PENTAX Medical
3 Paragon Drive
Montvale, New Jersey • 07645-1725
Toll-free: 800-431-5880 • Tel: 201-571-2300

July 19, 2017

U.S. URGENT FIELD CORRECTION

Notification Regarding Correction to Endoscope Suction Arm for PENTAX Medical Video Bronchoscopes, Ultrasound Bronchoscopes, and Video Nasopharyngolaryngoscopes

Dear Valued Customer,

The purpose of this communication is to inform you that PENTAX Medical has become aware that the screw connecting the suction arm to the control body on some of its legacy endoscopes may loosen with time. A loose suction arm 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 could potentially cause cross-contamination between patients.

Identification of Affected Products

Table 1 provides a list of the affected products. Please note that while this field action affects legacy endoscopes, endoscopes manufactured by PENTAX Medical after January 26, 2011 have a corrected design, and are NOT subject to this field action.

Table 1

Model Number	Product Name	Endoscopes Affected
EB-1170K	Video Bronchoscope	Purchased from 10/25/2006 – January 26, 2011
EB-1570	Video Bronchoscope	Purchased from 8/23/2003 – January 26, 2011
EB-1570AK	Video Bronchoscope	Purchased from 3/30/2009 – January 26, 2011
EB-1570K	Video Bronchoscope	Purchased from 10/24/2002 – January 26, 2011
EB-1970AK	Video Bronchoscope	Purchased from 4/23/2007 – January 26, 2011
EB-1970K	Video Bronchoscope	Purchased from 10/24/2002 – January 26, 2011
EB-1970TK	Video Bronchoscope	Purchased from 12/3/2008 – January 26, 2011
EB-1970UK	Video Bronchoscope	Purchased from 1/14/2009 – January 26, 2011
VNL-1570STK	Video Nasopharyngolaryngoscope	Purchased from 4/26/2007 – January 26, 2011

Customer Instructions

Enclosed with this letter is a field correction response form. The form identifies the affected endoscopes which have been sold to your facility. Please forward this letter and the enclosures to the department in which the above referenced items are in use. It is suggested that the end user of the affected products completes this form and returns it to PENTAX Medical.

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Check if the affected products in Table 1 are in use at your facility. Record on the customer response form whether the affected products are still owned by your facility. If a customer indicates that they own an endoscope affected by this field action, PENTAX Medical will contact them to have the product repaired.

Contact Information

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

Tel: 800-431-5880 (8:30 AM – 5:00 PM, Monday – Friday, EST)
Fax: 201-799-4063 (alternate 201-391-4189)
Email: customeradvisories@pentaxmedical.com

This field correction is being made with the knowledge of the U.S. Food and Drug Administration.

PENTAX Medical regrets any inconvenience that may result from this action and appreciates your patience as we introduce these updated instructions. Please be assured that maintaining patient safety and quality is our utmost priority.

Sincerely,

PENTAX of America Inc.
Department of Quality Assurance & Regulatory Affairs

Attachments:
Customer Response Form, Control Number MK-976