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

April 09, 2021

URGENT MEDICAL DEVICE CORRECTION

For United States Customers

Re: PENTAX Medical ED34-i10T2 duodenoscope instructions for use (IFU).

Dear Healthcare Professional,

This letter is to inform you that PENTAX Medical ("PENTAX") is conducting a voluntary corrective action of **PENTAX Medical ED34-i10T2** duodenoscope units.

These duodenoscope units are Class II devices and offered for sale in the USA. PENTAX Medical has identified an issue in relation to the application of the OE-A63 (Single-Use Sterile Distal End Cap with Elevator from the ED34-i10T2 duodenoscope). If not properly attached and verified per the instructions for use, this end cap can unexpectedly fall off of the duodenoscope during procedures. This can result in unforseen events such as mucosal injury, lacerations, or bleeding of the patient. Detachment of the distal end cap (OE-A63) into the oral cavity of the patient may also result in aspiration.

As a result, we have updated our instructions for use (IFU) for both the OE-A63 distal end cap and ED34-i10T2 duodenoscope. The warning section of the IFU has been updated to notify users of the associated risks with the distal end cap (OE-A63) unexpectedly becoming detached during a procedure. In addition, the IFU has been updated to notify users of what immediate actions should be taken in case the event occurs.

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.: 2021-004-C

PENTAX Medical ED34-i10T2 duodenoscope instructions for use (IFU).

Contact Information	
Name	
Title	
Telephone	
Fax Number	
Email address	

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

☐ I have received the Instructions for Use (IFU) for ED34-i10T2.

Signature of Receipt and Acknowledgement	Date

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

- Fax 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).

Below is a list of the affected products our records show your facility has purchased.

Model	Serial Number
ED34-i10T2	