Pentax Europe GmbH
Julius-Vosseler-Str. 104
22527 Hamburg
Germany

Date
Ref. FSCA-PMJ-17-04-1

To: <Customer address>

MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

Regarding: Correction to Endoscope Suction Arm

Dear Valued Customer,

The purpose of this communication is to inform you that PENTAX Europe GmbH has become aware that some customers may own endoscopes where the screw connecting the suction nipple (suction arm) to the control body could loosen with time. A loose suction nipple may result in inadequate suctioning due to leakage of air. There is also the potential for organic debris to accumulate in the space between the suction nipple and control body. In some cases, these events can cause cross-contamination between patients. Even though we have initiated a service action to address this issue already in November 2010 and this service action meanwhile should have been applied to all devices in the market, we now re-initiate this action in order to be sure no devices remain non-modified at your facilities. As of today, PENTAX Europe GmbH did not receive any complaints since 2010 and no incidents ever came to our knowledge.

Identification of Affected Devices

Table 1 provides a list of the affected devices. Please note that the scopes manufactured after 30th July 2010 have a corrected design, and are NOT subject to this field action.

Table 1

Product Name	Model Number
PENTAX Video Bronchoscope	EB-1170K, EB-1570, EB-1570AK, EB-1570K, EB-1970, EB-1970AK, EB-1970K, EB-1970TK
PENTAX Ultrasound Bronchoscope	EB-1970UK
PENTAX Video Nasopharyngolaryngoscope	VNL-1570
PENTAX Video Cystoscope	ECY-1570, ECY-1570K

Customer Instructions

Please check if the affected devices in Table 1 are in use at your facility. Please record on the customer response form whether the affected units are still in use or not at your facility. If you indicate that you own an endoscope affected by this field action, PENTAX Medical will contact you in order to get the device checked and if necessary, repaired.
In order to facilitate this you will receive a customer response form enclosed with this letter. Please forward this letter and the enclosures to the department in which the above referenced items are in use. We strongly recommend that the end user of the affected products complete this form and return it to your local PENTAX office or PENTAX distributor.

Contact Information

Pentax Europe GmbH
Julius-Vosseler-Str. 104
22527 Hamburg
Germany

If you have any questions regarding this action, please feel free to contact us at:

Tel: {Telephone number}
Fax: {Fax number}
Email: {E-mail address}

We sincerely regret any inconvenience caused by this action and appreciate your immediate attention to this matter. Please be assured that maintaining a high level of safety and quality is our highest priority.

Sincerely,

PENTAX Europe GmbH

[redacted]

Attachments:
Customer Response Form, Ref.: FSCA-PMJ-17-04-2

CUSTOMER RESPONSE FORM

Acknowledgement and Receipt Form

«CUSTOMER_NAME»
«STREET_ADDRESS»
«CITY», «STATE» «ZIP_CODE» «COUNTRY»
CUSTOMER NUMBER: «CUSTOMER_NUMBERS»
REF.: FSCA-PMJ-17-04-2

Ref.: FSCA-PMJ-17-04
Field Safety Correction Action regarding an "Endoscope Suction Arm" for PENTAX Medical Endoscopes

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:

- Faxing this completed form to PENTAX QA/RA Department 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 Corrective Action Coordinator {name of FCA coordinator} at:

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

For your reference below is a list of the affected products our records show your facility has purchased.

Model Number	Serial Number		
«M1»	«S1»	___ unit is still active	___ unit is no longer owned by facility
«M2»	«S2»	___ unit is still active	___ unit is no longer owned by facility
«M3»	«S3»	___ unit is still active	___ unit is no longer owned by facility
«M4»	«S4»	___ unit is still active	___ unit is no longer owned by facility
«M5»	«S5»	___ unit is still active	___ unit is no longer owned by facility
«M6»	«S6»	___ unit is still active	___ unit is no longer owned by facility
«M7»	«S7»	___ unit is still active	___ unit is no longer owned by facility