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

2021-04-xx
Ref: FSCA-PMJ-21-04

To:
«CUSTOMER_NAME»
«STREET_ADDRESS»
«POST_CODE» «CITY»,
«COUNTRY»

URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

Re: Instructions for Use of the ED34-i10T2 PENTAX Medical Video Duodenoscope and OE-A63 Single Use Sterile Distal End Cap with Elevator

Dear esteemed User,

this letter is to inform you that PENTAX Medical ("PENTAX") is conducting a voluntary Field Safety Corrective Action (FSCA) regarding the Instructions for Use (IFU) of the devices as stated below:

- PENTAX Medical Video Duodenoscope ED34-i10T2
- PENTAX Medical Single Use Sterile Distal End Cap with Elevator OE-A63

This FSCA was initiated in order to alert you and provide you with revised IFUs regarding the potential risk of improper attachment of the Single Use Sterile Distal End Cap OE-A63 to the endoscope. Please be informed that PENTAX Medical has identified the following may occur when the Single Use Sterile Distal End Cap is not properly attached:

- Cap falling off
- The elevator does not get lifted
- The elevator does not get back to its neutral position

We have received complaints regarding the aforementioned observations. These have led to incidents, which need to be reported to the Competent Authorities by the user. Please note, these incidents could have been avoided when following the IFU meticulously and the devices can be continued to be used safely by attaching the Single Use Sterile Distal End Cap properly as already described within the current IFU.

Customer Instructions:

PENTAX Medical does provide you with the revised IFU, which describes more clearly on how to attach the Single Use Sterile Distal End Cap properly to the device. In addition, enclosed with this letter you will receive a Field Safety Corrective Action Response Form. Please complete the form and return to PENTAX Medical by using the email address listed below.

Incidents experienced with the use of these devices must be reported immediately to PENTAX at vigilance.emea@pentaxmedical.com. Independent from this, incidents must be reported to national Competent Authorities as per the Regulation (EU) 2017/745 ("EU-MDR") and / or national Medical Device Regulation by the user facility.

Contact Information:

In case you may have any questions regarding this Field Safety Corrective Action, please feel free to contact your local PENTAX Medical representative at:

Tel:

Email:

Sincerely,

PENTAX Europe GmbH

Dr. Stephan Lunau

Leader Regulatory Affairs EMEA

Person Responsible for Regulatory Compliance

Field Safety Corrective Action
CUSTOMER RESPONSE FORM

«CUSTOMER_NAME»
«STREET_ADDRESS»
«POST_CODE» «CITY»,
«COUNTRY»

REF.: FSCA-PMJ-21-04
Instructions for Use (IFU) of the ED34-i10T2 PENTAX Medical Video Duodenoscope and OE-A63 Single Use Sterile Distal End Cap with Elevator

- I have read and understand the instructions provided in the Field safety Notification (FSN).

Contact Information	
Name	
Title	
Telephone	
Fax Number	
Email address	

Signature / e-Signature of Receipt and Acknowledgement	Date

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

- Return this completed form to local PENTAX representative as scanned *.pdf copy via Email to {e-mail address}.

If you have any questions regarding this action, please feel free to contact your PENTAX Sales Representative at:

Tel: {telephone number}
E-mail: {email address}