

RE-ONE DEVICE FOR TRANSPORT, EXAMINATION AND HANDLING OF OCULAR BULBS

Classification of the product

Sterile medical device -  0476.

This instruction for use are intended for RE-ONE 01 and RE-ONE 02 medical devices.

Package

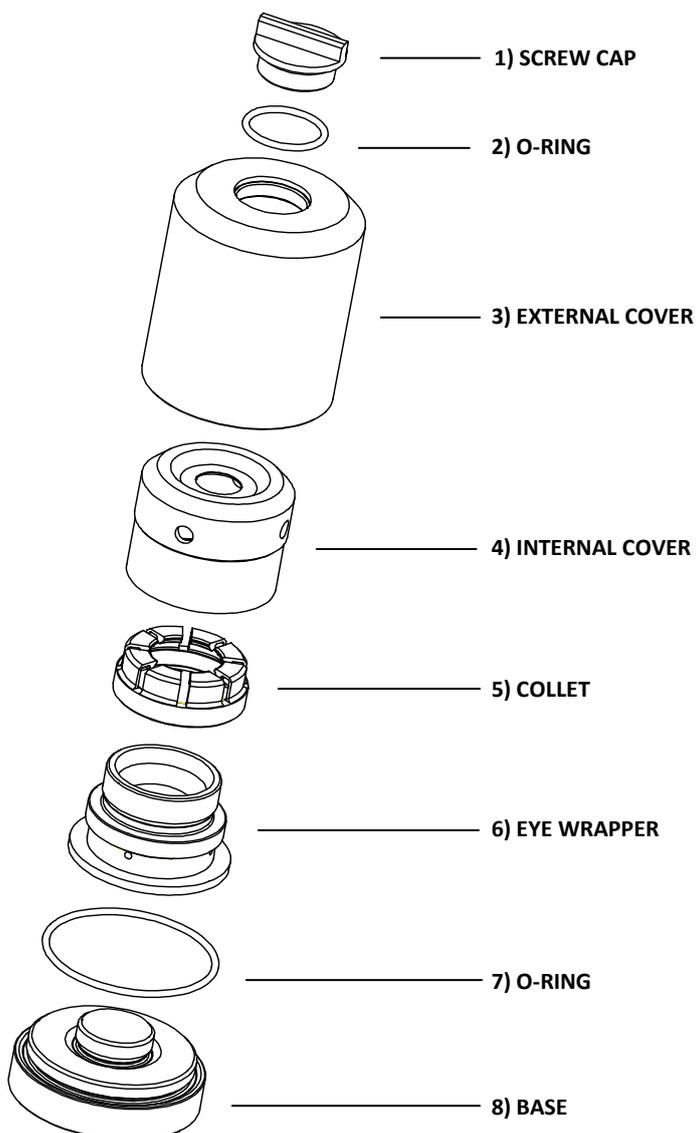
The medical device is packed in single envelope bag suitable for ethylene oxide sterilization – 2 devices per box.

Indications

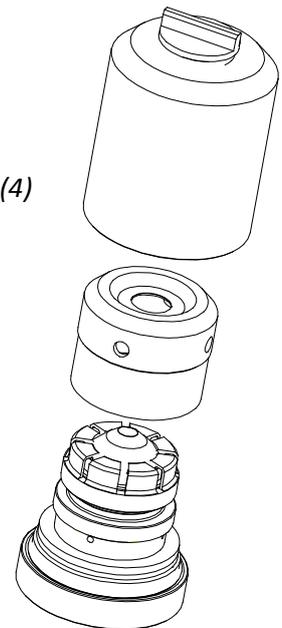
This medical device is intended for transport, examination/microscopic observation and handling of ocular bulbs for the purpose of cornea procurement or research.

Warnings and special precautions for use

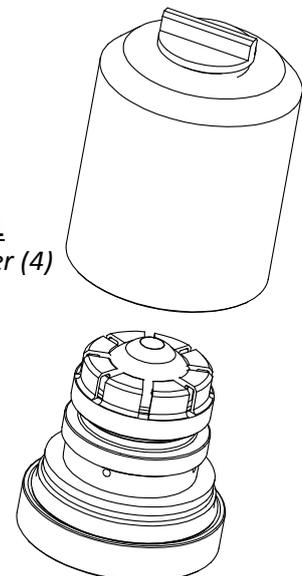
- Do not use if the package is opened or damaged.
- Do not reuse. Once the product has been used for the first time, any residuals of the product are not suitable for the repeated use as the product is no longer sterile.
- Do not re-sterilize. Repeated sterilization may cause cross-contamination for the patient and the operator.



REF: RE-ONE02
With *Internal Cover (4)*



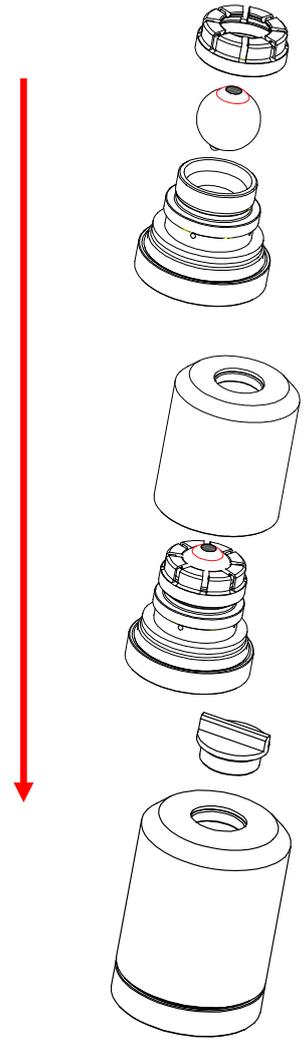
REF: RE-ONE01
Without *Internal Cover (4)*



INSTRUCTIONS FOR USE

TRANSPORT

- Check the expiration date indicated on the package.
- Open the package.
- Unscrew the *External Cover* (3), *Internal Cover* (4) if present and the *Collet* (5).
- Insert the eyeball, with the cornea facing upwards, in the *Eye Wrapper* (6).
- Screw the *Collet* (5) paying attention to the center of the cornea, so that the *Collet* (5) teeth are in contact only with the sclera and not with the cornea.
- Pay attention and do not to generate too much pressure to avoid ocular damages.
- For code RE-ONE 02, *Internal Cover* (4) can also be screwed, so that it can be carried with the whole device to its destination. The *Internal Cover* (4) has no use during transport (It will subsequently be necessary for observation under the microscope), but screwing it to the *eye wrapper* (6) it can be transported to the destination with the device.
Warning: the *Internal Cover* (4) is screwed only partially to the *eye wrapper* (6) so it is not in contact with the eye bulb.
- Screw the *External Cover* (3)
- Unscrew the *Screw Cap* (1)
- Insert special liquids for transport.
- Screw the *Screw Cap* (1)
- Check that the eyeball is completely immersed in the transport liquid to prevent cornea drying.
- Transport the RE-ONE device with the eyeball in refrigerated containers intended to maintain a temperature between +2°C and +10°C, as the normal procedures for organs transportation.
- During the transportation do not shake excessively the RE-ONE device containing the eyeball. Undesired eyeball movements may happen due to excessive movements with possible corneal damages.
- Deliver to destination the RE-ONE device containing the eyeball as quick as possible.
The permanence of the eyeball in the RE - ONE should not exceed 48 hours.



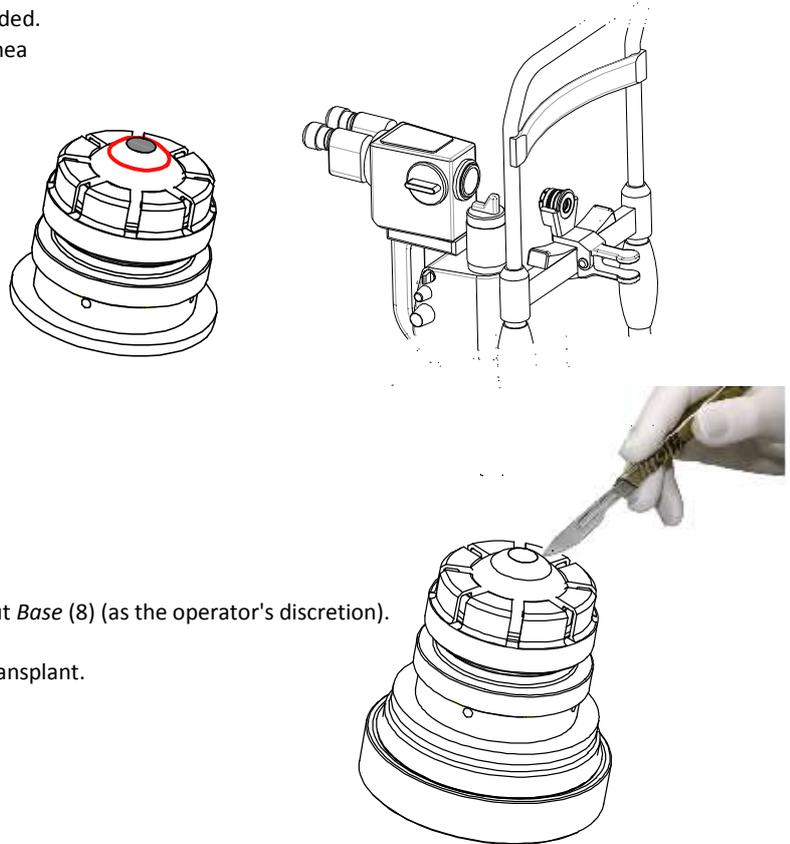
CORNEA OBSERVATION UNDER MICROSCOPE

- Unscrew the *Screw Cap* (1) and remove the transport liquid.
- Unscrew the *External Cover* (3) and the *Base* (8).
- The internal cover must be screwed so that the central circular opening is in contact with the bulb, creating a closed compartment at corneal level.
- Pour the working liquid into the *Internal Cover* (4) section, in contact with the cornea.
- Put the whole under microscope for the observation of corneal endothelium.



CORNEA OBSERVATION WITH SLIT LAMP (possible if you have the specific RE-ONE Support for slit lamp, side Figure)

- For such observation the *Eye Wrapper* (6) and the *Collet* (5) are needed.
- During this observation is suggested to constantly humidify the cornea to prevent from corneal epithelium damages.



HANDLING (CORNEOSCLERAL BUTTON CUTTING)

- Can be done with *Eye Wrapper* (6) and the *Collet* (5), with or without *Base* (8) (as the operator's discretion).
- After cutting remove the corneal button and, if necessary, store it in special containers for cryopreservation, waiting for the transplant.

Shelf life

3 years with unopened package.

How to store

Store the device in fresh and dry place, away from light and heat sources. Do not freeze. The expiry date is applied to the product which is correctly stored in an intact package. Do not use after expiry date.

 <p>RE-ONE Sagl 6912 Pazzallo-Lugano - Switzerland www.re-one.ch e-mail: info@re-one.ch</p>	Symbols used on the labels			
		Do not reuse - For single use		Manufacturer
		Product code		Sterilized using ethylene oxyde
		Batch code		Protect from light and heat
		Expiry date		Store in dry place
		Do not use if the package is opened or damaged		Do not resterilize
		Consult instructions for use		
		Medical device according to Directive 93/42/CEE		