

EN (English)



Irrigating & Aspiring Cannula

APPLICABLE FOR THE MODELS

21G,22G,23G

DEVICE DESCRIPTION

This is a disposable ophthalmic cannula of different gauge and needle lengths. This device is supplied sterile in peel open pouches. Based on stability studies, the shelf life for sterile products is recommended to 5 years from the date of sterilization. The product life is mentioned on the product label.

INTENDED USE / INDICATION FOR USE

This product is used for maintaining or forming anterior chamber and irrigating cornea during surgery. It may be used for injection and removal of air, fluids, viscoelastic substances and meiotic during ophthalmic surgery.

MATERIALS USED

Silicone, Stainless steel, polypropylene

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

Irrigating & Aspiring Cannula is supplied sterile, packed in a peel open pouch. Such packed pouches are enclosed within an outer printed box. The overall packing contains Irrigating & Aspiring Cannula and medical literature inserted in an outer enclosing box, with external identification stickers.

CAUTION/WARNING

- Read instructions before use.
- Do not use the product if the package is damaged or open consult for instruction 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 re-use of device such as HIV, Hepatitis, etc.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- Keep out of reach of children.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Do not use the device after sterility expiry date.

PRECAUTION

- Ensure before use that product/packaging is not 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 ophthalmic cannula and inspect visually.
- Remove the cannula from sterile packaging and twist the needle cover to remove it.
- Insert the cannula at incision site.
- Use the Irrigating & Aspiring Cannula for injection or removal of air, fluids & viscoelastic substance during ophthalmic surgery.

EXPIRATION DATE

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

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 reported 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.

EXPLICATION OF SYMBOLS:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	This side up
	Temperature Limit
	Humidity Limitation
	Keep Out of reach of children
	Handle with care

Symbol	Meaning
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged and consult Instructions for use
	Do not re-use
	Single Sterile Barrier System, sterilized using Ethylene Oxide
	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier



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