

UPDATE: Importance of Following Validated Reprocessing Instructions for PENTAX ED-3490TK Video Duodenoscopes: FDA Safety Communication

The FDA is providing an important update to our February 19, 2016 [Safety Communication](#) to inform users about a design issue with the PENTAX ED-3490TK duodenoscope that could increase the risk of patient infection. This communication contains updated recommendations to help prevent the spread of infection associated with the use of these devices.

Date Updated: January 17, 2017

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

Summary of Problem and Scope:

In [February 2016](#), PENTAX 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 continues to recommend that facilities using PENTAX ED-3490TK Video Duodenoscopes train staff on the updated instructions and implement them, if you have not already done so.

Since the February 2016 communication, PENTAX provided the FDA with additional information related to a potential risk associated with the design and manufacturing of the ED-3490K duodenoscope. Cracks and gaps in the adhesive that seals the device's distal cap to its distal tip can occur, which can lead to microbial and fluid ingress. These areas can be challenging to clean and high-level disinfect and may increase the risk of infection transmission among patients.

To inform their customers of this issue, PENTAX distributed a [Customer Notification Letter](#) on January 17, 2017 that:

- Explains the design issue and describes the potential for infection risk associated with the ED-3490TK duodenoscope.
- Outlines PENTAX's strategy to closely inspect the distal cap area of all customers' ED-3490TK duodenoscopes.
- Stresses the importance of following the reprocessing instructions according to the device label.
- Recommends that users closely inspect their duodenoscope and remove from use duodenoscopes that show signs of physical damage.
- Offers support to customers who need further assistance.

The validated manual reprocessing procedures for the ED-3490TK duodenoscope outlined in the February 2016 [Safety Communication](#) remain the same. Health care facilities **should continue to meticulously follow** these validated instructions when reprocessing Pentax's ED-3490TK duodenoscopes, paying close attention to any physical damage. These reprocessing instructions when followed correctly, are intended to effectively clean and high-level disinfect the duodenoscope channels, elevator area, and exterior of the device, and should reduce the risk of device contamination.

Updated Recommendations for Health Care Facilities and Staff

In addition to the recommendations in the February 2016 [Safety Communication](#), the FDA also recommends that facilities and staff that use and reprocess PENTAX's ED-3490TK Video Duodenoscope do the following:

- Implement the reprocessing procedures for PENTAX's ED-3490TK Video Duodenoscope in accordance with the manufacturer's reprocessing instructions issued in [February 2016](#).
 - In lieu of manual high-level disinfection, facilities may opt to use the ED-3490TK Video Duodenoscope with an Automated Endoscope Reprocessor (AER) that has provided validation data and test reports to FDA that demonstrate acceptable high-level disinfection or liquid chemical sterilization of duodenoscopes. See this [link](#) for updated AER Validation Testing Statuses.
- Immediately remove from service for assessment, and repair or replace any duodenoscope that shows visible signs of damage. Examples of damage may include: loose parts, damaged channel walls, kinks or bends in tubing, holes in the distal end, cracks and gaps in the adhesive that seals the device's distal cap or other signs of wear or damage.
- Train appropriate staff on PENTAX's validated reprocessing instructions and implement them, if you have not done so already.
- Contact your PENTAX Medical sales representative if you need to arrange for in-servicing and training regarding the validated 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.

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** 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** 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**.

Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements** 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)** 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**.

Contact Information:

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

Additional Resources

- **PENTAX Customer Notification Letter. January 2017.**
- **PENTAX Customer Notification Letter. February 2016.**
- **FDA orders duodenoscope manufacturers to conduct postmarket surveillance studies in health care facilities**
- **Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices. CDC Health Advisory. September 11, 2015.**
- **Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication**
- **Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff (PDF - 792KB)**
- **Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication**

- [Infections Associated with Reprocessed Duodenoscopes](#)
- [Information about Automated Endoscope Reprocessors \(AERs\) and FDA's Evaluation](#)

[More in Safety Communications](#)

[Information About Heparin](#)

[Reducing Risks Associated with Medical Device Misconnections](#)

<u>Reducing Risks through Standards Development for Medical Device Connectors</u>	<u>Information for</u>	
<u>Health Care Facilities</u>	<u>Tips for Health Care Providers to Reduce Medical Device</u>	
<u>Misconnections</u>	<u>Information for Home Use</u>	<u>Examples of Medical Device</u>
<u>Misconnections</u>	<u>Information for Manufacturers of Small Bore Connectors and Medical Devices with</u>	
<u>Connectors</u>	<u>Report a Problem to the FDA About Medical Device Misconnections</u>	<u>FDA</u>
<u>Activities</u>	<u>Additional Resources</u>	