Field Safety Notice Reference: FSN 20160602 ED-530XT Duodenoscope

URGENT FIELD SAFETY CORRECTIVE ACTION

FUJIFILM ED-530XT Duodenoscope

Dear Customers,

This letter is to advise you of the revised FUJIFILM Operation Manuals for the FUJIFILM ED-530XT and ED-530XT8 Duodenoscope (hereinafter "ED-530XT"). The ED-530XT is a medical endoscope for the duodenum and upper GI tract. It is intended for observation, diagnosis, and endoscopic treatment of the esophagus, stomach and duodenum.

FUJIFILM is providing all users of the ED-530XT with revised Operation Manuals and samples of new disposable distal end cleaning brush. The Operation Manuals have been revised to reflect newly validated manual cleaning and high-level disinfection procedures.

This action is being taken as a result of publicized reports of multi-drug resistant bacteria on endoscopes used for Endoscopic Retrograde Cholangiopancreatogram (ERCP) procedures. Given these reports and in an abundance of caution, FUJIFILM and FUJIFILM Medical Systems, U.S.A., Inc. have been working with the U.S. Food and Drug Administration ("FDA") to validate the reprocessing procedures that are provided in the revised Operation Manuals.

Comprehensive revisions, as described below, have been made to the ED-530XT Operation Manuals, "Preparation and Operation" and "Cleaning, Disinfection and Storage." These revisions modify the cleaning and disinfection processes and require the use of a new disposable distal end cleaning brush [Model WB1318DE] to be used for the cleaning of the duodenoscope's distal tip, forceps elevator and elevator recess, in addition to the usage of the existing Fujifilm valve cylinder cleaning brush [Model WB11002FW2]. Three samples of WB1318DE disposable distal end brush and one sample of WB11002FW2 valve cylinder cleaning brush are being provided per scope model along with this Field Correction letter and a copy of the revised ED-530XT Operation Manuals containing FUJIFILM reprocessing recommendations. You can purchase additional new disposable distal end brushes [Model WB1318DE] and valve cylinder cleaning brushes [Model WB11002FW2] from your local sales representative.

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Below are the main differences in the revised ED-530XT manual reprocessing (cleaning and high-level disinfection) procedures:

Pre-Cleaning

- *During immersion of the scope tip in detergent solution, move the forceps elevator back and forth and aspirate detergent solution while the forceps elevator is raised and while lowered.*

Manual Cleaning

- *Additional brushing of the distal tip, forceps elevator and elevator recess first using the existing Fujifilm valve cylinder cleaning brush [Model WB11002FW2] and then using the new [Model WB1318DE] disposable cleaning brush.*
- *Additional flushing of detergent and rinse water onto the forceps elevator/recess while the elevator is both raised and lowered.*
- *Additional flushing steps and increased channel flushing volumes of detergent and rinse water.*

Manual High-Level Disinfection

- *Additional flushing of disinfectant and rinse water onto the forceps elevator/recess while the elevator is both raised and lowered. Additional raising and lowering of the elevator while immersed in disinfectant solution and rinse water.*
- *Additional flushing steps and increased flushing volumes of disinfectant and rinse water through the scope's internal channels.*

The revised reprocessing techniques were developed and validated in accordance with FDA's recommendations set forth in its March 17, 2015, guidance document entitled, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*.

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One copy of each of the revised Operation Manuals, three samples of the disposable distal end cleaning brush [Model WB1318DE] and one valve cylinder cleaning brush [Model WB11002FW2] are included with this notice. Additional copies of the manuals and brushes can be requested through your local sales representative.

All prior versions of the Operation Manuals for the ED-530XT are superseded by these revised Operation Manuals and shall be disposed. Please check with your facility's applicable supply departments to determine if you have any copies of the superseded operation manuals.

Please complete the enclosed customer feedback form and return it via e-mail or fax.

Please note that you must return the completed form even if you do not have any Operation Manuals to dispose. This information is essential in order to maintain recall effectiveness information.

FUJIFILM's endoscopy distributor has a dedicated team of Clinical Specialists (CS) who visit customer facilities and perform reprocessing in-servicing and training. If you would like to set up a site visit with our CS team to have an in-service regarding these updated FUJIFILM duodenoscope reprocessing instructions, please contact your local sales representative.

Thank you for your support. Please contact your local sales representative if you have any questions regarding this field correction, any of our products, or would like assistance.

We regret any inconvenience that this action may cause, but we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Yours sincerely,
FUJIFILM

Aquilant Endoscopy
Aquilant House, Unit B1-B2, Bond Close, Kingsland Business Park, Basingstoke, Hampshire, RG24 8PZ, England - Tel.: 01256 365 456

FIELD SAFETY NOTICE

Product: Duodenoscope
- ED-530XT
- ED-530XT8

Type of Action: Notification of the instruction manual revision

Dear Customers,

FUJIFILM is issuing this Field Safety Notice for Duodenoscope ED-530XT and ED-530XT8.
This Field Safety Notice is intended to inform you about the following:

- what the problem is
- the actions that should be taken by the customer/user

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Description of the problem

This action is being taken as a result of publicized reports of multi-drug resistant bacteria on endoscopes used for Endoscopic Retrograde Cholangiopancreatogram (ERCP) procedures. Given these reports and in an abundance of caution, FUJIFILM and FUJIFILM Medical Systems, U.S.A., Inc. have been working with the U.S. Food and Drug Administration ("FDA") to validate the reprocessing procedures that are provided in the revised Operation Manuals.

Actions to be taken by customer/user

1. **Segregate the Product.** Please do not use the affected endoscopes until all superseded operation manuals have been taken away from your inventory (regardless of their location). Please dispose these old manuals.
2. **Complete the Customer Feedback Form.** Complete and return the Customer Feedback Form (even if you do not currently have any of the superseded operation manuals to dispose).
3. **Return the Complete Customer Feedback Form**
   via e‐mail or fax

FUJIFILM is committed to providing products and services of the highest quality. Your satisfaction with FUJIFILM products and with our response to this issue is very important to us.
If you have any questions about this matter, please contact your local FUJIFILM office.

Yours sincerely,
FUJIFILM

Aquilant Endoscopy
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FIELD SAFETY NOTICE

Customer Feedback Form

Please complete this feedback form and fax or email it back.
Thank you for your cooperation.

Customer/Facility Name:

Address:

Instrument Serial Number:

☐1. We do not have superseded versions of the aforementioned operation manuals in stock or on hand.
☐2. We have disposed all superseded versions of the aforementioned operation manuals we had in stock or on hand.

(Please also let us know if you no longer own any of the following endoscope models by checking below)

☐1. We no longer own the ED-530XT and/or ED-530XT8 endoscope(s).

Customer Name:

Position:

Signature:

Date:

Phone number:

If we have the wrong contact information about you, please correct below:
Customer/Facility Name:

Address:

Please FAX or email this completed form to:
Aquilant Endoscopy
Aquilant House, Unit B1-B2, Bond Close, Kingsland Business Park, Basingstoke, Hampshire, RG24 8PZ, England:
FAX: 01256 365 486
Email: qualitycontrol@aquilantservices.com