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**ENDOSHIELD DSEK GRAFT INJECTOR SYSTEM**  
**INSTRUCTION FOR USE**

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions prior to use. Observe all contraindications, warnings and cautions noted in these directions. Failure to do so may result in patient complications. To view an instructional video go to [www.keramed.com](http://www.keramed.com).

**Instruction for Use:**

Description: each package contains one injector and 2 cartridges. The second cartridge is to be used as a spare. If the second cartridge is not used, it should be disposed of along with the injector body and the first cartridge.

The Endoshield injector is a sterile disposable single use device designed to allow the safe injection of an 8.0 to 9.0 mm stromal-endothelial corneal graft for Descemet's stripping endothelial keratoplasty (DSEK) through a 3.2 mm or larger clear corneal incision. The graft thickness should be between 100 and 200 microns. Preferably, the graft is prepared by using a Barron punch.

**Patient Disclosure:**

As with any procedure, DSEK and the use of the Endoshield injector have benefits and risks. Prior to use, always review the benefits, risks, and alternatives with your patients.

**Indications for Use:**

The Endoshield DSEK Graft Injector is a device used to curl and insert an 8.0 – 9.0 mm DSEK graft for surgical placement in the human eye through a 3.2 mm or larger incision.

**Contraindications:**

The Endoshield injector is contraindicated if it is not desirable to insert a DSEK graft through a small corneal incision or if the patient has any contraindications to DSEK surgery.

**Warnings**

- Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damage DO NOT USE and contact KeraMed Inc. or its authorized representative.
- The device is intended only for Single Eye Use. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the

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device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited, the transmission of infection disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

### Directions for Use

Care should be taken that the DSEK graft is properly loaded into the cartridge by the surgeon under direct visualization of the operating microscope. It is also important to visualize the smooth advancement of the DSEK graft under high magnification. Gentle and controlled insertion of the injector cartridge into the anterior chamber through a clear corneal incision is advised to avoid damage to the anterior chamber structures or to the lens.

### Preparation of the Injector for DSEK Graft Insertion

**Warning:** DO NOT ADVANCE THE PLUNGER OR PUSH ON THE THUMBREST UNTIL THE CARTRIDGE HAS BEEN LOADED WITH THE DSEK GRAFT AND LOCKED INTO POSITION

### Hydration of the Foam Tipped Plunger

**Warning:** DO NOT ADVANCE THE PLUNGER DURING HYDRATION. The end of the injector body with the foam tipped plunger located inside the injector body should be placed into a container of sterile balanced salt solution for a period of at least 2 minutes prior to loading of the cartridge. The balanced salt solution should completely cover the foam tip during the hydration period.

### Preparation of the DSEK Graft

1. The donor cornea is divided into anterior lamellae and posterior lamellae manually, by a microkeratome or by a femtosecond laser. The posterior lamellae (DSEK graft thickness) should be between 100 and 200 microns.

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**Warning:** THE DONOR CORNEA MUST BE SOAKED IN BALANCED SALT SOLUTION. The entire donor cornea needs to be soaked in balanced salt solution for between 10 and 20 minutes prior to trephinating the DSEK graft with a corneal punch.

2. The surgeon prepares the DSEK donor graft by a corneal punch e.g. Baron punch of 8.0 to 9.0 mm.
3. Immediately, before loading the graft into the injector, excess balanced salt solution is removed using a surgical sponge without touching the corneal endothelium.

### Preparation of the Cartridge and Loading of the DSEK Graft

1. It is important that the lumen and the loading area of the cartridge are dry prior to loading of the graft. The presence of a pool of liquid on the loading area or within the lumen may interfere with proper graft curling.
2. The surgeon grasps the stromal edge of the donor graft with .12 toothed forceps and pulls the graft into the open Endoshield cartridge stromal side down. The graft is pulled as far forward as possible. The position of the graft should be similar to Fig. 1.
3. A non-dispersive viscoelastic e.g. Healon is then used to apply a thin coating over the entire endothelium.



Fig. 1

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The surgeon then carefully closes the cartridge so that the graft is curled inward inside the cartridge. Under direct visualization with the operating microscope, the position of the graft should appear symmetric when looking from the back end Fig 2.



Fig. 2

From the side, the loaded cartridge should appear like Fig. 3:



Fig. 3

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### Placement of the Loaded Cartridge into the Injector Body

1. The surgeon holds the injector so that it is pointing away from him or herself and the slot at the end of the injector body is facing upward. The surgeon then places the closed cartridge with wings pointing upward into the end of the injector body. The cartridge is pushed all the way back as shown in diagram 4.

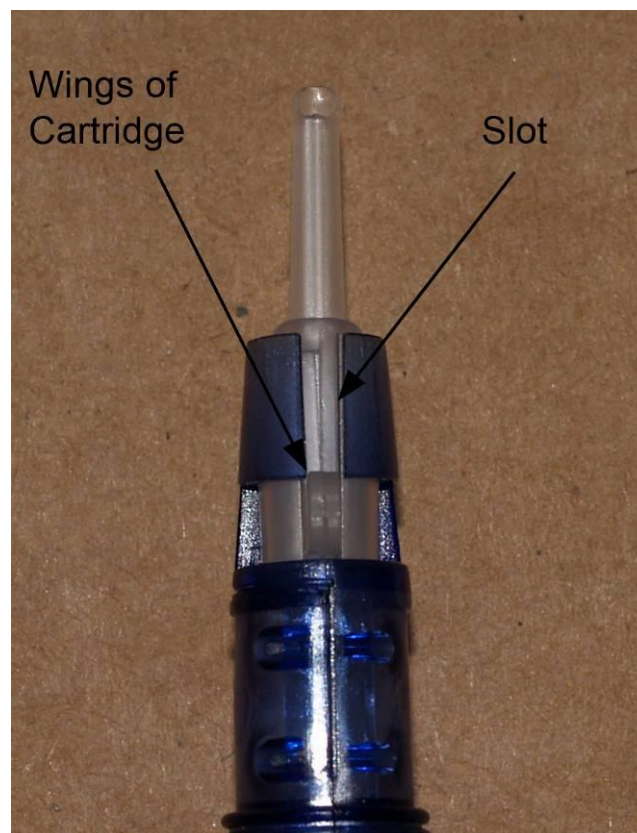


Fig. 4

2. The surgeon then turns the wings of the cartridge to lock it into position. **For a right handed surgeon, the wings of the cartridge should be turned towards the right. For a left handed surgeon, the wings of the cartridge should be turned towards the left. See Figure 5.**

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**For Right Handed Surgeon**



Fig. 5a

**For Left Handed Surgeon**



Fig. 5b

3. The surgeon confirms correct positioning of the cartridge by verifying that the thumb of the dominant hand is placed on the thumb-rest and that the “wings” of the cartridge are pointing down. See Fig. 6 which illustrates the correct way to hold the injector for a right handed surgeon.

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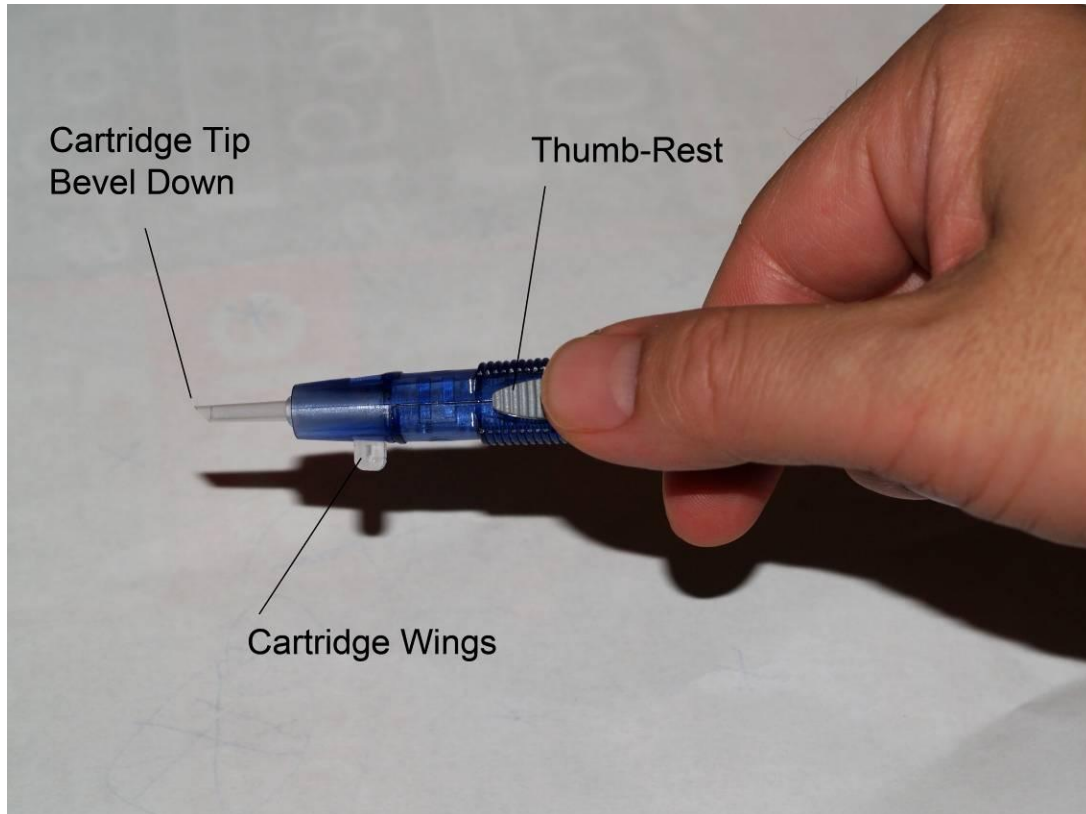


Fig. 6.

4. Under direct visualization under the microscope the surgeon slowly advances the foam tipped plunger by pushing the thumb-rest with the thumb of the dominant hand. The surgeon will look to see that the graft is advancing and that the foam tip is not encroaching the inside of the graft.
5. The surgeon will advance the graft until the distal end of the graft is about 1 mm away from the tip of the cartridge.

### **Injection of the DSEK Graft**

The surgeon will place the tip of the cartridge **bevel side down** into the clear corneal incision and slowly advance the cartridge tip until the entire cartridge bevel is just inside of the anterior chamber. During the insertion of the cartridge tip, it is recommended that counter-traction be applied by grasping the limbus with a .12 toothed forceps.

Once the cartridge bevel is inserted inside of the anterior chamber:

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1. The surgeon will then slowly advance the graft by pushing against the thumb-rest with his (her) thumb.
2. The graft will slowly come out of the cartridge tip and open endothelial side down. It is important that the surgeon carefully observe the unfolding process to insure that the graft is in the proper orientation and that the graft has completely disengaged from the cartridge. The direction of the graft unfolding may be adjusted by turning the injector clockwise or counterclockwise.
3. If the graft does not completely release spontaneously from the end of the cartridge, a second instrument e.g. Sinsky hook may be inserted through a paracentesis incision to complete the release of the DSEK graft.
4. Once the graft is completely inside the anterior chamber, the foam tip of the plunger is retracted back into the cartridge tip.
5. The cartridge tip is then withdrawn from the cornea.
6. The surgeon then completes the DSEK procedure.

**Storage Conditions**

Store at room temperature.

**Product Information**

Each tray contains two STERILE cartridges and one STERILE Injector body. The tray is sealed to prevent contamination. The cartridge and injector body are made of medical grade polymers.

**Manufacturer**

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