PENTAX Medical
3 Paragon Drive
Montvale, New Jersey • 07645-1725
Toll-free: 800-431-5880 • Tel: 201-571-2300

February 7, 2018

URGENT MEDICAL DEVICE CORRECTION AND REMOVAL
For United States Customers Only

Re: PENTAX Medical Duodenoscope Model ED-3490TK
Replacement of Forceps Elevator Mechanism, O-Rings, Distal End Covering, and Operation Manual Update

Dear Healthcare Professional,

This letter is to inform you that PENTAX Medical ("PENTAX") is conducting a voluntary recall/corrective action of all ED-3490TK duodenoscopes in order to replace the forceps elevator mechanism, O-rings, and distal end covering. In January 2017, PENTAX informed ED-3490TK customers about a potential issue associated with the distal end of the ED-3490TK. The January 2017 customer letter offered recommendations intended to reduce the potential risk for contamination and subsequent patient injury and also conducted a no-charge duodenoscope inspection process of the distal end covering.

The ED-3490TK duodenoscope is a flexible gastrointestinal endoscope used in procedures such as endoscopic retrograde cholangiopancreatography (ERCP). PENTAX has worked closely with the U.S. Food and Drug Administration (FDA) to mitigate the potential risk of infection in flexible endoscopy, and is conducting this field action with the knowledge of the FDA.

On February 7, 2018, FDA cleared an updated design for the ED-3490TK duodenoscope (K161222). The current voluntary recall/corrective action is being taken to replace the forceps elevator mechanism, the O-rings, and the distal end covering with materials and processes consistent with the design features of the cleared updated ED-3490TK. In addition, a periodic duodenoscope inspection process is being implemented for the forceps elevator mechanism, and is described in the updated Operation Manual (S206 R00) which is enclosed with this letter. The updated information can be found on page 22 of the Operation Manual. The Reprocessing Instructions For Use (S041 R02) have not changed and should be closely followed.

Customer Instructions:

Enclosed with this letter is a new Operation Manual (S206 R00) and a Field Correction Response Form (MK-1065 Rev B). Please discard all old copies of the ED-3490TK Operation Manual, and replace with the new Operation Manual enclosed in this package. Additional copies of the Operation Manual can be downloaded from the PENTAX Medical (USA) website located at http://www.pentaxmedical.com/pentax/en/99/1/Customer-notices. The Reprocessing IFU has not changed.

PENTAX Medical
3 Paragon Drive
Montvale, New Jersey • 07645-1725
Toll-free: 800-431-5880 • Tel: 201-571-2300

The response form identifies the serial numbers of the affected duodenoscopes which have been sold to your facility. Please complete this form, and return it to PENTAX Medical using the e-mail address or fax number listed below. Upon return of the response form, PENTAX will contact your facility to arrange the return of the ED-3490TK for the forceps elevator mechanism, O-rings and distal end covering updates. Loaner units will be supplied to customers as needed. You can continue to use your ED-3490TK duodenoscope until you are contacted to update your unit. PENTAX will continue to conduct distal tip inspections every 6 months on units that have not been updated.

PENTAX reminds its customers of the importance of using the ED-3490TK according to its current labeling. Customers must ensure that all reprocessing personnel are knowledgeable and thoroughly trained on the current Operation Manual and Reprocessing IFU for these devices. Meticulous cleaning of the elevator recesses and attention to following all reprocessing instructions are required. Additionally, PENTAX recommends that you immediately remove from use any ED-3490TK duodenoscope that shows visible signs of wear or physical damage. Continuing to use devices with integrity issues (i.e.; holes, cracks, kinks, and scratches) can contribute to persistent device contamination and subsequent patient infection.

Adverse events experienced with the use of this product should be reported as soon as possible to PENTAX at vigilance@pentaxmedical.com and the FDA's MedWatch Adverse Event Reporting program.

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