

VAPOR-CLEAN™

THE Orange Filters for Malignant Hyperthermia

Instructions for Use:

Single Patient Use, Not Intended for Reprocessing







Intended use: To remove unwanted anesthetic gas from the breathing circuit.


Intended patient population: Surgical patients being ventilated by an anesthesia gas machine.


Instructions for use


1. Turn off the anesthesia vaporizer
2. Increase fresh gas flow to >10 L/min for at least 90 seconds to flush the vapor from the anesthesia delivery system
3. Place one of the Vapor-Clean canisters on the inspired port of the anesthesia machine and the other canister on the expired port of the anesthesia machine.
4. Replace the breathing bag and connect a new breathing circuit between the patient and the Vapor-Clean canisters. Maintain fresh gas flow at >3L/min.


Warnings

-  **Warning:** This device contains charcoal and charcoal dust. If damaged, the charcoal dust may leak from the device. The physical nature of this dust may produce eye irritation.
-  **Warning:** Sterilization of this device with Ethylene Oxide will exhaust the anesthetic absorber and render the device useless.
-  **Warning:** Do not soak, rinse, sterilize or reuse this device as reprocessing may render the device nonfunctional.
-  **Warning:** This product contains activated charcoal. Activated charcoal in contact with strong oxidizers such as ozone, liquid oxygen, chlorine gas, permanganate, etc. may result in fire.
-  **Warning:** Do not use this device when intending to anesthetize patients using vapor.
-  **Warning:** In a patient that is known, or suspected, of having malignant hyperthermia, the safest course of action is to use a ventilator which has never been exposed to anesthetic vapors.

 **Warning:** Bench testing has demonstrated that this product removes at least 99% of anesthetic vapors (isoflurane, sevoflurane and desflurane). This means that 1% of anesthetic vapor emitted by an anesthesia gas machine may be inhaled by the patient.

 **Warning:** This device is capable of removing residual anesthetic from the breathing circuit for 12 hours of continuous use. Replace the Vapor-Clean canisters with a new set after 12 hours of use on a single patient. Replace the Vapor-Clean canisters with a new set after 60 minutes of use on a patient who is exhaling volatile anesthetics.

 **Warning:** This device does not capture or scavenge nitrous oxide.

 **Warning:** This device has not been tested using any anesthetics agents other than isoflurane, sevoflurane and desflurane.

Cautions

Federal (USA) law restricts this device to sale to, or on order of, a physician.

This device and its packaging contain **no** natural latex

Device Specifications

Connections

Anesthesia machine side:	22 mm female
Breathing circuit side:	22 mm male


Resistance to Flow: <3.0 cm H₂O at 1 liter per second
<1.5 cm H₂O at 0.5 liter per second

Minimum Anesthetic Removal: ≥99 % removed
Internal volume: 92 ml

Storage Conditions

Store at temperatures between 15° C and 40°C
Store at relative humidity between 15% and 95% non-condensing

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