

**URGENT: MEDICAL DEVICE CORRECTION****MAJ-1443 and MAJ-1444 Valves**

<b>Product Name</b>	<b>Model Number</b>	<b>Serial/Lot Numbers</b>	<b>UDI DI</b>
Suction Valve	MAJ-1443	All	04953170355912
Air/Water Valve	MAJ-1444	All	04953170355929
Endoscope Reprocessor	OER-Elite	All	04953170404047
Endoscope Reprocessor	OER-Pro	All	04953170258589

Date: 12-Feb-2026

Attention: Endoscopy Department, Infection Prevention and Control, Sterile Processing Department, Operating Room, Risk Management

Dear Healthcare Provider:


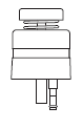
Olympus is writing to inform you of updated instructions for reprocessing pertaining to the MAJ-1443 Suction Valve and MAJ-1444 Air/Water Valve. These products have been designed for use with an Olympus ultrasound endoscope (GF-UC140P-AL5, GF-UE160-AL5, and GF-UCT180) for the gastrointestinal (GI) tract. The MAJ-1443 Suction Valve is intended to remove fluids, debris, or air from the patient and to remove the water from the balloon. The MAJ-1444 Air/Water Valve is intended to feed air to remove fluids or debris adhering to the objective lens, to feed water for lens washing, and to fill the balloon with sterile water.

**Reason for Action:**

Olympus is informing you that the **MAJ-1443 and MAJ-1444 are no longer reprocessing compatible with the OER-Pro and OER-Elite automated endoscope reprocessors.** This means the MAJ-1443 and MAJ-1444 can no longer be high-level disinfected using the OER-Pro or the OER-Elite and must instead be reprocessed by the validated methods described in the updated Instructions for Use (IFU).

Effective immediately, **users should cease reprocessing the MAJ-1443 and MAJ-1444 Valves in an OER-Pro or OER-Elite.** The updated MAJ-1443/MAJ-1444 Instructions for Use, attached to this letter, detail the acceptable reprocessing methods in section 7.2.

**Figure 1: Updated List of Compatible Reprocessing Methods**

		Air/water valve (MAJ-1444)	Suction valve (MAJ-1443)
			
Ultrasonic cleaning <sup>1</sup>		✓	✓
Manual cleaning	Neutral, Non-Enzymatic detergent	✓	✓
	Neutral, Enzymatic detergent	✓	✓
Manual disinfection <sup>2</sup>	2.0 – 3.4% glutaraldehyde	✓	✓
Drying	Alcohol	✓	✓
Automatic cleaning and disinfection <sup>2</sup>	AER		
	OER-AW <sup>3</sup>	✓	✓
	OER-Pro <sup>4</sup>	✗	✗
	OER-Elite <sup>4</sup>	✗	✗
Sterilization	Steam (autoclaving)	✓	✓
	Ethylen oxide gas	✗	✗

✓ compatible      ✗ not compatible

Olympus has not received any complaints for the MAJ-1443 or MAJ-1444 valves related to reprocessing or infection. Olympus also reviewed complaints received for the compatible ultrasound endoscopes (GF-UC140P-AL5, GF-UE160-AL5, and GF-UCT180) and identified seven (7) complaints related to infection; however, the complaints did not contain sufficient information for Olympus to determine if the infection was related to reprocessing of either the endoscope or its accessories.

Olympus is currently updating the Instructions for Use for the OER-Elite, OER-Pro, and compatible ultrasound endoscopes, as needed, regarding reprocessing of the MAJ-1443 and MAJ-1444 valves. **Users should refer only to the current MAJ-1443 and MAJ-1444 Instructions for Use, attached to this letter, for appropriate valve reprocessing instructions.**

**Detailed Explanation:**

As part of a recent 510(k) submission, Olympus was required to demonstrate compliance with current United States Food and Drug Administration (FDA) reprocessing validation requirements that were not in place at the time of original product submission. For the 510(k) submission, Olympus completed full re-validation of manual cleaning, manual high-level disinfection, and steam sterilization for MAJ-1443 and MAJ-1444. Automated high-level disinfection of these valves in the OER-Pro and OER-Elite was not included in this re-validation. Therefore, automated high-level disinfection of these valves is no longer listed as a validated reprocessing method in the revised IFU. These changes are outlined in the updated MAJ-1443/MAJ-1444 IFU (see Figure 1 above).

This IFU change for MAJ-1443 and MAJ-1444 regarding reprocessing compatibility does not reflect the discovery of a new or increased infection risk signal or a failure of the previous reprocessing methods. The MAJ-1443 and MAJ-1444 IFU has now been updated to align with the FDA's current reprocessing validation guidance and includes the reprocessing methods that have been fully validated by Olympus under the newer criteria. For MAJ-1443 and MAJ-1444, the fully validated methods include manual cleaning, manual high-level disinfection, and sterilization.

**Risk to Health:**

Olympus's assessment of this issue has determined that infection risk associated with valves previously reprocessed with the OER-Pro/OER-Elite is rare and is not likely to cause harm based on the considerations described below.

If MAJ-1443 Suction Valves and MAJ-1444 Air/Water Valves are reprocessed using an OER-Pro and/or OER-Elite Reprocessor and not manually cleaned and disinfected according to the current revised IFU instructions, there is a potential risk that the devices may remain contaminated or be inappropriately reprocessed. Such exposure could lead to a patient infection. Any resulting infection may require additional medical management, including treatment with oral or intravenous antibiotics.

Olympus's assessment of this issue included a review of relevant literature and complaint data. A small number of post-market complaints and literature reports described febrile or infectious events following procedures involving Olympus EUS scopes. However, no consistent valve-related failures, contamination source, or infection cluster were identified. Considering Olympus's global complaint history, the absence of confirmed valve-related infections, and the continued use of manual cleaning and high-level disinfection methods, the risk of patient infection associated with reusable EUS valves is considered rare.

**Actions Required:**

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Effective immediately, **users should cease reprocessing the MAJ-1443 and MAJ-1444 valves in an OER-Pro or OER-Elite.**
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification and the full extent of the MAJ-1443 and MAJ-1444 reprocessing steps as detailed in the attached Instructions for Use (IFU). The updated IFU can also be accessed electronically through OlympusConnect.com.
4. Replace any existing copies of the MAJ-1443/MAJ-1444 IFU with the updated IFU attached to this letter. Add a copy of this letter and MAJ-1443/MAJ-1444 IFU to your OER-Pro and/or OER-Elite documentation.
5. If you have further distributed this product, identify your customers and forward this notification to them.
6. Olympus requests that you acknowledge receipt of this letter. Acknowledge receipt of this letter through the Olympus web portal:
  - a. Go to <https://olympusamerica.com/recall>
  - b. Enter the recall number "**0492**"
  - c. Complete the form as instructed.

Olympus requests you to report any complaints, including infection, to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@Olympus.com.

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Sr. Manager  
Field Corrective Action, Americas