

## Flute Handle (Charles)

### DEVICE DESCRIPTION

This is a simple instrument for passive aspiration of intraocular fluids.

### INTENDED USE/ INDICATION FOR USE

This is an ophthalmic device used for passive aspiration of intraocular fluids during a Vitreo Retinal Surgery.

### CONTRAINDICATIONS

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

### HOW SUPPLIED

FLUTE HANDLE (CHARLES) is supplied un-sterile, packed in a plastic container and then this plastic container is enclosed within an outer printed box. The overall packing contains FLUTE HANDLE (CHARLES) and medical literature insert, in an outer enclosing box, with external identification stickers.

### CAUTIONS

For External use only.

#### ⚠ WARNING

- Only qualified medical practitioner should use the device.
- Do not use the device if the package is open or damaged.
- Read instruction before use.
- Store at specified temperature and humidity.
- The used FLUTE HANDLE (CHARLES) and pouch should be disposed off in compliance with the local regulatory requirements.
- For External use only.
- Keep out of reach of children.



### PRECAUTIONS

- When handling the product care should be taken to avoid damage from handling.

### DIRECTION FOR USE

1. Open the pouch and then keep the FLUTE HANDLE (CHARLES) on a sterile surface.
2. The product should be stored at Temperature 10°C-30°C and Humidity 45RH-65RH.
3. Mishandling or improper transport can cause damage to the device or packaging.

### 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.

### REUSE OF DEVICE

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

### EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacture
	Keep away from sunlight
	Consult instructions for use
	Re-use
	Authorized Representative in the European Community
	This side up
	Do not use hook

Symbol	Meaning
	Conformity of European Norm
	Batch Code
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Handle with care
	Maximum stacking
	Medical Device
	Non-Sterile

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