July 21, 2017

FUJIFILM Medical Systems U.S.A., Inc., Endoscopy Division

URGENT MEDICAL DEVICE CORRECTION AND REMOVAL

RE: Fujifilm Duodenoscope Model ED-530XT
Replacement of Forceps Elevator Mechanism, Distal End Cap, and New Revision of Operation Manuals

ATTENTION: Endoscopy Department, Infection Control and Reprocessing Unit at Health Care Facilities

Dear Health Care Professional:

This letter is to inform you that FUJIFILM Medical Systems U.S.A., Inc., Endoscopy Division ("FMSU-ES") is conducting a voluntary recall affecting Fujifilm’s duodenoscope model ED-530XT. This action includes replacement of the ED-530XT forceps elevator mechanism and O-ring seal, replacement of the distal end cap, and new Operation Manuals.

The ED-530XT duodenoscope is a medical endoscope intended for the visualization of duodenum and upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

The FDA cleared the updated design and labeling for the ED-530XT on July 21, 2017. The updated design and labeling were implemented in an abundance of caution to help reduce the potential risk to health that may be associated with inadequate reprocessing of the device. Pursuant to this clearance, FMSU-ES is providing you updated ED-530XT Operation Manuals (Operation and Preparation: 202B1237697H 160819-9.0-DT-US2 and Cleaning, Disinfection and Storage: 202B1259902E 160819-6.0-DT-US2). Please remove and replace all current manuals and destroy old ones upon receipt of the new manuals.

FMSU-ES will contact all customers that have the duodenoscope by October 2017, with details for returning the ED-530XT for replacement parts. These updates are consistent with FDA’s recent clearance of ED-530XT under 510(k) number K152257.

Providing the information requested on the Field Action Verification Form is essential for making sure any ED-530XT duodenoscopes at your facility are returned for appropriate replacement parts. Please contact your FMSU-ES sales representative if you have any questions regarding this field action.
This field action plan also allows continued use of your current ED-530XT until you are contacted by FMSU-ES for replacement parts as early as October 2017. While remediation of the scopes will take approximately two weeks to complete, FMSU-ES will provide interim duodenoscopes on loan for continuity of care.

Once received, FMSU-ES will replace the forceps elevator mechanism with O-ring and the distal end cap at the FMSU-ES service center in Wayne, NJ. Materials and processes used to update the ED-530XT duodenoscopes are consistent with FDA’s recent clearance of ED-530XT (K152257). Once this recall is closed, FMSU-ES will make any necessary recommendations for future maintenance of these devices.

The new ED-530XT Preparation and Operation Manual (202B1237697H 160819-9.0-DT-US2) differs from the prior revision in that it contains the following:

- Requirement for the users to send their ED-530XT duodenoscope once a year for annual inspection of forceps elevator mechanism to properly maintain the device. This information can be found in Chapter 1 Safety, Section 1. Precautions in Using Endoscope, subsection 5) Annual return and inspection on page 1-3 of the manual.

The new ED-530XT Cleaning, Disinfection and Storage (CDS) Manual (202B1259902E 160819-6.0-DT-US2) differs from the prior revision in that it contains the following:

- Requirement for the users to send their ED-530XT duodenoscope once a year for annual inspection of forceps elevator mechanism to ensure proper maintenance of the device. This information can be found in the Important Safety Information on page 2 of the CDS manual.

- Recommendation for preconditioning the product at defined temperature and humidity parameters prior to the optional use of ethylene oxide on page 9-3.

NOTE: This action is specific to the ED-530XT.

Fujifilm regrets any inconvenience that this action may cause and appreciates your understanding and cooperation. This action is being undertaken to ensure the highest level of patient safety and customer satisfaction. You may contact me directly at (973) 686-2479 if you have any further questions regarding this field action.

Sincerely,

Larry Picciano
Sr. Director Quality and Regulatory Affairs

Enclosures
In addition, the following steps should be followed upon receipt of this letter; the information in the form will be used to schedule the future return of any ED-530XT duodenoscope at your facility for appropriate replacement parts.

**STEPS FOR RECALL OF FUJIFILM ED-530XT DUODENOSCOPE**

1. **Acknowledge this notice.** Check on the attached Field Action Verification Form to indicate you have read and understand this recall.

2. **Indicate if you do NOT have any affected duodenoscopes or Operation Manuals** by checking item 2 on the attached Field Action Verification Form.

3. **Upon receipt of enclosed new Operation Manuals,** remove and replace any older operation manuals from your facility, and destroy and dispose of properly. Update the attached Field Action Verification Form when you have completed this step.

4. **Identify affected products in your facility.** Using the attached Field Action Verification Form, please identify the number of ED-530XT duodenoscopes at your facility and document their respective serial numbers. Your FMSU-ES sales representative can assist you in completing the form if necessary. It is important to appropriately document any ED-530XT duodenoscopes so that FMSU-ES can schedule future return for replacement parts.
ED-530XT Field Action Verification Form
Product Identification and Operators Manual Replacement

Please check/complete the appropriate response(s):

☐ We have read and understand the field action described in this letter.

☐ We do NOT have the affected product and/or superseded versions of aforementioned Operation Manuals in stock or on hand.

☐ We have received new Operation Manuals and we have destroyed and properly disposed of superseded versions.

☐ We have duodenoscope(s) that are affected and understand that FUJIFILM Medical Systems U.S.A., Inc., Endoscopy Division will request for return and upgrade of these later in 2017.

<table>
<thead>
<tr>
<th>Product</th>
<th>Model Number</th>
<th>Number of Units</th>
<th>Serial Number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duodenoscope</td>
<td>ED-530XT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ACCOUNT NAME: ____________________________________________

ADDRESS: __________________________________________________

CITY: ____________ STATE: ________ ZIP CODE: ________________

NAME (PRINT): __________________________ SIGNATURE: ___________

TITLE: ________________________________ EMAIL: __________________

TEL.: _______________________________ DATE: _________________