EN (English)

Irrigating & Aspirating Cannula

APPLICABLE FOR THE MODELS

23/23, 22/23, 23/22

DEVICE DESCRIPTION

This is a disposable ophthalmic cannula of different gauge and needle lengths. This device is supplied sterile in peel open pouches.

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.

TARGET AGE GROUP

Use All Age Groups

DURATION OF USE

Transient Use (Less than 60 Minutes). It is recommended to withdraw the product after 60 minutes from the patient. The user is accountable for any type of problem taking place in case of use after 60 minutes of the same

STORAGE CONDITIONS

Store at specified temperature and humidity (Temperature in between 5°C to 55°C and Humidity in between 55RH to 75RH).

CONTRAINDICATIONS

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

INDICATION/INTENDED APPLICATION

Eyeball (Supporting devices for Ophthalmic Surgery)

MODE OF ACTION

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/manufacturing. The product life is mentioned on the product label.

HOW SUPPLIED

Irrigating & Aspirating Cannula is supplied sterile, packed in a peel open pouch. Ten (10) such pouches are enclosed within an outer printed box. The overall packing contains Irrigating & Aspirating Cannula and medical literature insert, in an outer enclosing box, with external identification stickers.

DEVICE LIFE

The expiration date of the product is the sterility expiration date. The product should not be use after the indicated sterility expiration date.

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/Warning (Read instruction before use)
	Manufacturer Logo
سا	Date of Manufacturing
3	Do not resterilize
Ωi	Consult IFU
类	Keep away from sunlight
2	Don't re-use
EC REP	Authorized European Representative
111 100 UF	This side up
⊗	Do not use hook

Mfg. Facility: MADHU INSTRUMENTS PVT. LTD.

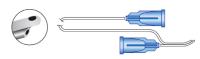
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MATERIALS USED

Stainless Steel, PF

CAUTIONS

Do not use the device if the sterilized package is open or damaged.

MARNING

- Madhu Instruments Pvt. Ltd does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients are as under:-
 - The used Irrigating & Aspirating Cannula tip might be blunt or has burrs. Do not use the cannula if the cannula tip is blunt or has burrs.
- Only qualified medical practitioner should use the device. Do not use the device if the sterilized package is open or damaged.
- Sterility is guaranteed only when the packing is neither opened nor damaged.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Do not reuse the device.
- Read instruction before use.
- Store at specified temperature and humidity.
- The used Irrigating & Aspirating Cannula and pouch should be disposed off in compliance with the local regulatory requirements.
- Do not use the device after sterility expiry date.
- The device is not for implant.
- Keep out of reach of children.

PRECAUTIONS

When handling the product care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments such as forceps etc.

DIRECTION FOR USE

- Open the sterile Irrigating & Aspirating Cannula pouch (BY AN UNSTERILE PERSON) and drop the inner pouch on a sterile surface without touching it.
- Use the Irrigating & Aspirating Cannula as per the intended use and correct surgical procedure

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.

	Symbol	Meaning
	C € 2460	Conformity of European Norm with Notified Body Number
	LOT	Batch/Lot Number
	\square	Date of Expiry
Ì	5°C 55°C	Temperature Limitation
		Do not use if package damaged
	55 RH 75RH	Moisture Limitation
١	STERILE EO	EO Sterile Product/Device
	AMERICA VITTO	Handle with care
	8	Maximum stacking



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