

Urgent Field Safety Notice

Recall: Tubing set, Irrigation, PC,

Article no. 031523-10

Batches: 190930 and 191008

(08/04/2020)

Sender:

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Str. 34
D-78532 Tuttlingen, Germany

Addressee:

All users and operators

Affected products:

031523-10, tubing set, irrigation, PC
Batches: 190930 and 191008

A. Description of the problem including the identified cause:

The affected tubing sets contain a module that codes the application of the tubing set, allowing specific flow and pressure settings in the corresponding pump. With regard to the two affected batches, codes from another application were erroneously included in some of the sets.

B. Description of the corrective action:

Recall of the affected batches

C. Risk for patients, users or third parties when continuing to use this product:

When an application is pre-selected on the pump, an error message will be displayed if an incorrectly coded tubing set is attached.

If the tubing set was already attached before switching on the pump, the application will appear in gray and will not be selectable. However, if a different mode was selected, higher pressures and/or flow rates may be available.

D. Risks for patients who have already been treated with affected products:

No further measures are necessary for patients who have already been treated.

E. Timetable for the action:

Feedback is requested by August 31, 2020

F. What measures are to be taken by the addressee?

Please confirm the receipt of this letter with the enclosed feedback form.

Discontinue use of the affected products!

Please return the affected products to us and enclose a copy of the feedback form. This will make it easier to identify the products and avoid any follow-up questions.

G. Contact

KARL STORZ SE & Co. KG

Robert Herz

Phone: +49 (0)7461 708 7348 (during business hours)

Fax: +49 (0)7461 708 45581

H. Transmission of the urgent field safety notice:

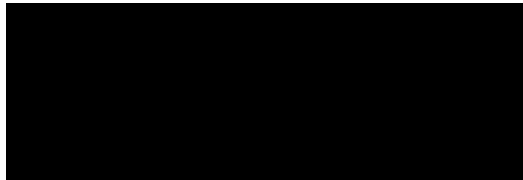
This **urgent field safety notice** must be passed on to all users of the products listed above and all other persons who need to be aware within your organization. If you have transferred these products to third parties, please transmit a copy of this notice or alert the contact listed below. Please keep this notice at least until the corrective action has been fully implemented.

The competent supervisory authority has received a copy of this urgent field safety notice.

We thank you for your cooperation and understanding for this measure.

Sincerely,

KARL STORZ SE & Co. KG



p.p. Robert Herz
- Department Leader Vigilance -

Feedback form

Recall: 200824323

This is a product recall – please only return the products/batches indicated!

We hereby confirm that the safety information has been received and, where applicable, passed on.

The products received have been used as follows:

Article no.	Batch	Received quantity	Consumed quantity	Discarded quantity	Returned quantity
031523-10	190930				
031523-10	191008				

We have passed on affected products to the following facilities:

Contact data for facility

Hospital
or organization (stamp):

I confirm that I have read and understood the safety instruction and that I have implemented it accordingly.

Name: _____

Title/position: _____

Signature: _____

Date: _____

Please send this form to:
vigilance@karlstorz.com

or

Fax: +49 (0)7461 708 45581

or by post to

KARL STORZ SE & Co. KG
Attn: Robert Herz
- Department Leader Vigilance -
Dr. Karl-Storz-Str. 34
78532 Tuttlingen, Germany