Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 161 **dated** 25/11/24 **Regarding SFDA Recall of Aggressive Cutter, Full Radius Resector, Aggr. Pro Line Shaver Blade, Round Burr, Aggressive Barrel Burr, Finish Barrel Burr, Semi Hooded Barrel Burr, Aggressive Barrel Burr, sterile from (mfr: Karl Storz SE & Co. Kg).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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سلطنة عُمان
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Circular No. 161 / 2024

23 -05-1446 H
25 -11-2024

Recall of Aggressive Cutter, Full Radius Resector, Aggr. Pro Line Shaver Blade, Round Burr, Aggressive Barrel Burr, Finish Barrel Burr, Semi Hooded Barrel Burr, Aggressive Barrel Burr, sterile from Karl Storz SE & Co. Kg.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/167
Product	Aggressive Cutter, Full Radius Resector, Aggr. Pro Line Shaver Blade, Round Burr, Aggressive Barrel Burr, Finish Barrel Burr, Semi Hooded Barrel Burr, Aggressive Barrel Burr, sterile.
Manufacturer	Karl Storez SE & Co.Kg.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Artikel (Name): 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) Please refer to the attachment for the affected LOT numbers.
Reason	It was found that there are holes in the sterile barrier system.
Action	1. Immediately quarantine and discontinue use of associated part numbers listed in the attachment. 2. Contact the local agent to return the affected products.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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

Rev 1: October 2024

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

Date: 14/10/2024

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.

Hausadresse:
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E-Mail: info@karlstorz.com
www.karlstorz.com

Bankverbindungen:
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Kreissparkasse Tuttlingen
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Volksbank Schwarzwald-Donau-Neckar eG
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Kommanditgesellschaft:
KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen/Germany
Sitz der Gesellschaft: Tuttlingen
Handelsregister:
Stuttgart HRA 450442
USt.-ID-Nr. DE 142931059
WEEE-Reg.-Nr. DE 74465858

Persönlich haftender Gesellschafter:
KARL STORZ Verwaltungs SE
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen/Germany
Sitz der Gesellschaft: Tuttlingen
Handelsregister: Stuttgart HRB 762524
Geschäftsführender Direktor:
Karl-Christian Storz
Vorsitzende des Verwaltungsrats:
Dr. h. c. mult. Sybill Storz

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

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

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