

Cystotome Cannula

APPLICABLE FOR THE MODELS

25G, 26G, 27G, 30G

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

A disposable sterile ophthalmic cannula used for capsulorhexis, inter capsular/ endo capsular and can - opener capsulotomy technique. Sharp tips (both side) is used to puncture and cut/tear the capsule.

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 device.

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

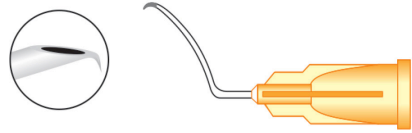
This is a disposable ophthalmic cannula of different gauge and needle lengths. This device is supplied sterile in peel open pouches. Based on stability studies, the shelf life for sterile products is recommended to 5 years from the date of sterilization/manufacturing. The product life is mentioned on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

HOW SUPPLIED

Cystotome 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 Cystotome Cannula and medical literature insert, in an outer enclosing box, with external identification stickers.

MATERIALS USED

Stainless Steel, PP



CAUTIONS

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

WARNING

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

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
	Caution/Warning (Read instruction before use)
	Manufacturer Logo
	Date of Manufacturing
	Do not re-sterilize
	Consult IFU
	Keep away from sunlight
	Don't re-use
	Authorized European Representative
	This side up
	Do not use hook

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
	Conformity of European Norm with Notified Body Number
	Batch/Lot Number
	Date of Expiry
	Temperature Limitation
	Do not use if package damaged
	Moisture Limitation
	EO Sterile Product/Device
	Handle with care
	Maximum stacking

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