July 01, 2021

URGENT MEDICAL DEVICE CORRECTION

For United States Customers

Re: PENTAX Medical endoscopic reprocessing instruction for use (rIFU).

Dear Healthcare Professional,

This letter is to inform you that PENTAX Medical (“PENTAX”) is conducting a voluntary corrective action of impacted **PENTAX Medical** Video Upper GI Scopes (EG) and Video Colonoscopes (EC) families related to reprocessing endoscopic units.

These endoscopic units are Class II devices and offered for sale in the USA. PENTAX Medical has identified issues with the reprocessing IFUs (rIFUs) where the reprocessing user would have to identify what configuration endoscope is being worked on and to ensure the reprocessing is performed in a safe and effective manner. As a result, PENTAX separated the EC and EG rIFUs into 5 separate rIFUs and conducted a Human Factor study and subsequently cleared by the FDA. This regrouping of rIFUs did not require changes to the reprocessing instructions for use, nor were there any changes to the design, intended use, or indications for use of the EG family and EC family of endoscopes.

The following models are included in this corrective action:

Colonoscope Family Description	Endoscope Family Description	Colonoscope Models
Colonoscope Family # 1	Colonoscopes with One Instrument Channel and a Water Jet Channel	EC-2990Li, EC-3490Li, EC-3890Li, EC-3490TLi, EC-3490LK, EC-3890LK, EC3890LZi, EC34-i10L, EC38-i10L
Colonoscope Family # 2	Colonoscopes with Two Instrument Channels and a Water Jet Channel	EC-3890TLK

Gastroscope Family Description	Endoscope Family Description	Gastroscope Models
Gastroscope Family # 1	Gastroscopes without a Water Jet Channel	EG-2790i, EG-1690K, EG-2490K, EG-2790K, EG27-i10
Gastroscope Family # 2	Gastroscopes with a Water Jet Channel	EG-2990i, EG-2990K, EG-3490K, EG29-i10
Gastroscope Family # 3	Gastroscopes with Two Instrument Channels and a Water Jet Channel	EG-3890TK

The grouping will allow the following for reprocessing personnel:

- Eliminate the need to identify optional configurations of instrument channels and water jet channels
- Simplify the instructions and graphics in the individual rIFUs

Please replace any previous versions of rIFUs with the most current revision. Please note that this documentation set is current as of this date. For future updates, please refer to the PENTAX online IFU library at https://ifu.pentaxmedical.com.

Customer Instructions: Please complete the enclosed Field Correction Response Form upon receipt of this package, and email to PENTAX at customeradvisories@pentaxmedical.com.

Adverse events experienced with the use of this product should be reported as soon as possible to PENTAX at vigilance@pentaxmedical.com.

Contact Information: PENTAX regrets any inconvenience that this action may cause and appreciates your understanding and cooperation. PENTAX will issue additional communications as further information becomes available. Please be assured that maintaining patient safety and quality is our utmost priority.

If you have any questions regarding this action, please feel free to contact us at:

- Tel: 1-800-431-5880 (8:30 AM – 5:00 PM, Monday – Friday, EST)
- Fax: 201-799-4063 (alternate 201-391-4189)
- Email: customeradvisories@pentaxmedical.com

Sincerely,

PENTAX Medical

PENTAX of America, Inc.
3 Paragon Drive
Montvale, New Jersey • 07645
Toll-free: 800-431-5880 • Tel: 201-571-2300
Fax: 201-391-4189

FIELD CORRECTION RESPONSE FORM

Response is Required

«CUSTOMER_NAME»
«STREET»
«CITY», «STATE» «ZIP_CODE» «COUNTRY»
CUSTOMER NUMBER: «CUSTOMER_NUMBERS»
REF.: 2021-005-C

PENTAX Medical endoscopic reprocessing instruction for use (rIFU).

I have read and understand the instructions provided in the customer notification letter.

Contact Information	
Name	
Title	
Telephone	
Fax Number	
Email address	

☐ I have received the USB drive along with the enclosed instruction sheet.

Signature of Receipt and Acknowledgement	Date

Upon completion of the form and signing, please return the form by either one of the following methods:

- Faxing this completed form to PENTAX QA/RA Department at 201-799-4063 (alternate 201-391-4189)
- Email a pdf copy of the completed form to customeradvisories@pentaxmedical.com.

If you have any questions regarding this action, please feel free to contact your PENTAX Territory Manager or PENTAX Medical Customer Service at 800-431-5880 (8:30am – 5:00 pm EST, Monday – Friday).