U.S. URGENT FIELD CORRECTION
Use of Disposable Water Bottle Assembly and Instructions for Use Addendum for PENTAX Video Processors, Light Sources & Endoscopes with Air/Water Channels

Dear Valued Customer,

PENTAX Medical video processors and light sources are utilized with a disposable water bottle assembly comprised of a tubing adaptor and sterile water bottle that is intended to provide water and air for the cleaning of the objective lens of PENTAX Medical endoscopes. It has come to our attention that the PENTAX Medical Video Processor EPK-i5010 has been shipped with a reusable PENTAX Medical water bottle assembly (OS-H4) which has not been cleared for use with the EPK-i5010 in the United States. As a result, all customers that have previously received an OS-H4 water bottle with an EPK-i5010 for use with an endoscope with an air/water channel should discard these bottles and should use the PENTAX Medical DispoCap Air Tubing in their place. Users of other PENTAX Medical video processors and light sources should also discard their reusable PENTAX water bottle assemblies (OS-H2 & OS-H4) and replace them with the PENTAX Medical DispoCap Air Tubing. In addition, PENTAX Medical is issuing an Addendum to the Operation and Reprocessing Instructions for Use (IFU) for certain models of endoscopes to remove non-applicable steps as they relate to the water bottle assembly in the pre-cleaning of the endoscope in the procedure room.

The pre-cleaning steps in these Operation and Reprocessing IFUs include an instruction to turn the lever on the water bottle to the ‘drain’ position in order to empty the water channel, however, this action is unique to the reusable PENTAX Medical water bottle and is not relevant for a disposable water bottle assembly. As a result, PENTAX Medical is issuing the attached IFU Addendum which instructs customers to disregard this step. The pre-cleaning instructions are otherwise accurate and complete as it pertains to the disposable water bottle assembly. This addendum should be placed in the Operation and Reprocessing IFUs originally provided with the endoscope at the time of purchase. Please ensure that user departments discard any PENTAX OS-H2/OS-H4 water bottles and transition to the PENTAX Medical DispoCap Air Tubing (Model 100160P) for use with a disposable sterile water bottle.

Response Form
Enclosed with this letter is a Field Correction Response Form. Please forward this letter and the enclosures to the relevant department in your facility so that they may review the information provided and complete the response form. Please note that you must return the completed form even if you do not have any OS-H2/OS-H4 water bottles to discard. Your local sales representative can assist you in completing this form. This information is essential in order to maintain recall effectiveness information required by FDA.

Contact Information
If you have any questions regarding this action, please feel free to contact Paul Silva, PENTAX Americas Recall Coordinator at:

Tel: 800-431-5880 ext. 2064 (8:30 AM – 5:00 PM, Monday – Friday, EST)
Fax: 201-799-4063
Email: recall.coordinator@pentaxmedical.com
Please contact PENTAX Medical customer service to place orders for the PENTAX Medical DispoCap Air Tubing, Model 100160P.

Tel: 800-431-5880
Email: salesupport2@pentaxmedical.com

This 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.

**AFFECTED PRODUCTS**

The following PENTAX Endoscopes with air/water channels (all serial numbers) which utilize PENTAX Video Processors and Light Sources (EPK-i5010, EPK-1000, EPK-i and LH-150-PC) with PENTAX Reusable Water Bottles:

<table>
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<tbody>
<tr>
<td>PENTAX Transnasal Endoscopes</td>
<td>EE-1540, EE-1580K</td>
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<tr>
<td>PENTAX Video Duodenoscope</td>
<td>ED-3490TK</td>
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<tr>
<td>PENTAX Video Ultrasound Gastroscopes</td>
<td>EG-3630U, EG-3630UR, EG-3670URK, and EG-3830UT</td>
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<tr>
<td>PENTAX Video Sigmoidoscopes</td>
<td>ES-3831, ES-3840, and ES-3870K</td>
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<tr>
<td>PENTAX Fiber Endoscopes</td>
<td>FC-38LV, FD-34V, FG-16V, FG-24V, FG-29V, FG-34UX, FG-36UX, FG-38UX, and FS-34V</td>
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<tr>
<td>PENTAX Small Bowel Enteroscopes</td>
<td>VSB-3430K</td>
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Sincerely,

Paul Silva
PENTAX of America Inc.
Director of Regulatory Affairs

Attachments:
- Reprocessing IFU Addendum, Control Number D04-IFU-0001206, Rev. A
- Field Correction Response Form, Control Number F04-FLD-0001198, Rev. A