



Date: January 16, 2024

**URGENT: MEDICAL DEVICE FIELD CORRECTIVE ACTION**

**Product: MAJ-2318 Water Filter**

**UDI: 04953170401473**

**Lot Number: 36A, 37A, 38A**

**ATTENTION: ENDOSCOPY DEPARTMENT**

Dear Health Care Practitioner:

Olympus has become aware of an issue that requires your attention. This letter pertains to the MAJ-2318 Water filter, which is compatible with the following series of Olympus Endoscope Reprocessors: OER-ELITE™, OER-Pro™ and OER-MINI™. This water filter has been designed to prevent rinse water contamination in the OER Endoscope Reprocessors.

Olympus confirmed there is a possibility that the water filter MAJ-2318 may have been assembled improperly. Specifically, the adapter may be installed on the incorrect end of the filter body. The potentially affected lot numbers are listed in Attachment 1. If customers use a defective filter, the tap water supplied to the OER Endoscope Reprocessors may not be properly filtered. As a result, unfiltered tap water would be used for reprocessing.

**Risk to Health:**

A properly functioning filter helps remove tap water microorganisms from the rinse water and is designed to help prevent potential device contamination and any subsequent infection risk from potable water sources. Using a defective filter may expose a patient to a potentially contaminated device if contaminated water was utilized during and after high-level disinfection, which presents a risk of infection or sepsis. Although Olympus received a complaint identifying this manufacturing issue, Olympus has not received any reported injuries or patient infections associated with this issue.

In the event an improperly assembled MAJ-2318 water filter was installed in an OER Endoscope Reprocessor, users are advised to consult with their internal infection prevention team regarding facility water quality and consider any other variables which affect water quality for their OER machine.

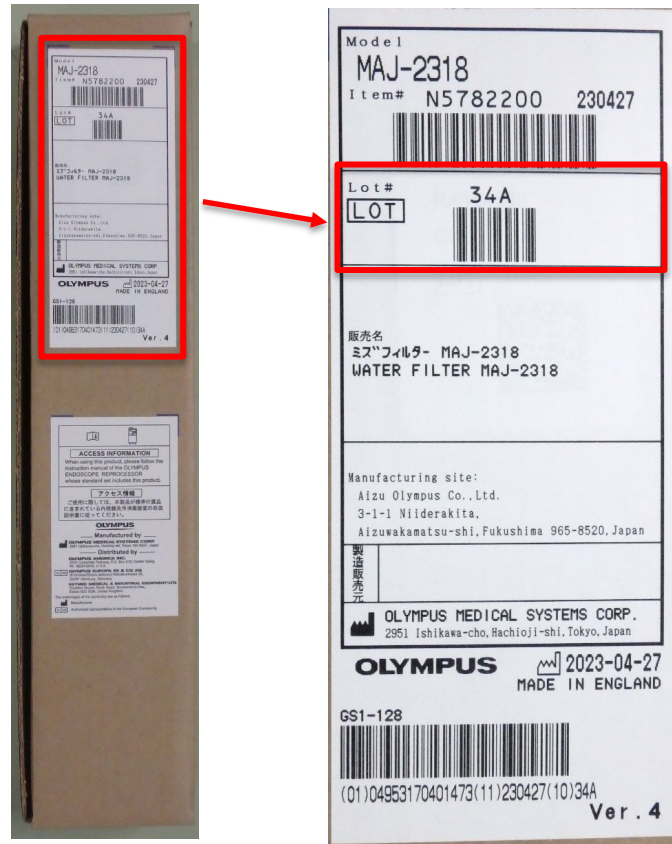
**Action steps to be taken by the end user:**

Based upon our distribution records, Olympus has determined that your facility has purchased one or more of the affected devices with a lot number listed in Attachment 1. Olympus requires that you take the following actions.

1. Immediately assess all MAJ-2318 that you have at your facility to check the model and lot number.

## A. Action for new MAJ-2318

- Inspect your new MAJ-2318 for the affected lot numbers. The lot number can be found on the package according to Figure 1.

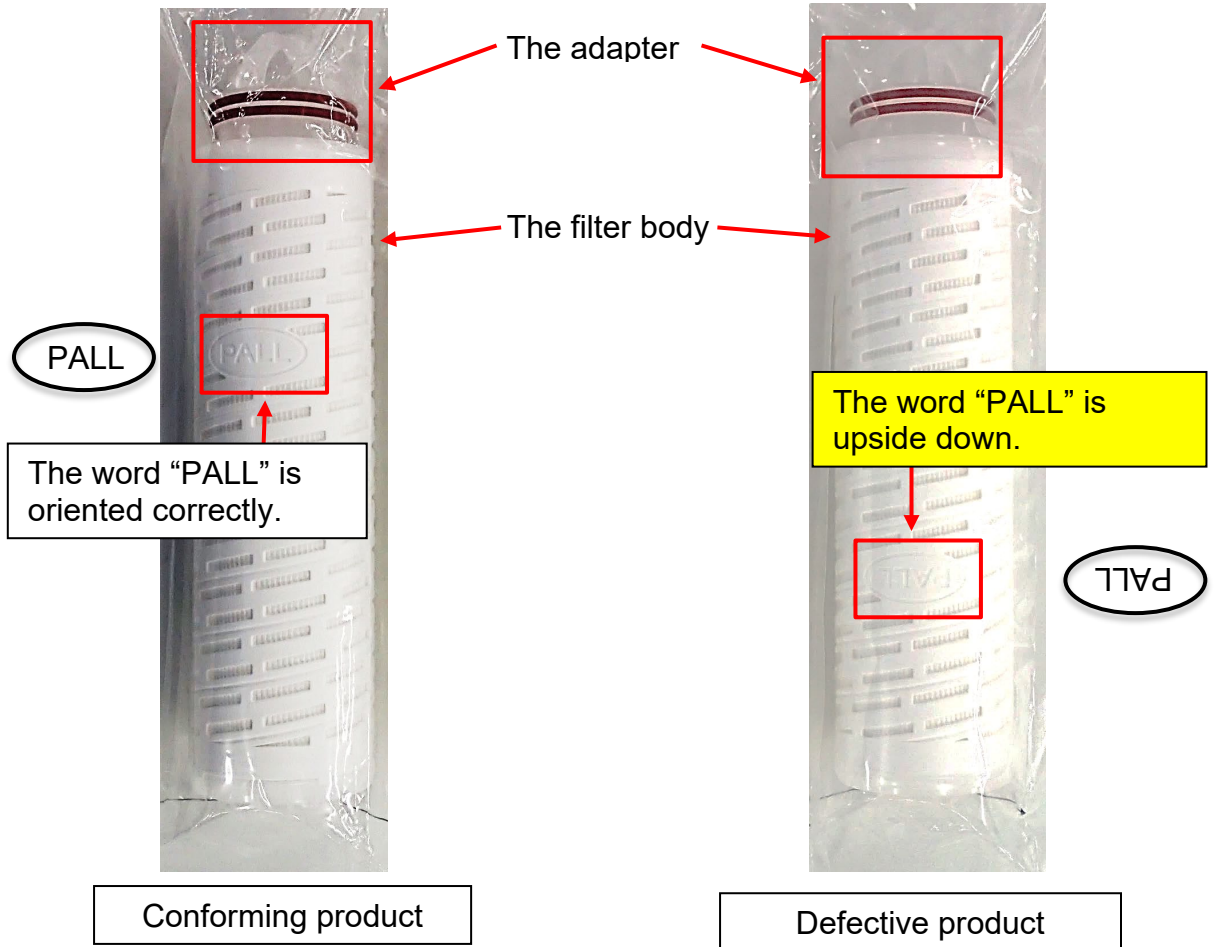


**Figure 1: Location of Lot number on MAJ-2318 Water Filter**

- If you have a product with the affected lot number, please take the product out of the box and, without opening the plastic wrapper, check the position of the adapter according to the following inspection criteria:

**In conforming products**, the word “PALL” can be seen in the correct orientation when the adapter is turned up.

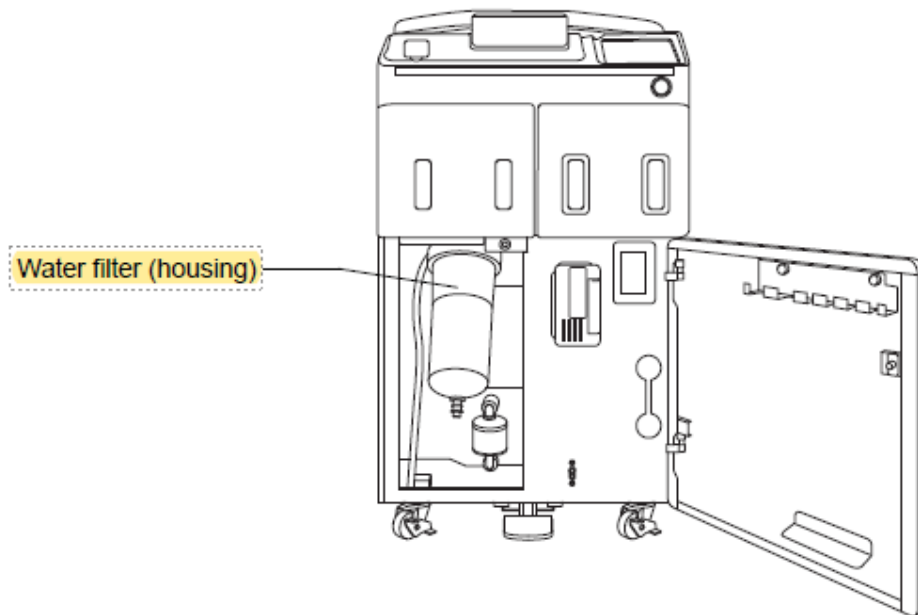
**In the defective product**, the word "PALL" can be seen upside down when the adapter is turned up.



- If you confirm the product is conforming, you can use it.
- **If you confirm the product is defective**, please call your Olympus Customer Service in step 2.

B. Action for MAJ-2318 which is **installed** in Olympus OER-ELITE, OER-PRO and OER-MINI Automated Endoscope Reprocessors:

- Locate the MAJ-2318 installed in your OER machine. See below for housing location for installed filters



- If you are in possession of the carton box that the MAJ-2318 was received in, or if you have any records which show the lot number of the currently installed MAJ-2318, please check the lot number.
  - If you confirm that an MAJ-2318 from the affected lot is installed, or if the lot number is unknown, please replace the MAJ-2318 with a new one according to the filter replacement instructions in the IFU. Please quarantine the removed MAJ-2318.
  - If the lot number of an installed MAJ-2318 is NOT part of the affected lot number, the installed MAJ-2318 can be used as is.
- 2. If you confirmed your new MAJ-2318 is defective, please call your Olympus customer service representative at 1-800-848-9024, option 2. Olympus will issue a Return Material Authorization to return any affected product at no charge to you and a credit will be applied to your facility upon return of the affected product.

If you had to replace the MAJ-2318 in your OER machine as described above, Olympus will issue a credit to your facility for your MAJ-2318 and a bottle of disinfectant needed to disinfect the OER Reprocessor water line after a water filter change.

- 3. Regardless of whether you have a defective MAJ-2318, please access the Olympus recall portal to indicate that you have received this notification.



- a. Go to <https://olympusamerica.com/recall>.
  - b. Enter the recall number "0440"
  - c. Complete the form as instructed.
4. In addition, if you have further distributed this product, please reach out to those facilities and notify them at once of this field action and appropriately document your notification process. Your notification to your customers may be enhanced by including a copy of this field action notification letter.

If you require assistance with the inspection, please contact the Olympus Technical Assistance Center at 1- 800-848-9024, option 1.

Please report any adverse events and/or irregularities associated with the use of the MAJ-2318 to Olympus by contacting the Olympus Technical Assistance Center at 1-800-848-9024, option 1, and the FDA. Adverse reactions 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 appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me at (647) 999-3203 or by e-mail at [Cynthia.Ow@Olympus.com](mailto:Cynthia.Ow@Olympus.com).

Sincerely,

*Cynthia Ow*

Cynthia Ow  
FCA Regional Lead, Americas