



INSTRUCTIONS FOR USE

BREATHING FILTERS (HME Filter)

*Please Read All Instructions Carefully Before Use (Sterile, for single use only)

SSIPL/IFU/BF/01. Rev. No.:00, Dt. 12.08.23

PRODUCT DESCRIPTION:

HME Filter (SMD SS 752):

A screening device made from filter media & ABS typically installed in a breathing circuit and which has a membrane pore size small enough to retain bacterial pathogens. This device is typically used in breathing systems to prevent the system from becoming infected and increasing the risk of cross infection of a subsequent patient. It is intended for short term use.

Product Information: Principle method of filtration is electrostatic.

INTENDED PURPOSE:

Intended to conserve a portion of the patient's exhaled heat and moisture, and condition inspired gas by warming and humidifying it & reduce the transmission of microbes and other particulate matter in breathing systems and used for short term.

INDICATIONS:

Patient connected with ventilator under below condition:

- Surgery & Emergency situations (when a person is unable to breathe on their own)
- Lung disease
- Severe pneumonia
- Respiratory failure
- Other conditions that affect breathing.

Use up to 24 hours. For adults with Tidal Volumes > 300 ml.

CONTRAINDICATIONS:

- Copious secretions (either sputum or pulmonary oedema).
- Active Humidification
- Patients producing fulmination, frothy secretions within their airway and lungs.

LIMITATION:

NA

INTENDED USER

Doctor or trained healthcare professional

INTENDED PATIENT POPULATIONS

All Age Group

DIRECTIONS FOR USE:

- Open the package by tearing off from the bottom edge V shape opening. Do not use scissors or cutter to open the package to avoid product damage.
- Securely connect the product to the patient end of the circuit by using a twisting action to ensure a leak free and tight fit.
- Test the product following air supply equipment's instruction to make sure the product is compatible with the equipment used the product has no leakage and occlusion
- If using the sampling port, connect the gas sampling line securely, otherwise make sure the monitoring port for CO2 is closed when it's not used.
- Patients should be monitored constantly whenever they are using the product.
- Check the product periodically: It must always be replaced when it become unfit for its intended use.

WARNING:

- DO NOT REUSE! This product is FOR SINGLE PATIENT USE ONLY; reuse of this product can result in cross-infection.
- DO NOT soak, wash or sterilize this product. Avoid contact with chemicals, cleaning agents, or hand sanitizers.
- Discard after use in accordance with applicable hospital requirement or local laws and regulations.

- The use of this product is restricted to a qualified Doctor or Healthcare professional only.

PRECAUTIONS AND CAUTIONS:

- Check the integrity of product packaging before use. DO NOT use if package is damaged.
- Do NOT use the HMEF with a heated humidifier or nebulizer.
- Do not clean or Re-use the device,
- The product should be used immediately after opening the packing
- Do not use the device after expiry Date mentioned on the Label.

ADVERSE EFFECTS:

- Decrease in the body temperature.
- Respiratory acidosis with hypercapnia.
- Mechanical occlusion of breathing circuits.
- When the filter is replaced, the contaminated filter mats can release infectious material.
- Harmful decomposition products of filtered-out bacteria.

CLINICAL BENEFITS:

1. Reduced the rate of nosocomial infection.
2. Cost effective
3. Decreased patient morbidity
4. Preventing patients from succumbing
5. Effectively removed influenza H1N1A virus particles from the airstream
6. HME Filter is protective effect and can be of value in the treatment of asthma
7. Effectively reduces bronchial obstruction
8. Reduces risk of Viral and Bacterial cross contamination between parents.

RESIDUAL RISKS:

1. Pneumothorax
2. Pneumonia, Difficulty in breathing
3. Airway Obstruction, Infection
4. Allergic reaction

SUPPLY:

HME Filter (SMD SS 752)



MATERIAL USED:

Item	Material	Specification
Main body	ABS	Medical Grade
Filter	Filter	Medical Grade

STERILITY:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused devices.

STORAGE:

The Device should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.

DEVICE DISPOSAL:

Used Devices may be contaminated with infectious and/or other hazardous materials. Discard used devices in the container meant for infectious waste. Unused expired devices should be disposed of as per local regulations.

















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NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

SYMBOLS:

	Catalogue No.		See instructions for Use
	Cautions		Keep Dry
	Do not use it if the packaging is damaged.		Sterile Barrier System
	Single-Use		Do not Re-sterilize
	Batch / Lot No.		Ethylene Oxide Sterilized
	Date of Mfg.		Unique Device Identifier
	Date of Exp.		Medical Device
	Avoid Direct Sunlight		Keep in a dry place between 5°C to 45°C
	Phthalate Free		

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