

Cystotome Cannula

APPLICABLE FOR THE MODELS

25G, 26G, 27G, 30G

DEVICE DESCRIPTION

This is a disposable ophthalmic cannula of different gauges 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) are used to puncture and cut/tear the capsule.

TARGET AGE GROUP

Use All Age Groups

DURATION OF USE

Transient Use (Less than 60 Minutes).

STORAGE CONDITIONS

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

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: -
 - a. The used Cystotome Cannula tip might be blunt or have burrs. Do not use the cannula if the cannula tip is blunt or has burrs.
- Only qualified medical practitioners should use the device.
- Do not use the device if the sterilized package is open or damaged.
- Sterility is guaranteed only when the packaging 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 used 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.

EXPLANATION OF SYMBOLS:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	Medical Device
	Do not use hook
	This side up
	Temperature Limit
	Humidity Limitation
	Keep Out of reach of children
	Handle with care

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
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged
	Do not re-use
	Conformity of European Norm with Notified Body Number
	Authorized Representative in European Community
	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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