



Field Safety Notice

Dear customer,

We are writing to inform you of a potential safety issue with our product, Medical Carbon dioxide 5L (brand name). Our team has identified a risk that may cause harm to patients, and we believe it is our responsibility to bring this to your attention. Please forward this information to the relevant users of Medical Carbon dioxide at your hospital.

Affected products and how to identify them:

- Medical Carbon dioxide 5L (KOLDIOXID (MEDICINTEKNISK PRODUKT)). Insert label name of impacted product.

Intended medical purpose:

- CO₂ is intended to be used in combination with other medical devices for the following purposes: As insufflation gas for surgical and diagnostic endoscopic procedures through body orifices and artificial orifices.

What is the problem, and in which circumstances it can occur?

- We have identified a few cylinders of medical device Carbon dioxide 5L where the valve of the cylinder could not be opened and used. The concerned valves were closed with a too excessive torque during production and may not be opened with normal force first time.

Hazard/harm associated with the issue:

- If the valve cannot be opened during e.g., laparoscopic surgery, it may disrupt the medical procedure and may cause risk to patient health.

Actions that should be taken by the customer / user in order to prevent risks for patients or users:

- Check immediately or the latest before preparing any medical procedure that all your Medical Carbon dioxide 5L cylinders including all backup cylinders can be opened: The healthcare professional must connect the cylinders to the application device or pressure regulator first and only then verify that the valves can be opened. This should be part of the routine preparation of cylinder set up and include a check of the backup cylinder.

CAUTION!!

The valve must only be opened when connected to a suitable application device or pressure regulator.

- If the valve can be opened, the product can be used without any limitations.

- If the valve cannot be opened, please send the cylinders back to following contact according to the normal routine. Label and quarantine the cylinder to avoid use until return to Linde Gas AB.

Address: (Linde local Customer Service/address)

Replacement cylinders will be sent accordingly.