

08. April 2014  
Ref: FSCA-PMJ-14-02-1

### Field Safety Corrective Action

#### IFU Addendum for proper use of endoscopic accessories with PENTAX Ultrasound Video Gastroscopes EG-3830UT, EG-3630U and PENTAX Ultrasound Fibre Gastroscope FG-36UX

To: Customer address...

**Attention:** Risk Manager  
Urgent: Medical Device Field Safety Corrective Action

Dear Valued Customer,

Pentax has initiated a Field Safety Corrective Action involving the Instructions For Use to clarify the method for advancing an accessory aspiration needle in the Pentax Ultrasound Video Gastroscopes, EG-3830UT and EG-3630U and Ultrasound Fibre Gastroscope FG-36UX.

#### Issue

Recently PENTAX has been notified of a potential risk related to the use of the Ultrasound Video Gastroscopes EG-3830UT and EG-3630U and Ultrasound Fibre Gastroscope FG-36UX in combination with aspiration needles if the Instruction For Use is not followed carefully by the user. Especially, if the user fails to properly position the elevator while advancing the aspiration needle through the endoscope, the needle can get derailed from the elevator (as shown in the picture below). This could result in the needle not being visible neither in the endoscopic nor in the sonographic field of view. This could subsequently result in a potential risk to health for the patient, such as a perforation.



The aspiration needle is  
"derailed" from the elevator.

Figure 1

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**PENTAX Ultrasound Video Gastroscopes EG-3830UT, EG-3630U and**  
**PENTAX Ultrasound Fibre Gastroscope FG-36UX**

**Instructions**

The instructions specific to the use of the Ultrasound Video Gastroscopes EG-3830UT and EG-3630U and Ultrasound Fibre Gastroscope FG-36UX, in combination with endoscopic 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 and Ultrasound Fibrescopes (Part Numbers: FG-36UX: Z166, revision 08; EG-3630U 、 EG-3830UT : Z258, revision 12) 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 Ultrasound Video Gastroscopes EG-3830UT and EG-3630U and Ultrasound Fibre Gastroscope FG-36UX in combination with endoscopic accessories. Please ensure to update the appropriate sections of the Owner's Manual PENTAX Ultrasound Upper GI Video Scopes EG-3630U and EG-3830UT and Ultrasound Fibrescope FG-36UX with the attached addendum. Failure to follow the addendum may result in possible injury to patients.

In addition, enclosed with this letter is the field correction response form. Please forward this letter, to the relevant 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**

*Each region should describe the contact point such as phone#, person in charge, E-mail address, and so forth*

Sincerely,

**Attachments:**

- Addendum sheet to the Owner's manual for the PENTAX Ultrasound Video Gastroscopes EG-3830UT and EG-3630U and the Ultrasound Fibre Gastroscope FG-36UX
- Confirmation of receipt