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

Rev 1: October 2024

FSN Ref: 24-0004 FSCA Ref: PFA-24-0004

Date: 17/10/2024

Urgent Field Safety Notice
Product RECALL

28208BKS	**Aggressive Cutter, sterile**
28206CBS	**Full Radius Resector, sterile**
28205NDS	**Aggr. Pro Line Shaver Blade, sterile**
28205FDS	**Round Burr, sterile**
28205HES	**Aggressive Barrel Burr, sterile**
28205GDS	**Finish Barrel Burr, sterile**
28208IDS	**Semi Hooded Barrel Burr, sterile**
28205HDS	**Aggressive Barrel Burr, sterile**

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

Unique Device Identifier (s) (UDI-DI) : n/a
Affected serial or lot numbers: See table in attachment

FSN Type: *1st Rev.*

I. Identification of Affected Devices

The medical devices are suitable for use in minimally invasive investigations and treatments of a joint such as knee joints, shoulder joints, hip joints, small and medium joints (such as elbows, wrists, and ankles). Shaverblades are intended to remove tissue/bone. Shaverblades are surgically invasive and meant for transient use.

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

a. Desciption of the product problem

It was found that there are holes in the sterile barrier system. This issue affects the attached lot numbers of the referenced KARL STORZ article numbers.

b. Backround of the issue

During the update of the technical documentation, it was determined that there are holes in the sterile barrier system; due to the compromised sterile packaging, the affected products are being recalled.

c. Hazard giving rise to the FSCA

Due to the compromised sterile packaging, 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.

Related to this action, no specific follow-ups on patients who have already been treated with products affected are required.

b. Action Being Taken by the Manufacturer

Recall of the affected products.

Artikel	Name	Alternative
28205HES	Aggressive Barrel Burr, sterile	28205HE - Aggressive Barrel Burr
28205HDS	Aggressive Barrel Burr, sterile	28205HD - Aggressive Barrel Burr

Please return the completed (signed and stamped) 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]

This document was created electronically and is valid without signature

Affected LOT numbers:

28208BKS	28206CBS	28205NDS	28205FDS	28205HES	28205GDS	28208IDS	28205HDS
81375N	83233N	83468N	82968N	84978N	82969N	83236N	83219N
84424N	83478N	84074N	84246N	82127N	83245N	83268N	83466N
84813N	84444N	83220N	83460N	86078N	84247N	82133N	84250N
85013N	85877N	84265N	84416N	88756N	84804N	84447N	85184N
86065N	90894N	84410N	84440N	89950N	85880N	85362N	84808N
86387N		85015N	85352N	90679N	85353N	86364N	86084N
88675N		84809N	86057N	90911N	87045N	87863N	86085N
88377N		85357N	87456N	92548N-3	90214N	86807N	86388N
89289N		86362N	86361N	92548N-2	86380N	88483N	86049N
89032N		87048N	86091N	92548N-1	90532N	89033N	87864N
89365N		91382N	87049N	93707N	93023N	89024N	88408N
89635N		93323N	88223N	93027N	91039N	89905N	88481N
89971N			82233N	92955N	95046N	89679N	88767N
90202N			88755N	91032N	95679N	89959N	89027N
93038N			88491N	95051N		90913N	89657N
91838N			89902N	92995N		92551N-2	89949N
			90702N			92552N-1	89957N
			90200N			92552N-2	90510N
			90531N			92551N-1	91490N
			92248N			91318N	93330N
			93022N			93033N	93349N
			96143N			91381N	91031N
			95045N			93086N	90910N
						94862N	91040N
							93026N
							93997N
							93035N