Carbon Dioxide, Medical Device

Linde Gas

Instructions for use: Information for the user

Read the entire instructions for use carefully because they contain important information. The instructions for use are an integral part of the medical device and must always be available to the user, e.g., the physician. Before working with the medical device, you must know and understand its function and handling.
Please note that a number of the points listed in this Instruction for Use may also pose a safety risk to the physician / user of Carbon Dioxide. Therefore, it is particularly important that the use of Carbon Dioxide must always be carried out by staff who have been trained with regard to the hazards associated with Carbon Dioxide. For detailed information, see also chapters 5, 6, and 7.

These instructions for use include:

1. Intended Purpose

CO_2 is intended to be used in combination with other medical devices for the following purpose:

- As insufflation gas for surgical and diagnostic endoscopic procedures through body orifices and artificial orifices

2. Intended Clinical Benefits

Medical CO2 has proven to be safe and effective in establishing an adequate visible field in all medical indications described in chapter 4.1.1. It has characteristics of an ideal gas to establish pneumoperitoneum including not flammable or explosive, easily excreted, and completely nontoxic to patients.

3. Intended use environment

Health care offices or institutions
No specific ambient conditions apply, other than those listed under section 6 “Precautions for Transport / Storage”.

4. Indication, Dosage, Method and Duration of Use

4.1 Insufflation Gas

4.1.1 Medical indication

CO_2 gaseous for insufflation to enhance visibility in the following medical procedures:

- Laparoscopy
- Diagnostic hysteroscopy
- Endoscopic vein harvesting in coronary artery bypass operations
- Other endoscopic applications

4.1.2 Intended patient population

CO2 can be used for general population undergoing surgical or diagnostic endoscopic procedures through body orifices or artificial orifices. Limitations are determined by patient conditions and clinical predispositions as described in the “Contraindication” and “Precaution” sections of the IFU.

There are no known additional undesirable effects in the paediatric or elderly population than in adults.

As a principal, it is suggested that laparoscopy with the use of capnoperitoneum during pregnancy should be performed under strict individual risk benefit consideration and with fetal monitoring.

Breast feeding should not take place during or in close connection with carbon dioxide use.

4.1.3 Dosage and Duration of Use

The amount, speed and duration of insufflation depend on the medical indication and are to be determined individually by the treating physicians.

Repeated applications depend on the amount of applied CO2 in the previous treatment, duration of insufflation and on the individual patient condition. This must be considered individually by the treating physicians. The duration of application is limited according to the classification rule "short-term".

It is recommended that carbon dioxide insufflation of the abdomen, extraperitoneal and preperitoneal spaces and thorax is preferably performed under general anaesthesia with controlled ventilation. When insufflating the abdominal cavity, a pressure-controlled insufflation system should be used, applying the lowest possible intra-abdominal pressure. Hypercapnia should be prevented by appropriate anaesthetic management (e.g., increasing the respiratory minute volume). When insufflating the chest, it is recommended to keep the intrathoracic pressure as low as possible, otherwise mediastinal displacement or acute restriction of cardiac output may occur.

4.1.4 Intended users

Medical personnel (e.g., physicians)
Medical intervention may only be performed by physicians who have experience in the field of minimally invasive surgery and are trained in the handling of CO_2.

Personnel for logistics of the cylinders (e.g., technical personnel, nurses)
No demographic or physical restrictions when working according to the Linde safety data sheet, which means that users should be trained in the handling of CO_2.

4.1.5 Method and application

Insufflation should only be performed by physicians who have experience in the field of minimally invasive surgery. It should be performed with a state-of-the-art insufflation system. The insufflation system should be flooded with CO_2 to reduce the risk of air embolism at the start of insufflation. Ensure that the carbon dioxide is sufficiently preheated and humidified.

5. Contraindications, Warnings, Precautions, Side-Effects

- → Should any incidents or side-effects occur during the use of Carbon Dioxide, which are not described in chapter 5.1.3, these must be reported to the manufacturer Linde.
- → If you notice side-effects that are already described in chapter 5.1.3, you can also report them to the manufacturer Linde.
- → If a serious incident occurs in relation to Carbon Dioxide, this serious incident must be reported immediately to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

5.1 Insufflation Gas

5.1.1 Contraindications

Medical CO_2 must not be used during surgical hysteroscopic procedures because of the increased risk of gas embolism.

Laparoscopy is contraindicated in cases of increased intracranial pressure (tumours, trauma, etc.).

Outside of these cases, the use of CO_2 in laparoscopy does not present any particular contraindications provided that the patient tolerates the increased intra-abdominal pressure without cardiac or respiratory consequences.

5.1.2 Warnings and precautions

→ Before using CO_2 as insufflation gas, the specific risks of the respective medical procedure and the patient-specific risks must be evaluated and considered

→ For laparoscopy, cases of CO_2 retention have been documented, with cardiovascular effects, pneumothorax, emphysema, embolism, hypoxia. Use under medical supervision.

→ In addition, with regard to insufflation, particular caution is required in following medical conditions:
- obstructive or restrictive pulmonary dysfunction
- cardiac insufficiency
- coronary heart disease
- cardiac arrhythmias

→ Patients at risk for gaseous embolism (history of abdominal or pelvic surgery, patients with primary biliary cirrhosis or other diseases of the biliary tract) and patients suffering from heart and/or lung conditions should be monitored closely, and the procedure times should be shortened.

→ Whenever CO_2 is used as insufflation gas, the risk of gas entering the surrounding tissue (emphysema), adjacent cavities (e.g., pneumothorax) and the vascular system (gas embolisms) must be assessed. The lowest effective pressure must be aimed for.

→ Intraoperative factors, including a higher ETCO2 level (i.e., ≥50 mmHg), prolonged operation duration (i.e., ≥200 min) and rapid and higher CO2 insufflation pressure, may account for a pneumothorax.

→ Excessive pressure can cause mechanical damage to the body cavities during insufflation. In this case, the physician must initiate the necessary countermeasures. Excessive carbon dioxide reabsorption during insufflation leads to hypercapnia and acidosis. If respiratory compensation is inadequate or absent, acute life-threatening impairment of circulation and gas exchange may occur, and in rare cases gas embolism may result. In an emergency, the CO2 supply must be stopped immediately,

and appropriate medical treatment must be initiated (adequate volume therapy, intubation and controlled ventilation to maintain or restore normocapnia).

→ Due to the risk of gaseous embolism caused by a pneumoperitoneum, vital parameters of the patients should be monitored continuously.
Always use the lowest-pressure pneumoperitoneum, as this may contribute to less analgesic requirement, shorter hospitalization, decreased patients pain perception and higher satisfaction about surgery as well as possibly limit nausea and vomiting the day after laparoscopy.

→ In hypovolaemic patients, especially in those with haemorrhagic shock, a capnoperitoneum should be inserted with great caution and only after adequate volume substitution, as a deterioration of the circulatory parameters is to be expected.

→ CO_2 insufflation of joint cavities should not be performed in pre-existing fractures because of an increased risk of gas embolism.

→ With the vein harvesting procedure there is a risk of gas embolism with intravascular migration of CO_2. There is also a general risk of clot formation. The influence of CO_2 on clot formation is small. Anticoagulation must be carried out according to the instructions of the attending physician.

→ The intraoperative and postoperative use of a pneumatic compression device and early mobilisation are recommended to prevent deep vein thrombosis in pregnant women.

→ In order to maintain the lung volume taking part in gas exchange and to prevent a reduction of functional residual capacity (FRC) an adequate positive airway pressure / positive end expiratory pressure (PEEP) should be used.

→ Intraoperative monitoring of CO_2 concentrations using capnography is recommended.

→ The active aspiration of gas at the end of the procedure can help to reduce pain on the day of the intervention.

→ Patients undergoing emboli may be either asymptomatic or experience mild symptoms or suffer from complete cardiovascular collapse and/or without clinical sequelae. Clinical signs and symptoms of emboli include chest pain, wheezing, breathlessness, bronchoconstriction, cyanosis, jugular venous distension, right heart failure, tachycardia, bradycardia, arrhythmia, asystole, hypotension, altered mental status, and cardiovascular collapse. For the detection of air emboli, transesophageal echocardiography can be used. During laparoscopic procedures if gas embolism is suspected, the pneumoperitoneum must be released, the gas insufflation should be discontinued and the patient must be placed in the Trendelenburg position.

→ When performing endoscopic procedures in children, CO_2 insufflation should be limited to selected procedures, such as those with higher likelihood of intestinal hyperinflation, peritoneal insufflation, or need for electrocautery.

5.1.3 Side-effects

→ The following side effects are known with the stabilisation and expansion of body cavities:
- CO_2 retention
- Gas embolism
- Emphysema i.e., skin emphysema or scrotal emphysema
- Pneumothorax
- Mediastinal emphysema, pneumoperitoneum, or pneumothorax after accidental endoscopic perforation
- Systemic consequences due to intra-abdominal pressure increase and excessive reabsorption of CO_2
- Abdominal or shoulder pain
- Deep vein thrombosis
- Cardiac and respiratory function impairment
- Nausea, vomiting
- Bloating
- Atelectasis

→ The consequences of an intra-abdominal pressure increase can be:
- Decrease in venous return (associated with reduced organ perfusion),
- Increase in intrathoracic pressure,
- Decrease in cardiac output due to decrease in preload and increase in afterload
- Decrease in pulmonary compliance and limitation of functional residual capacity
- Vagal reactions due to peritoneal distension
- Shoulder pain
- Systemic and pulmonary vascular resistance
- Peritoneal desiccation and damage
- Impaired splanchnic
- Hepatic and abdominal wall perfusion
- Decreased gastric mucosal oxygen saturation
- Pain

→ The consequences of carbon dioxide absorption can be:
Hypercapnia disorders of the acid-base balance (acidosis; cardiac arrhythmias; bradyarrhythmias, cardiac arrest, tachycardia, sympathetic stimulation with centrally triggered vasoconstriction) and lung edema.

→ There is a risk of cooling and lowering of the core body temperature with prolonged insufflation or insufflation of large amounts of CO_2 that can lead to intraoperative hypothermia specially in paediatric patients and patients with increasing age and body mass index.

→ In case of sudden onset of unusual arrhythmias, systolic and/or diastolic murmurs, acute cardiovascular depression or a sudden drop in end-expiratory CO_2 concentration, the presence of a rare gas embolism must be considered.

→ Complications of CO_2 insufflation during laparoscopy:
- Atelectasis
- Rare instances of arrhythmia, bradyarrhythmia, cardiac arrest, bradycardia
- Renal function impairment due to compression of inferior vena cava (a rare complication that was reported only in one study)

→ Side effects CO_2 insufflation during laparoscopy:
- Shoulder-tip pain (STP)

→ Side effects CO2 insufflation during endoscopic thyroidectomy:
- Voice hoarseness (laryngoscopy)
- Emphysema

→ Side effects CO2 insufflation during colonoscopy:
- Abdominal discomfort
- Abdominal bloating and flatulence
- Postoperative ileus
- Anatomic distortion
- Belching

→ Complications of CO_2 insufflation during endoscopy of the gastrointestinal tract:
- Pneumomediastinum
- Pneumoperitoneum

→ Complications of CO_2 insufflation during endoscopic vein harvesting (EVH)
- Pneumoperitoneum/scrotal distension
- Graft injury, intraluminal clot formation, CO2 embolism, systemic CO2 absorption and acute compartment syndrome

→ During insufflation of joint cavities, the resorption of CO_2 is increased with the formation of subcutaneous emphysema.

5.1.4 Interactions

Interaction of Carbon Dioxide with other medication has not been reported.

5.1.5 Pregnancy and lactation

Current available scientific data does not allow a general recommendation on the risk benefit profile during pregnancy and breast-feeding. This is mainly not related to the medical device (CO2) itself as by the procedure. The decision for the use must be taken by the physician under strict consideration of the risk benefit profile of the individual patient.

5.1.6 Trafficability and the operation of machines

No special precautions are necessary.

6. Precautions and Warnings for Transport and Storage

- → The carbon dioxide is supplied in pressurised cylinders. These cylinders contain both gaseous and liquid product.
- → Only store and transport gas cylinders with closed valves and with the protective device provided (e.g., protective cap).
- → Protect the valve from mechanical overstressing.
- → During storage, transportation and use, restrain cylinders using an appropriate means (chains, hooks, etc.) to keep them in a vertical position and prevent them from falling.
- → Store at ambient temperature below 50 °C and do not expose to sunlight or heat, may burst if heated.
- → Store in a clean, well-ventilated room. Gas/vapours are heavier than air. They can accumulate in closed rooms, especially on the floor or in low-lying areas.
- → Therefore, do not place cylinders in stairwells, corridors, passageways and recreation or consumption rooms.
- → Empty and full cylinders must be labelled and stored separately from each other. When storing empty cylinders ensure that the valves are kept shut.
- → Keep out of reach of children.
- → The expiry date is printed on a separate batch label on the cylinder. Do not use the medical device after this date! The expiry date also applies to opened cylinders without restriction. The retest date according ADR requirements of the receptacle is indicated on the neck of the cylinder; the retest date of the test refers exclusively to the possibility of transport by road and does not refer to the expiry date of the product.

7. Safe Withdrawal

7.1 General safety instructions

- → CO_2 may only be removed from upright cylinders. Otherwise, there is a risk of solid carbon dioxide escaping ("dry ice snow").
- → Before opening the valve, pay attention to the valve, it might be cold what can lead to cold burn.
- → Opening the valve abruptly is likely to lead to the liquid phase of the product and therefore introduce the risk of cryogenic burns (cold). In the event of a burn, flush with plenty of lukewarm water. Contact of solid carbon dioxide with skin or eyes leads to frostbite (cold burns) or severe eye damage.
- → Using the product at a high flow rate (> 5 l/min) may cause ice on the cylinders and connections.

→ Ingress of liquid carbon dioxide into application device can cause serious malfunctions.

→ Carbon dioxide is heavier than air. At high concentrations there is a danger of asphyxiation. Use only in rooms with sufficient ventilation to maintain CO2 concentrations within the occupational exposure limits (OELs). Apply only by qualified personnel.

→ In the event of gas escapes, close the leaking valve, ventilate the room well and evacuate it. Never use leaking cylinders and check that emergency measures have been taken.

→ Check the cylinder before use to ensure that it is in perfect condition and suitable for the intended use.

→ Remove the tamper-evident seal from the cylinder; ensure that the cylinder's fitting is clean and free of foreign bodies. Open the cylinder valve slowly until a hissing sound can be heard, then close it immediately (this procedure purges any foreign bodies). Repeat the procedure 2 to 3 times.

→ In case of any abnormalities do not use the product and contact the manufacturer.

→ It should be noted that the gas pressure in the cylinders remains constant regardless of the level of the remaining liquid (57.3 bar at 20 °C) and thus does not allow any conclusion to be drawn about the remaining quantity. As CO2 is a compressed liquefied gas, the weight will decrease quickly as soon as there is no more liquid in the cylinder. Therefore, during use, only the weight of the cylinder can give an indication of the remaining liquid level.

CO_2 is available in pressurised cylinders, for safe withdrawal the following must be observed:

→ Before each use, the compressed gas cylinder must be checked gravimetrically for the amount of CO_2 present.

Safe removal of individual cylinder

The filling quantity (kg) results from the product of the filling factor (0.75) and the specific cylinder volume, stamped on the cylinder shoulder.

Example 2-litre cylinder: 2 l × 0.75 kg/l = 1.5 kg CO_2

Actual weight minus tare weight results in actual quantity of CO_2 available.

Safe removal of bundles

Before use, check the bundle for residual pressure.

Bundle à 12 single cylinders Quantity approx. 450 kg.

Ensure that always a reserve cylinder / bundle is available.

→ Do not lift cylinders by their valves.

→ Never squeeze a cylinder into a holder, into which it is difficult to fit.

→ Misuse of the pressure containers, filling by the user or by third parties and decanting into other cylinders are not permitted. Do not transfer compressed gas from one cylinder to another.

7.2 Operating CO_2 cylinders with a pressure reducer

→ Carbon dioxide is not sterile and not free of particles. For use during laparoscopic surgery, it is recommended to use a single-use 0.22 µm bacteriological filter that is compatible with CO2 (non-sterile gas) and designed for pressures of at least 20 mmHh.

→ CO_2 may only be used after vaporisation (conversion to the gaseous state). Vaporisation is a physical process that takes place automatically in the cylinder or bundle.

→ Check the output connection of the cylinders for cleanliness before connecting the pressure reducer; clean any dirty connections with an oil- and grease-free cloth. Keep the interface between the cylinder and the pressure reducer clean. Check the condition of the seals.

→ Only open cylinder with a pressure reducer connected. Before opening the cylinder valve, check the connected fittings (e.g., pressure reducer, flowmeter) for their closed condition. The pressure reducer must be relieved.
Open the cylinder valve slowly turning to the left, never with force and as far as it will go. Tighten the pressure reducer/flowmeter preferably by hand to avoid damaging the seals.

→ Never stand in front of the valve, but always position yourself on the side opposite the pressure reducer, behind the cylinder and at some distance from it. Never expose the patient directly to the gas flow.

→ At low room temperatures or if intensive use causes the cylinder to cool down, the flow may drop or stop due to insufficient pressure in the cylinder.
In case of heavy icing at the pressure reducer, interrupt the withdrawal and continue to use the cylinder only after it has completely thawed.

→ Close the cylinder valves after use, let the pressure of the pressure reducer drop by holding the flow meter open, close the flow meter and then loosen the adjusting screw of the pressure reducer (not with integrated pressure reducers).

7.3 Fittings and application devices

→ Please verify that your cylinder is intended to provide gaseous CO2.

→ CO_2 must be connected to one or more other medical devices to fulfil its intended purpose.

→ Before use, read the manufacturer's instructions supplied with the equipment or device associated with the medical CO2 and follow the recommendations of the physician or surgeon. In particular, check the suitability and condition of the equipment.

→ The fittings and application devices used must be compatible and approved for the intended use. Use standardised fittings or hoses specifically designed for medical CO2.

→ Connect the cylinder to the associated device:
- Screw fitting: align the fittings on the regulator and the cylinder.
- Clamp fittings: Match the positioning pins to the specific holes.
Screw on the equipment by hand until it cannot be tightened any further (in some cases, using a spanner can damage the seal).
- Before opening the valve, check that the connections have been fitted correctly.
- Open the cylinder valve slowly, without forcing it or opening it fully.
- Always close the cylinder valve after use
- Do not disconnect the connector from the cylinder without first purging the residual compressed gas.

→ Before returning for refilling, remove all accessories, hoses, etc. that were not already connected on delivery.

→ Use standard medical CO2 thread that are designed according to ISO 5145 Gr.2 No.17

→ Gas leak: close the valve and bleed the connection system. If the leak persists, put the cylinder outside and release the gas without attempting to patch or repair the valve. Return the defective cylinder to the manufacturer.

8. Cleaning and Disinfection

→ Before cleaning and disinfection, close the application device and, if necessary, release the pressure from the connected fittings.

→ If exterior cleaning is required, please use only a clean cloth. The cloth can be dry or moistened with clean water. We recommend wipe disinfection of the outer surfaces.

→ For disinfection wipe (not spray) cylinders with 70% solution of Isopropanol (IPA) or 70-75% Ethanol in water or as an alternative wipe (not spray) cylinders with 0.5-1.5% solution of H_2O_2 (hydrogen peroxide) in water. If other disinfection solutions are used, check that they are compatible with brass, plastic materials of the components (including the stickers) and the medical gas.
When the application unit is used in a hospital, the requirements and practices of the hospital hygiene plan must be observed accordingly.

→ Do not immerse the valves in water or other liquids. Do not bring any liquids into the application connections.

→ Only hygienically perfect and clean cylinders (without gross contamination) may be returned.

9. Maintenance, Servicing and Disposal

→ **Error - Cause – Remedy**

Error	Cause	Remedy
Leakage from e.g. - Valve/cylinder connection - Filling connection - Pressure gauge on pressure reducer - Bundle screw connection		Close the cylinder valve/ bundle valve, move the containers to a ventilated area and call your Linde Service.
No gas flow, although the pressure gauge shows that the cylinder is not empty.	1. Cylinder valve is closed. 2. Malfunction	1. Open the valve by turning it anticlockwise. 2. Call the Linde Service.

→ No modifications may be made to the cylinder.

→ Do not carry out repairs on a defective valve. Repair and maintenance may only be carried out by Linde authorised and qualified personnel.

→ Unauthorised maintenance or repair will inevitably lead to the exclusion of liability.

→ Linde cylinders are always to be returned to Linde and not to dispose of them yourself.

10. Further Information

→ Please feel free to contact Linde with any questions or anomalies.

→ Carbon Dioxide as a medical device is classified as class IIa according to Annex VIII of the European Medical Device Regulation 2017/245.

→ Carbon dioxide is a very stable, non-flammable and inert, colourless and odourless gas that is heavier than air and has the following physicochemical properties:

  → Molar mass: 44,010 g/mol

  → Sublimation point at 1.013 bar: 194.65 K (-78,5 °C)

  → Vapour pressure at 20 °C: 57 bar

  → 1 kg of medical gas contains as active ingredient component: carbon dioxide, at least 995 g. The medical device contains no other ingredients.

→ Further product and safety relevant information is available in the corresponding product and safety data sheet.

→ Stay away from MR scanners. The cylinders are not compatible with magnetic fields (MRI).

→ Identification: white cylinder body, grey nosepiece.

→ The cylinder is equipped with a valve, with rupture disc.

11. Labelling

	European Conformity mark of the medical device
	Manufacturer
	Medical Device
	Unique Device Identifier
	Batch number
	Use-by date, Expiry date
	Upper limit of temperature
	Keep away from sunlight
	Caution, warning notice
	Consult instructions for use or consult electronic instructions for use

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