

Date
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FIELD SAFETY CORRECTIVE ACTION

Updated Instructions for Use for
ED-3490TK Video Duodenoscope
Updated Reprocessing / Additional warning

To: <Customer address>

Dear Valued Customer,

The purpose of this communication is to inform you that PENTAX Medical is issuing an updated Reprocessing Instructions for Use (IFU) and Operation IFU for the PENTAX Medical ED-3490TK Video Duodenoscope. The Reprocessing IFU includes updated validated procedures for cleaning and high level disinfection. Both the Reprocessing IFU and Operation IFU include additional warnings regarding the potential for instrument channel obstruction. Both sets of updated instructions shall be implemented immediately.

Revised Reprocessing IFU

The updated PENTAX Medical ED-3490TK Reprocessing Instructions for Use include additional text, figures, cautions, and warnings that are designed to improve clarity and reflect the newly validated manual cleaning and high level disinfection 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:
 - ✧ New steps detailing brushing with existing PENTAX Medical cleaning brushes 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
- High Level Disinfection (HLD):
 - ✧ 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

Revised Reprocessing IFU and Operation IFU

Additional warning regarding the potential for instrument channel obstruction is included in both the Reprocessing IFU and Operation IFU.

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

Please discard prior versions of the Reprocessing IFU / Operation IFU and replace with updated Reprocessing IFU S059-R00 and updated Operation IFU Z933-R06. Please refer to the table as follows:

Table 1: Comparison table for new IFUs and old IFUs

New Operation IFU	Z933-R06
New Reprocessing IFU	S059-R00
Old Operation IFU	Z933-R04 or lower version
Old Reprocessing IFU	Z863-R16 or lower version

Users must follow these instructions in order to properly operate and reprocess the PENTAX Medical ED-3490TK Video Duodenoscope. Please contact your PENTAX Medical sales representative for any inquiry regarding the new procedures.

Contact Information

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Email: vigilance.emea@pentaxmedical.com

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,
PENTAX Europe GmbH
Dr. Stephan Lunau
Leader RA EMEA
Safety Officer for Medical Devices

