

ThermoShield™
HME Breathing Filters

Product Data Sheet

PRODUCT: ThermoShield™ HME Filters



DESCRIPTION / FUNCTION

The Flexicare ThermoShield™ consists of a Heat & Moisture Exchange medium together with an Electrostatic filter medium. Heat and Moisture Exchange Filters (HMEFs) are used to protect patients and ventilators from cross infection and to warm and humidify the inspired gases. Breathing filters protect patients from bacterial and viral contamination. Flexicare's ThermoShield™ Filters use an electrostatic medium constructed of permanently charged bipolar rectangular split fibres which are able to capture airborne particles.

HMEFs are intended to help prevent the transmission of bacteria and viruses and prevent cross infection to and from the patient during anaesthesia, artificial respiration and other types of assisted ventilation such as in the critical care environment. Additionally, an HMEF provides a degree of Heat and Moisture retained from the patient's expired gases, which is then returned to the patient in the next inspired breath. In anaesthesia applications, an HMEF is normally positioned at the patient end of the breathing system between the circuit Y-piece and the patient airway.

ThermoShield™ Filters are designed to be used in pre-hospital, hospital and homecare environments by trained personnel.

WARNINGS

- Do not use between patient and a humidification device (e.g Active Humidifier) or Nebuliser device.
- Change the filter after a maximum period of use of 24 hours.
- REPLACE this device if it becomes soiled or otherwise unfit for its application.
- NEVER attempt to 'dry out' a breathing system or a breathing system filter.
- DISPOSE of all breathing system components immediately after use on highly infectious patients regardless of option of multiple use (e.g. Tuberculosis (TB), HIV, Hepatitis C, Creutzfeldt-Jacob variant (CJD) and for all ICU patients).
- Breathing systems and components must be removed after use and safely discarded, even if a filter is used.

SPECIFICATION / KEY FEATURES

- Combines electrostatic filtration and HME media.
- Electrostatic filter media provide a high degree of efficiency.
- HME media provides high moisture output to each inspired breath.
- 22M/15F connectors complying with ISO 5356 providing universal connections.
- The design of the filter conical connectors provides unidirectional fitting of the filter and prevents errors in connection.
- Patient side clearly marked on device housing for correct fitting.
- Lightweight design of ThermoShield™ filters reduces drag on the breathing system.
- Rounded ergonomic shape with no sharp edges reduces the risk of pressure marking.
- Optional luer port allows easy ETCO2 sampling.
- Available Sterile or Non-sterile.
- Available as Adult or Mini (for short term Adult use and/or Paediatric)

PRODUCT RANGE & PART NUMBERS

Product Code	Description	Quantity
ThermoShield™		
038-41-350	Adult Bacterial / Viral Filter + HME	50
038-41-330	Adult Angled Bacterial / Viral Filter + HME	50
038-41-355	Adult Bacterial / Viral Filter + HME (with tethered cap port)	50
038-41-335	Adult Angled Bacterial / Viral Filter + HME (with tethered cap port)	50
038-41-355LS	LuerSafe Adult Bacterial / Viral Filter + HME (with self-sealing port)	50
038-41-335LS	LuerSafe Adult Angled Bacterial / Viral Filter + HME (with self-sealing port)	50
038-41-356	Adult Bacterial / Viral Filter + HME (with tethered cap port) + Low Profile Elbow (22M/15F)	50
038-41-357	Adult Bacterial / Viral Filter + HME (with tethered cap port) + 15mm tube + Low Profile Elbow (22M/15F)	50
038-41-359	Adult Bacterial / Viral Filter (with tethered cap port) + Expandable Catheter Mount with Double Swivel Elbow & Elastomeric Cap	50
ThermoShield™ Mini		
038-42-350	Mini Bacterial / Viral Filter + HME	50
038-42-355	Mini Bacterial / Viral Filter + HME (with tethered cap port)	50
038-42-355LS	LuerSafe Mini Bacterial / Viral Filter + HME (with self-sealing port)	
038-42-356	Mini Bacterial / Viral Filter + HME (with tethered cap port) w+ Low Profile Elbow (22M/15F)	50
038-42-356LS	LuerSafe Mini Bacterial / Viral Filter + HME (with self-sealing port) + Low Profile Elbow (22M/15F)	50
038-42-357	Mini Bacterial / Viral Filter (with tethered cap port) + Expandable Catheter Mount with Double Swivel Elbow & Elastomeric Cap	50
ThermoShield™ Sterile		
038-41-350STR	Adult Bacterial / Viral Filter + HME	50
038-41-330STR	Adult Angled Bacterial / Viral Filter + HME	50
038-41-355STR	Adult Bacterial / Viral Filter + HME (with tethered cap port)	50
038-41-335STR	Adult Angled Bacterial / Viral Filter + HME (with tethered cap port)	50
038-41-355LSSTR	LuerSafe Adult Bacterial / Viral Filter + HME (with self-sealing port)	50
038-41-335LSSTR	LuerSafe Adult Angled Bacterial / Viral Filter + HME (with self-sealing port)	50
038-41-357STR	Adult Bacterial / Viral Filter + HME (with tethered cap port) + 15mm tube + Low Profile Elbow (22M/15F)	50
038-41-359STR	Adult Bacterial / Viral Filter (with tethered cap port) + Expandable Catheter Mount with Double Swivel Elbow & Elastomeric Cap	50
ThermoShield™ Sterile Mini		
038-42-355STR	Mini Bacterial / Viral Filter + HME (with tethered cap port)	50

MATERIALS

Component	Material
Filter Housing	Polypropylene (PP)
Luer Port Tethered Cap	Polyvinylchloride (PVC)
HME	Paper HME
Internal Filter Pad	Polypropylene (PP)/ synthetic fibre blend
LuerSafe™ Port	Polypropylene (PP), Silicone

LATEX CONTENT

Flexicare's ThermoShield™ HME Filters do not contain natural rubber latex.

DEHP CONTENT

Flexicare's ThermoShield™ HME Filters do not contain phthalate DEHP.

SINGLE USE

Flexicare's ThermoShield™ HME Filters a Single Use device and should be disposed of after use. Do not re-sterilise (if applicable) or autoclave.

STERILITY

Flexicare's ThermoShield™ HME Filters are available in both non-sterile/clinically clean and sterile states. Sterile variants are identified by "STR" suffix on part number and relevant symbols on device packaging. Sterile product is sterilised by gaseous ethylene oxide (EO).

STORAGE

Store in a cool, dry place out of direct sunlight.

SHELF LIFE

Flexicare declares a shelf life of five years from the date of sterilisation or manufacture. This is based on the stability of the devices' components and raw materials sourced. Expiry date is clearly marked on individual product pouch.

DISPOSAL CONSIDERATIONS

Dispose as clinical waste, in accordance with hospital policy, local guidelines and regulations.

PACKAGING MATERIALS

Non-sterile

Primary – Polybag – Low Density Polyethylene (LDPE)

Sterile

Primary - Top Web – EO Permeable Paper

Blister Pack – Polyvinylchloride (PVC)

All variants

Secondary – Carton / Box - Cardboard