

Date

Ref: FSCA-PMJ-18-02-1

MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

PENTAX Duodenoscope ED34-i10T

To: <Customer address>

RE: Field Safety Notice Duodenoscope Model ED34-i10T Replacement of Forceps Elevator Mechanism and O-rings.

This letter is to inform you that PENTAX Medical ("PENTAX") is conducting a Field Safety Corrective Action on all ED34-i10T duodenoscopes in order to replace the forceps elevator mechanism and O-rings.

This FSCA was initiated in order to replace the forceps elevator mechanism and the O-rings consistent with the design of the upgraded duodenoscope model ED34-i10T. In addition, PENTAX implemented a periodic duodenoscope inspection process for the forceps elevator mechanism, which is described in the Operating Instruction for Use (S051-R01) and in the addendum of the Operating Instruction for Use (Z985-R08). The Reprocessing Instructions For Use (Z977-R05) 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 beginning in June 2018, PENTAX will contact your facility to arrange the return of the ED34-i10T for the forceps elevator mechanism and O-rings 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 this 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.

PENTAX

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You can continue to use your ED34-i10T duodenoscope until you will be contacted to update your device.

PENTAX reminds all users of the importance using the ED34-i10T according to current Instructions for Use. Users must ensure that all reprocessing personnel are knowledgeable and thoroughly trained on the current Operations 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 ED34-i10T 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-18-02-2
FSCA-PMJ-18-02-7 Addendum (No.411-R00_E_flier)