PENTAX Europe GmbH
Julius-Vosseler-Straße 104
22527 Hamburg
Germany

Date
Ref: FSCA-PMJ-18-01-1

MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

PENTAX Duodenoscope ED-3490TK

To: <Customer address>

RE: Field Safety Notice Duodenoscope Model ED-3490TK Replacement of Forceps Elevator Mechanism, O-rings and Distal End Cap.

This letter is to inform you that PENTAX Medical ("PENTAX") is conducting a Field Safety Corrective Action on all ED-3490TK duodenoscopes in order to replace the forceps elevator mechanism, O-rings, and distal end cap. In February 2017, PENTAX informed ED-3490TK customers about a potential issue associated with the distal cap of the ED-3490TK, ref. "FSCA-PMJ-17-01". The February 2017 customer letter offered recommendations intended to reduce the potential risk of contamination and subsequent patient injury and instituted a free-of-charge duodenoscope inspection process of the distal tip.

This FSCA was initiated in order to replace the forceps elevator mechanism, the O-rings and the distal end cap with materials and processes consistent with the design features of the upgraded duodenoscope model ED-3490TK. In addition, PENTAX implemented a periodic duodenoscope inspection process for the forceps elevator mechanism, which is described in the Operations Instruction for Use (S164 R00) and in the addendum of the Operation Instruction for Use (Z933-R07). The Reprocessing Instructions For Use (S059-R01) have not changed and should be closely followed.

Customer Instructions:

Enclosed with this letter is a Field Safety Corrective Action Response Form.

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 and starting beginning in June 2018, PENTAX will contact your facility to arrange the return of the ED-3490TK for the forceps elevator mechanism, O-rings and distal end cap upgrades. Loaner devices will be supplied to customers as needed.
Please add the addendum of the Operation Instruction for Use (Z933-R07) to the existing IFUs at your files and make sure that all relevant staff is being informed accordingly.

PENTAX Medical duodenoscopes have been safely used in more than one million ERCP procedures globally for over 10 years. As is the case for many other types of endoscopic procedures, the rate of infection during ERCP procedures remains low, and for most patients, the benefits of the procedure outweigh the risk.

You can continue to use your ED-3490TK duodenoscope until you are contacted to upgrade your device. PENTAX will continue to conduct distal tip annual inspections of devices that have not been updated with this FSCA.

PENTAX reminds all users of the importance using the ED-3490TK according to current Instructions for Use. Users must ensure that all reprocessing personnel are knowledgeable and thoroughly trained on the current Operating 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. leakage, holes, cracks, kinks, and scratches) can contribute to persistent device contamination and subsequent patient infection.

Incidents experienced with the use of this product must be reported immediately to PENTAX at vigilance.emea@pentaxmedical.com. Independent from this, incidents must be reported to national Competent Authorities as per local Medical Device Regulation.

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 your local PENTAX Medical representative at:

Tel:
Fax:
Email:

Sincerely,

PENTAX Europe GmbH
Leader Regulatory Affairs EMEA
Safety Officer for Medical Devices

Dr. Stephan Lunau

Attachments:
Customer Response Form, Ref.: FSCA-PMJ-18-01-2
FSCA-PMJ-18-01-7 Addendum (No.411-R00_E_flier)