

Bimanual Cannula

APPLICABLE FOR THE MODELS

21G, 22G, 23G

DEVICE DESCRIPTION

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

INTENDED USE/ INDICATION FOR USE

This device is used for irrigation and aspiration of the anterior chamber.

TARGET AGE GROUP

Suitable for use on all age groups

DURATION OF USE

Transient Use (Less than 60 Minutes).

STORAGE CONDITIONS

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

CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to stainless steel or polypropylene.

INDICATION/INTENDED APPLICATION

Eyeball (Supporting device for Ophthalmic Surgery)

MODE OF ACTION

Irrigation line is connected to the irrigation handpiece and the aspiration tube from the machine is connected to the aspiration handpiece. Gauge and tip design is selected as per the surgeon choice and requirement of the surgical procedure. Irrigation is controlled by controlling the irrigation fluid bottle height whereas the aspiration speed is controlled by changing the setting on the phaco machine.

HOW SUPPLIED

Bimanual Cannula is supplied sterile, packed in a peel open pouch. One (01) such pouch is enclosed within an outer printed box. The overall packing contains Bimanual Cannula and medical literature insert, in an outer enclosing box, with external identification stickers.

MATERIALS USED

Stainless Steel, PP

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 Bimanual Cannula pouch (BY AN UNSTERILE PERSON) and drop the bimanual cannula on a sterile surface without touching it.
- Use the Bimanual 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.

EXPLANATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country Manufacture
	Do not re-sterilize
	Consult instructions for use
	Keep away from sunlight
	Do not re-use
	Authorized Representative in the European Community
	This side up
	Do not use hook
	Conformity of European Norm with Notified Body Number



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 as under: -
 - The used Bimanual Cannula tip might be blunt or has burrs. Do not use the cannula if the cannula tip is blunt or has burrs.
 - The used Bimanual Cannula tip might get blocked from debris of previous case.
 - Re-use of device may lead to microbial contamination.
 - Re-use of device may cause contagious or communicable diseases.
- 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.
- Read instructions before use.
- Store at specified temperature and humidity.
- The used Bimanual 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.

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 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
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Single Sterile Barrier System with protective packaging outside, Sterilised using Ethylene Oxide
	Model Number
	Handle with care
	Maximum stacking
	Medical Device
	Catalogue Number

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