



**Silicon Tip Cannula**

**APPLICABLE FOR THE MODELS**

Regular/Brush Tip (20G, 23G, 25G, 27G) With transparent tip / Green tip.

**DEVICE DESCRIPTION**

A disposable (20G, 23G, 25G, 27G) blunt tipped needle mounted with a 10mm long piece of a silicone tube through the internal bore of the needle such that only a 1 mm tip of the silicone tube is exposed out of the needle. The silicone tip can also be fenestrated to create a brush like quality. The Silicone tip cannula is protected by a plastic cap and is individually packed & sealed in a pouch before sterilization. Based on stability studies, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

**INTENDED USE / INDICATION FOR USE**

A disposable sterile single use Silicone tip Cannula (20G, 23G, 25G, 27G) is used for atraumatic removal of intraocular fluids by active or passive aspiration during vitreo-retina ophthalmic surgical procedures. Due to a very soft silicone tip, the device is useful for atraumatic brushing of the retinal surface with simultaneous aspiration. It is also helpful for repositioning of retinal folds or breaks.

**MATERIALS USED**

Stainless Steel, Silicone, PP

**TARGET AGE GROUP**

Can be used for 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 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 materials used in construction of the device.
- Do not use high viscosity fluids.

**HOW SUPPLIED**

Silicone tip Cannula is supplied sterile, packed in a peel open pouch. Such packed pouches are enclosed within an outer printed box. The overall packing contains Silicone tip Cannula and medical literature inserted in an outer enclosing box, with external identification stickers.

**EXPIRATION DATE**

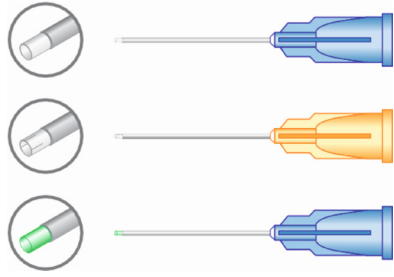
- The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

**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's office regarding product return/exchange.

**EXPLANATION OF SYMBOL:**

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



**CAUTION/ WARNING**

- Do not use the product if the package is damaged or open consult for instruction for use.
- Do not use the device if the sterilized package is open or damaged.
- The product is designed for single use only.
- If re use it may lead to cross contamination.
- 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**

- Ensure before use that product/package is not 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 Silicone Tip Cannula and inspect visually.
- Remove the cannula from sterile packaging and twist the needle cover to remove it.
- Flush the cannula with saline solution to check the proper functioning of the device.
- DO NOT pull the silicone tube out of the needle.
- Fix the cannula on a flute handle or a backflush tightly and insert the silicone tip of the cannula through the scleral incision or trocar cannula.
- After inserting the silicone tip of the cannula through the scleral incision. Start active or passive aspiration during vitreo-retina ophthalmic surgical procedures.

**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 reported to Madhu Instruments Pvt. Ltd.

**DISPOSAL OF THE USED DEVICE**

The used device should be disposed off in compliance applicable local, state and country's laws and regulations.

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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