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

Rev 1: April 2023

FSN Ref: 23-0002 FSCA Ref: PFA-23-0002

Date: 25/04/2023

Urgent Field Safety Notice
Product RECALL
26196HR – TAKE-APART Bipolar Spring Handle
26184HM – TAKE-APART Bipolar Ring Handle

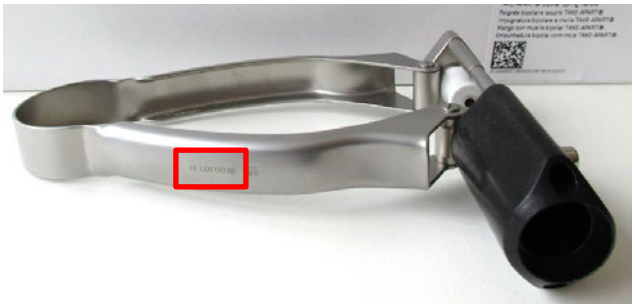
For Attention of: Representatives for medical product safety, users, operators, distributors

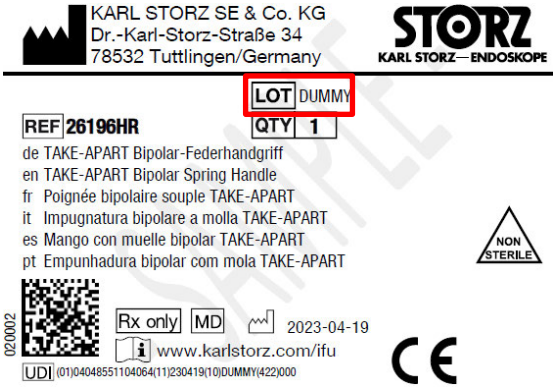
Commercial name(s):	26196HR – TAKE-APART Bipolar Spring Handle	
	26184HM – TAKE-APART Bipolar Ring Handle	
Unique Device Identifier (s) (UDI-DI) :	4048551000787UM	
Device Model/Catalogue/part numbers :	**26196HR**	**26184HM**
Affected serial or lot numbers:	XN01	XN01
	WN02	WN01
FSN Type:	*1st Rev.*	

I. Identification of Affected Devices

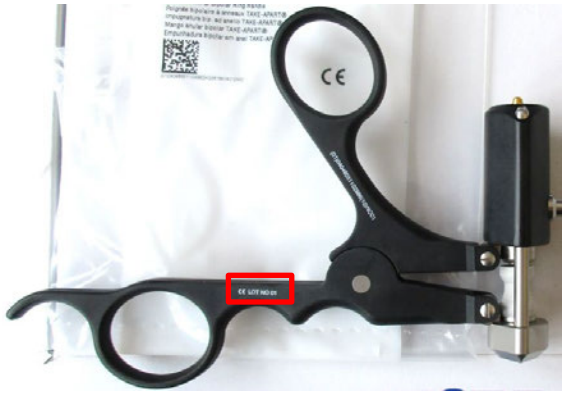
Handles are for using TAKE-APART operating instruments in laparoscopic surgery, gynecology, and urology, in diagnostic and operative thoracic surgery, thyroid surgery (extracervical access), in NOTES, in transanal procedures, and in arthroscopy. Handles are designed for short-term use in surgically invasive procedures. The medical devices are tool-like instruments that are suitable for use during minimally invasive examinations and treatments.

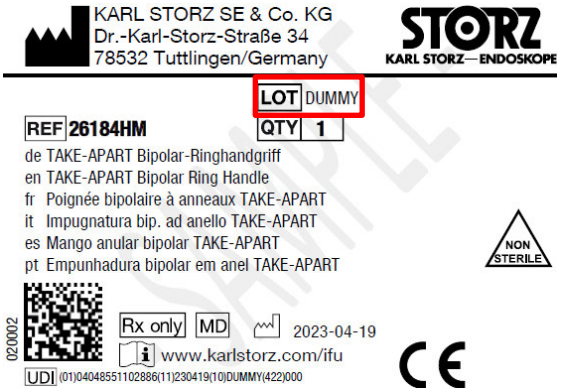
26196HR





26184HM





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

a. Desciption of the product problem

The deviations affect certain production LOTs of the referenced KARL STORZ TAKE-APART Handles.
The mounted instrument cannot reach the mechanical stop position or being pulled inside the shaft too far.

b. Backround of the issue

During quality control in production, it was observed that types of guiding tubes with different lengths were mixed up. Because the mounted instrument cannot reach the specified position, the affected devices are recalled.

c. Hazard giving rise to the FSCA

As the specified position of the instrument cannot be reached, there is a potential for short circuits in combination with HF application and patient and/or user may be exposed to a higher risk of reversible thermal injuries in tissues. The use of the affected TAKE-APART Handles should be discontinued.

d. **Risks to patient/user or third parties**

The use of an affected handle in combination with HF application has a risk of reversible of reversible thermal injuries in tissues to patient and/or user.
There is no subsequent risk to 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 LOT 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 distributed the devices listed, please promptly forward this letter to those recipients, and indicate contact details of the recipient on the feedback form.
4. Return the filled feedback 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.

Since there is no subsequent risk to the patient, no follow-up of patients or review of patient's previous results recommended.

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]
[redacted]
Global Patient Health & Regulatory Compliance

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