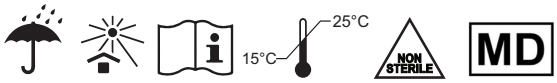
mem*sorb*™

CO_2 Removal Device for
Anaesthesia Workstations

Instructions for Use

Product Code: MS-DR



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1. For Professional Use Only

mem*sorb*™ 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

mem*sorb*™ is intended:

- for the removal of carbon dioxide (CO_2) from the gas mixture in anaesthetic circuits;
- to be used on Dräger Medical Fabius®[1], Primus®[2], Zeus®[3], and Perseus®[4] anaesthesia machine platforms; and
- for use in general anaesthesia procedures that utilise the agents desflurane or sevoflurane.

mem*sorb*™ may also be used for procedures that utilise intravenous or total intravenous anaesthesia.

mem*sorb*™ is **NOT** intended for use with the anaesthetic agent nitrous oxide (N_2O).

WARNING

Risk to patient!

mem*sorb*™ is intended for use in adult populations 18 years of age and older.

3. Principle of Operation

mem*sorb*™ is a membrane-based technology that uses simple diffusion principles for the removal of CO_2 during general anaesthesia procedures. The selectively permeable membrane has two functions:

- to allow CO_2 to pass through the membrane; and
- to ensure that anaesthetic agents are retained within the anaesthetic circuit.

NOTE

mem*sorb*™ 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 CO_2 found in the patient-derived exhaled air stream to the low CO_2 found in the air-oxygen mixture. The air-oxygen stream flushes the extracted CO_2 from the unit into a scavenging system.

NOTE

mem*sorb*™ uses membrane-based technology and therefore inspired CO_2 **is not** a measure of the device function. Inspired CO_2 levels in excess of 5 mmHg may be observed.

Manage expired CO_2 levels as per the anaesthesia machine manufacturer's instructions.

[1-4] Registered trademark of Drägerwerk AG & Co. KGaA 2020

WARNING

Risk to patient!

mem*sorb*™ must only be used in conjunction with CO_2 monitoring.

CO_2 removal will not take place in the breathing system when mem*sorb*™ 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.**

mem*sorb*™ removes moisture from the machine-side gas mixture. mem*sorb*™ 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 mem*sorb*™ in a dry location between +15 °C and +25 °C with no exposure to direct sunlight or UV light. Under such conditions, mem*sorb*™ is usable until the expiration date as indicated on the device label.

NOTE

Handle mem*sorb*™ with care. Damage may occur if the unit is bumped or knocked.

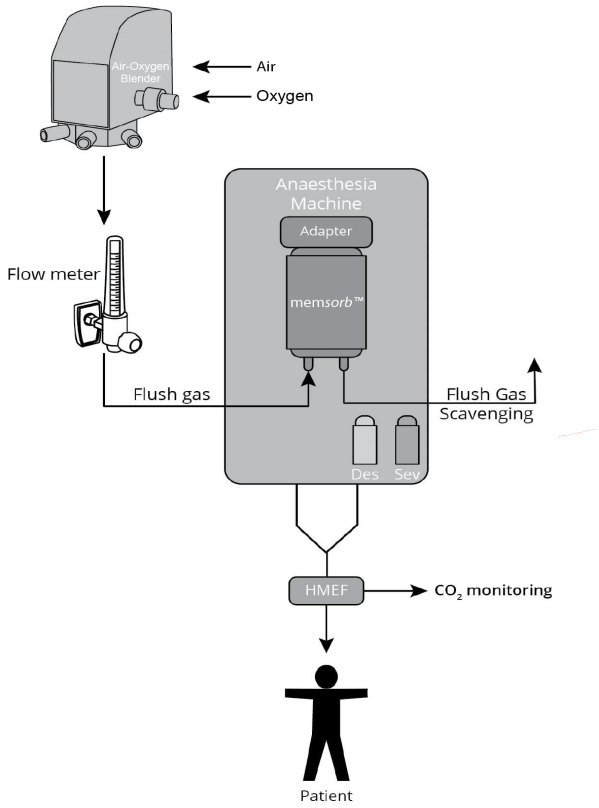
5. Installation Materials

Equipment and Materials Provided

- mem*sorb*™ Product Code: MS-DR

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 (O_2) 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 mem*sorb*™



- 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 mem*sorb*™ to the scavenging system
- Tubing adapters as necessary

GENERAL

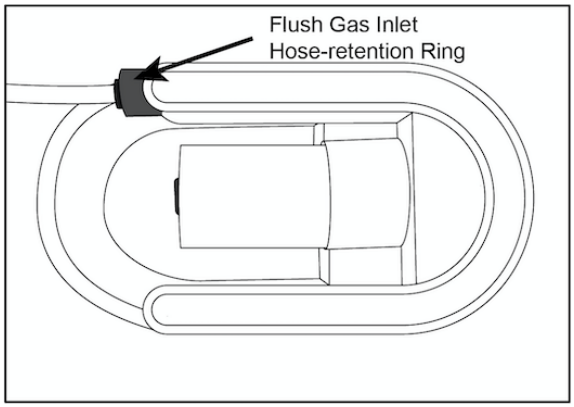
- The device label on mem*sorb*™ should be visible during use.
- Ensure all outer tubing surfaces are smooth and undamaged. Check for any kinks or obstructions in the tubing.
- Ensure all tubing is securely connected to the correct ports of mem*sorb*™.
- Do not modify connections, as gas leakage may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

6. Installation Procedure

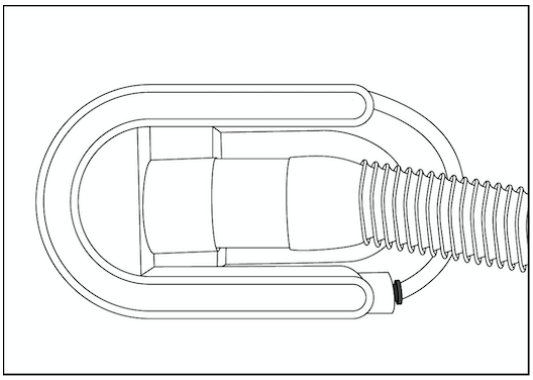
NOTE

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.

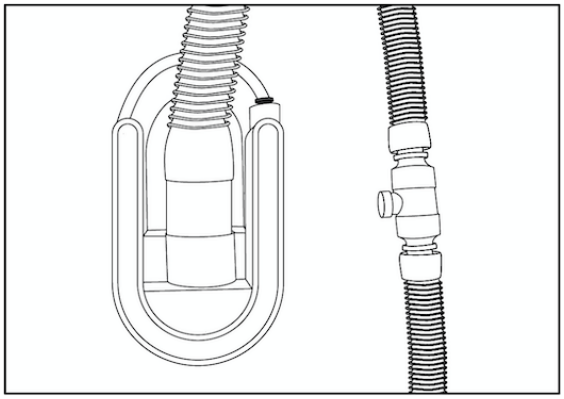
1. Ensure a medical air-oxygen blender assembly (with flow meter) is securely installed onto the anaesthesia machine.
2. Connect the flush gas supply from the blender to the bottom of mem*sorb*™:
   i. Ensure the end of the tubing is cut squarely and cleanly.
   ii. Confirm the dark grey hose-retention 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 mem*sorb*™. Internal lock claws grab and hold the tubing. Firmly pull on the tubing to ensure it is secure (see figure below).



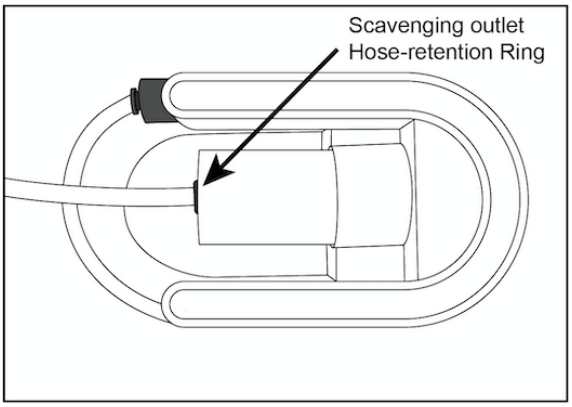
   iv. If the tubing becomes dislodged, re-insert the tubing into the flush gas inlet until the tubing is firmly in place.
3. Scavenging systems:
   i. For **passive** scavenging systems:
      i.1. Connect the passive scavenging system to mem*sorb*™ using 30 mm scavenging tubing to the flush gas outlet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



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



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

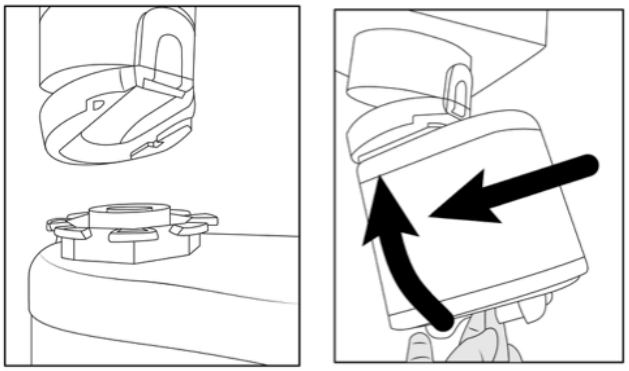


      ii.2. Ensure the end of the tubing is cut squarely and cleanly.
      ii.3. Confirm the dark grey hose-retention ring is in the scavenging outlet.

ii.4. Push the 5/16” tubing roughly 13 mm (1/2") into the scavenging outlet at the bottom of mem*sorb*™. 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 mem*sorb*™ into CLIC adapter by sliding it down the rails and then pushing it gently upwards until it clicks into place. If there is resistance, check alignment and repeat.



5. Perform a functional leak test. Choose the functional leak test method appropriate for your machine model.

NOTE

The manufacturer’s self-test must be performed with CLIC adapter in bypass mode.

mem*sorb*™ requires a specialty functional leak test.

Functional Leak Test:
Draeger Medical **Fabius®**, **Perseus®**, & **Zeus®**[5] machines

1. Ensure the breathing circuit is fully assembled including the breathing bag, HMEF, and circuit tubing before performing leak test.
2. Set the blender dial to 100 % O_2. Failure to do this will cause unreliable functional leak test results.
3. Turn on the flow meter and ensure that the gas flow is set to 13 Lpm to 15 Lpm.
4. Set the adjustable pressure-limiting (APL) valve to maximum.
5. Occlude the breathing circuit on the patient side of the Y-piece.
6. Press the O_2 flush button on the anaesthesia machine until the pressure meter reaches approximately 35 cmH_2O.
7. Allow the pressure meter to drop to at least 30 cmH_2O to equilibrate the system.
8. Press the O_2 flush button on the anaesthesia machine until the pressure meter reaches approximately 35 cmH_2O.
9. Observe the pressure drop. mem*sorb*™ passes the functional leak test if the pressure drop observed is ≤ 5 cmH_2O after 7 seconds.
10. If the leak test fails, refer to **FUNCTIONAL LEAK TEST TROUBLESHOOTING** and then repeat steps 1 to 9 above.
11. Upon repeat failure, remove mem*sorb*™ from service, install a new mem*sorb*™, and repeat leak testing.
12. After leak testing is successful, set the APL valve to spontaneous (Spont) and un-occlude the breathing circuit on the patient side of the Y-piece. mem*sorb*™ is now ready for use.

[5] Registered trademark of Drägerwerk AG & Co. KGaA 2020

Functional Leak Test

Dräger Medical **Primus®[6]** machines

1. Ensure the breathing circuit is fully assembled including the breathing bag, HMEF, and circuit tubing before attempting leak test.
2. Set the blender dial to 100 % O_2. Failure to do this will cause unreliable functional leak test results.
3. Turn on the flow meter and ensure that the gas flow is set to 13 Lpm to 15 Lpm.
4. Set the adjustable pressure-limiting (APL) valve to maximum.
5. Occlude the breathing circuit on the patient side of the Y-piece.
6. Press the O_2 flush button on the anaesthesia machine until the pressure meter reaches approximately 45 cmH_2O.
7. Allow the pressure meter to drop to at least 40 cmH_2O to equilibrate the system.
8. Press the O_2 flush button on the anaesthesia machine until the pressure meter reaches approximately 45 cmH_2O.
9. Observe the pressure drop. mem*sorb*™ passes the functional leak test if the pressure drop observed is ≤ 15 cmH_2O after 21 seconds.
10. If the leak test fails, refer to **FUNCTIONAL LEAK TEST TROUBLESHOOTING** and then repeat steps 1 to 9 above.
11. Upon repeat failure, remove mem*sorb*™ from service, install a new mem*sorb*™, and repeat leak testing.
12. After leak testing is successful, set the APL valve to spontaneous (Spont) and un-occlude the breathing circuit on the patient side of the Y-piece. mem*sorb*™ is now ready for use.

FUNCTIONAL LEAK TEST TROUBLESHOOTING		
Failure mode	**Probable cause**	**Corrective action**
Breathing circuits leaks	Anaesthesia circuit tubings are not properly connected	Ensure all connections are tight
CLIC adapter is not seated properly	Adapter is not fully engaged	Turn adapter clockwise until it is fully engaged with the anaesthesia machine
CLIC adapter does not seal against unit	Seals are compromised by damage or accumulation of debris	Visually inspect and replace or clean rubber seals inside the CLIC adapter
Flush concentration is < 100 % O_2	Blender has not been set to 100 % O_2	Set blender to 100 % O_2
Unit does not slide into the CLIC adapter due to a collision with the anesthesia machine geometry	The CLIC adapter may not be fully seated on the anesthesia machine and the misalignment leads to a collision of mem*sorb*™ with the machine geometry	Ensure the CLIC adapter is fully turned and tightened onto the anesthesia machine

7. Cleaning

[6] Registered trademark of Drägerwerk AG & Co. KGaA 2020

CAUTION

Do **NOT** attempt to sterilise or disassemble mem*sorb*™ 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 mem*sorb*™:

- 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%)

8. Removal

1. Turn off the flow meter and ensure that flush gas flow has reached 0 Lpm.
2. Press the release button on the CLIC adapter.
3. Allow mem*sorb*™ to swing open on its mounting and pull mem*sorb*™ unit off its mounting.
4. Disconnect scavenging system from mem*sorb*™ 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 mem*sorb*™ 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 mem*sorb*™ units to the address given below.

10. Disposal

mem*sorb*™ 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 mem*sorb*™ unit to DMF Medical for recycling. Please contact us for further instructions on returning the unit.

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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
EU REP Authorized Representative in the European Union	CE 2797 BSI Group Notified Body	