



FUJIFILM Medical Systems, USA Inc., Endoscopy Division

January 13, 2017

MEDICAL DEVICE REMOVAL

ED-250XL5/XT5 and ED-450XL5/XT5 Duodenoscopes

Dear Valued Customer:

The purpose of this letter is to advise you that FUJIFILM Medical Systems, USA Inc., Endoscopy Division (FMSU-ESD) is conducting a product removal of all duodenoscope models ED-250XL5, ED-250XT5, ED-450XL5, and ED-450XT5 in the United States. These devices are indicated for the visualization of the duodenum and upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum. After discussions with the U.S. Food and Drug Administration (“FDA”), FMSU-ESD has made a business decision to replace these older duodenoscope models with the currently marketed model, the ED-530XT. This removal will result in the exclusion of these legacy models from the scope of the FDA 522 order. As a result of this product removal, FMSU-ESD is hereby requesting the return of all 250 and 450-series model duodenoscopes from your facility.

FMSU-ESD will replace all returned units with a new ED-530XT, along with required accessories, at no cost to you. Alternatively, reasonable reimbursement for the return of the duodenoscopes may be provided to you.

The affected model and serial numbers are listed in the table below.

Product	Model Number	Serial Number
Duodenoscope	ED-250XL5	ALL
Duodenoscope	ED-250XT5	ALL
Duodenoscope	ED-450XL5	ALL
Duodenoscope	ED-450XT5	ALL

PLEASE NOTE: NO OTHER FMSU-ESD PRODUCTS ARE INVOLVED IN THIS REMOVAL.

It should be noted that FMSU-ESD is not conducting this product removal due to a known safety risk. FMSU-ESD has not received any recent reports of adverse events associated with these legacy scopes; nevertheless, the company has made the business decision to undertake this action for the purposes of providing all U.S. users with the company’s most recent model of duodenoscope, which



also includes the company's latest cleaning and reprocessing guidelines. It should be noted that this administrative action is limited to the U.S. market.

Please check with your Endoscopy Department Head and / or Risk Management to determine if you have any affected product. Please remove any affected product from circulation and return it to FMSU-ESD in accordance with the instructions provided below. FMSU-ESD will either replace the product free of charge with its currently marketed duodenoscope model, the ED-530XT, or provide reasonable reimbursement for the returned duodenoscopes within 60 days of the date the endoscopes are received at FMSU-ESD.

Please complete the enclosed tracking/verification form and return it scanned to FUJIFILM Medical Systems USA, Inc., Endoscopy Division (FMSU-ESD):

- via e-mail to scontreras@fujifilm.com;
- via fax to (973) 872-4723; or
- via mail to:

**FUJIFILM Medical Systems USA, Inc., Endoscopy Division
Sarah Contreras, Quality Systems Manager
10 High Point Drive
Wayne, NJ 07470**

You must complete and return this form even if you do not have any affected product. Your local sales representative can assist you in completing this form and returning any affected product. Returning the affected product and providing the information requested on the tracking/verification form is essential for maintaining removal effectiveness information required by FDA.

If you would like to set up a site visit with our Field Support team to have an in-service, please make arrangements via email at: fmsuesdin-service@fujifilm.com.

Thank you for your support. Please contact your FMSU-ESD sales representative if you have any questions regarding this removal, any of our products, or if you would like assistance.

We regret any inconvenience that this action may cause, but we appreciate your understanding, as we are taking this action for purposes of ensuring customer satisfaction.

Sincerely,

**Sarah Contreras
QS Manager
Enclosures**



STEPS FOR REMOVAL of

ED-250XL5/XT5 and ED-450XL5/XT5 Duodenoscopes

The Tracking/Verification Form attached to this letter must be completed and returned even if you do not have any affected product.

- 1. Segregate the Product.** Please immediately remove **all** aforementioned product from circulation.
- 2. Contact FMSU-ESD Customer Care,** at (800) 385-4666, option 1 to obtain a Return Merchandise Authorization number.
- 3. Complete the Tracking/Verification Form.** Complete and return the enclosed tracking/verification form (even if you do not currently have any of the affected product). Your FMSU-ESD sales representative can assist you in completing the form.
- 4. Return the Tracking/Verification Form** via e-mail to scontreras@fujifilm.com, via fax to (973) 872-4723 or via mail to FMSU-ESD, Sarah Contreras, QS Manager, 10 High Point Drive, Wayne, NJ 07470. Please include the RMA number, as applicable.
- 5. Package the Returned Goods.** Package the ED-250/450 duodenoscope(s) that are being returned in an appropriate shipping box. Place a copy of the completed Tracking/Verification Form in the box, appropriately seal the box, and send it on or before March 31, 2017 to:

Attention: Sarah Contreras, QS Manager
FMSU-ESD
10 High Point Drive,
Wayne NJ 07470
- 6. Receipt of New Model.** Customers will receive a replacement model ED-530XT or reasonable reimbursement within 60 days of the time the endoscopes are received at FMSU-ESD.



Tracking/Verification Form for Effectiveness Check

PLEASE FILL OUT AND RETURN

(via e-mail to scontreras@fujifilm.com)

Product	Model Number	Serial Number <i>(list endoscope serial numbers on hand)</i>
Duodenoscope	ED-250XL5	
Duodenoscope	ED-250XT5	
Duodenoscope	ED-450XL5	
Duodenoscope	ED-450XT5	

- 1. We do not have any stock of the affected product.
- 2. We have _____ product(s) that will be returned to FUJIFILM Medical Systems USA, Inc., Endoscopy Division.

Please include the RMA Number(s): _____

- 3. We have read and understand the removal instructions provided in the January 13, 2017 letter. We acknowledge that FUJIFILM Medical Systems USA, Inc., Endoscopy Division will provide a model ED-530XT duodenoscope or reasonable reimbursement within 60 days, as selected below. Please check one:
 - Reasonable reimbursement
 - A replacement endoscope, model ED-530XT

ACCOUNT NAME: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP CODE: _____

PRINTED NAME: _____

TITLE: _____

SIGNATURE: _____

DATE: _____