



Urgent product safety information

200799955

regarding

Karl Storz: Low pressure tube, CO2

2020-02-26

Product description: Low pressure tube, CO2. The low pressure tube serves as a supply line between the central gas supply and insufflation units (article numbers: UI400, UI500, 26432020-1, 26430520-1).

Article numbers: UI001; UI002; UI003;

Serial numbers: all

Sender: Karl Storz SE & Co. KG,
Dr.-Karl-Storz Straße 34,
78532 Tuttlingen, Germany

Addressee:

All users, operators, and safety officers at clinics and hospitals

Identification of the medical devices concerned:

Article	Designation
UI001	Low pressure tube, CO2, 150 cm
UI002	Low pressure tube, CO2, 300 cm
UI003	Low pressure tube, CO2, 600 cm

Description of the problem including the identified cause:

Karl Storz has been informed that the low pressure CO₂ tubes stated above may contain an incorrect component in the connecting plug. The diameter of the component deviates from the specified dimension.

Inadvertently connecting the CO₂ plug to an O₂ connection point may result in a flow of gas under certain circumstances. The CO₂ plug will not engage fully in the O₂ connection point; however, it is possible that, if a misaligned connection is established and tension is therefore exerted on the tube, the plug may become wedged in the connection point, resulting in a flow of gas. If connected correctly, the plug would have to be pushed all the way into the O₂ connection point in order to establish a constant gas flow.

The potentially affected low pressure CO₂ tubes are correctly labeled with CO₂ and, in accordance with the instructions for use, are not intended for use with O₂.

The insufflation of O₂ and the use of HF surgical instruments could cause reversible or irreversible injuries to patients. No such incidents have been reported in connection with this problem to date.

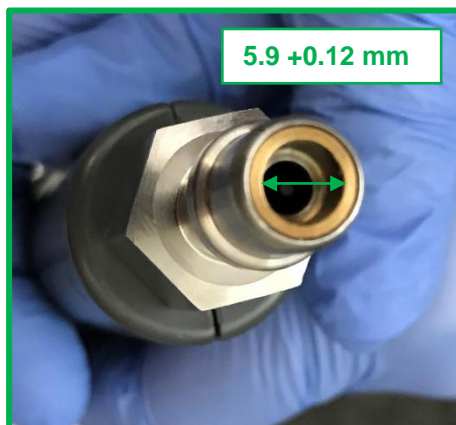


Figure 1: Correct inner diameter
5.9 +0.12 mm

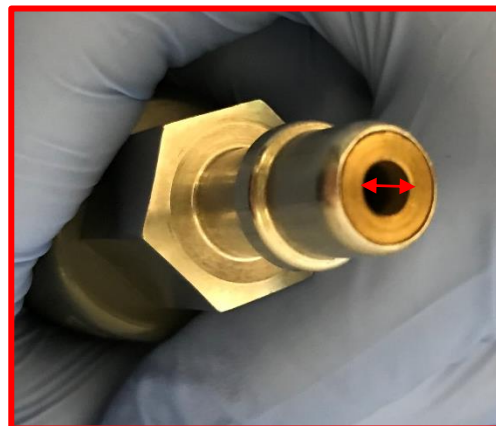


Figure 2: Incorrect inner diameter

What measures are to be taken by the addressee?

According to our records, you have been supplied with at least one of the products stated above and are therefore affected by this action.

Please read this letter carefully and take the following measures:

1. Check your stocks immediately. Locate all potentially affected products and check their inner diameter (see Figure 1). The article number is located on the respective product. Faulty products must be returned to Karl Storz SE & Co. KG. Contact your sales representative/distributor to arrange for a replacement.
2. Forward this product safety information to any internal parties who may be affected.

3. Ensure that these instructions continue to be observed in your facility until all necessary internal measures have been completed.
4. Inform Karl Storz if potentially affected products have been passed on to other facilities.
 - a. Please provide the recipients' contact details so that Karl Storz can provide them with the necessary information.
 - b. Please note that, if you are a distributor, you are responsible for informing the affected customers.
5. Complete the enclosed customer response form. You may no longer have these products in your stocks on site.

Please return the completed form to us so we can update our records. This will also ensure that we do not send you further letters about this subject unnecessarily. Please complete the form and return it to us even if you do not currently have any of the products stated above in your stocks.
6. Send the completed response form to the fax or e-mail address on the form by March 15, 2020.

If you have any questions about this action, please get in touch directly with the contact person listed below.

We hereby confirm that the relevant national authorities in your country have been informed about this safety-related corrective action.

Thank you in advance for your prompt response to this matter. We apologize for any inconvenience caused.

Contact:

Robert Herz
Karl Storz SE & Co. KG
Phone: +49 (0)7461 708 7348 (during business hours)
Fax: +49 (0)7461 708 45581

Sincerely,



p.p.

Robert Herz

Karl Storz SE & Co. KG

Customer response form: 200799955

Karl Storz: Low pressure tube, CO2

Product description: Low pressure tube, CO2. The low pressure tube serves as a supply line between the central gas supply and insufflation units.
Article numbers: UI001; UI002; UI003;
Serial numbers: all
Sender: Karl Storz SE & Co. KG,
 Dr.-Karl-Storz Straße 34,
 78532 Tuttlingen, Germany

Customer no. _____
 Hospital _____
 ZIP, town _____
 Contact person _____
 Phone no. _____

- I confirm that I have read and understood the product safety information 200799955 and that I have implemented it accordingly.
- We do not have any of the listed products in our stocks
- The following products have been identified:

Article no.	Batch	Quantity supplied

Name: _____
 Signature: _____
 Date: _____

We have passed on affected products to the following facilities:

Contact data for facility

Insert customer no.

Please send this form to:
vigilance@karlstorz.com

or

Fax: +49 (0)7461 708 45581

or by post to

KARL STORZ SE & Co. KG
z. H. Robert Herz
- Abteilungsleiter Vigilance -
Dr. Karl-Storz-Str. 34
78532 Tuttlingen, Germany

Insert customer no.