INSTRUCTIONS FOR USE OF MEDICAL DEVICE CARBON DIOXIDE

Air Liquide HEALTHCARE

CE 0476

Date of revision: July 2018
Ref: 4206 v3
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Read all of this Instructions for use carefully before you start using Medical Device Carbon Dioxide
Keep this Instruction for use as you may need to read it again
If you have any other questions, please contact your usual supplier.

1. WHAT IS MEDICAL DEVICE CARBON DIOXIDE FROM AIR LIQUIDE GAS AB AND INDICATIONS?

The **Medical Device Carbon Dioxide** intended to be used in Laparoscopy, Colonoscopy and Computed Tomographic Colonoscopy CTC is a Medical Device of Class IIa in accordance with the Annex IX of the Medical Device Directive 93/42/EEC.

Processes of Laparoscopy: To perform a laparoscopy, the Medical Device Carbon Dioxide is insufflated between the two layers of the peritoneum, in order to create a peritoneal cavity (pneumoperitoneum) useful for diagnosis or performing surgical procedures.
Processes of Colonoscopy and Computed Tomographic Colonoscopy (CTC): To perform colonoscopy and CTC, CO_2 is insufflated into the colon to create a chamber inside the colon, distending its walls and ensuring that it can be visualize or scanned accurately.

Gas composition: Medical Device Carbon Dioxide fulfills the specification described in the monograph of the latest edition of the European Pharmacopoeia (CO2 ≥ 99.5%, CO ≤ 5 ppm, NOX ≤ 2 ppm, S-TOTAL ≤ 1 ppm and H2O ≤ 67 ppm).

2. NECESSARY INFORMATION BEFORE USING MEDICAL DEVICE CARBON DIOXIDE

MEDICAL DEVICE CARBON DIOXIDE MUST ONLY BE USED BY TRAINED HEALTH CARE PERSONNEL

Warnings

- This product should only be used for Laparoscopy or Colonoscopy and Computed Tomographic Colonoscopy. It must not be inhaled or used for applications other than those specified in the instructions for use.
- Medical Device carbon dioxide is not sterile; therefore, a bacteriological filter should be used (porosity: 0.22µm, resistant to a pressure of 20 mmHg and compatible with Medical Device carbon dioxide).
- Medical Device carbon dioxide may act as an asphyxiant by displacing air in closed spaces. This gas is heavier than air and can therefore accumulate in low-lying areas (ditches, gullies, under floors, etc.), thus making the atmosphere hazardous. It-must only be used in well-ventilated rooms.
- Medical Device carbon dioxide is supplied into containers in a liquefied form under pressure. During a sudden rapid opening of the valve the exit gas can be liquefied again and will cause frostbite by contact with the skin. When using carbon dioxide in liquefied form it is appropriate to wear protective gloves.

Application materials

- Use Medical Device carbon dioxide with adapted and undamaged application materials compatible with this gas.
- Follow the recommendations provided by the manufacturers of insufflators and other equipment (Medical Devices) used for Laparoscopy or Colonoscopy and Computed Tomographic Colonoscopy.

When handling and connecting a cylinder of Medical Device carbon dioxide

- The necessary precautions must be taken if the cylinder is to be used in an operating theatre as the packaging is not sterile.
- Never force a cylinder into a support in which it does not fit comfortably.
- Do not use a cylinder unless its valve is protected with a protective collar.
- Check that the cylinder is equipped with an intact tamper-proof system when used for the first time.
- Never lift a cylinder up by its valve.
- Do not attempt to repair a faulty valve.
- Cylinders must be kept in a vertical position to prevent any risk of splashing liquids that may result in severe cryogenic-type burns.
- Prior to use and during storage, the cylinder must be supported or placed in a support to ensure that it cannot fall over.
- Do not connect the cylinder to a hose that is not connected to an insufflator.
- Open the valve slightly before attaching the pressure regulator to expel any dust that it may contain.
- Precautions must be taken when connecting the cylinder (purging of the connections and different materials) to prevent the entry of moisture.
- Use pressure regulators and hoses with connectors suitable for the valve: Use a specific type C connection that complies with national standards for medical connections. The use of parts that have similar but not identical characteristics is dangerous and strictly prohibited.
- Do not tighten the accessories with mechanical help as this may damage the coupling.
- Never use an intermediate connector to connect two devices that do not fit together.
- It is strictly prohibited to “fill” a cylinder of Medical Device carbon dioxide from another cylinder (only the manufacturer is qualified to fill gas cylinders).

3. HOW TO USE MEDICAL DEVICE CARBON DIOXIDE:

- Only the physician (surgeon) should decide the quantity and flow of gas needed depending on the required effect and the condition to be treated.
- Prior to any intervention, it should be ensured that the product used is medical device carbon dioxide (CE 0476).

- The gas pressure remains constant at constant temperature (49.5, bar) irrespective of the level of liquid remaining and does not reflect the quantity remaining in the cylinder. The pressure only decreases rapidly when the cylinder no longer contains any liquid gas. Only the weight of the cylinder allows its content to be calculated before or during use.
- Open the valve slowly.
- Never use force to open the valve or open it to its maximum.
- Never perform several successive pressurizations of the pressure regulator or hose
- Always stand behind the cylinder, never directly in front of the valve outlet.
- Never expose the patient or healthcare personnel to the gas flow.
- Do not touch the outlet connections and flexible tubes during use. They are at a very low temperature and there is a risk of burns for users.
- Close the cylinder valve after use and allow the pressure in the pressure regulator or hose to slowly decrease.
- Ventilate the place of use.

4. WHAT ARE THE POSSIBLE SIDE-EFFECTS OF MEDICAL DEVICE CARBON DIOXIDE:

4.1 Contraindications

There are no absolute contraindications to the use of carbon dioxide in the approved indications.

4.2 Special warnings and precautions for use

- The use of carbon dioxide in patients with or at risk of acidosis or hypercapnia (such as patients with chronic respiratory disease, respiratory depression) and during resuscitation should be cautious.
- Warnings and precautions for insufflation common to all types of insufflating gases apply.
- In ventilated patients, ventilatory pattern needs to be adjusted to allow CO_2 elimination.
- Some situations (prolonged surgery, Trendelenburg position) may impede attempts at increasing ventilation to maintain normocapnia.
- In situations where $ETCO_2$ and $PaCO_2$ do not reliably correlate (e.g. prolonged surgery, preoperative pulmonary pathology), carbon dioxide monitoring by arterial blood gas test (ABG) instead of capnography may be required.
- Patients with chronic obstructive lung disease are at theoretically higher risk of hypercapnia with CO_2 insufflation.
- Subcutaneous carbon dioxide emphysema may increase the level and duration of hypercapnia.
- Hypercapnia may increase the risk of coronary ischemia in patients suffering from ischemic heart disease.
- In some patients suffering from respiratory disorders, it may be necessary to prolong artificial ventilation postoperatively, until CO_2 is eliminated completely.
- In patients who present with baseline elevated intracranial pressure (ICP) or head trauma, laparoscopy should be used cautiously, as abdominal insufflation affects intracranial pressure and carbon dioxide may enhance that effect.

In the event of a <u>leak</u>

- In closed spaces, an atmosphere containing less than 19,5% oxygen is hazardous and may result in loss of consciousness and asphyxia.
- Similarly, exposure to CO_2 concentrations higher than 3%-5% may result in cardiac and respiratory alterations, nausea and headache and may lead to loss of consciousness.
- In the event of a leak and if the product cannot be evacuated, evacuate the room; never enter a room before ensuring that the oxygen content is higher than18% and the CO_2 content is < 1%.
- In the event of feeling unwell: Evacuate the person concerned to a normal atmosphere; if gas levels in the atmosphere are hazardous, only enter a room wearing a self-contained breathing device designed for that purpose. Initiate artificial respiration immediately and contact the fire department and emergency service. If necessary, administer oxygen using a manual respirator. Continue until the emergency services arrive.

In the event of contact with skin and eyes

- Immediately rinse the eyes with a large volume of water for at least 15 minutes and consult a doctor.
- In the event of freezing, spray the skin with cold water (15 to 25°C) for at least 15 minutes, apply a sterile dressing and consult a doctor.

<u>Paediatric population</u>

Small children warrant close CO_2 monitoring during laparoscopy and during the immediate postoperative period.

4.3 Interaction with other medicinal products and other forms of interaction

<u>Combinations requiring precautions for use</u>

There are increased chances of arrhythmias occurring with halothane in spontaneously breathing patients due to hypercarbia.

4.4 Fertility, pregnancy and lactation

Pregnancy: common recommendations regarding abdominal gas insufflation apply; there is no recommendation specific to the use of carbon dioxide. There are no data showing detrimental effects to human fetuses from CO_2 insufflation.

4.5 Undesirable effects

In addition to undesirable effects of insufflation and associated procedures that occur independently of the gas used for insufflation the following undesirable effects have been described as specific to CO_2 or increased with CO_2 compared to other gases:

- Gastrointestinal disorders: pneumatosis intestinalis, abdominal pain, abdominal discomfort, bloating.
- Musculoskeletal and connective tissue disorder: shoulder pain.
- Nervous system disorders: increased intracranial pressure.
- Metabolism and nutrition disorders: hypercapnia, acidosis.
- Cardiac disorders: sinus tachycardia, ventricular extra systoles, myocardial ischaemia.
- Renal and urinary disorders: renal insufficiency, oliguria.

5. HOW TO TRANSPORT AND HANDLE MEDICAL DEVICE CARBON DIOXIDE:

- Protect cylinders from physical damage: do not drag, roll, slide or drop.
- When moving cylinders, even for short distances, use a cart, trolley, hand truck etc. designed to transport cylinders.
- Leave valve protection caps in place until the cylinder has been secured against either a wall or bench or placed in a cylinder stand and is ready for use.
- The product must be handled in accordance with good medical hygiene and safety procedures.
- Ensure the complete gas system was (or is regularly) checked for leaks before use.
- Avoid suck back of water, acid or alkalis.

More information about safety and precautions for transporting and handling gas cylinders can be found in the Safety Data Sheet, at:
http://alsafetydatasheets.com/download/dk/Carbondioxide_compressed-DK_ENG.pdf

6. HOW TO STORE MEDICAL DEVICE CARBON DIOXIDE:

- Gas cylinders must be stored in specially designated locations where there is no risk of fire, free from flammable materials, protected, dry, sheltered and with natural or artificial ventilation to expel gases to the open air and which maintain an atmosphere containing more than 18% oxygen and a temperature of less than 50°C.
- Cylinders should be stored in the vertical position and properly secured to prevent from falling over.
- Stored cylinders should be periodically checked for general conditions and leakage.
- Empty gas cylinders must be stored separately and identified as such.
- All full and empty cylinders must be stored with the valve closed and the protective collar and cap must not be removed.
- Store cylinders in location free from risk fire and away from sources of heat and ignition.
- Keep away from combustible material.
- Observe all regulations and local requirements regarding storage of cylinders.
- Cylinders should not be stored ion conditions likely to encourage corrosion.
- Do not use after the expiry date which is stated on the cylinder label.

7. FURTHER INFORMATION:

Medical Device carbon dioxide is supplied liquefied at a pressure of 49.5 bar. See list of models below.

Cylinder size (l)	Load (kg)	Pressure (bar)
2,5	1,8	49.5
5	3.75	49.5
8	6	49.5
10	7.5	49.5
20	15	49.5
50	37.5	49.5

For more information about Medical Device Carbon Dioxide, contact your local representative:
Air Liquide Gas AB Lundavägen 151 S-212 24 Malmö SWEDEN.

- Keep the medical device out of reach and sight of children
- Do not smoke
- Do not bring a flame close
- Do not grease

Symbols commonly used by Air Liquide GAS AB in medical device labelling (labels/IFU/etc.)

Symbol	Title/Description
	**Manufacturer** The product is produced by the manufacturer whose name and address are stated next to the symbol.
	**Catalogue number** The product´s catalogue (item) number.
	**Consult instructions for use** The user instructions contain important cautionary information (warnings/precautions) and must be read before using the product.
	**Warning** Text marked with a warning symbol must be read before using the product.
	**CE mark** The product is in conformity with the requirements set out in the European CE marking directive.