

Backflush Handle (Active Aspiration)

DEVICE DESCRIPTION

This instrument incorporates a silicon backflush reservoir on the conventional Charles Flute Handle which helps in safe backflushing of the incarcerated tissue during active aspiration of intraocular fluids. Handle is made of polycarbonate and all connectors are made of Nylon. Reservoir and connecting tube for vitrectomy machine is made of silicon. Backflush Handle (Active Aspiration) is individually packed and sealed in a peel open pouch. Once opened, silicon tip cannula of desired gauge can be attached to the active aspiration handle.

INTENDED USE / INDICATION FOR USE

Backflush Handle (Active Aspiration) is used for atraumatic removal of intraocular fluids by active 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.

CONTRAINDICATIONS

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

HOW SUPPLIED

Backflush Handle (Active Aspiration) is supplied unsterile, packed in a peel open pouch. Ten (10) such pouches are enclosed within an outer printed box. The overall packing contains Backflush Handle (Active Aspiration) and IFU, in an outer enclosing box, with external identification labels.

CAUTIONS

Do not use the device if the sterilized package is open or damaged.

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

EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution/Warning (Read instruction before use)
	Manufacturer Logo
	Date of Manufacturing
	Keep away from sunlight
	Consult IFU
	Re-Use
	Authorized European Representative
	This side up
	Do not use hook

WARNING

1. Only qualified medical practitioner should use the device.
2. Read instruction before use.
3. Store at specified temperature and humidity.
4. The used Backflush Handle (Active Aspiration) and pouch should be disposed off in compliance with the local regulatory requirements.
5. For External use only.
6. 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 Backflush handle (active aspiration) pouch (BY AN UNSTERILE PERSON) and drop the handle on a sterile surface without touching it.
- Attach desired gauge of silicon tip cannula to the handle at the luer lock end.
- Take silicon tip cannula and flush the same along with silicon reservoir with saline solution to check and make sure the female hub is not blocked.
- Connect the female connector to the vitrectomy machine.
- Insert the silicon tip of the cannula through the scleral incision and start active 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.

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.

REUSE OF DEVICE

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

Symbol	Meaning
	Conformity of European Norm
	Batch/Lot Number
	Date of Expiry
	Temperature Limitation
	Do not use if package damaged
	Moisture Limitation
	Handle with care
	Maximum stacking

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