

## Vitrectomy Infusion Cannula

### DEVICE DESCRIPTION

An ultra-thin wall cannula (20g) with 45degree beveled tip along with flexible silicon tubing. The flexible tubing is 25cm (10inch) and attaches to an infusion source. The metallic collar around the 20g needle tip can be used to suture the device to the sclera.

### INTENDED USE / INDICATION FOR USE

A disposable sterile single use Vitrectomy Infusion Cannula is used for infusion of irrigation fluids or surgical fluid like silicon oil / PFCL during vitreo-retina ophthalmic surgical procedure.

### CONTRAINDICATIONS

The device is contraindicated for patients with known silicon and plastic sensitivity.

### HOW SUPPLIED

Vitrectomy Infusion Cannula is supplied sterile, packed in a peel open pouch. Ten (10) such pouch is enclosed within an outer printed box. The overall packing contains Vitrectomy Infusion Cannula and medical literature insert, in an outer enclosing box, with external identification stickers.

### 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 Vitrectomy Infusion Cannula might be blocked. Check the blockage before inserting in the eye.
  - Check for sharpness on suture tying flanges.
- 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 devices that have been re-sterilized.
- Do not reuse the device.
- Read instruction before use.
- Store at specified temperature and humidity.
- The used Vitrectomy Infusion Cannula and pouch should be disposed off in compliance with the local regulatory requirements.



- Do not use the device after sterility expiry date.
- For External use only.
- 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 Vitrectomy Infusion Cannula pouch (BY AN UNSTERILE PERSON) and drop the inner pouch on a sterile surface without touching it.
- Flush the cannula with saline solution to check and make sure the silicone tube is not blocked. DO NOT pull the silicon tube out of the needle.

### EXPIRATION DATE

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.

### 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.

### EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacture
	Do not re-sterilize
	Consult Instructions for use
	Keep away from sunlight
	Don't re-use
	This side up
	Do not use hook

Symbol	Meaning
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Sterilised using Ethylene Oxide
	Handle with care
	Maximum stacking
	Medical Device
	Catalogue Number

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