FSCA-PMJ-16-04-1

MEDICAL DEVICE FIELD SAFETY CORRECTION

<Business name>
<Address>
<City, State>
<Country>

<Date (*include prior to the initiation of the distribution of the letter in the country/region*)>

To: <Customer Address>

RE: **Notification of Error Correction in Instructions for Use**

Dear Valued Customer,

PENTAX Medical has become aware of an error in the description of an Instructions for Use of ULTRASOUND UPPER GI VIDEO SCOPES EG-3870UTK, EG-3670URK. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Affected Product details:

ULTRASOUND UPPER GI VIDEO SCOPES EG-3870UTK, EG-3670URK

Number of Instructions for Use: Z845

Revision No.: R13-R14

Safety issue:

WARNING

The errors in the instructions for use (IFU) shown in the following table are corrected in the right column. Following to the erroneous description in the IFU may result in ineffective reprocessing, posing a risk of cross-contamination.

Safety Instructions:

Although no incidents have been reported, please be informed about the following errors and correction:

Page	Error	Correct
p70	WARNING: The cleaning detergent solution should remain in contact with the ALL internal channels and external endoscope surfaces for the time period recommended by the manufacturer of the disinfectant.	WARNING: The disinfecting solution must remain in contact with the ALL internal channels and external endoscope surfaces for the time period recommended by the manufacturer of the disinfectant.

Contact information:

<Describe how the customer – consignee can contact PENTAX Medical with any question. Contact name with phone number, email 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.

If you have any question regarding this action, please feel free to contact your local office of PENTAX Medical.

Sincerely,
PENTAX Europe GmbH
Leader RA EMEA, Safety Officer for Medical Devices

Dr. Stephan Lunau