

FUJIFILM Medical Systems, U.S.A., Inc. removes certain older duodenoscope models from clinical use: FDA Safety Communication

Date Issued: January 13, 2017

Audience:

Users and reprocessors of the FUJIFILM Medical Systems, U.S.A., Inc. (Fuji) ED-530XT duodenoscope, as well as users of Fuji's ED-250XL5, ED-250XT5, ED-450XL5 and ED-450XT5 duodenoscopes including:

- Gastroenterologists
- Gastrointestinal surgeons
- Endoscopy nurses
- Staff working in endoscopy reprocessing units in health care facilities
- Infection control practitioners
- Facility risk managers

Medical Specialties:

Gastroenterology, Infection Control

Device:

Fuji ED-250XL5, ED-250XT5, ED-450XL5 and ED-450XT5 legacy duodenoscope models (250/450 duodenoscope models)

Summary of Problem and Scope:

Fuji informed the Agency of its plans to remove legacy 250/450 duodenoscope models from clinical use based on the limited number currently in use. On January 13, 2017, Fuji notified its customers by issuing a **Customer Notification Letter**

[https://www.fujifilmusa.com/products/medical/endoscopy/pdf/ED250 and 450 Duodenoscopes Removal 011217.pdf](https://www.fujifilmusa.com/products/medical/endoscopy/pdf/ED250_and_450_Duodenoscopes_Removal_011217.pdf)



<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm> that:

- Explains Fuji will replace the 250/450 duodenoscope models with the ED-530XT model, in addition to necessary accessories (i.e. brushes) at no cost.
- Outlines Fuji's strategy to facilitate the replacement process.
- Offers training and support to customers at their request to assist with ED-530XT duodenoscope use.

In **December 2015** ([/MedicalDevices/Safety/AlertsandNotices/ucm478290.htm](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)),

Fuji issued validated manual reprocessing instructions for the ED-530XT duodenoscope to replace those provided in the original device labeling. At that time, the FDA recommended that users and health care facilities apply the revised reprocessing instructions for the ED-530XT duodenoscope to reprocess the older 250/450 duodenoscope models while formal validation testing continued for these particular models.

The validated manual reprocessing procedures for the ED-530XT duodenoscope

outlined in the December 2015 **Safety Communication**

[/MedicalDevices/Safety/AlertsandNotices/ucm478290.htm](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) remain the same.

Health care facilities should continue to use these validated instructions when reprocessing Fuji ED-530XT duodenoscope models. The validated reprocessing instructions when followed correctly, are intended to effectively clean and high-level disinfect the Fuji ED-530XT duodenoscope.

Recommendations for Health Care Facilities and Staff

In addition to the recommendations in the December 2015 [Safety Communication \(/MedicalDevices/Safety/AlertsandNotices/ucm478290.htm\)](#), the FDA also recommends that facilities and staff do the following:

- Remove from circulation and return your facility's 250/450 duodenoscope models to Fuji as outlined in Fuji's Customer Notification Letter.
- Train appropriate staff on Fuji's validated reprocessing instructions for the ED-530XT model and implement them as soon as possible.
- Implement the reprocessing procedures for Fuji's ED-530XT duodenoscope in accordance with the manufacturer's reprocessing instructions issued in [December 2015 \(/MedicalDevices/Safety/AlertsandNotices/ucm478290.htm\)](#).
- Immediately remove from service to assess, repair and/or replace any duodenoscope that shows signs of damage. Examples of damage may include: loose parts, damaged channel walls, kinks or bends in tubing, holes in the distal end, or other signs of wear or damage.
- Contact your Fuji (FMSU-ESD) sales representative if you have any questions or concerns regarding this removal, a damaged device, or the validated reprocessing instructions for the ED-530XT duodenoscope.

FDA's recommendations are based on currently available information.

FDA Activities:

The FDA continues to closely monitor the association between reprocessed endoscopes and the transmission of infectious agents by:

- Working closely with duodenoscope and [Automated Endoscope Reprocessor \(/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm483896.htm\)](#) manufacturers as they validate their reprocessing instructions to a level adequate to clean and high-level disinfect their devices.
- Proactively communicating recommendations to health care providers and end users to help mitigate the risk associated with infection transmission and reusable medical devices.
- Working with the health care community, professional societies, international public health agencies, federal partners and state and local governments to investigate the association between reprocessed reusable medical devices and cases of bacterial infection in health care facilities.

Visit the Infections Associated with Reprocessed Duodenoscopes [webpage \(/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm\)](#) for a complete listing of actions the Agency has taken on this issue. The Agency will continue to provide updates as appropriate.

Reporting Problems to the FDA:

Device manufacturers and user facilities must comply with the applicable [Medical Device Reporting \(MDR\) regulations \(/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm\)](#).

Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements \(/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm\)](#) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. Health care providers should submit voluntary reports of the transmission of an infection due to an inadequately cleaned duodenoscope to the agency via the [Medical Device Reporting \(MDR\) \(/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm\)](#) process.

If a health care provider suspects bacterial contamination—either because of an increase in infections, or because of the results of bacterial surveillance culturing of duodenoscopes—the health care provider should file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program \(/Safety/MedWatch/HowToReport/ucm2007306.htm\)](#).

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041 or 301-796-7100.

Additional Resources

- [Fuji Customer Notification Letter to 250 and 450 duodenoscope customers. January 13, 2017](https://www.fujifilmusa.com/products/medical/endoscopy/pdf/ED250_and_450_Duodenoscopes_Removal_011217.pdf)
(https://www.fujifilmusa.com/products/medical/endoscopy/pdf/ED250_and_450_Duodenoscopes_Removal_011217.pdf)
(</AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)
- [Fuji Customer Notification Letter to ED-530XT duodenoscope customers. December 23, 2015.](http://www.fujifilmusa.com/products/medical/endoscopy/pdf/urgent_field_correction_ed_530XT.pdf)
(http://www.fujifilmusa.com/products/medical/endoscopy/pdf/urgent_field_correction_ed_530XT.pdf)
(</AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)
- [Fuji Customer Notification Letter to 250 and 450 duodenoscope customers. December 23, 2015.](http://www.fujifilmusa.com/products/medical/endoscopy/pdf/urgent_field_correction_ed_250_450.pdf)
(http://www.fujifilmusa.com/products/medical/endoscopy/pdf/urgent_field_correction_ed_250_450.pdf)
(</AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)
- [FDA orders duodenoscope manufacturers to conduct postmarket surveillance studies in health care facilities](/NewsEvents/Newsroom/PressAnnouncements/ucm465639.htm)
(</NewsEvents/Newsroom/PressAnnouncements/ucm465639.htm>)
- [Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication. September 2015.](/MedicalDevices/Safety/AlertsandNotices/ucm462949.htm)
(</MedicalDevices/Safety/AlertsandNotices/ucm462949.htm>)
- [Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices. CDC Health Advisory. September 11, 2015.](http://emergency.cdc.gov/han/han00382.asp) (<http://emergency.cdc.gov/han/han00382.asp>)
- [Fujifilm Corp 510k Status Letter - August 12, 2015 \(PDF - 604KB\)](/downloads/MedicalDevices/ResourcesforYou/Industry/UCM458552.pdf)
(</downloads/MedicalDevices/ResourcesforYou/Industry/UCM458552.pdf>)
- [Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication](/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm) (</MedicalDevices/Safety/AlertsandNotices/ucm454766.htm>)
- [Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff \(PDF - 792KB\)](/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf)
(</downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf>)
- [Design of Endoscopic Retrograde Cholangiopancreatography \(ERCP\) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication](/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm)
(</MedicalDevices/Safety/AlertsandNotices/ucm434871.htm>)
- [Infections Associated with Reprocessed Duodenoscopes: FDA website](/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm)
(</MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm>)
- [Information about Automated Endoscope Reprocessors \(AERs\) and FDA's Evaluation](/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm483896.htm)
(</MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm483896.htm>)

[More in Safety Communications](/MedicalDevices/Safety/AlertsandNotices/default.htm)
(</MedicalDevices/Safety/AlertsandNotices/default.htm>)

[Information About Heparin](/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm) (</MedicalDevices/Safety/AlertsandNotices/ucm135345.htm>)

[Reducing Risks Associated with Medical Device Misconnections](/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)
(</MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm>)