

EN (English)



Backflush Handle (Passive Aspiration)

DEVICE DESCRIPTION

This instrument incorporates a silicone backflush reservoir on the conventional Charles Flute Handle which helps in safe backflushing of the incarcerated tissue during passive aspiration of intraocular fluids. The handle is made of aluminum and the reservoir is made out of silicone.

INTENDED USE / INDICATION FOR USE

A disposable sterile Backflush Flute Handle (Passive aspiration) used for atraumatic removal of intraocular fluids by passive aspiration during vitreo-retina ophthalmic surgical procedures. Safety feature of a backflush reservoir can be used to reflux back the unwanted tissue or fluid aspirated during the procedure. This device is used with desired ophthalmic cannula to complete the intended use.

MATERIALS USED

Aluminum, Silicone

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 Room Temperature

CONTRAINDICATIONS

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

the opening of the reservoir and gently press the reservoir.

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

EXPLANATION OF SYMBOLS:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	Medical Device
	This Side Up
	Keep Out of reach of children
	Handle with care



HOW SUPPLIED

The backflush handle is supplied non-sterile, packed in a plastic container and this plastic container is enclosed within an outer box. The overall packaging contains a Backflush handle and medical literature (IFU) with external identification labels.

CAUTION/WARNING

- The use of this product is restricted to a qualified doctor or medical practitioners.
- Read instructions before use.
- For External use only.
- Keep out of reach of children.
- This device is supplied non-sterile and must be cleaned, disinfected and sterilized before first use and any subsequent use.
- Inspect the devices carefully for damage, cracks, or malfunctions before each use.
- Do not use damaged devices.

PRECAUTIONS

- Ensure before use that product/packaging is not tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

- Sterilize the backflush handle after removing from the storage case by heat or gas sterilization and drop the handle on a sterile surface without touching it.
- Attach desired gauge of silicone tip cannula to the handle at the luer lock end.
- Insert the silicone tip of the cannula through the scleral incision and start passive aspiration by starting the irrigation. To stop aspiration, cover the opening of the silicone reservoir with one finger.
- To resume aspiration, remove the finger. In case there is a need to backflush the aspirated fluids/tissue, cover

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.

REUSE OF DEVICE

The device should undergo a detailed multi step process of cleaning & sterilization before reuse.

Symbol	Meaning
	Maximum stacking
	Batch Code
	Do not use if package is damaged and consult instructions for use
	Non-Sterile
	Catalogue Number
	Unique device identifier
	Re-use

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