

Indications for Use Statement

510(k) Number: K090738

Device Name: ThermoFlo™ filter/HME
FilterFlo™ filter

Indications for Use:

FilterFlo™ filter is a breathing system filter which is designed to reduce possible airborne or liquid-borne cross contamination with micro-organisms and particulate matter via anesthetic or ventilator breathing systems.

The FilterFlo™ filter may either be used on the patient side or on the device side of the ventilator / anesthetic device and is used as a hygienic measure alternatively to decontamination of breathing system and / or breathing gas conveying parts of the ventilator.

The ThermoFlo™ filter/HME is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The product is the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport since heated humidified are almost impossible to use. The ThermoFlo™ filter/HME should be used with patients who have a Tidal Volume between 250 - 1500 ml.

The products mentioned above are designed as disposable single patient use and should be changed at least every 24 hours.


Prescription Use XX
(Part 21 CFR 801 Subpart D)

or

Over-the-counter use ___
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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