

memsorb™

CO₂ Removal Device for
Anaesthesia Workstations

Instructions for Use

Product Code: MS-GE



DMF Medical Incorporated

109 Williams Ave, Unit 6
Dartmouth, Nova Scotia

Canada B3B 2E3

info@dmfmedical.com

www.dmfmedical.com

Toll Free: 1-833-MEMSORB

1-833-636-7672

Fax: 1-902-417-1560

1. For Professional Use Only

memsorb™ is intended to be used under the constant supervision and attention of qualified health care professionals.

If any serious incident occurs in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



CAUTION

The use of this medical device requires full understanding and adherence to the information in the Instructions for Use. This device may only be used for the purposes described in the Intended Use section. Read all **WARNING** and **CAUTION** sections carefully. Disregarding these sections constitutes a violation of the Intended Use of the device.

2. Intended Use

memsorb™ is intended:

- for the removal of carbon dioxide (CO₂) from the gas mixture in anaesthetic circuits;
- to be used on GE Aisys® anaesthesia machine platforms; and
- for use in general anaesthesia procedures that utilise the agents desflurane or sevoflurane.

memsorb™ may also be used for procedures that utilise intravenous or total intravenous anaesthesia.

memsorb™ is **NOT** intended for use with the anaesthetic agent nitrous oxide (N₂O).



WARNING

Risk to patient!

memsorb™ is intended for use in adult populations 18 years of age and older.

3. Principle of Operation

memsorb™ is a membrane-based technology that uses simple diffusion principles for the removal of CO₂ during general anaesthesia procedures. The selectively permeable membrane has two functions:

- to allow CO₂ to pass through the membrane; and
- to ensure that anaesthetic agents are retained within the anaesthetic circuit.

NOTE

memsorb™ must be used with an air-oxygen blender.

The air-oxygen concentration in the flush gas affects the patient-gas concentration and as a result **they should be matched using the blender.**

The patient-derived exhaled air stream enters the extra-capillary space of the device, while an air-oxygen mixture is introduced into the lumen of the hollow fibers of the membrane. This establishes a gradient in concentration across the membrane from the high CO₂ found in the patient-derived exhaled air stream to the low CO₂ found in the air-oxygen mixture. The air-oxygen stream flushes the extracted CO₂ from the unit into a scavenging system.

NOTE

memsorb™ uses membrane-based technology and therefore inspired CO₂ is **not** a measure of the device function. Inspired CO₂ levels in excess of 5 mmHg may be observed.

Manage expired CO₂ levels as per the anaesthesia machine manufacturer's instructions.



WARNING

Risk to patient!

memsorb™ must only be used in conjunction with CO₂ monitoring.

CO₂ removal will not take place in the breathing system when memsorb™ is removed.

Safe operation requires that the air-oxygen flush gas flow **must be** maintained at 13 to 15 litres per minute **at all times.**

memsorb™ removes moisture from the machine-side gas mixture. memsorb™ must be used with a Heat and Moisture Exchange Filter (HMEF) installed between the patient and anaesthetic circuit to retain moisture on the patient side and to prevent cross-contamination.

4. Storage and Handling

Store memsorb™ in a dry location between +15 °C and +25 °C with no exposure to direct sunlight or UV light. Under such conditions, memsorb™ is usable until the expiration date as indicated on the device label.

NOTE

Handle memsorb™ with care. Damage may occur if the unit is bumped or knocked.

5. Installation Materials

Equipment and Materials Provided

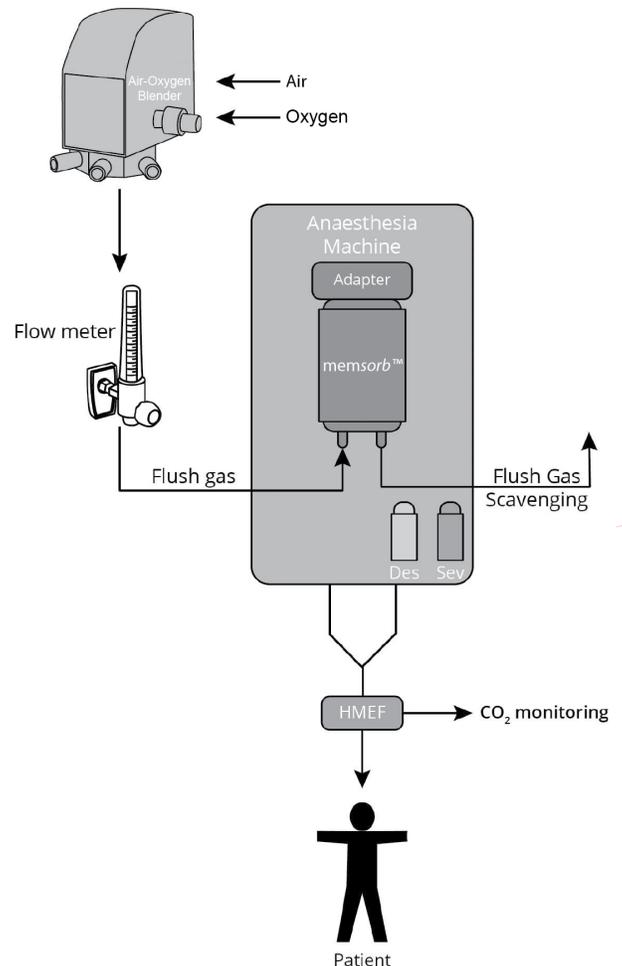
- memsorb™ Product Code: MS-GE

Required but Not Provided:

- Anaesthesia machine equipped with rebreathing circuit and gas monitoring
- Heat and moisture exchanger with bacterial and viral filter (HMEF)
- Medical oxygen (O₂) and medical air supply for connecting to the blender
- Medical air-oxygen blender able to provide 21 % to 100 % medical oxygen in medical air
- A flow meter with the ability to maintain and display the blender flow rate of 13 to 15 litres per minute (Lpm)
- 1/4" tubing for connecting flow meter output to memsorb™
- Scavenging system that is capable of handling a minimum flow rate of 15 Lpm
- For passive scavenging systems: 30 mm (ANSI Standard) hose or a same-size adapter for connecting memsorb™ to the scavenging system
- For passive scavenging systems: a scavenging pressure relief valve that conforms to ISO 80601-2-13
- For active scavenging systems: 5/16" tubing for connecting memsorb™ to the scavenging system
- Tubing adapters as necessary

GENERAL

- The device label on memsorb™ should be visible during use.
- Ensure all outer tubing surfaces are smooth and undamaged. Check for any kinks or obstructions in the tubing.
- Ensure all tubing is securely connected to the correct ports of memsorb™.
- Do not modify connections, as gas leakage may occur.
- Tubing should be directed away from high-traffic areas.
- Minimise strain on tubing when the unit has been installed.

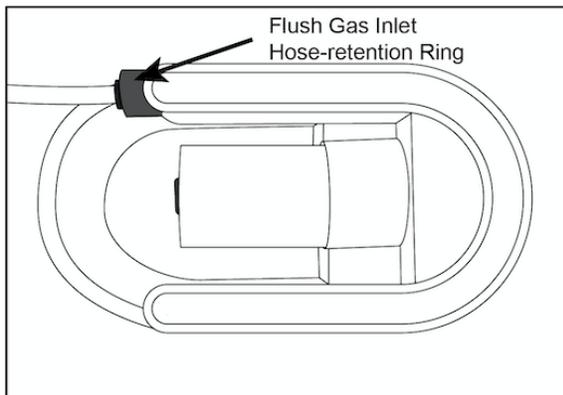


6. Installation Procedure

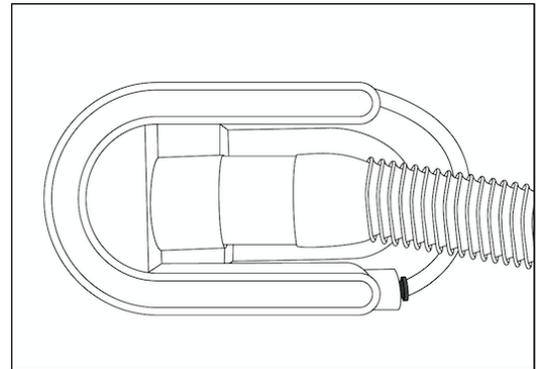
NOTE

The blender and flow meter should be in an easy-to-reach location and clearly visible to the operator. Use with serviced anaesthesia machines. Ensure pressure relief valve functions per manufacturer's specifications.

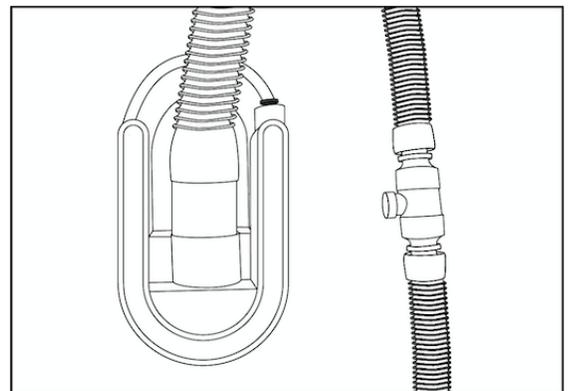
1. Ensure a medical air-oxygen blender assembly (with flow meter) is securely installed onto the anaesthesia machine.
2. Connect the flush gas supply from the blender to the bottom of memsorb™:
 - i. Ensure the end of the tubing is cut squarely and cleanly.
 - ii. Confirm the dark grey hose-retention ring is in the flush gas inlet.
 - iii. Push the 1/4" tubing approximately 13 mm (1/2") into the flush gas inlet at the bottom of memsorb™. Internal lock claws grab and hold the tubing. Firmly pull on the tubing to ensure it is secure (see figure below).



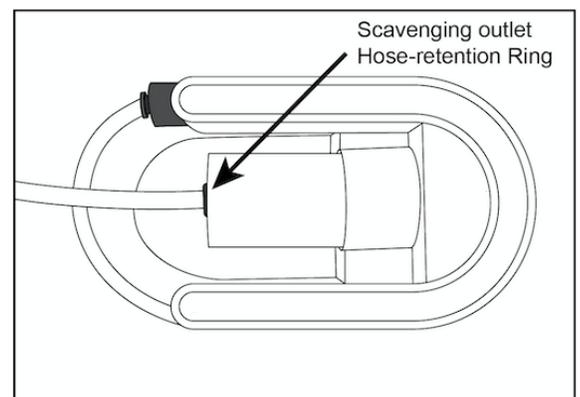
- iv. If the tubing becomes dislodged, re-insert the tubing into the flush gas inlet until the tubing is firmly in place.
3. Scavenging systems:
 - i. For **passive** scavenging systems:
 - i.1. Connect the passive scavenging system to memsorb™ using 30 mm scavenging tubing to the flush gas outlet (see figure below).



- i.2. Ensure scavenging pressure relief valve is in-line with 30 mm hose connected to memsorb™ and placed within 30 cm to 60 cm (12" to 24") of memsorb™ (see figure below).

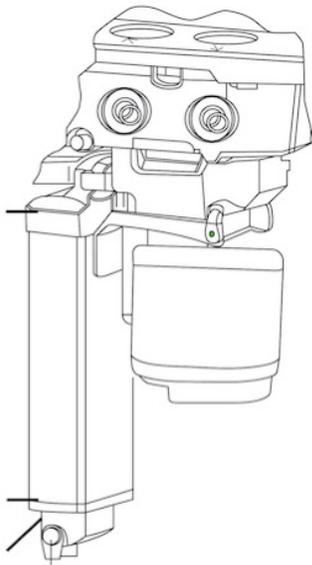


- ii. For **active** scavenging systems:
 - ii.1. Connect the active scavenging system to memsorb™ using 5/16" tubing to the scavenging outlet (see figure below).



- ii.2. Ensure the end of the tubing is cut squarely and cleanly.
 - ii.3. Confirm the dark grey hose-retention ring is in the scavenging outlet.

- ii.4. Push the 5/16" tubing roughly 13 mm (1/2") into the scavenging outlet at the bottom of memsorb™. Internal lock claws grab and hold the tubing. Firmly pull on the tubing to ensure it is secure.
 - ii.5. If the tubing becomes dislodged, re-insert the tubing into the scavenging outlet until the tubing is firmly in place.
4. Install memsorb™ into the EZchange canister holder by inserting it into the holder and then pushing it gently upwards until it clicks into place.



5. Perform an internal machine leak test with memsorb™ installed. Ensure the blender is set to 100 % O₂ and the flow meter is delivering 15 Lmp flush gas. If the machine leak test passes, the unit is ready to use. If the machine leak test does not pass, refer to Leak Test Troubleshooting table below.

LEAK TEST TROUBLESHOOTING		
Failure mode	Probable cause	Corrective action
Breathing circuits leaks	Anaesthesia circuit tubings are not properly connected	Ensure all connections are tight
EZchange canister holder does not seal against the top of the unit	Seals are compromised by damage or accumulation of debris	Visually inspect and replace or clean rubber seals inside the canister holder

7. Cleaning



CAUTION

Do **NOT** attempt to sterilise or disassemble memsorb™ under any circumstances.

Only the outer casing may be cleaned. Cleaning agents based on the following ingredients and concentrations are compatible with the external surfaces of memsorb™:

- Isopropyl alcohol
- Ethanol
- Hypochlorite solution (≤ 14 %)
- Quaternary ammonium compounds, C12-18-alkyl [(ethylphenyl) methyl] dimethyl, chlorides (≤ 0.125 %)
- Sodium percarbonate (≤ 50 %)
- Citric acid (≤ 10 %)
- Benzalkonium chloride (≤ 0.5 %)
- Didecyl dimethyl ammonium chloride (≤ 30 %)
- Polyhexamethylene biguanide (PHMB) (≤ 0.1 %)
- Ethylene glycol monobutyl ether (2-Butoxyethanol) (≤ 5 %)
- Diisobutyl phenoxy ethoxy ethyl dimethyl benzyl ammonium chloride (≤ 0.28 %)
- UNDECETH-5 (≤ 10%)

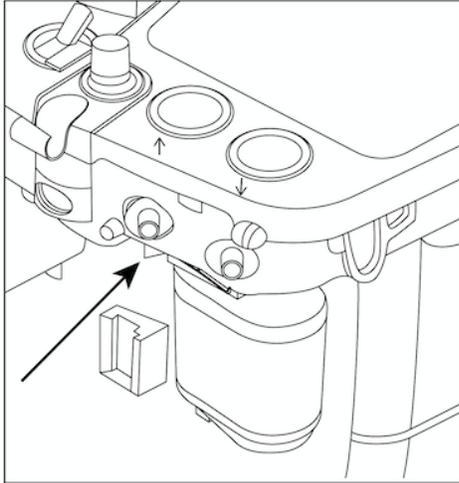
NOTE

If using End Tidal control, ensure the patient O₂ concentration reaches the target value and match the blender concentration before initiating end tidal control.

If not done in this order, a volume drop may be observed in the bellows. To correct for the volume drop, simply flush in O₂.

8. Removal

1. Turn off the flow meter and ensure that flush gas flow has reached 0 Lpm.
2. Press the absorber canister release button on the machine.



3. Allow memsorb™ to swing open on the EZchange canister holder and pull memsorb™ unit off its mounting.
4. Disconnect scavenging system from memsorb™ by removing scavenging tubing from the scavenging outlet. Active: Push 5/16" tubing into fitting. Compress and hold release ring and pull tubing out. Passive: Remove 30 mm hose.
5. Remove the air-oxygen supply. Push 1/4" tubing into fitting. Compress and hold release ring and pull tubing out.

9. Replacement

1. Replace memsorb™ at expiry or when there is a failed leak test. Ensure to follow the installation and leak testing procedures prior to use.
2. Return expired and/or failed memsorb™ units to the address given below.

10. Disposal

memsorb™ is made of non-hazardous materials and can be disposed per local regulations.

In an effort to protect our planet, we encourage you to return the memsorb™ unit to DMF Medical for recycling. Please contact us for further instructions on returning the unit.



DMF MEDICAL INCORPORATED

109 Williams Ave, Unit 6
 Dartmouth, Nova Scotia
 Canada B3B 2E3
 info@dmfmedical.com
 www.dmfmedical.com
 Toll Free: 1-833-MEMSORB / 1-833-636-7672
 Fax: 1-902-417-1560



OBELIS S.A

Registered Address:
 Bd. Général Wahis, 53
 1030 Brussels,
 Belgium
 Tel: +32.2.732.59.54
 Fax: +32.2.732.60.03
 E-mail: mail@obelis.net www.obelis.net

Symbols Table		
 Manufacturer	 Country of manufacture	 Consult instructions for use
 Use-by date	 Non-Sterile	 Catalogue Number
 Serial Number	 Keep away from sunlight	 Keep-dry
 Medical Device	 Temperature Limit	 Caution / Warning
 Authorized Representative in the European Union		