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

Rev 1: November 2023

FSN Ref: 23-0015 FSCA Ref: PFA-23-0015

Date: 29/11/2023

Urgent Field Safety Notice
Product RECALL

615000	BEYER Antrum Punch
615010	Antrum Punch, 65°, 11 cm
615025	Sphenoid Punch, 30°, 11 cm
648500	Sphenoid Punch, 3.2 x 4 mm
648523	Sphenoid Punch, 30°, 1.6 x 2 mm
662797	Galea Spring Hook, 31 cm
723014	Uvula Retractor
723400	Optical Biopsy and Grasping Forceps
11003MB	Grasping Forceps, flexible, 1 mm
26161UH	Working Insert, with steering lever
11540OS	Optical Scissor

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

Commercial name(s):

615000 - BEYER Antrum Punch

615010 - Antrum Punch, 65°, 11 cm

615025 - Sphenoid Punch, 30°, 11 cm

648500 - Sphenoid Punch, 3.2 x 4 mm

648523 - Sphenoid Punch, 30°, 1.6 x 2 mm

662797 - Galea Spring Hook, 31 cm

723014 - Uvula Retractor

723400 - Optical Biopsy and Grasping Forceps

11003MB - Grasping Forceps, flexible, 1 mm

11540OS - Optical Scissor

26161UH - Working Insert, with steering lever

Unique Device Identifier (s) (UDI-DI) :	n/a
Device Model/Catalogue/part numbers :	**615000; 615010; 615025; 648500; 648523; 662797; 723014; 723400; 11003MB; 11540OS; 26161UH**
Affected serial or lot numbers:	all
FSN Type:	*1st Rev.*

I. Identification of Affected Devices

615000; 615010; 615025; 648500; 648523; 662797; 723400: These instruments are intended for use during sinus surgery. They can be used for transnasal access for external skull base surgeries during sinus surgeries, or if transnasal access for other external skull base surgeries is indicated by the attending physician.

723014: For diagnostic use during post-rhinoscopy. Non-invasive use.

11003MB: The medical devices are suitable for use during endoscopic examinations and treatments in bronchoscopy.

11540OS: The scissors are used for cutting tissue in fetoscopy. Scissors are intended for temporary use during invasive surgical procedures. The use of the instrument is indicated when a fetoscopy is ordered by the attending physician.

26161UH: Sheaths are intended to create a working or irrigation channel. Sheaths are surgically invasive and meant for short term use. The medical devices are suitable for procedures in fetal surgery.

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

a. Description of the product problem

It was found that there is not 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 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

i. V. Karim Djamshidi
Vice President
Global Patient Health & Regulatory Compliance

This document was created electronically and is valid without signature