

February 19, 2016

URGENT FIELD CORRECTION
Updated Instructions for Use for
PENTAX Medical ED-3490TK Video Duodenoscope

Dear Valued Customer,

The purpose of this communication is to inform you that PENTAX Medical is issuing an updated Reprocessing Instructions for Use (IFU) [S041_R00] and Operation IFU [Z933_R06] for the PENTAX Medical ED-3490TK Video Duodenoscope. The Reprocessing IFU includes updated validated procedures for cleaning, high level disinfection, and sterilization. The Operation IFU provides instruction to the user for the detection and resolution of a clogged channel and ensures consistent reference to the Reprocessing IFU for direction regarding the cleaning, high level disinfection and sterilization of the ED-3490TK. Both sets of instructions should be implemented as soon as possible. For your convenience paper copies of the Reprocessing and Operation IFUs are enclosed with this letter.

This action is being taken as a result of publicized reports of multi-drug resistant bacteria on endoscopes used for Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures. Given these reports, and in an abundance of caution, PENTAX Medical has been working with the U.S. Food and Drug Administration ("FDA") to validate the reprocessing procedures that are provided in the updated Reprocessing IFU.

Revised Instructions

The updated PENTAX Medical ED-3490TK Reprocessing Instructions for Use include additional text, figures, cautions, and warnings that are intended to clarify and reflect the newly validated manual cleaning, high level disinfection and liquid chemical sterilization procedures. The following is an overview of some of the main changes in the updated Reprocessing IFU:

- 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 (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

The following is an overview of some of the main changes in the updated PENTAX Medical ED-3490TK Operation IFU:

- Changed the term "reprocessing/ maintenance manual" to "Instructions for Use (Reprocessing)" throughout the IFU
- Changed the Front Cover reference to the Reprocessing IFU for Cleaning, High Level Disinfection, and Sterilization Instructions
- Added warning regarding the potential for instrument channel obstruction
- Removed the summary of the reprocessing method in Section 4.0 Care After Use, and instructed reader to reference the Reprocessing IFU

Instructions Regarding Prior Versions of the Reprocessing and Operation Instructions for Use

Please ensure that user departments discard prior versions of the Reprocessing IFU (Z863) and Operation IFU (Z933). Users must read and follow these instructions in order to properly operate and reprocess the PENTAX Medical ED-3490TK Video Duodenoscope. Please check with your facility's applicable supply departments to determine if you have any copies of the prior versions of the IFUs and replace the existing versions with those enclosed.

PENTAX Medical has a dedicated team of clinical specialists who visit customer facilities and perform reprocessing in-servicing and training. Please contact your PENTAX Medical sales representative at your earliest convenience to arrange for training regarding these new procedures. Customers are also invited to register to the PENTAX Medical Patient First website (<http://patientfirst.pentaxmedical.com>) to gain access to the latest revision of these and all other current-generation PENTAX Medical endoscope IFUs in digital format.

Response Form

Enclosed with this letter is a Field Correction Response Form. The form identifies all PENTAX Medical ED-3490TK Video Duodenoscopes that have been consigned (sold, loaned, or leased) to your facility. Please forward this letter and the enclosures to the relevant department in your facility so that they may review the information provided and complete the response form. Please note that you must return the completed form even if you do not have any IFUs to discard. Your local sales representative can assist you in completing this form. This information is essential in order to maintain recall effectiveness information required by FDA.

Contact Information

If you have any questions regarding this action, please feel free to contact Paul Silva, PENTAX Americas Recall Coordinator at:

Tel: 800-431-5880 ext. 2064 (8:30 AM – 5:00 PM, Monday – Friday, EST)
Fax: 201-799-4063
Email: recall.coordinator@pentaxmedical.com

This corrective action is being made with the knowledge of the U.S. Food and Drug Administration.



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PENTAX Medical regrets any inconvenience that may result from this action and appreciates your patience as we introduce these updated instructions. Please be assured that maintaining patient safety and quality is our utmost priority.

Sincerely,



Paul Silva
PENTAX of America Inc.
Director of Regulatory Affairs

Attachments:

- ED-3490TK Reprocessing IFU S041_R00
- ED-3490TK Operation IFU Z933_R06
- Customer Response Form, Control Number F04-FLD-0000957