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## English Instructions for Use

### HMEF Filters and HMEF Filters with attachments

The filters are used on patient breathing circuits to avoid the potential for any cross-contamination between the patient and the machine.

For use within Anaesthesia, Respiratory and Critical Care clinical areas. Indicated for use with patients whose upper airways are being bypassed by an artificial tracheal airway or receiving artificial ventilator support.

Filters can be supplied with accessories, such as mouthpiece, elbow and catheter mounts.

Bi-directional Filter – Foam/Corrugated Cellulose HME paper, patient side.

**CAUTION:** A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in harm to the patient.

Any use of the medical device requires full understanding and strict observation of all portions of these Instructions for Use. The medical device may only be used for the purpose specified under "Intended Use". Observe all CAUTION statements throughout this manual and all statements on medical device labels. The manufacturer disclaims any liability for patient injury caused by noncompliance with these statements.

The product may only be used on the patient side.

Never use the filter in combination with active humidifiers or medical nebulizers due to the risk of pressure build-up and insufficient patient ventilation.

Following installation of the filter, the breathing circuit must be tested for leaks. Check that all connections are secure.

When setting the ventilator parameters, take added dead space (internal volume) into account. The type of filter which is adequate as well as the effect of added dead space shall be judged by a physician on an individual patient basis.

The medical device IFU is not available for each individual filter. Only one copy of the Instructions for Use is included in the distribution package and should therefore be kept in an accessible location for users.



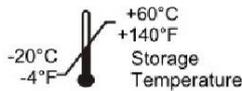
Medical device is only to be used by healthcare professionals.

User has the responsibility to report any serious incident that has occurred in relation to the medical device, to the manufacturer, EC REP and the competent authority of the Member State in which the user and/or the patient is established.

To avoid contamination and soiling, the product should remain packaged until ready to be used.



Do not use the product if the packaging and/or product is damaged.



If product was kept outside the stated storage temperature, product functionality cannot be guaranteed.



Store the product at room temperature, in dry place, free of dust and not exposed to direct sunlight.

Handle filter with care. Abusive handling can damage the filter.

For Your Safety and that of Your Patients, follow the Instruction for Use of the machine!

Before installation, check that all system components are free of obstructions and of foreign bodies. Otherwise, use is limited, or faulty operation is possible.

Inappropriate connection to other devices can result in a patient hazard.

Medical device products have been designed, tested and manufactured exclusively for disposable use and for a period of use not exceeding 24 hours following the first opening of the primary packaging.

Do not use after expiry date stated on primary packaging.



Manufacturing date



Expiry date

Monitor filter performance during the use. If any changes to filter performance or appearance are observed, change the filter to new one.

Always keep spare filter ready to exchange with the one in use, if any of the below are observed:

- Increase in resistance;
- Filter is visibly soiled or damaged or if it rattles;
- Excessive condensation;
- Associated alarm.

If the product features a Luer Port, it is used exclusively for gas monitoring. The introduction of gases or liquids via the Luer Port connection can cause serious injury to the patient.



The products must not be reused, cleaned or sterilized if bought sterile / not to be sterilised after use in order to re-use. Exceptions from this rule will be stated within the Instruction For Use for the particular products code if applicable. Reuse, cleaning or sterilization may lead to failure of the products, risk infection and injury to the patient.



This product is for single patient use only.



This product is latex and PHT free.



Batch code symbol.

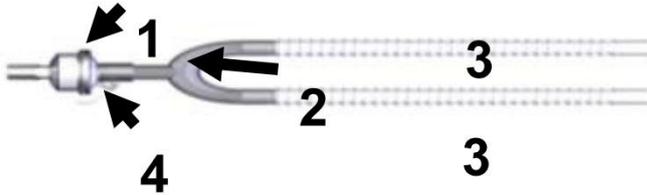
**Rxonly**

Prescription only.

Following use, the products must be disposed of in accordance with the local hospital hygiene and waste disposal regulations.

**Shelf Life: 3 years**

1. Combination breathing system filter/heat and moisture exchanger
2. Y-piece
3. Breathing Circuit
4. Luer Port (optional)



EC REP

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