

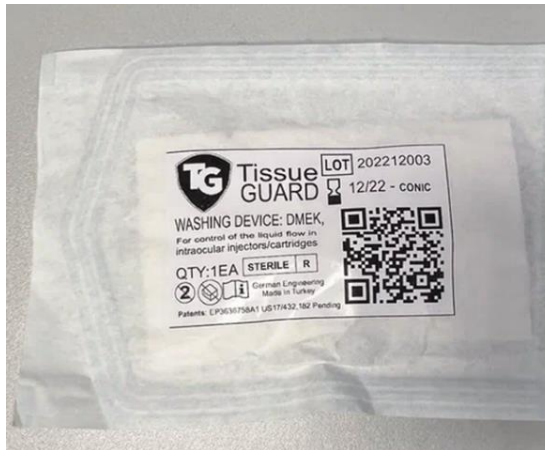
OPERATION MANUAL

for

Sterile **washing device** for DMEK and DSAEK Injectors *to control the washing or coloring of the graft in order to prevent the escape of the graft (DMEK or DSEK).*

Attention: The device is for single use only.

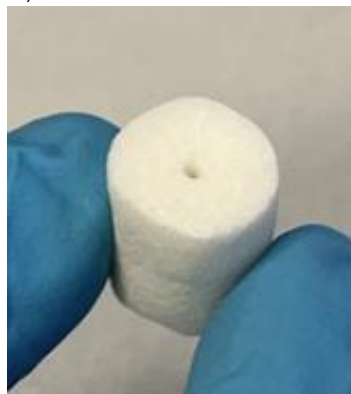
Attention: Do use if the packaging damaged



Device intention of use: The device is to be attached to the Injector during the DMEK (*or DSAEK, DSEK*) graft washing or coloring to control the liquid flow and, thus, prevent the graft from escaping from the Injector during the washing of the DMEK (*or DSAEK, DSEK*) graft. The devices also can be used for positioning the graft to the tip of the Injector for the transplantation.

Attention: The device is not intended to touch the graft. If the graft touches the washing device, slightly aspirate the graft back into the Injector, the device is not toxic to the graft, but mechanical contact should be prevented.

Device description: The device is made from a medical grade PVA-sponge, which is a hydrophilic material with high water uptake volume. The device is very soft when wetter. The device has a cylinder shape with a round cavity from one side, which allows the insertion of the Injector.



Material composition : Polyvinylalcohol (PVA) is a white, sponge-like material.

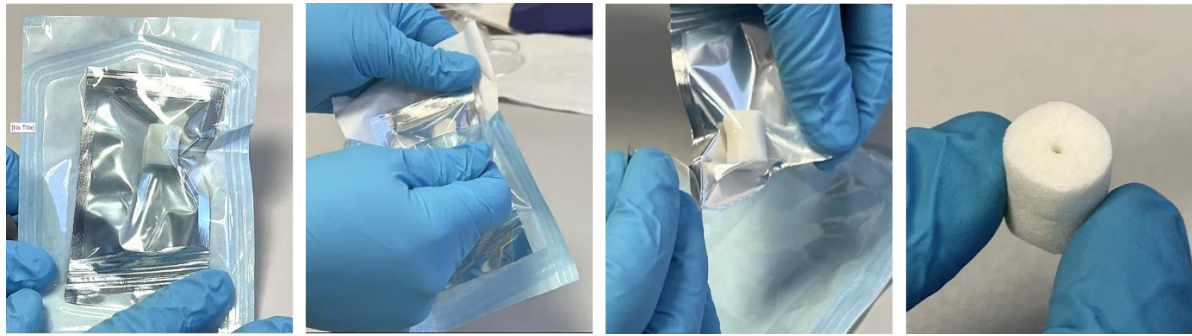
Note 1: The material is heat-sensitive; do not heat more than 100 C.

Note 2: The material has a high moisture absorption rate; it is soft and elastic when wet but hard and rigid when dry.

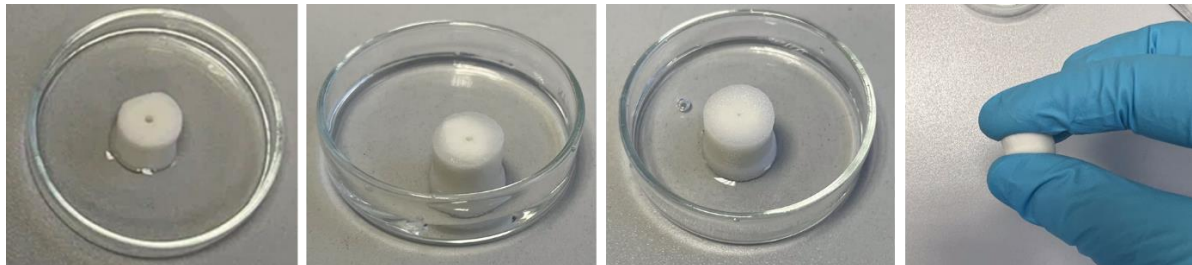
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General Use of Washing Device:

1. Remove the device from the double packaging in a sterile environment. As shown



2. Wet with Basic Saline Solution (BSS) (or similar isotonic salt solution) by depositing the device in a container with sterile BSS. The device will swell a little and become soft in response to the wetting, which can be checked by compressing the device with fingers.



Attention: The device can be used only after wetting. The washing device dries slowly in an open environment. The device should be kept in contact with the solution prior the use.

3. Attach the Injector with the preloaded DMEK graft to a syringe filled with 2-3 mL of BSS to ensure that the graft remains in the Injector.
4. Insert the Injector into the cavity of the washing device and hold it gently, as it is shown in the image. The washing device should be pushed against the Injector in order to prevent the DMEK graft from escaping during the washing process.



Attention: The Injector must be inserted into the end of the cavity, which can be felt by resistance

5. The tissue is ready to be washed by slowly pushing through the rinsing solution by slowly pushing the solvent through the Injector. The washing device prevents a fast liquid flow in the Injector, thus minimizing user error and graft ejection. The DMEK graft can be moved toward the washing device during the washing.



Gently remove the washing device. The DMEK graft is ready for implantation