

Air Injection & Irrigation Cannula

APPLICABLE FOR THE MODELS

16G, 19G, 20G, 21G, 23G,25G, 26G, 27G, 28G, 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 maintaining or forming anterior chamber and irrigating cornea during surgery. It may be used for injection and removal of air, fluids, viscoelastic substances and miotics during ophthalmic surgery.

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

Air Injection & Irrigation 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 Air Injection & Irrigation 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.

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

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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 Air Injection & Irrigation 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 Air Injection & Irrigation 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 Air Injection & Irrigation Cannula pouch (BY AN UNSTERILE PERSON) and drop the inner pouch on a sterile surface without touching it.
- Use the Air Injection & Irrigation 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
	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
	Model Number

EC REP

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