KARL STORZ SE & Co. KG • PO Box 230 • 78503 Tuttlingen/Germany

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Urgent Field Safety Notice: #200862444
Product RECALL
031122-25 – Filter, Insufflation

May 2021

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

Addressee:
Representatives for medical product safety, users, operators, distributors

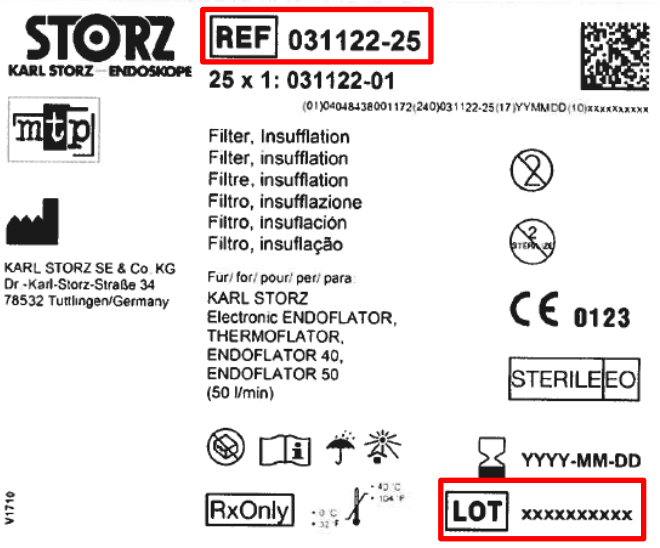
FSCA identification:	200862444
Action type:	RECALL
Affected product:	031122-25 / -01 – Filter, Insufflation
Affected batches:	18L0473FAX
	18L0474FAX
	18L0475FAX
	18L1286FAX
	18L1287FAX
	19C0145FAX
	19D0638FAX
	19E0681FAX
	19E0682FAX
	19J0567FAX
	19K0524FAX
	19K1052FAX
	20A0688FAX
	20A0689FAX
	20B0623FAX
	20C0679FAX
	20E1017FAX
	20E1018FAX
	20F1129FAX
	20F1131FAX
	20F0942FAX
	20F0943FAX

A. Description of the problem including the identified cause:
KARL STORZ was informed about potential deviations of validated parameters for ethylene oxide sterilization at sterilization provider Steril Milano. The deviations affect certain production LOTs of KARL STORZ's Insufflation Filter 031122-25 and occurred between March 2018 and February 2021. These deviations were the subject of circulars by the Italian Ministry of Health, dated 11 March and 30 March 2021.
Affected LOTs which are at KARL STORZ´ stock have been quarantined.
KARL STORZ has conducted sterile testing with products available (LOT 20F0942FAX & LOT 20F0943FAX) and identified that one of two tested LOT (LOT 20F0943FAX) developed bacterial growth. Therefore, it cannot be guaranteed that sterilization was successful on all products that went through the sterilization process at Steril Milano.

B. Identifying affected product:

Primary package label

Secondary package label



C. Description of the corrective action:
Recall of all affected batches.
For replacement, please contact your responsible KARL STORZ representative.

D. Risks for patients/users/third parties if the products are used again:
As it cannot be guaranteed that the products affected are sterile, there is a risk that patient may be exposed to a higher risk of infection. The products of listed LOTs shall no longer be used.

E. Risks for patients who have already been treated with affected products:
To date, no incidents have been reported to KARL STORZ in connection with the above-described problem – the corrective action (RECALL) is a preventive measure.

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

1. Immediately quarantine and discontinue use of associated LOT numbers listed.
2. Pass on this urgent field safety notice to all users of the products listed above and all other persons who need to be aware within your organization.
3. If you have distributed the devices listed, please promptly forward this letter to those recipients, and indicate contact details of the recipient on the feedback form.
4. Return the filled feedback form by Fax or E-Mail to the indicated contact.
5. Get in touch with your KARL STORZ representative to return affected products.

Please keep this notice at least until the corrective action has been fully implemented.
The national competent 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. Christiane Klaiber
Safety Officer Medical Devices
Vigilance
Complaint & Vigilance Management Systems

p. p. Uwe Gölz
Senior Director
Global Quality Excellence
Global Quality Management

This document was created electronically and is valid without signature

Feedback form

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I hereby confirm that the safety information has been received and, where applicable, passed on.
I confirm that I have read and understood the safety information and that it was implemented accordingly.

Contact Information	
Hospital / Organization	
Name / Title	
Telephone	
E-Mail address	

Signature of Receipt and Acknowledgement	Date

The products received have been used as follows:

Article no.	Batch	Received quantity	Consumed quantity	Discarded quantity	Quarantined quantity
031122-25					
031122-25					
031122-25					
031122-25					
031122-25					
031122-25					
031122-25					

We have passed on affected products to the following facilities:

	Facility 1	Facility 2	Facility 3
Hospital / Organization			
Postcode			
City			
Street			
Telephone			
E-Mail			
Contact Person			

Please send the feedback form to:
vigilance@karlstorz.com

or

Fax: +49 (0)7461 708 45581