

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.

PENTAX

MEDICAL

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

[Redacted]

[Redacted]

[Redacted]

Attachments:

Customer Response Form, Ref.: FSCA-PMJ-18-01-2

FSCA-PMJ-18-01-7 Addendum (No.411-R00_E_flier)

CUSTOMER RESPONSE FORM
Acknowledgement and Receipt Form

«CUSTOMER_NAME»

«STREET_ADDRESS»

«CITY», «POST_CODE» «COUNTRY»

CUSTOMER NUMBER: «CUSTOMER_NUMBERS»

REF.: FSCA-PMJ-18-01-2

PENTAX Medical Duodenoscope Model ED-3490TK
Replacement of Forceps Elevator Mechanism, O-Rings, and Distal End Cap

- I have read and understand the instructions provided in the customer notification letter.

Contact Information	
Name	
Title	
Telephone	
Fax Number	
Email address	

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** at **{fax number}** Attn: Regional FSCA coordinator
- Email a pdf copy of the completed form to **{e-mail address}**.

If you have any questions regarding this action, please feel free to contact your **PENTAX Sales Representative** or Field Safety Corrective Action Coordinator **{name of FSCA coordinator}** at:

Tel: **{telephone number}**
 Fax: **{fax number}**
 E-mail: **{email address}**

Please fill in the list below with the serial numbers of the affected devices (**ED-3490TK**) which your facility has purchased and whether they are still in use or not.

Serial number	Does facility still own?	Serial number	Does facility still own?	Serial number	Does facility still own?
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No

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

MEDICAL

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

[Redacted]

[Redacted]

[Redacted]

Attachments:

Customer Response Form, Ref.: FSCA-PMJ-18-02-2

FSCA-PMJ-18-02-7 Addendum (No.411-R00_E_flier)

CUSTOMER RESPONSE FORM
Acknowledgement and Receipt Form

«CUSTOMER_NAME»

«STREET_ADDRESS»

«CITY», «POST_CODE» «COUNTRY»

CUSTOMER NUMBER: «CUSTOMER_NUMBERS»

REF.: FSCA-PMJ-18-02-2

PENTAX Medical Duodenoscope Model ED34-i10T
Replacement of Forceps Elevator Mechanism and O-Rings

- I have read and understand the instructions provided in the customer notification letter.

Contact Information	
Name	
Title	
Telephone	
Fax Number	
Email address	

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 at {fax number} Attn: Regional FSCA coordinator
- Email a pdf copy of the completed form to {e-mail address}.

If you have any questions regarding this action, please feel free to contact your PENTAX Sales Representative or Field Safety Corrective Action Coordinator {name of FSCA coordinator} at:

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

Please fill in the list below with the serial numbers of the affected devices (ED34-i10T) which your facility has purchased and whether they are still in use or not.

Serial number	Does facility still own?	Serial number	Does facility still own?	Serial number	Does facility still own?
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No