

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

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

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

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

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

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.

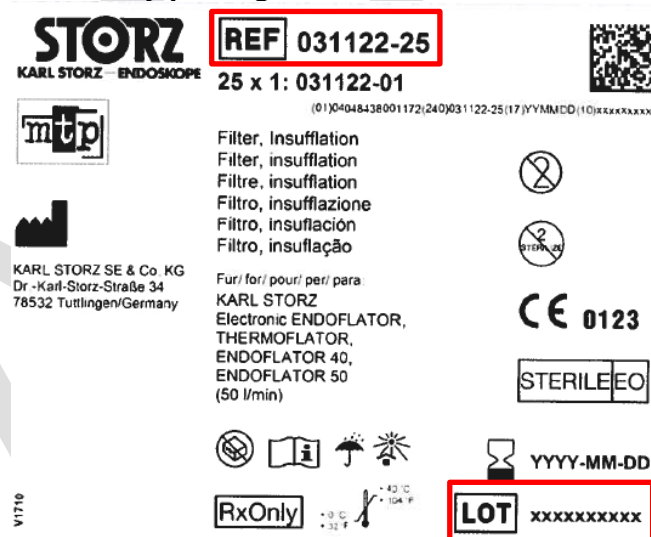
KARL STORZ has conducted sterile testing with products available (LOT 20F0942FAX & LOT 20F0943FAX) and identified that one of two tested LOT (LOT 20F0943FAX) developed bacterial growth. Therefore, it cannot be guaranteed that sterilization was successful on all products that went through the sterilization 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 customer feedback form 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