

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

PENTAX Validates Reprocessing Instructions for ED-3490TK Video Duodenoscopes: FDA Safety Communication

Date Issued: February 19, 2016

Audience: Users of the PENTAX Medical (PENTAX) ED-3490TK Video Duodenoscope and reprocessing facilities 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: PENTAX ED-3490TK Video Duodenoscope model

PENTAX has issued updated, validated manual reprocessing instructions for the ED-3490TK Video Duodenoscope to replace those provided in the original device labeling. The FDA reviewed these updated reprocessing instructions and the validation data and recommends that facilities using PENTAX ED-3490TK Video Duodenoscopes train staff on the updated instructions and implement them as soon as possible.

Summary of Problem and Scope:

As noted in the FDA's [February 2015 Safety Communication \(/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm\)](#), the complex design of duodenoscopes may impede effective reprocessing. Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices. If not properly reprocessed, residual body fluids and organic debris may remain in microscopic crevices of the device following an attempted cleaning and high level disinfection. If these residual fluids contain microbial contamination, subsequent patients may be exposed to serious infections. The FDA has been working with duodenoscope manufacturers as they modify and validate their reprocessing instructions to further enhance the safety margin of their devices and show with a high degree of assurance that their reprocessing instructions, when followed correctly, effectively clean and disinfect the duodenoscopes.

In February 2015, PENTAX began modifying its reprocessing protocol and, in May 2015, initiated testing to validate its updated reprocessing instructions. Between July and September 2015, PENTAX conducted additional testing to ensure its high-level disinfection protocols demonstrated an adequate safety margin. In October 2015, PENTAX submitted their cleaning, high-level disinfection and sterilization reports to the FDA. The Agency reviewed this data and requested additional cleaning tests, which PENTAX conducted. PENTAX submitted additional test data in January 2016, which the Agency reviewed and found to be adequate.

The updated reprocessing instructions for the ED-3490TK Video Duodenoscope include a more rigorous protocol for pre-cleaning, manual cleaning, high-level disinfection and liquid chemical sterilization procedures. In addition, updated instructions include additional text, figures, cautions and warnings intended to clarify the validated reprocessing procedure. The Agency believes that when followed, these updated, validated reprocessing instructions demonstrate consistent and reliable cleaning, high-level disinfection and sterilization of PENTAX's ED-3490TK's Video Duodenoscope.

PENTAX sent a [letter dated February 19, 2016](http://pentaxmedical.com/pentax/en/99/2/Urgent-Field-Correction-Updated-Instructions-for-Use-for-PENTAX-Medical-ED-3490TK-Video-Duodenoscope/)

(<http://pentaxmedical.com/pentax/en/99/2/Urgent-Field-Correction-Updated-Instructions-for-Use-for-PENTAX-Medical-ED-3490TK-Video-Duodenoscope/>)

(<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>) to

health care facilities and other users of the ED-3490TK Video Duodenoscope outlining the updated, validated reprocessing instructions. Updated Reprocessing Instructions for Use (IFU) and the Operation IFU accompanied the notification letter that PENTAX sent to its ED-3490TK customers.

Please note the key changes to the reprocessing procedure for PENTAX's ED-3490TK Video Duodenoscope:

Pre-cleaning:

- Additional detail regarding flushing of the elevator mechanism with detergent

Manual Cleaning:

- Additional detail regarding detergent solution preparation and use
- New steps detailing brushing with existing PENTAX Medical cleaning brushes (models CS-C9S and CS6021T) and flushing of the elevator mechanism
- Increased volumes of fluids for internal channels
- Additional detail regarding brushing of the instrument channel inlet
- Increased number of endoscope rinses after detergent immersion
- Additional warning regarding the potential for instrument channel obstruction

Manual High Level Disinfection (HLD):

- Additional detail regarding high level disinfectant preparation and use
- Additional detail regarding flushing of the elevator mechanism during HLD
- Increased volumes of fluids for internal channels
- Increased number of endoscope rinses after disinfectant immersion

Sterilization:

- Removal of ethylene oxide as a sterilization method
- Addition of STERIS System 1E® as a liquid chemical sterilization method

In addition, the FDA has the following recommendations for facilities and staff that use and reprocess PENTAX's ED-3490TK Video Duodenoscope:

- Implement the updated manual cleaning and high level disinfection procedures for PENTAX's ED-3490TK Video Duodenoscope in accordance with the manufacturer's reprocessing instructions. Facilities that opt to sterilize the ED-3490TK Video Duodenoscope should also follow sterilization procedures in accordance with STERIS' instructions.
- Train appropriate staff on PENTAX's updated reprocessing instructions and implement them as soon as possible.
- Contact your PENTAX Medical sales representative to arrange for in-servicing and training regarding the updated duodenoscope reprocessing procedures. PENTAX will also follow up with customers to assess their in-servicing or training needs.

FDA's recommendations are based on currently available information. If new, important information becomes available, FDA will update its recommendations.

FDA Activities:

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

- Working closely with duodenoscope and Automated Endoscope Reprocessor (AER) manufacturers as they validate their reprocessing instructions to a level adequate to clean and 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 after ERCP, or because of the results of bacterial surveillance culturing of duodenoscopes—we encourage the health care provider to 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

- [PENTAX Customer Notification Letter](#) (<http://pentaxmedical.com/pentax/en/99/2/Urgent-Field-Correction-Updated-Instructions-for-Use-for-PENTAX-Medical-ED-3490TK-Video-Duodenoscope/>) ([/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](#))
- [FDA orders duodenoscope manufacturers to conduct postmarket surveillance studies in health care facilities, October 2015](#) ([/NewsEvents/Newsroom/PressAnnouncements/ucm465639.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)
- [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 \(PDF - 1.3MB\) \(/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf\)](/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 \(/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm\)](/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)

[Preventing Tubing and Luer Misconnections \(/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm\)](/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)

