EN (English)

Artificial Anterior Chamber

DEVICE DESCRIPTION

The Artificial Anterior Chamber is comprised of three pieces (made in Titanium): Base with tissue pedestal, tissue retainer and locking ring.
The base has two ports with silicon tubing, in-line pinch clamps and female Luer Lok connectors. Either port may be used to inject or aspirate viscoelastic, balanced salt solution or air beneath the donor cornea.

INTENDED USE/ INDICATION FOR USE

This is a mechanical ophthalmic device used to firmly hold the doner cornea (14-18mm) on a bed of viscoelastic, inflate it and cut it with the suction trephine from the epithelial side, cutting from the ophthalmic side products a more perfect donor to host match which dramatically reduces surgically induced astigmatism.

CONTRAINDICATIONS

Not Known.

HOW SUPPLIED

Artificial Anterior Chamber is supplied un-sterile, in individual leather box. The overall packing Artificial Anterior Chamber and medical literature insert, in an outer leather box, with external identification stickers.

CAUTIONS

For External use only.

⚠ WARNING

1. Read all instructions before use.
2. This device is supplied in a non-sterile state and must be cleaned, disinfected and sterilized before first use and any subsequent use.
3. Proper cleaning and disinfection steps need to be followed to ensure that the sterilization steps are effective.
4. Using mechanical processes such as pre-cleaning and ultrasonic cleaning greatly increases the effectiveness of the cleaning process.
5. For effective reprocessing, the pre-cleaning should begin as soon as the surgery has been completed but no more than 30 minutes after the surgery.
6. The complete cleaning process must take place within the next two (2) hours of completing the pre-cleaning.
7. Follow instructions and warning as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.
8. Wherever possible avoid the use of abrasive materials for cleaning and drying.
9. Incorrect handling and care or misuse can lead to premature wear of these devices.
10. Inspect these devices carefully for damage, cracks or malfunctions before each use.
11. Do not use damaged devices.
12. Use only approved disinfectant solutions (e.g., FDA, DGHM, CE Mark…).
13. Ensure cleaning and disinfection solutions fully contact all device surfaces and lumens.
14. Store devices in a cleaned, disinfected and dry state.
15. Do not soak in Acetone or other Solvents.
16. Automated cleaning is not recommended.

Pre-Cleaning Steps

1. Disassemble the Artificial A.C parts.
2. All devices that have been used must be submerged into cold, de-ionized water (<40 Degree Celsius) immediately after use for removing large soiling.
3. All surfaces must be cleaned with a soft bristle toothbrush to remove macroscopic contaminants. Special attention is required for uneven surfaces (such as knurled handles) to remove all macroscopic contaminants.
4. Scrub the inside and outside of the device with a soft bristled nylon brush until all visible soil is removed.
5. DO NOT use a fixating detergent or hot water (>40 Degree Celsius) – this may cause fixation of the residue on the device causing the reprocessing steps to fail. A fixating detergent contains aldehyde solution that may cause fixation of the blood contaminants on the device.
6. Soak the instruments in an enzymatic detergent with a pH level between 6-9 for 10 minutes at 40 Degree Celsius
7. The device must be rinsed with distilled or deionized water at least 3 times.
8. For all hollow parts and tubes (example: silicon tubes), use a disposable syringe (50ml or more) and rinse in normal direction of flow at least 3 times with distilled or deionised water.

Ultrasonic Cleaning

Some devices may be heavily soiled during a surgery and require additional pre-cleaning using an ultrasonic bath. When ultrasonic cleaning is done, care must be taken that the exposure time and concentrations recommended by the manufacturers of the cleaning solution are observed, and cleaning and disinfection agents are compatible with devices.

1. The devices must be placed on a silicone mat in the ultrasonic cleaner. DO NOT place devices in contact with any metal surface on the ultrasonic cleaner.
2. To reduce or avoid endotoxin contamination, it is recommended to change the cleaning solution from the ultrasound cleaner after each and every use.
3. If more than one device is being placed in the ultrasonic cleaner, ensure that none of the devices have any large areas of corrosion (rusted, flaky, or deep stained) before placing in the cleaner.
4. When using an enzymatic detergent, care must be taken to submerge the device completely in the cleaning solution.
5. Turn on the ultrasonic bath (38 KHz) for 10 minutes.
6. After the ultrasonic treatment, scrub the inside and outside of the device with a suitable soft bristled nylon brush until all visible soil is removed.
7. Flush the internal channels and the outside with distilled or deionised water to remove the cleaning detergent. A free flow of water through the device is required.
8. Ensure that the ultrasonic bath is not contaminated before use. Contamination can increase the risk of corrosion and impairs the effective cleaning process. Criteria for contamination – visibly observe the water in the bath for contaminations, dirt, debris, or other coloration of the water. If contamination is observed, the water bath must be replaced with new distilled or deionised water.

DISINFECTION

1. Disinfectant Solutions (e.g., approved by FDA, CE mark etc) may be used in accordance with label instructions of the disinfectant manufacturer. Special attention needs to be paid to disinfectant manufacturers recommended concentrations and contact durations. Ensure that disinfectant solution makes complete contact with all device surface and lumens.
2. To avoid damage to the device, do not exceed recommended exposure time.
3. After manual disinfection, soak and rinse in cool water for 1 min and thoroughly flush lumens. Repeat this procedure 3 times with fresh rinse water to ensure complete removal of the disinfectant solution.
4. Dry the device carefully with lint free tissue or hospital grade compressed air and place it in a dry storage box.
5. After the cycle is finished, the device needs to be inspected for any damage, cracks or malfunctions.

STERILIZATION

1. Make sure that the devices have been cleaned and inspected before sterilization.
2. Verify that the sterilizer is functioning properly on a regular basis.
3. Make sure that preventive maintenance, cleaning and inspection of the sterilizer is performed on a scheduled basis, according to the manufacturer's instructions.
   a) By EO (Ethylene Oxide): Kindly follow EO sterilizer manufacturer's instructions and settings for sterilization of the device. It is recommended to pack and seal the clean and disinfected device in medical grade peel open pouches before EO sterilization.
   Caution: Label the pouch with date of sterilization as per your SOP for labelling & handling in house sterilized devices.
   b) By Steam autoclaving: It is recommended that devices are sterilized using steam autoclaving procedure that is regularly used in hospitals and surgery center. The following table provides the suggested cycles based on recommended practices-

Steam Sterilization Cycle	Preparation	Exposure Time (Minimum Time)	Temperature	Drying Time (Minimum Time)
Gravity Displacement	Wrapped	15 Minutes	132° C /270° F	20 Minutes
Pre-Vacuum	Wrapped	4 Minutes	132° C /270° F	20 Minutes
Pre-Vacuum	Wrapped	3 Minutes	134° C /273° F	20 Minutes
Flash/ Immediate Use	Unwrapped	3 Minutes	132° C /270° F	N.A.

Note: Consult the manufacturer of your steam autoclave to confirm appropriate temperature and sterilization times. Other methods, times, and temperatures may also be used, but after validation of those methods.

PRECAUTIONS

- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

- Inject balanced salt solution into the tubing port. Remove the excess BSS from the well in the tissue pedestal.
- Put a drop of viscoelastic material into the well of the tissue pedestal before placing the donor cornea. Place the donor cornea on the pedestal with the epithelium facing up and viscoelastic beneath the endothelium.
- With the donor tissue in place, carefully align the slot in the tissue retainer with the guide pin projecting from the base and press down firmly.
- Place the locking ring over the tissue retainer carefully and turn clockwise until the ring is locked firmly in place.
- Additional viscoelastic, BSS or air may now be injected to obtain the desired pressure beneath the donor cornea. Pinch clamp may be locked to maintain the desired pressure while the donor cornea is being cut.
- Use a Vacuum Trephine for cutting the donor cornea.

RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected in nature, severity or incidence must be report to Madhu Instruments Pvt. Ltd.

DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with the local regulatory requirements.

REUSE OF DEVICE

The device should undergo a detailed multi step process of cleaning & sterilization before reuse.

EXPLICATION OF SYMBOL:

Symbol	Meaning
⚠	Caution
	Manufacturer
	Date of Manufacture
	Keep away from sunlight
	Consult instructions for use
	Re-use
EC REP	Authorized Representative in the European Community
	This side up
	Do not use hook

Symbol	Meaning
CE	Conformity of European Norm
LOT	Batch Code
5°C 55°C	Temperature Limit
	Do not use if package is damaged
55 RH 75RH	Humidity Limitation
	Handle with care
4	Maximum stacking
MD	Medical Device
NON STERILE	Non-Sterile

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