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

Rev 1: March 2024

FSN Ref: 23-0017 FSCA Ref: PFA-23-0017

Date: 19/03/2024

Urgent Field Safety Notice
Product RECALL

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

Article number(s) / Commercial name(s):	**8694 - LASER Application Instrument, 23 cm** **461000 - LEUNIG-GREVERS LASER Application**
Affected serial or lot numbers:	all
FSN Type:	*1st Rev.*

I. Identification of Affected Devices

8694: Laser instrument guides with vapor evacuation are used to guide the provided telescopes and/or instruments (e.g., laser probes) during laser surgery. An integrated channel is used for vapor evacuation. Laser instrument guides are designed for transient use in surgically invasive interventions.

461000: The laser instrument guide with vapor evacuation is used to guide the provided telescopes and/or instruments (e.g., laser probes) during laser surgery. An integrated channel is used for vapor evacuation. The laser instrument guide is designed for transient use in surgically invasive interventions.

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

a. Description of the product problem

It was found that there is insufficient evidence to show that the reprocessing method of the products was adequately validated. This issue affects all lot numbers of the referenced KARL STORZ article numbers.

b. Background of the issue

During the update of the technical documentation, it was determined that there is insufficient evidence of the validation of the reprocessing methods; therefore, the affected products are being recalled.

c. Hazard giving rise to the FSCA

As there is no specific evidence of a validated reprocessing method, once the instruments have gone through reprocessing after use, there is an increased risk of the patient being exposed to an infection. The use of the above-mentioned products should be discontinued.

d. Risks to patient/user or third parties

The use of one of the affected products carries the risk of infection or nosocomial infection for the patient.
There is no further risk for the patient or user.

e. 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 associated part 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 or may have distributed the devices listed, please identify and promptly notify those recipients, or provide KARL STORZ a list of customers who received/may have received the products listed.
4. Return the filled feedback form by Fax or E-Mail to the indicated contact within 15 calendar days from the date of receipt.
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.

It is up to the user to decide on the follow-up of the patients or review of the previous results in the various cases.

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:
Telephone:
E-Mail:

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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