VAPOR-CLEAN

Removes Unwanted Anesthetic Gas from the Breathing Circuit

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 H_2O at 1 liter per second
<1.5 cm H_2O 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

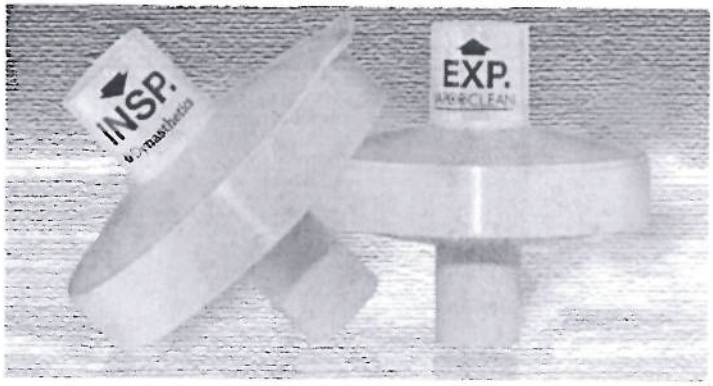
Manufactured by:
Dynasthetics
3487 West 2100 South #300
Salt Lake City, Utah 84119
www.dynasthetics.com
801-484-3820

U.S. Patent No.: 8,485,187, 8,800,561. Other patents pending.

Vapor-Clean Filters for MH-Susceptible Patients

For the MH-Susceptible Patient

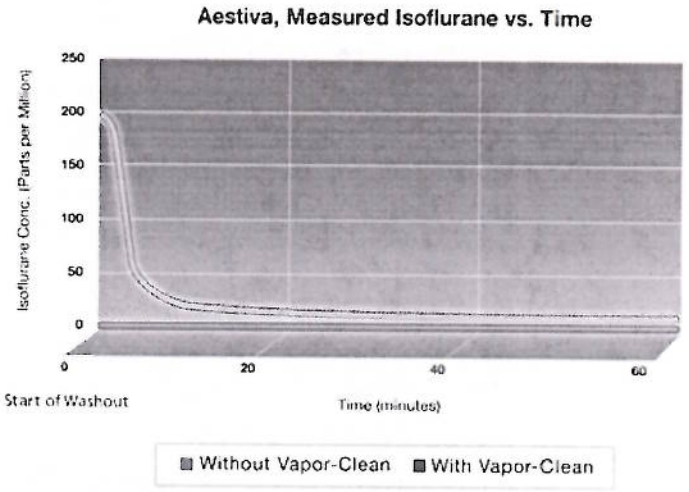
The internal components of modern anesthesia machines capture and hold volatile anesthetics which are released when the machine is used for a new patient. Even trace amounts of vapor can be harmful for susceptible patients. Previously, flushing the anesthesia machine with high fresh gas flow for an extended time before a case was thought to help decrease the risk to susceptible patients. Now, in less than 90 seconds, Vapor-Clean activated charcoal filters reduce exposure to less than 5ppm of desflurane, sevoflurane and isoflurane molecules from reaching the patient for an entire case lasting up to 12 hours.



Workstation Type	Anesthetic Agent	Published washout time (time to inspired agent less than 5 parts per million)	Time to inspired agent less than 5 parts per million with Vapor-Clean filters
Ohmeda Aestiva	Isoflurane	54 minutes[2]	Less than 1 minute[1]
Ohmeda Aestiva	Sevoflurane	48 minutes[2]	Less than 1 minute[1]
Ohmeda Aestiva	Desflurane	27 minutes[2]	Less than 1 minute[1]
Draeger Apollo	Isoflurane	84 minutes[3]	Less than 1.5 minutes[1]
Draeger Apollo	Sevoflurane	46 minutes[3]	Less than 1 minute[1]
Draeger Apollo	Desflurane	53 minutes[3]	Less than 1 minute[1]
Draeger Primus	Isoflurane	64 minutes[4]	
Ohmeda Aestiva	Sevoflurane	55 minutes[5]	Less than 1 minute[1]
Draeger Fabius	Sevoflurane	104 minutes[5]	
GE Avance	Sevoflurane	61 minutes[5]	
Maquet Flow-i	Sevoflurane	48 minutes[5]	
GE Aisys	Sevoflurane	55 minutes[5]	

Traditional Flushing Takes Longer Than You Think

The table is a summary of published studies that show the extended periods of flushing needed without the Vapor-Clean filters before modern anesthesia delivery systems can be used for MH-susceptible patients.



The data plot at right shows concentration of anesthetic vapor in an Ohmeda Aestiva anesthesia machine after the machine was used to deliver isoflurane at 1 MAC for 2 hours. Without the Vapor-Clean, it took over 60 minutes of flushing the machine at 10 L/minute before the vapor emitted by the machine was safely below 5 parts per million. Under the same conditions, when using the Vapor-Clean filters, the machine was ready in less than 2 minutes.

No Rebound Effect with the Vapor-Clean

Patients are not exposed to a rebound effect as the Vapor-Clean filters block vapors for the entire case.

Standardize Anesthesia Machine Preparation for MH

- Compatible with all anesthesia machines
- Two-year minimum shelf life
- Reduces costly operating room delays due to "surprise" MH-susceptible patients
- Negligible additional breathing circuit resistance
- No need to remove CO_2 absorbant
- Compatible with both standard two-limb and coaxial breathing circuits

For an MH Crisis: Curtail Exposure to Volatile Agents Without Delaying Dantrolene

In the event of an MH crisis, physicans can quickly turn off the anesthetic gas, place the Vapor-Clean and curtail further exposure without delaying the administration of dantrolene, and without switching to manual ventilation.

Without the Vapor-Clean, the time needed to replace the anesthesia machine, or change the circle system and CO2 absorbant can often delay the administration of dantrolene.

The Vapor-Clean allows for safe, uninterrupted mechanical ventilation during an MH crisis

Dynasthetics

DYNASTHETICS, LLC

3487 W. 2100 S. #300
Salt Lake City, UT 84119
Telephone: 801-484-3820

INTERNATIONAL

Now available in select countries

CE MARK RECEIVED

Seeking further distribution
Contact us if your company may be interested