Rev 1: April 2022

FSN Ref: 22-0002

Date: April 1, 2022

Urgent Medical Device Recall Notice
Certain KARL STORZ Flexible Endoscopes for ENT and Bronchoscopic Use

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

Commercial name(s):	See Appendix
Device Model/Catalogue/part numbers :	See Appendix
Affected serial numbers:	All serial numbers of devices listed
FSN Type:	New FSN, Ref.: 22-0002

I. Identification of Affected Devices

The flexible endoscopes subject to this notice are single channel endoscopes with an attached T-Luer that are intended for various ENT and bronchoscopic indications for diagnostic and therapeutic use and that contain recommended methods of high-level disinfection in their instructions for use.

II. Reason for the Medical Device Recall Notice

a. Description of the product problem

This Recall notice describes a labeling update to correct the instructions for use for certain flexible endoscopes (bronchoscope and nasopharyngolaryngoscope) described in the Appendix and advise that high-level disinfection should not be used as a method of reprocessing. Customers that do not have access to a sterilization method recommended in the applicable instructions for use for these endoscopes should discontinue use of the endoscopes and return them to KARL STORZ as described below.

b. Background of the issue

Supplemental validation testing of the efficacy of the manual high-level disinfection process was performed. Testing showed that the required efficacy level of disinfection was not achieved. To the extent included in the current applicable instructions for use, the following methods are being removed as reprocessing methods from the instructions for use of the affected endoscopes.

- Manual High-Level Disinfection:
  - Cidex-OPA
  - Revital-Ox™ RESERT® (e.g., 2.0% Accelerated Hydrogen Peroxide solution)

- Automated High-Level Disinfection via an Automated Endoscope Reprocessor:
  - Medivators AER
  - Reliance EPS
  - EvoTech ECR

c. Hazard giving rise to the notice

As the efficacy of the manual high-level disinfection process cannot be assured for the affected products, there is a risk that the patient may be exposed to a higher risk of infection. You should discontinue use of high-level disinfection as a method of reprocessing the affected endoscopes.

d. Risks to patient/user or third parties

The use of a flexible endoscope that is incompletely reprocessed with an ineffective disinfection phase has a potential to transmit a patient infection.

III. Type of Action to mitigate the risk

a. Action to be taken by the user

1. Immediately **discontinue the use of all high-level disinfection methods** for reprocessing the affected endoscopes.
2. The affected endoscopes should be **sterilized after each** use by one of the sterilization methods recommended in the instructions for use specific to each endoscope.
3. If your facility does not have access to a sterilization method recommended in the applicable instructions for use, immediately discontinue use of the affected endoscopes. *KARL STORZ will provide you with instructions for returning your endoscopes upon receipt of your completed Acknowledgment Form.*
4. Ensure that all relevant personnel in your organization review this Urgent Medical Device Recall Notice. To help ensure that the affected endoscopes are sterilized after each use, please direct the personnel responsible for reprocessing in your organization to maintain and rely upon this Urgent Medical Device Recall Notice in the same manner that they would other reprocessing instructions until updated instructions for use are available for the affected endoscopes.
5. KARL STORZ anticipates that updated instructions for use for affected endoscopes reflecting the changes described in this Urgent Medical Device Recall Notice will be available by April 18, 2022 at https://spwebspace.karlstorz.com/sites/HLDCorrection/SitePages/Home.aspx . Once the updated instructions for use are available, please discard any prior versions of the instructions for use for the affected endoscopes that you may possess.
6. If you have sold or transferred any of the affected endoscopes to third parties, please promptly forward this letter to all such third parties.
7. Please legibly complete the enclosed Acknowledgment Form and return it as soon as possible via the contact information specified on the form.

b. Action being taken by the manufacturer

KARL STORZ is updating the instructions for use of the affected endoscopes to remove all high-level disinfection methods. These updated instructions for use will be made available as described above.

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

Please notify KARL STORZ of any adverse events or quality problems associated with your use of the affected endoscopes. Adverse events or quality problems may also be reported to FDA's MedWatch Adverse Event Reporting program.

If you have any questions regarding this action, please use the contact information provided below:

Telephone: 1-888-352-9616
Fax: 1-888-912-7088
E-Mail: karlstorz7041@sedgwick.com

On behalf of KARL STORZ, we thank you for your help and apologize for any inconvenience.

Sincerely,

KARL STORZ Endoscopy-America, Inc.

ACKNOWLEDGMENT FORM

Urgent Medical Device Recall Notice – 22-0002

Please complete this form and return it to us by faxing it to 1-888-912-7088 or emailing it to karlstorz7041@sedgwick.com. Please check all applicable boxes.

☐ I confirm that I have read and understood the "Urgent Medical Device Recall Notice" and completed all actions requested.

Check one of the two boxes below.

☐ My facility will sterilize the affected flexible endoscopes after each use by one of the sterilization methods recommended in the applicable instructions for use and will implement a procedure to ensure the affected scopes are sterilized and not reprocessed through high-level disinfection.

☐ My facility does not have access to a sterilization method recommended in the applicable instructions for use and will discontinue use of the affected scopes.

Number of scopes to be returned:_____

Upon receipt of your completed Acknowledgment Form, KARL STORZ will provide you with instructions for returning your endoscopes.

Check one of the two boxes below.

☐ My organization has previously sold or transferred one or more of the affected flexible endoscopes to a third party, and I have forwarded the "Urgent Medical Device Recall Notice" to all such third parties.

☐ My organization has not sold or transferred any of the affected flexible endoscopes to a third party.

Contact Information:

Facility Name	
Address	
Contact Person & Title	
Signature	
Phone	
Email	

APPENDIX
Affected Endoscopes

Scope Base Part Number	Scope Kit Number	Product Description	Current IFU
11001RD1	11001RDK1	KARL STORZ Slim Nasopharyngolaryngoscope	96216006US V5.0 (10-2018)
11005BC1	11005BCK1	Flexible Bronchoscope	Z21493US-BA (06/2019)