

Backflush Flute Needle with Silicon tip cannula

DEVICE DESCRIPTION

A disposable (20G/23G/25G) blunt tipped needle mounted with a 10mm long piece of a silicon tube through the internal bore of the needle such that only a 2mm tip of the silicon tube is exposed out of the needle. This needle is connected to a silicon reservoir and an aluminum handle. The handle stabilizes the instrument and the silicon reservoir helps in safe reflux of the unwanted tissue/fluid aspirated into the tip. The silicon tip can also be fenestrated to create a brush like quality. The tip of the needle is either kept straight or can be curved at 45 degree to facilitate aspiration of fluids from difficult angles and locations. The Backflush Flute Needle is individually packed & sealed in a pouch before sterilization.

INTENDED USE/ INDICATION FOR USE

A disposable sterile Backflush Flute Needle with silicon tip cannula (20G/23G/25G) is used for atraumatic removal of intraocular fluids by active or passive aspiration during vitreo-retina ophthalmic surgical procedures with a safety feature of a backflush reservoir which can be used to reflux back the unwanted tissue or fluid aspirated during the procedure. Due to a very soft silicon 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.

CONTRAINDICATIONS

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

HOW SUPPLIED

Backflush Flute Needle with Silicon tip cannula is supplied sterile, packed in blister and then in a peel open pouch. Ten (10) such pouch is enclosed within an outer printed box. The overall packing contains Backflush Flute Needle with Silicon Tipped 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: -

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.

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



- The used Backflush Flute Needle with Silicon tip cannula might be blocked. Check the blockage before inserting in the eye.
 - The Silicon Tip should not be pulled out.
 - Check back flush action before use.
- 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 Backflush Flute Needle with Silicon tip 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 Backflush Flute Needle pouch (BY AN UNSTERILE PERSON) and drop the inner pouch on a sterile surface without touching it.
- Flush the silicon tip cannula and silicon reservoir with saline solution to check and make sure the silicone tube is not blocked. DO NOT pull the silicon tube out of the needle.
- Insert the silicon tip of the cannula through the 20G scleral incision and start passive aspiration by starting the irrigation. To stop aspiration, cover the opening of the silicon reservoir with one finger. To resume aspiration, remove the finger. In case there is a need to backflush the aspirated fluids/tissue, cover the opening of the reservoir and gently press the reservoir.

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
	Sterilised using Ethylene Oxide
	Handle with care
	Maximum stacking
	Medical Device
	Catalogue Number

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