
Urgent Field Safety Notice
Recall
regarding
article list / article number / batch

2019-12-23

Sender:
Karl Storz Endoskope 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:
List of articles

Article	Batch	Designation
030247-10	W-027318	Tubing Set, Suction
030247-10	W-027622	Tubing Set, Suction
030247-10	W-029299	Tubing Set, Suction
030247-10	W-028852	Tubing Set, Suction
030247-10	W-029546	Tubing Set, Suction
031123-10	W-029606	Filter, Insufflation
031200-03	W-028530	Insufflation Tubing Set, with Gas Filter
031200-03	W-028538	Insufflation Tubing Set, with Gas Filter
031200-03	W-029601	Insufflation Tubing Set, with Gas Filter
031200-03	W-029596	Insufflation Tubing Set, with Gas Filter
031200-10	W-027781	Insufflation Tubing Set, with Gas Filter
031200-10	W-029053	Insufflation Tubing Set, with Gas Filter
031200-10	W-028738	Insufflation Tubing Set, with Gas Filter
031200-10	W-029058	Insufflation Tubing Set, with Gas Filter
031200-10	W-028726	Insufflation Tubing Set, with Gas Filter
031200-10	W-028592	Insufflation Tubing Set, with Gas Filter
031200-10	W-028702	Insufflation Tubing Set, with Gas Filter
031200-10	W-029048	Insufflation Tubing Set, with Gas Filter
031200-10	W-029561	Insufflation Tubing Set, with Gas

Article	Batch	Designation
		Filter
031200-10	W-029536	Insufflation Tubing Set, with Gas Filter
031200-10	W-029427	Insufflation Tubing Set, with Gas Filter
031222-10	W-027713	Insufflation Tubing Set, with Gas Filter
031222-10	W-027720	Insufflation Tubing Set, with Gas Filter
031222-10	W-027808	Insufflation Tubing Set, with Gas Filter
031222-10	W-028719	Insufflation Tubing Set, with Gas Filter
031222-10	W-028611	Insufflation Tubing Set, with Gas Filter
031222-10	W-027786	Insufflation Tubing Set, with Gas Filter
031222-10	W-028120	Insufflation Tubing Set, with Gas Filter
031222-10	W-028707	Insufflation Tubing Set, with Gas Filter
031222-10	W-029273	Insufflation Tubing Set, with Gas Filter

031222-10	W-029280	Insufflation Tubing Set, with Gas Filter
031322-10	W-027197	Insufflation Tubing Set, with Gas Filter
031322-10	W-028171	Insufflation Tubing Set, with Gas Filter
031322-10	W-027939	Insufflation Tubing Set, with Gas Filter
031322-10	W-028207	Insufflation Tubing Set, with Gas Filter
031322-10	W-029039	Insufflation Tubing Set, with Gas Filter
031322-10	W-029437	Insufflation Tubing Set, with Gas Filter
031322-10	W-029442	Insufflation Tubing Set, with Gas Filter
031322-10	W-029531	Insufflation Tubing Set, with Gas Filter
031322-10	W-029541	Insufflation Tubing Set, with Gas Filter
031322-10	W-029566	Insufflation Tubing Set, with Gas Filter
031432-10	W-029261	Insufflation Tubing Set, with Gas Filter
031432-10	W-028543	Insufflation Tubing Set, with Gas Filter
031432-10	W-029432	Insufflation Tubing Set, with Gas Filter
031532-10	W-026437	Insufflation Tubing Set, with Gas Filter
031532-10	W-026871	Insufflation Tubing Set, with Gas Filter
031532-10	W-027332	Insufflation Tubing Set, with Gas Filter
031532-10	W-028922	Insufflation Tubing Set, with Gas Filter
031532-10	W-028928	Insufflation Tubing Set, with Gas Filter
031532-10	W-028940	Insufflation Tubing Set, with Gas Filter
031532-10	W-028934	Insufflation Tubing Set, with Gas Filter
031622-10	W-029555	Insufflation Tubing Set, with Gas Filter

Description of the problem including the identified cause:
It is suspected that the listed products had increased residues of the sterilization gas ethylene oxide (EO) at the time of delivery because a validation parameter (temperature during outgassing) had not been monitored.

If these products are used further, there is a risk that patients may come into unnecessary contact with ethylene oxide (EO).
Due to the relatively short duration of application and the expected low ethylene oxide exposure to the patient, no further measures are required for patients who have already been treated.

What measures are to be taken by the addressee?
Please read this safety information carefully and forward it to the appropriate places in your organization.
Locate and remove all affected products from your facility. The article number and batch number are located on the respective product and packaging. If the sales carton has been discarded, the products can be identified by the ending -01 in the article number (e.g.: 031222-10 on the carton - 031222-01 on the sterile packaging).
The products must be returned to Karl Storz Endoskope SE & Co KG. You will receive a corresponding credit note.

Please return the attached acknowledgement of receipt by January 15, 2020 to avoid further reminders.

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.

Contact:

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

Sincerely,

p.p. Robert Herz
Karl Storz Endoskope SE & Co. KG

Feedback form for EO recall

We hereby confirm that the safety notice has been received and, in the event that products have been distributed, this safety notice has also been distributed.

The products received have been used as follows:

Article no.	Batch	Received quantity	Consumed quantity	Discarded quantity	Returned quantity

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 Manager Vigilance -
Dr. Karl-Storz-Str. 34
78532 Tuttlingen, Germany

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: _____