

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

**Urgent Field Safety Notice: #200873725**  
**Product RECALL**

**091361-06 / 091361-01 – FIVE S 3.5x65, sterile, for single use (Flexible Intubation Video Endoscope)**

12 August 2021

**For Attention of:**

Representatives for medical product safety, users, operators, importer, distributors

**Commercial name(s):** FIVE S 3.5x65, sterile, for single use  
**Device Catalogue/ number:** 091361-06 / 091361-01  
**Affected LOT numbers:** All LOTs with remaining shelf life  
**FSN Type:** New Field Safety Notice  
**FSN Identification number:** 200873725

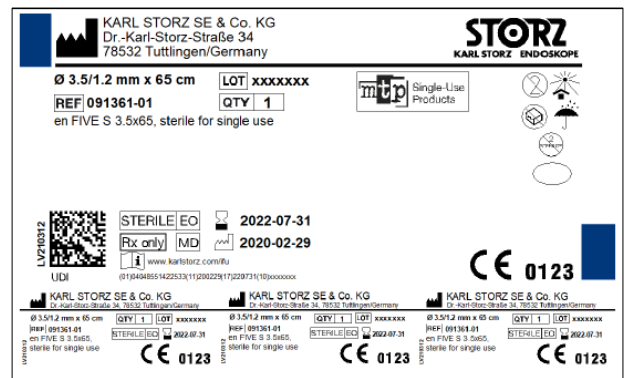
**A. Identification of Affected Devices**

This FIVE S Flexible Intubation Video Endoscope is used for endotracheal/nasal intubation. Intubation endoscopes are used to inspect the upper and lower airways, to check the tube position with double lumen tubes and for monitoring during percutaneous tracheostomy.

**Secondary Package Label**



**Primary Package Label**



**B. Description of the product problem and background of the issue**

For products affected, the required sterility assurance level was not achieved during recent testing of the sterilization process performed by our contract sterilizer. This testing was initiated as a result of a regular requalification review. The affected products therefore may not be "sterile" as claimed.

Office Address:  
KARL STORZ SE & Co. KG  
Dr.-Karl-Storz-Straße 34  
78532 Tuttlingen/Germany  
Phone: +49 7461 708-0  
Fax: +49 7461 708-105  
E-Mail: info@karlstorz.com  
www.karlstorz.com

Bank Accounts:  
Volksbank Schwarzwald-Donau-Neckar eG  
SWIFT: GENO DES1TUT  
IBAN: DE97 6439 0130 0000 7720 03  
Commerzbank AG Tuttlingen  
SWIFT: COBA DE FF 643  
IBAN: DE69 6438 0011 0271 3305 00

Kreissparkasse Tuttlingen  
SWIFT: SOLA DES 1 TUT  
IBAN: DE79 6435 0070 0000 0013 22  
Deutsche Bank AG Tuttlingen  
SWIFT: DEUT DES5653  
IBAN: DE09 6537 0075 0211 6390 00

Limited Partnership:  
KARL STORZ SE & Co. KG  
Dr.-Karl-Storz-Straße 34  
78532 Tuttlingen/Germany  
Place of Business: Tuttlingen  
Commercial Register:  
Stuttgart HRA 450442  
VAT-ID-No. DE 142931059  
WEEE Reg.-No. DE 74465858

Unlimited Partner:  
KARL STORZ Verwaltungs SE  
Dr.-Karl-Storz-Straße 34  
78532 Tuttlingen/Germany  
Place of Business: Tuttlingen  
Commercial Register: Stuttgart HRB 762524  
Managing Director:  
Karl-Christian Storz  
Chair of the Supervisory Board:  
Dr. h. c. mult. Sybill Storz

All units of 091361-06 and 091361-01 with remaining shelf life are within the scope of this corrective action.

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

As sterility cannot be assured for the affected products, there is a risk that the patient may be exposed to a higher risk of infection. As a result, you should discontinue use of the affected products. There are no known or expected long-range consequences for patients already treated successfully. To date, KARL STORZ has not received reports of any infections or other adverse events associated with any affected products.

**D. Action to be taken by the user**

1. Immediately quarantine and discontinue use of the affected products.
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 affected products to third parties, please promptly forward this letter to the recipients of the products and indicate contact details of the recipient on the Acknowledgement and Response Form.
4. Return the Acknowledgment and Response Form to the contact listed below within 10 calendar days of receipt of this notice.
5. Get in touch with your local KARL STORZ representative to return affected products and to discuss suitable alternative products.

**E. Action Being Taken by the Manufacturer**

Affected lots at KARL STORZ facilities have been quarantined and further distribution has been stopped.

This notice must be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Your contact person for this is given below. If you have any questions about this measure, please contact your contact person directly.

Please return the completed reply form within 10 calendar days from the Date of receipt.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

We thank you for your help and apologize for any inconvenience.

Sincerley,

KARL STORZ SE & Co. KG



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**Attachment**  
Customer Acknowledgement and Response Form

## MEDICAL DEVICE RECALL RETURN RESPONSE Customer Acknowledgement and Response Form

Response is Required

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number	200873725
FSN Date	12 August 2021
Product/ Device name	FIVE S 3.5x65, sterile, for single use
Product Code	091361-06 / 091361-01
LOT Number	All LOTS with remaining shelf life

<b>2. Customer Details</b>	
Account Number	
Healthcare Organization Name	
Organization Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
E-Mail	

<b>3. Customer action undertaken on behalf of Healthcare Organization</b>	
By signing this form, I confirm the receipt of the Field Safety Notice and that I read and understood the Recall Notice from KARL STORZ ref: 200873725.	
Print Name	
Signature	
Date	

Please list the quantity of affected product at your facility, if you have no inventory, please tick the box below.

I do not have any affected devices in inventory.

Article No.	LOT Number:	Invoice/Despatch/PO number:	Quantity of pieces to be returned:
091361-06 (6 pcs x 091361-01)			Pieces:
091361-06 (6 pcs x 091361-01)			Pieces:
091361-06 (6 pcs x 091361-01)			Pieces
091361-06 (6 pcs x 091361-01)			Pieces
091361-06 (6 pcs x 091361-01)			Pieces
091361-06 (6 pcs x 091361-01)			Pieces
091361-06 (6 pcs x 091361-01)			Pieces

Please do not send goods before having received return permission and documentation.

Please complete this form and return it to the following contact even if you have no inventory within 10 calendar days of receipt:

**E-Mail <<local E-Mail address>>**

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.