210.0 mm

148.0 mm

INSTRUCTIONS FOR USE

HME FILTER

Indications:
- An endotracheal or tracheostomy tube is present and humidification of inspired gas during mechanical ventilation is required.

Contraindications:
- Patients with thick, copious, bloody secretions and /or massive hemoptysis.
- Patients with an expired tidal volume less than 70% of the delivered tidal volume (large broncho pleurocutaneous fistulas or absent endotracheal tube cuffs).
- Patients with body temperatures less than 32°C.
- Patients with high spontaneous minute volumes (>10L/min).

Instructions for use:
- The use of an HME will be instituted as a means of delivering humidification of inspired gases to all patients requiring mechanical ventilation via an artificial airway. The HME is properly positioned between the patient's artificial airway and the wye connector of the disposable adult ventilator circuit.
- HMEs will be selected for short term use for those patients anticipated to require mechanical ventilation for 48 hours or less.
- In the event a patient requires continuous mechanical ventilation for a period greater than 48 hours, the HME device will be discontinued and a heated humidifier along with a heated patient wire circuit is to be provided.
- HMEs should be visually inspected and replaced during patient ventilator systems checks if secretions are found to have contaminated the insert or filter.
- HMEs will not be utilized for patients requiring mechanical ventilation who have thick, copious secretions and/or massive increasingly tenacious when using an HME, then a heated humidifier and heated wire circuit should replace the HME, then a heated humidifier and wire circuit should replace the HME.
  Note : The use of an HME rather than heated humidifier along with a heated patient wire circuit under the above clinical conditions will required an MD order.
- An HME must be removed form the patient circuit during the administration of an inline aerosol nebuilizer or MDI treatment.

Medical Conditions:
- Use of the product is restricted to a qualified doctor or a paramedic staff.
- Read "instruction for use" carefully before use of the product.

Warnings:
- The product should not be reprocessed.
- Visually inspect and carefully check the product and packaging before use.
- Improper transport and handling may cause structural and/or functional damaged to device or packaging.
- The product is guaranteed sterile, non-pyrogenic and non-toxic if package is not opened or damaged.
- Do not expose to heat ir direct sun light.
- The product should be used immediately after opening the individual blister packing.
- Use ONLY standard Luer connection devices; non-standard connectors can damage the product.
- Do not recycle, clean or resterile.
- Re-use of this device may change its mechanical or biological feature and may cause device failure, allergic reactions or infections.
- MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Caution:
- Do not use if package is damaged.
- Discard after single use.

Target Age Group: For All age groups

Storage condition: Cool & Dry Place

Device Life: 05 Years

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon-122001, Haryana (INDIA)

REF Catalogue Number

LOT Lot No./Batch No.

Manufacturer

Date of Manufacturing

Use By / Expiry Date

Caution

Do Not Reuse

Do Not Resterilize

Non-Pyrogenic

Do Not Use If Package is Damage

Latex Free

Consult Instruction for Use

MD Medical Device

Keep Dry

Keep Away From Sunlight

STERILE EO Sterilized By Ethylene Oxide

EC REP Authorised Representative In The European Community

Rev.01 / 14.09.2023

REV BY	Q.A				**TITLE : Instructions for Use of HME Filter**	SHEET No. 1/1
	Q.C					
	Pro.				**For Party Code 000**	**DRW. No.:** I0201-IFU-000
CHD BY	Mkt.				**COLOR OF PRINT:** BLACK	REV.:- 01
DGN BY	Prahalad			DATE: 14.09.2023		
SCALE-N.T.S			TOLERANCE : ±2 mm		**REVISION DETAILS:** **REV. 01 :** Remove 'EC Representative' Address & Add 'Medical Device' symbol.	
MAIS INDIA MEDICAL DEVICES PVT. LTD. 525-P SECTOR-37, PACE CITY II, GURGAON (HR)						APPROVED BY: