

September 11, 2008

URGENT: PRODUCT CORRECTION

Revised Instructions for the High Level Disinfection of PENTAX 70 Series Endoscopes with a Forward Water Jet (FWJ) in the ASP Automatic Endoscope Reprocessor (AER)

Dear Risk Manager:

Advanced Sterilization Products division of Ethicon, Inc. (ASP) is notifying you that we have received customer reports of residual high-level disinfectant solution remaining in endoscopes that have been reprocessed in the ASP Automatic Endoscope Reprocessor (AER). If high-level disinfectant, or other fluids, remains in the endoscope after reprocessing, contact with patient mucous membranes may occur and result in chemical burns, irritation (chemical colitis), or other symptoms.

ASP has tested the PENTAX 70 series endoscopes containing a FWJ and has confirmed that residual fluids (disinfectant solution, enzymatic detergent, alcohol or water) may remain in the PENTAX 70 series endoscopes with a FWJ after reprocessing. To eliminate any residual fluids, ASP is recommending that customers perform the following actions when reprocessing PENTAX 70 series endoscopes with a FWJ. These actions are required even if you have not observed any residual fluid in endoscopes. Please destroy any copies of AD-52976-001 Rev. A (ASP AER Connection Diagram: PENTAX 70 Series) that you may have and replace them with the revised copy enclosed. Note: this affects only the drying/removal of residual fluid from the endoscope; high-level disinfection of the endoscope is not compromised.

Revised Instructions for PENTAX 70 Series Endoscopes with a FWJ

- 1. To ensure adequate perfusion of the Forward Water Jet Channel, Water Jet Check Valve Adapter OE-C12 must replace the existing Check Valve. OE-C14, the detachable rubber check valve, must be removed from the tip of the OE-C12 before reprocessing.** The re-usable OE-C14 should be processed along with the scope. The OE-C14 should be reinstalled on the OE-C12 prior to the next procedure. Users should always follow specific reprocessing instructions provided by endoscope manufacturers.
- 2. Reprocess the PENTAX 70 series endoscope with a FWJ by itself.** While the ASP AER has the capacity for reprocessing two endoscopes in a single cycle, our testing has shown that reprocessing only one PENTAX 70 series endoscope with a FWJ per cycle helps avoid residual fluids remaining in the endoscope.
- 3. Following disinfection of the PENTAX 70 series endoscope with a FWJ, perform a five-minute air or air and alcohol flush.** See enclosed instructions.

General Instructions for all Endoscopes

1. It is recommended that customers inspect all endoscopes after reprocessing to determine if any residual fluid remains in the endoscope. If residual fluid is observed in any endoscope, contact ASP immediately to determine if proper processing methods have been followed.

2. Users should always follow specific processing instructions provided by endoscope manufacturers. Please keep in mind that the Society of Gastroenterology Nurses and Associates (SGNA) recommends that all endoscope channels, including accessory channels should be dried with 70 % isopropyl alcohol until alcohol can be seen exiting the opposite end of each channel. If residual fluid persists upon processing endoscopes in the ASP AER, reprocess endoscopes manually per SGNA guidelines. Residual fluids can also occur using manual methods so please ensure appropriate SGNA drying recommendations are followed regardless of method used.

ASP is conducting testing of other endoscopes and will notify customers if ASP's testing indicates the need for special instructions.

Please distribute this information to all ASP AER users in your facility. If you have any questions or need assistance, please call our Customer Care Center at 888-783-7723, option 2.

Sincerely,



Mark Johnson
Vice President, Quality Assurance, Regulatory Affairs and Process Excellence

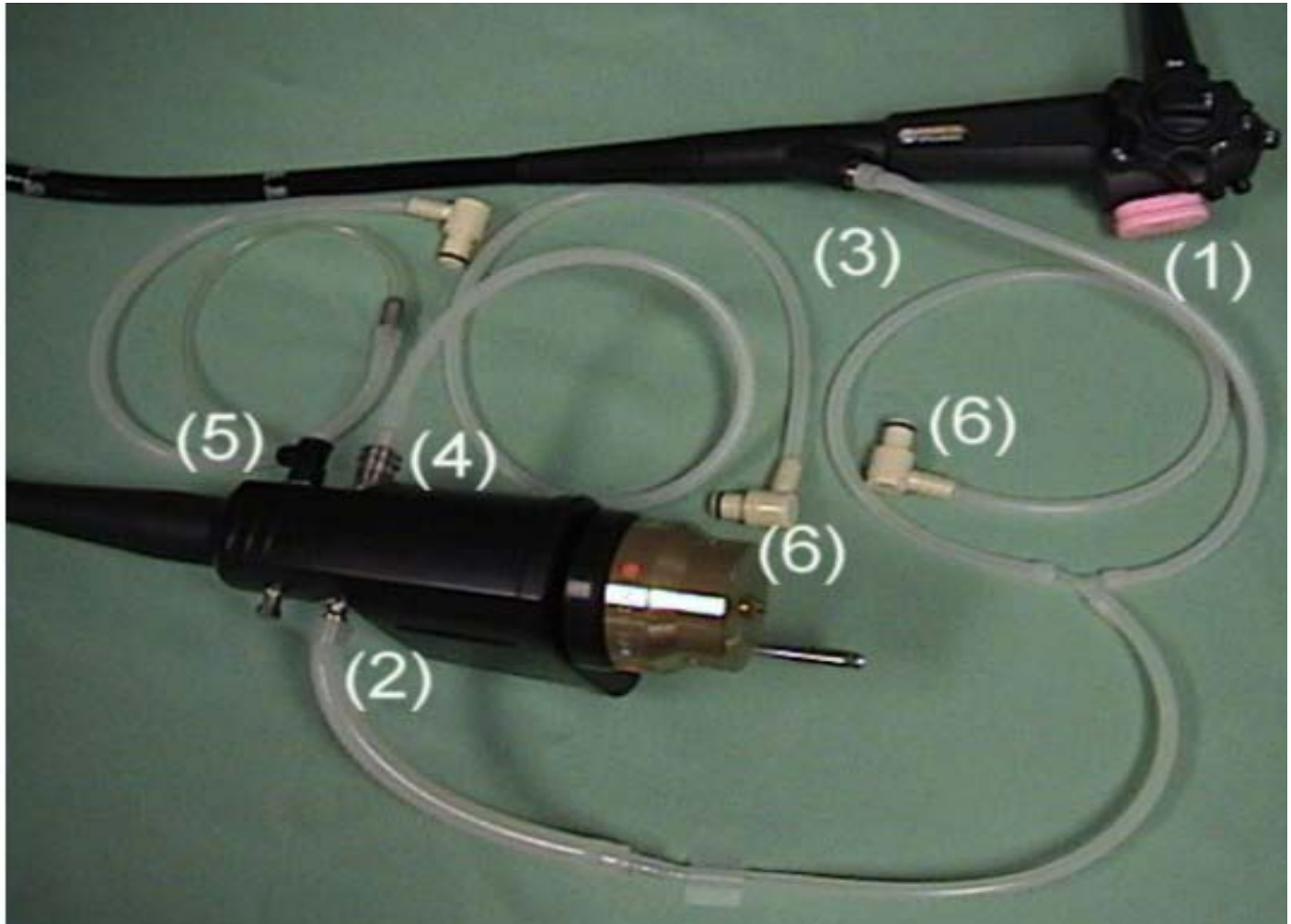
Enclosure: AD-52976-001, Rev. C, ASP AER Connection Diagram: PENTAX 70 Series



ADVANCED STERILIZATION PRODUCTS®

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Brand Series	ASP AER Connection Diagram: PENTAX 70 series with Forward Water Jet (FWJ) Reprocess only <u>one</u> endoscope per cycle
	Attach Soaking Cap
(1)	Attach Pentax Control Head Plug (Pink)
(2)	Attach one branch of ASP Tubing Set 20375 to Suction Barb
(3)	Attach other branch of ASP Tubing to Biopsy Inlet
(4)	Attach ASP Tubing 20366 to Pentax Air/water Cleaning Adapter OF-BG2, then attach to Air/Water Connector



<p>(5)</p>	<p>Attach ASP Tubing Set 20366 to Pentax Forward Water Jet Irrigation Tube OF-B113 then attach to Forward Water Jet.</p> <p>NOTE: To ensure adequate perfusion of the Forward Water Jet Channel, Water Jet Check Valve Adapter OE-C12 must replace the existing Check Valve. OE-C14, the detachable rubber check valve, must be removed from the tip of the OE-C12 before reprocessing.</p> <p>The re-usable OE-C14 should be processed along with the scope. The OE-C14 should be reinstalled on the OE-C12 prior to the next procedure.</p> <p>USERS SHOULD ALWAYS FOLLOW SPECIFIC MANUFACTURER’S INSTRUCTIONS PROVIDED BY ENDOSCOPE MANUFACTURERS</p>
<p>(6)</p>	<p>Attach Quick Connects to ASP Automatic Endoscope Reprocessor</p>
<p>(7)</p>	<p>Following disinfection of the Pentax 70 series endoscope with a FWJ, perform a five minute air or air and alcohol flush.</p>



OE-C12 adapter (left) and with OE-C14 rubber check valve removed (right)