EN (English)



Anterior Chamber Maintainer

APPLICABLE FOR THE MODELS

DEVICE DESCRIPTION

Anterior chamber maintainer (A.C. maintainer) is a very useful device in small incision cataract surgery like phacoemulsification and non-phaco small incision Bluementhal technique, since chamber collapse accounts for a large number of complications during these surgical procedures. The A.C. maintainer is connected to a separate saline bottle and the tip is inserted into the anterior chamber through the side port incision. In case there is any urge or the chamber becomes shallow, the saline from the bottle automatically fills the anterior chamber avoiding posterior capsule rupture or other surge related complications

INTENDED USE / INDICATION FOR USE

A disposable sterile Anterior Chamber Maintainer is used for maintaining the anterior chamber during an ophthalmic surgical procedure.

MATERIALS USED

Stainless Steel, Polycarbonate, Silicone

TARGET AGE GROUP

Can be used for all age groups.

INTENDED USER

Any of the registered medical doctor/medical professionals

DURATION OF USE

Transient Use (Less than 60 Minutes).

STORAGE CONDITIONS

Store at specified temperature and relative humidity (Temperature in between 10°C to 30°C and relative humidity in between 45% to 65%)

CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to any of the materials used in manufacturing of the device.

HOW SUPPLIED

Anterior Chamber Maintainer is supplied sterile, packed in a peel open pouch. Such packed pouches are enclosed within an outer printed box. The overall

should not be used after the indicated sterility expiration date, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

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.

EXPLICATION OF SYMBOLS

Symbol	Meaning
\triangle	Caution
-	Manufacturer
Z	Date and Country of Manufacture
Πi	Consult instructions for use
类	Keep away from sunlight
MD	Medical Device
⊗	Do not use hook
11	This side up
10°C 30°C	Temperature Limit
% 65% 45%	Humidity Limitation
(fi)	Keep Out of reach of children



packing contains Anterior Chamber Maintainer and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTION/WARNING

- Read instructions before use.
- Do not use if package is damaged and consult instructions for use. Do not use the device if the sterilized package is open or damaged.
- The product is designed for single use only.
- Reusing the device may cause the transfer of contagious and communicable diseases to the patient and other serious problems to patients due to reuse of device such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Keep out of reach of children.
- The used product and pouch should be disposed off in compliance with the
- local regulatory requirements.

 Do not use the device after sterility expiry date.

PRECAUTIONS

- Before use, please make sure that the product or packaging has not been tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

- Check the package sealing integrity to ensure sterility.
- Select the suitable size of Anterior Chamber Maintainer and inspect visually.
- Flush the cannula with saline solution to check and make sure the silicone tube is not blocked. DO NOT pull the silicone tube out of the needle.
- Use the Anterior Chamber Maintainer as per the intended use and correct surgical procedure.

EXPIRATION DATEThe expiration date of the product is the sterility expiration date. The product

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 applicable local, state and country's laws and regulations.

Symbol	Meaning
<u>4</u>	Maximum stacking
LOT	Batch Code
	Use by date
®	Do not use if package is damaged and consult instructions for use
2	Do not re-use
STERILEEO	Single Sterile Barrier System, sterilized using Ethylene Oxide
STERILE EO	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Do not re-sterilize
REF	Catalogue Number
UDI	Unique device identifier
	Handle with care

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