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

Rev 1: July 2023

FSN Ref: 23-0008 FSCA Ref: PFA-23-0008

Date: 04/07/2023

Urgent Field Safety Notice
Product RECALL
0915612-01 – FIVE S 5.3 x 65, sterile, for single use

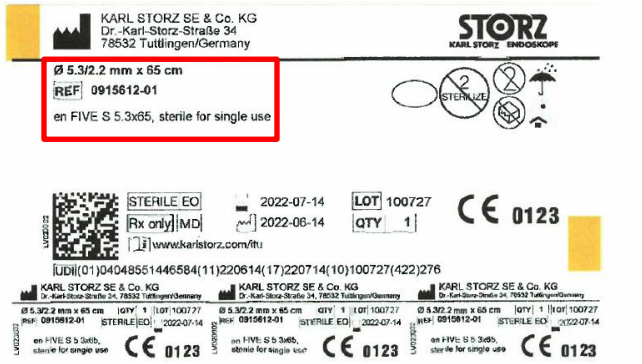
For Attention of: Representatives for medical product safety, users, operators, distributors

Commercial name(s):	0915612-01 - FIVE S 5.3 x 65, sterile, for single use (Pc.) 0915612-06 - FIVE S 5.3 x 65, sterile, for single use (Pck.)
Unique Device Identifier (s) (UDI-DI) :	4048551000064T6
Device Model/Catalogue/part numbers :	0915612-01 0915612-06
Affected serial or lot numbers:	All products with remaining shelf life
FSN Type:	*1st Rev.*

I. Identification of Affected Devices

Flexible intubation endoscopes are intended for endoscopic imaging of the airways, for endotracheal tube placement as well as for bronchoscopy in anaesthesia, intensive care and emergency medicine. Flexible intubation endoscopes with working channel enable insertion of non-active instruments in the airways as well as irrigation and suction.
Flexible intubation endoscopes are invasive (natural body orifice) and are intended for transient use.

0915612-01 - FIVE S 5.3 x 65, sterile, for single use (Pc.)



0915612-06 - FIVE S 5.3 x 65, sterile, for single use (Pck.)

II. Reason for the Field Safety Corrective Action (FSCA)

a. Description of the product problem and background of the issue

Within the revalidation of the sterilization process the revalidation failed.
Thus, there is no evidence available to proof a correct sterilization process for all products which have been sterilized since the last passed sterilization validation in March 2021.

b. Hazard giving rise to the FSCA

Due to a failed revalidation of the sterilization process, there is no proof of the sterility of the products.

c. Risks to patient/user or third parties

The hazardous situation, that a contaminated product is used could lead to the consequence of patient infection.
There is no subsequent risk to user or third parties.

d. Other information relevant to FSCA

To date, no incidents have been reported to KARL STORZ in connection with the above-described issue – the corrective action (RECALL) is a preventive measure.

III. Type of Action to mitigate the risk

a. Action to be taken by the user

1. Immediately quarantine and discontinue use of Material numbers listed above.
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 products listed, please promptly forward this letter to those recipients, and indicate contact details of the recipient on the Customer Reply From.

4. Return the filled Customer Reply Form by Fax or E-Mail to the indicated contact.
5. Get in touch with your KARL STORZ representative to return affected products.
6. Please report any incidents related to this issue to the manufacturer, dealer or local representative and, if applicable, to the national competent authority, as this is important feedback.

b. Action Being Taken by the Manufacturer

Recall of the affected products.

Please return the completed reply form within 15 calendar days from the Date of receipt.

Contact details of local representative (name, e-mail, telephone, address). This could be a distributor or KS subsidiary.

Name: Local contact person
Phone: Local contact person
E-Mail: Local contact person

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

On behalf of KARL STORZ, we thank you for your help and apologize for any inconvenience.

Yours sincerely,

KARL STORZ SE & Co. KG

[redacted]

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