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

January 19, 2021

URGENT MEDICAL DEVICE CORRECTION

For United States Customers

Re: PENTAX Medical "FDA-cleared" endoscopic instructions for use (IFU) and 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 endoscopic units.

These endoscopic units are Class I exempt and/or Class II devices and offered for sale in the USA. As part of a correction to a FDA regulatory compliance action PENTAX observed certain gaps in record keeping. As a result, we are unable to verify that in some cases, our customers received the latest version of operating instruction for use/reprocessing instruction for use (OIFU/RIFU) documentation. PENTAX is sharing the current OIFU/RIFU with customers in order to assure that the most current versions of these documents are in use. This is being provided electronically on the USB drive along with the enclosed instruction sheet.

Please note that this documentation set is current as of this date. For 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

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FIELD CORRECTION RESPONSE FORM

Response is Required

«CUSTOMER_NAME»

«STREET»

«CITY», «STATE» «ZIP_CODE» «COUNTRY»

CUSTOMER NUMBER: «CUSTOMER_NUMBERS»

REF.: 2021-001-C

PENTAX Medical "FDA-cleared" endoscopic instructions for use (IFU) and 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).