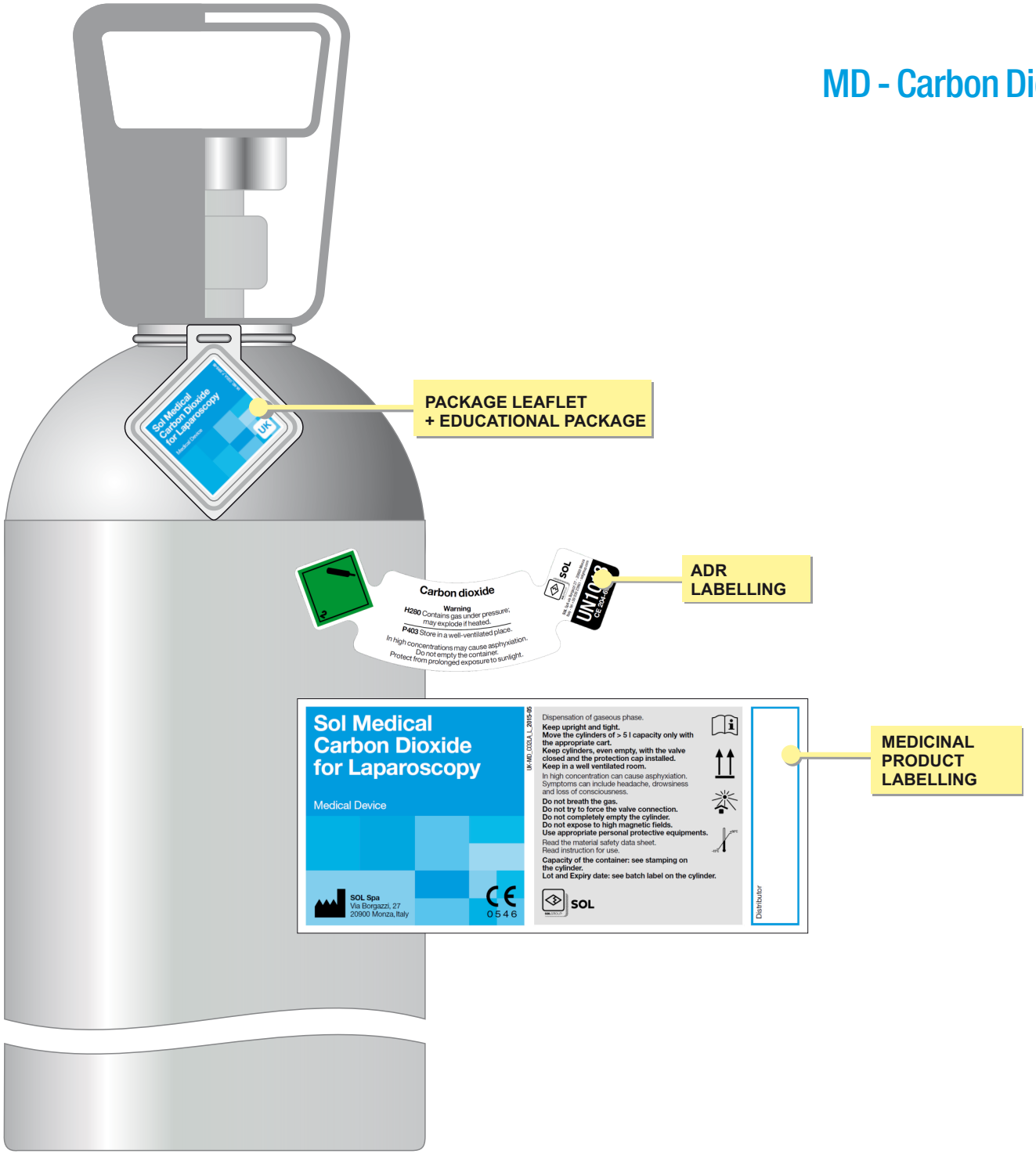
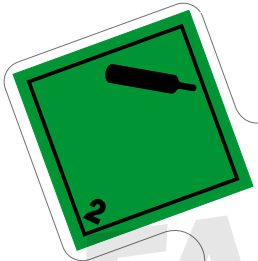
Labels on cylinders
MD - Carbon Dioxide for Laparoscopy

England





Carbon dioxide

Warning

H280 Contains gas under pressure; may explode if heated.

P403 Store in a well-ventilated place.

In high concentrations may cause asphyxiation.
Do not empty the container.
Protect from prolonged exposure to sunlight.

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Sol Medical Carbon Dioxide for Laparoscopy

Medical Device

SOL Spa
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20900 Monza, Italy

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0546

UK-MD_C02LA_L_**2015-05**

Dispensation of gaseous phase.

Keep upright and tight.
Move the cylinders of > 5 l capacity only with the appropriate cart.
Keep cylinders, even empty, with the valve closed and the protection cap installed.
Keep in a well ventilated room.

In high concentration can cause asphyxiation. Symptoms can include headache, drowsiness and loss of consciousness.

Do not breath the gas.
Do not try to force the valve connection.
Do not completely empty the cylinder.
Do not expose to high magnetic fields.
Use appropriate personal protective equipments.

Read the material safety data sheet.
Read instruction for use.

Capacity of the container: see stamping on the cylinder.
Lot and Expiry date: see batch label on the cylinder.

SOL
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Distributor

Sol Medical Carbon Dioxide for Laparoscopy

Medical Device

UK-MD_CO2LA_P_2015-05

UK

Instruction for use of CO_2 MD

Composition

Medical carbon dioxide for laparoscopy is a liquefied gas at its vapour tension (50 bar at 15°C) with the following specification:

Assay	CO_2	≥ 99,5 %
Impurities	CO	≤ 5 ppm (V/V)
	NO, NO_2	≤ 2 ppm (V/V)
	H_2O	≤ 10 ppm (V/V)
	Total Sulphur	≤ 1ppm (V/V)

Destination of use

Medical carbon dioxide for laparoscopy is used whenever in video endoscopic surgery an artificial space has to be created to obtain optimal sight and dissection space through the distension of the tissues at a pressure and flow, defined by the surgeon, and characteristic for the specific procedure and the patient conditions.

Available configuration

Cylinders' capacity (l): 1, 2, 5, 10, 13, 20, 40, 50. The connection can be specific for distribution country; the usable connections are indicated in the following table:

Connections	**PININDEX** EN ISO 407

Recommendations for use

- This cylinder is made of steel, thus it shall never be carried in an environment with a high magnetic field (like N.M.R.) or nearby.
- Keep the cylinder in upright position and tight.
- Keep the cylinder at environmental temperature before and during its use.
- The device is supplied with a protective seal that when removed cannot be replaced.
- Check the cleaning condition of the valve connections before every use.
- Connect the cylinder to equipments with standardized connections, according with the here above reported table, before opening the valve.
- Do not use any intermediate connection that can allow the connection of two devices not designed to be connected together.
- Do not stay in front of the valve outlet but always at the opposite side of the pressure reducer, behind the cylinder and well back.
- Open the valve slowly and progressively.
- The CO_2 is a liquefied gas at its vapour pressure. Thus the information supplied by a manometer connected to this device cannot indicate the amount of gas still available in the cylinder (pressure is constant). To define the residual content weighing is necessary.
The net content for the new device is stamped on the cylinder.
- The cap shall be re-screwed after every use and after having checked the valve closure, for all the cylinders provided with it.

Precautions for use

- This device is designed to be used by medical staff properly trained. It can be used by medical assistants only for the preparation for use.
- Use a pressure regulator to deliver the right pressure to the patient.
- Substantial amounts of air may be inflated into the peritoneal cavity from the tubing, if the system is not adequately purged.
- Purge the hose with CO_2 before insertion.
- All residual CO_2 should be removed from the peritoneal cavity once the procedure is finished.

Precautions for the storage

- Keep the cylinder in a well ventilated area, with temperatures between -15 °C and + 50° C.
- The prolonged exposition to temperatures higher than 50°C can cause the rupture of the breaking disk and the expulsion of the gas.
- To avoid damages due to shocks and falls:
- Keep the cylinder in upright position and tight.
- Move the cylinders of > 5 l capacity only with the appropriate cart.
- To avoid contamination leave a residual pressure in the empty cylinder.
- Keep cylinders, even empty, with the valve closed and the protection cap installed (when expected).

Safety information

Not flammable gas.

Read the material safety data sheet.

Protect hands and eyes when handling the cylinder.

In case of eyes and skin contact: Rinse eyes immediately with plenty of water for at least 15 minutes.

In case of frostbite: rinse with water for at 15 minutes.

In any case contact a physician.

Specific risks and potential side effects

In case of spillage in a confined atmosphere: small concentrations cause breathing acceleration.

Concentrations between 8 and 15% cause headache, nausea, vomit and drowsiness that can lead to loose consciousness.
The exposition to higher concentrations cause rapid circulatory failure associated with coma and death.

Known complications of carbon dioxide pneumoperitoneum inlcude:
- subcutaneous emphysema (SE), hypercarbia, pneumothorax, pneuomomediastinum, and embolism.
- Monitor of end-tidal CO_2 concentration is an indicator of development of those side effects.

Additional information

For any additional information or communications, please contact the manufacturer at the address herein reported or your local distributor.

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