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

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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		



	W 000000	Insufflation Tubing Set, with Gas
031222-10	W-029280	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

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## 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	Consumed	Discarded	Returned			
		quantity	quantity	quantity	quantity			
Please send the vigilance@kar								
or								
Fax: +49 (0)74	161 708 45581							
or by post to								
KARL STORZ Attn: Robert H - Department I Dr. Karl-Storz- 78532 Tuttling	erz Manager Vigilar Str. 34	nce -						
Hospital or org	janization (stam	ıp):						
I confirm that accordingly.	I have read a	nd understood	the safety ins	truction and tha	at I have implemente	d it		
Name:								
Title/position:								
Signature:								

Date: