

Autoclavable Corneal Shields

INSTRUCTIONS FOR USE

After every case application and before sterilization, always verify visually and manually the condition of both surfaces and edges of the device. For the comfort and safety of the patient during insertion of the corneal shield an ophthalmic topical anesthetic and ointment is recommended. Users must choose a shield size appropriate to the globe. During periorbital surgery the shields should cover the entire globe.

WARNING

- For all corneal shields, any scratch on the posterior surface or edges; or any pressure on the cornea during insertion or removal may increase the risk of CORNEAL ABRASION, etc.
- Do not use forceps to remove corneal shields, as the shields will be damaged.
- Do not use any device that has been dropped accidentally without thorough examination of its condition.
- Do not use any device that is scratched or damaged.
- Invasive corneal shields should not be left in place more than 60 minutes.
- Corneal shields are not for laser applications.
- For autoclavable corneal shields, extended use after 25 autoclave cycles is at user's risk (dispose of, if damaged.)

CLEANING PROCEDURE FOR THE INSTRUMENTS

Devices must be inspected and cleaned before initial sterilization, and subsequently between each patient use. Use procedures that have been previously established and validated for your facility or use the following recommendations.

- Do not use a brush or any abrasive pads or cleaning agents as they may damage devices.
 - Check surfaces of device for scratches or nicks, discard if necessary.
 - Do not use alcohol as it may damage the devices.
1. Before sterilizing, devices should be rinsed under warm running water to remove all debris.
 2. Wipe devices with moist sponge or gauze pad to eliminate any debris.
 3. Devices should be washed in a solution of water and neutral pH pre-soak detergent – DO NOT USE: CHLORIDE, STAIN REMOVERS, CHLORINE BLEACH, ENZYME CLEANING AGENTS, OR CLEANING AGENTS THAT CONTAIN ALKALIES.
 4. Devices should be cleaned, by hand, ultrasonic cleaner, or automatic washer sterilizer.

5. Rinse extensively with distilled water after manual cleaning and ultrasonic cleaning.
6. Sterilize according to manufacturer's instructions.

STERILIZATION RECOMMENDATIONS

All devices can be gassed with ETO. Autoclavable corneal shields can be sterilized by autoclave.



This symbol means that the product is sold non sterile.

- To prolong the useful life of corneal shields, use sterilization methods with lower temperature.
- For the rubber suction cups, do not use a Harvey Chemiclave 6000.
- Cold sterilization is not recommended, because chemical ocular burns have been reported, due to inadequate rinsing or leaching out of sterilizing solution. It may damage rubber suction cups. It also may damage plastic.

STEAM AUTOCLAVE

To sterilize devices, place them in a peel-pouch, on the sterilizer rack, in a single layer, as pressure from other devices may damage them. Use either method:

1. Gravity displacement minimum requirements:
250°F (120°C) for 30 minutes at 15 psi (103 kPa) or 270°F (134°C) for 15 minutes at 30 psi (207 kPa)
2. Prevacuum (flash) minimum requirements:
270°F (134°C) for 4 minutes at 30 psi (207 kPa)

ETHYLENE OXIDE (ETO) GAS

To sterilize devices, place them in a peel pouch, on the sterilizer rack, in a single layer, as pressure from other devices may damage them.

Follow your specific sterilizer equipment manufacturer's recommendations, or use cycles that have been previously established and validated for your facility. For example, devices can be safely sterilized in equipment such as the MDT Castle or an equivalent, according to the following protocol:

- Let steam enter to produce a relative humidity of 65± 5%. This takes 20-30 minutes.
- Sterilize with ethylene oxide at a pressure of 0.23± 0.02 psi (1.60± 0.15 kPa) and a temperature of 140°F (60°C) for 2 hours.
- Purge with air at 140°F (60°C) in order to remove remaining ethylene oxide. Two hours aeration is suggested.



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