package and handle the device using standard sterile procedures. Hold the device by the body and remove the white plastic platform card by gently pulling it down and away from the carrier-end of the device.
3. DO NOT remove the black locking guard until ready to insert tissue into anterior chamber.
4. The device is delivered with the allograft carrier already extended in the loading position.
5. Hold the device so the side printed with "EndoSarter®" faces up. Fig. 1.
6. Flush the device at the Luer connection with balanced salt solution and remove excess moisture from the carrier with an absorbent sponge (do not shake). Stop irrigation and DO NOT restart until the tip of the EndoSarter® is in the anterior chamber.
7. Allograft tissue is trephined by the surgeon to a preferred diameter.
8. Load the endothelial allograft onto the carrier, endothelium-side up. Place the donor tissue within the boundary of the alignment holes. Remove excess moisture from around the allograft with an absorbent sponge to enhance adherence of the allograft to the carrier during loading and deployment. Larger diameter allografts will overhang the carrier on the open side of the alignment holes. **WARNING: Do not allow the donor tissue to extend past the front end of the carrier or drape below the edge of the carrier.** Fig. 2.

Fig. 2



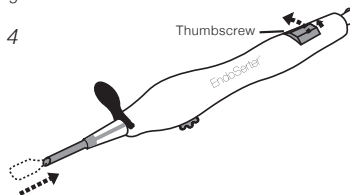
9. Apply a small amount of cohesive viscoelastic to the endothelium.
10. Rotate the blue thumbscrew in the direction of the arrow to load the tissue into the insertion sheath. As the tissue retracts and begins to roll, gently tuck the overhanging tissue edge under the opposite edge. Visualize the tissue loading until complete and, if necessary, repeat tucking on exposed edge(s). Allografts that do not overhang the carrier will not require tucking. Fig. 3.

Fig. 3



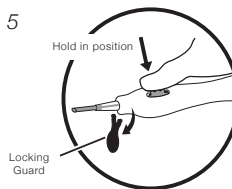
11. Rotate the blue thumbscrew only in the direction indicated by the printed arrow until all action stops. Then rotate 3 full revolutions past the point where tissue is observed to be fully retracted. Fig. 4.

Fig. 4



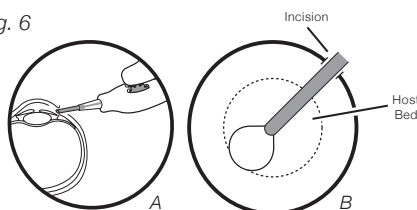
12. Roll the device 180 degrees so that the black deployment wheels are up.
13. Firmly hold the black deployment wheels in existing position. Gently remove and discard the locking guard. Fig. 5.

Fig. 5



14. Continue to hold the black deployment wheels while inserting the beveled tip of the insertion sheath into at least the center of the anterior chamber. **WARNING: Deployment wheels must be held securely to avoid damage to donor tissue during insertion.** Fig. 6A.

Fig. 6



15. Once the beveled tip of the insertion sheath is inserted into the anterior chamber, deepen the anterior chamber using gentle irrigation (e.g. bottleheight at 40 cm) through the device. Continue irrigation as the device is moved across the anterior chamber past the far edge of the stromal bed.
16. Deploy the allograft by rotating the black deployment wheels forward towards the patient. Move the black deployment wheels until the allograft is completely uncovered. **WARNING: The EndoSarter® uncovers the tissue allograft and the sheath will retract toward the incision during deployment.** Fig. 6B.
17. When the allograft has deployed, hold the black deployment wheels in their position, and remove the device from the anterior chamber.
18. Discard the EndoSarter® after use.

### Precautions

The device must be flushed with balanced salt solution prior to loading tissue. The tissue allograft must be placed within the boundary of the graft alignment holes on the carrier. Store the EndoSarter® in its sterile sealed package at room temperature. Contents are sterile unless package is opened or damaged. Do not resterilize.

### Surgical Procedure

Proper surgical technique and donor tissue handling is the responsibility of the individual surgeon. Surgeons must determine the suitability of any particular procedure based upon their medical training and experience.

### Warranty and Limitations of Liability

SightLife Surgical warrants that the EndoSarter®, when delivered, will conform to the device's current specifications and shall be free from defects in material workmanship for a period equal to the expiration date.



SightLife Surgical  
101 North Chestnut Street, Ste 303  
Winston-Salem, NC 27101

www.sightlifesurgical.com  
Tél. : +1 (844) 526 7632



Single Use Only



**EMERGO EUROPE**  
Molenstraat 15  
2513 BH, The Hague  
The Netherlands  
Tel: +31 (0)70 345 8570  
Fax: +31 (0)70 346 7299



® denotes trademark of SightLife Surgical.  
© 2016 SightLife Surgical. All rights reserved.



ES-899-NOV16