

Field Corrective Action

IFU Addendum for proper use of endoscopic accessories with PENTAX EG-3870UTK Ultrasound Video Gastroscope

April 27, 2012

To: Customer address...

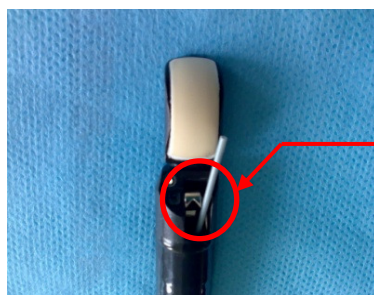
Attention: [Risk Manager](#)
[Urgent: Medical Device Field Corrective Action](#)

Dear Valued Customer,

Pentax has initiated a Field Corrective Action involving the revision of Instructions For Use to clarify the method for advancing an accessory in the Pentax Ultrasound Video Gastroscope, EG-3870UTK.

Issue

Recently PENTAX has been notified of a potential risk related to the use of the EG-3870UTK Ultrasound Video Gastroscope in combination with aspiration needles if the Instruction For Use is not followed carefully by the user. Specifically, if the user fails to properly position the elevator while advancing the aspiration needle through the endoscope, then the needle can disengage from the elevator (as shown on the picture below). This could result in the needle not being visible in the endoscopic or sonographic field of view, leading to the possibility of patient injury such as a perforation.



The aspiration needle is
"derailed" from the elevator.

Figure 1

Field Corrective Action

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Instructions

The instructions specific to the use of the EG-3870UTK Ultrasound Video Gastroscope, in combination with endoscope accessories, have been updated to include additional figures, cautions, and warnings (see attached addendum to the Owner's Manual PENTAX Ultrasound Upper GI Video Scopes (Part number Z485)) to aid in the proper method for advancing the endoscopic accessory into the field of view.

Therefore, we would like to ask all the users to read and carefully follow the attached addendum in order to properly operate the EG-3870UTK Ultrasound Video Gastroscope in combination with endoscope accessories. Please ensure to update the appropriate sections of the Owner's Manual PENTAX Ultrasound Upper GI Video Scopes (Part Number Z845, Revisions R00 through R12) with the attached addendum. Failure to follow the addendum may result in possible injury to patient.

The Owner's Manual PENTAX Ultrasound Upper GI Video Scopes (Part Number Z845) is being revised concurrently to incorporate the updated set of instructions detailed on the attached addendum (the instructions included in the addendum are translated for the purpose of this field action and final translation will be available upon release of the updated Instructions for Use).

In addition, enclosed with this letter is the field correction response form. Please forward this letter, along with the addendum to the Instructions For Use for the EG-3870UTK Ultrasound Video Gastroscope, and the field correction response form to the User Department(s) in your facility so they can review the information provided and complete the response form.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Contact Information

According to the local responsibility

Sincerely,

Wijnand Stijn
General Manager PENTAX Europe GmbH
Quality Assurance and Regulatory Affairs EMEA