



**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.

**MATERIALS USED**

Stainless Steel, Polypropylene

**TARGET AGE GROUP**

Use All Age Groups

**INTENDED USER**

Any of the registered medical doctor/medical professionals.

**DURATION OF USE**

Transient Use (Less than 60 Minutes).

**STORAGE CONDITIONS**

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

**CONTRAINDICATIONS**

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

**HOW SUPPLIED**

Air Injection & Irrigation Cannula is supplied sterile, in individual pouches, each packed 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.

**CAUTION/ WARNING**

- Do not use if package is damaged and consult instructions for use.
- Do not use the device if the sterilized package is open or damaged.
- The product is designed for single use only.



- Reusing the device may cause the transfer of contagious and communicable diseases to the patient and other serious problems to patients due to re-use of device such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- Keep out of reach of children.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Do not use the device after sterility expiry date.

**PRECAUTIONS**

- Before use, please make sure that the product or packaging has not been tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

**DIRECTION FOR USE**

- Check the package sealing integrity to ensure sterility.
- Select the suitable size of Air Injection & Irrigation Cannula and inspect visually.
- Remove the cannula from sterile packaging and twist the needle cover to remove it.
- Insert the cannula at incision site.
- Use the Air Injection & Irrigation Cannula 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.

**EXPIRATION DATE**

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

**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 applicable local, state and country's laws and regulations.

**EXPLICATION 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

Symbol	Meaning
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged and consult instructions for use
	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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**EC REP**

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