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

# Urgent Field Safety Notice: #200862159
# Product RECALL
# 10973HD – Video Mediastinoscope

May 2021

**Sender:**
KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen/Germany

**Addressee:**
Representatives for medical product safety, users, operators, distributors

| | |
|---|---|
| **FSCA identification:** | 200862159 |
| **Action type:** | RECALL |
| **Affected product:** | 10973HD – Video Mediastinoscope, with continuous proximal lateral slit, length 15 cm, for use with IMAGE1 S™ |
| **Affected serial number:** | ALL |

**A. Description of the problem including the identified cause:**
KARL STORZ determined an increased incident rate for the 10973HD – Video Mediastinoscope. Four incident reports where a patient injury and sharp edges on the tip of the device was reported, were received. For the predicate device no incident reports of this nature were received.
Compared to the predicate device, the current device has a changed design on the device tip, see Figure 1. As the tip is chamfered according to specification, the issue was therefore found to be design related.

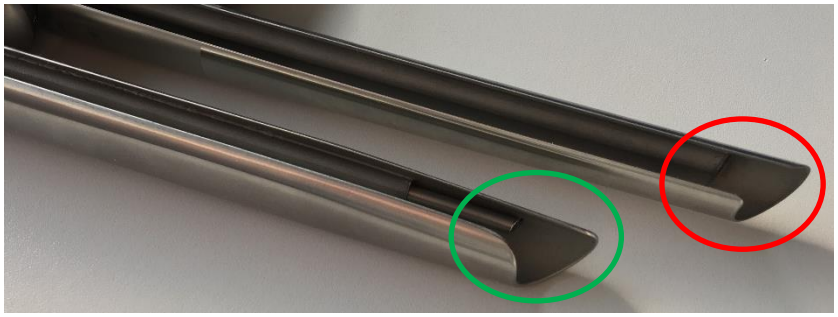
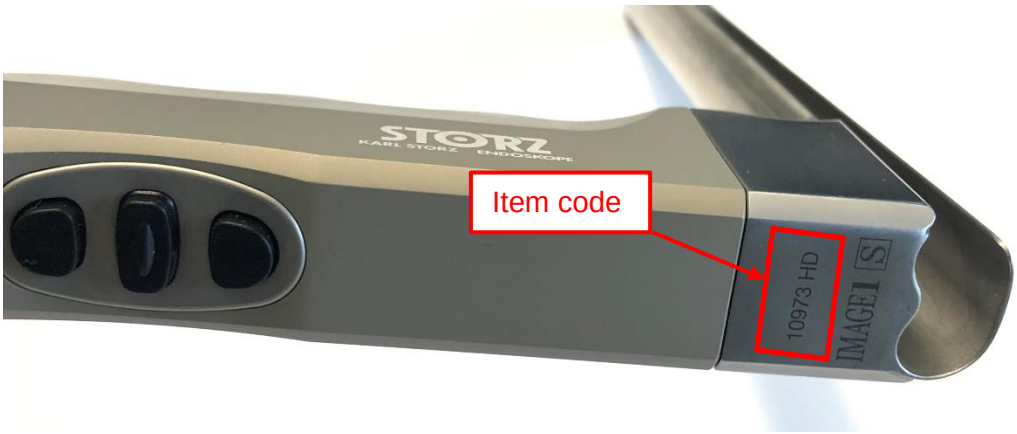


Figure 1: Former design green, current design red

**B. Identification of affected devices:**




**C. Description of the corrective action:**
Recall of all affected products.
For replacement, please contact your responsible KARL STORZ representative.

**D. Risks for patients/users/third parties if the products are used again:**
The current market feedback showed a higher risk of patient injury which included tracheal/bronchial laceration and/or bleeding. Due to the increased risk for injuries the products shall no longer be used.

**E. Risks for patients who have already been treated with affected products:**
No risks for patients who have already been treated successfully with the affected products.

**F. What measures are to be taken by the addressee?**

1. Immediately quarantine and discontinue use of the device.
2. Pass on this urgent field safety notice to all users of the product and all other persons who need to be aware within your organization.
3. If you have distributed the device, 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.

Please keep this notice at least until the corrective action has been fully implemented.
The national competent authority has received a copy of this urgent field safety notice.

We thank you for your cooperation and understanding for this measure.

Sincerely,

KARL STORZ SE & Co. KG

[redacted]

This document was created electronically and is valid without signature

# Feedback form

**Urgent Field safety notice: 200862159**
**Product RECALL**
**10973HD – Video Mediastinoscope**

I hereby confirm that the safety information has been received and, where applicable, passed on.
I confirm that I have read and understood the safety information and that it was implemented accordingly.

| Contact Information | |
|---|---|
| Hospital / Organization | |
| Name / Title | |
| Telephone | |
| E-Mail address | |

| Signature of Receipt and Acknowledgement | Date |
|---|---|
| | |

We have passed on affected products to the following facilities:

| | Facility 1 | Facility 2 | Facility 3 |
|---|---|---|---|
| Hospital / Organization | | | |
| Postcode | | | |
| City | | | |
| Street | | | |
| Telephone | | | |
| E-Mail | | | |
| Contact Person | | | |

Please send this form to:
vigilance@karlstorz.com

or

Fax: +49 (0)7461 708 45581