medicel
SWISS TECHNOLOGY FOR SURGERY

INSTRUCTIONS FOR USE

GÜELL DMEK INJECTOR SET

Single-use corneal endothelium injection system
for the injection of
ENDOTHELIUM IMPLANTS IN DESCEMET MEMBRANE ENDOTHELIAL KERATOPLASTY (DMEK)

DESCRIPTION

Thanks to the GÜELL DMEK™ hydraulic system, the GÜELL DMEK™ injection system allows implantation of corneal transplants using Descemet Membrane Endothelial Keratorplasty (DMEK).
The GÜELL DMEK™ injection system consists of the sterile GÜELL DMEK™ single-use injector with a silicone tip.

APPLICATION

Injection of self-rolling corneal endothelium transplants in Descemet Membrane Endothelial Keratoplasty (DMEK).
Non-self-rolling corneal endothelium implants with a high stroma proportion, such as those used in Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK), are not suitable for implantation with the GÜELL DMEK™ injection system.
The system is not suitable for the injection of intraocular lenses in cataract operations.

INSTRUCTIONS FOR USE

1. Open the blister in a sterile environment and remove the GÜELL DMEK™ injector (Fig. 1).
2. Fill the cartridge tip and the loading chamber of the GÜELL DMEK™ Injector with BSS until the cartridge tip and loading chamber are completely filled and covered with BSS (Fig. 2).
3. Gently lift the rolled implant from the tray, using sterile flat forceps and place in the loading chamber (Fig. 3). Minimize contact between the endothelium and the outer walls of the loading chamber. Next, flush the rolled implant along of the loading chamber into the cartridge tip using BSS, avoiding direct contact with the implant (Fig. 4), until the implant lies entirely within the cartridge tip. Depending on the surgical technique, an air bubble can be placed behind the implant in the cartridge tip (Fig. 5).
4. Then squeeze the loading chamber wings together until the "clicklock" mechanism clicks into place.
5. Push the blue injector plunger forward until the rear push plate is flush against the injector housing or until the wheel of the GÜELL DMEK™ Injector moves (Fig. 6).
6. There is a small lever on the surface of the injector that allows you to choose whether to operate the injector in forward and backward mode (lever in middle position) or in forward only mode (lever turned to the left) (Fig.7). In forward only mode, the backward movement of the plunger is disabled. When forward only mode is activated, this is signalled by a faint click when the plunger is pushed forward. You can switch between the forward and backward mode and the forward only mode at any time during the injection process by simply adjusting the lever.
7. If the silicone tip cannot be pushed into the loading chamber, withdraw the plunger into the starting position and straighten the silicone tip using sterile forceps.
8. Insert the cartridge tip through the incision and push over the iris to the distal edge of the pupil (Fig. 8).
9. Using your index finger, pull the wheel of the GÜELL DMEK™ Injector back slowly in order to push the implant forward (Fig. 9). When forward only mode is activated, you can hear a faint click when the plunger is pushed forward. As the implant is discharged, slowly withdraw the injector making sure the implant is not get under the iris. Only push the plunger forward until the implant has completely emerged, even if the plunger has not yet come to a stop.
10. Slowly withdraw the injector fully from the eye (Fig. 7).
11. Completely unroll the implant in the eye according to your chosen surgical technique.
12. Press the implant onto the cornea using a further air bubble introduced beneath the implant (Fig. 10).

PLEASE NOTE: The cartridge and the GÜELL DMEK™ single-use injector may only be used once and must not be re-sterilised/reconditioned. Reuse or re-sterilisation can reduce the performance of the product, which can result in serious adverse effects on the health and safety of the patient. Store at room temperature.

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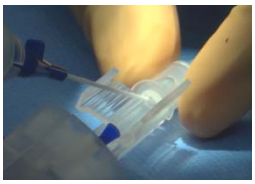

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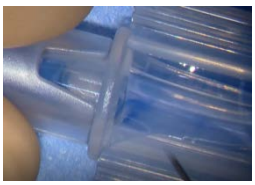

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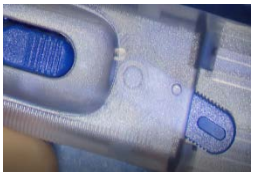

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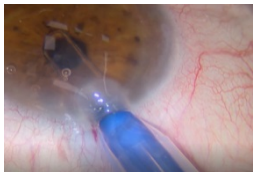

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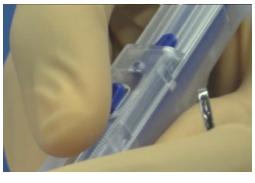

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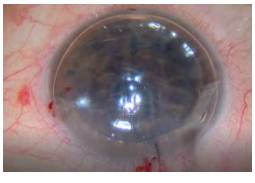

SIDE EFFECTS: Use the GÜELL DMEK™ injector during DMEK surgery may result in a slight reduction in endothelial cells in the donor transplant.

OPERATIONAL PROCEDURE

The appropriate surgical techniques are the responsibility of the respective surgeon. He or she must assess the appropriateness of the relevant procedure based on his or her education and experience.

GUARANTEE AND LIABILITY LIMITATION

The manufacturer guarantees that this product has been manufactured with the appropriate care and assumes no liability for side effects or resulting damages, losses or costs that may arise as a result of the direct or indirect use of this product. Manufacturer's liability is restricted to the performance of repairs resulting from product defects, which is clearly not the result of incorrect handling or the use of lenses not validated with this injector model.

ATTENTION: US federal regulations restrict the sale of this product to medical practitioners and those acting on their behalf. *

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LOT	Batch code		Do not reuse
	Use by		Do not resterilize
	Keep dry		Consult instructions for use
	Keep away from sunlight		Manufacturer
	Do not use if package is damaged	Rx ONLY	*
STERILE EO	Sterilized using Ethylene Oxide (EO)		