

URGENT: MEDICAL DEVICE REMOVAL
Endoscope Reprocessor Connecting Tubes

Product Name	Model/Catalog Number	Lot Numbers	UDI DI
CONNECTING TUBE	MAJ-2110	09A to 51A*	04953170404054
CONNECTING TUBE	MAJ-2111	09A to 51A*	04953170404061
CONNECTING TUBE	MAJ-2112	09A to 51A*	04953170404078
CONNECTING TUBE	MAJ-2113	09A to 51A*	04953170404085
CONNECTING TUBE	MAJ-2114	09A to 51A*	04953170404092
CONNECTING TUBE	MAJ-2115	09A to 51A*	04953170404108
CONNECTING TUBE	MAJ-2116	09A to 51A*	04953170404115
CONNECTING TUBE	MAJ-2117	09A to 51A*	04953170404122
CONNECTING TUBE	MAJ-2118	09A to 51A*	04953170404139
CONNECTING TUBE	MAJ-2119	09A to 51A*	04953170404146
CONNECTING TUBE	MAJ-2138	09A to 51A*	04953170404184
CONNECTING TUBE	MAJ-2330	09A to 51A*	04953170404207

*See Attachment 1 for full list of Lot Numbers distributed in the U.S. between Oct. 2020 to Feb. 2026.

Date: 25-MAR-2026

Attention: Endoscopy Department, Sterile Processing Department, Risk Management

Dear Healthcare Professional

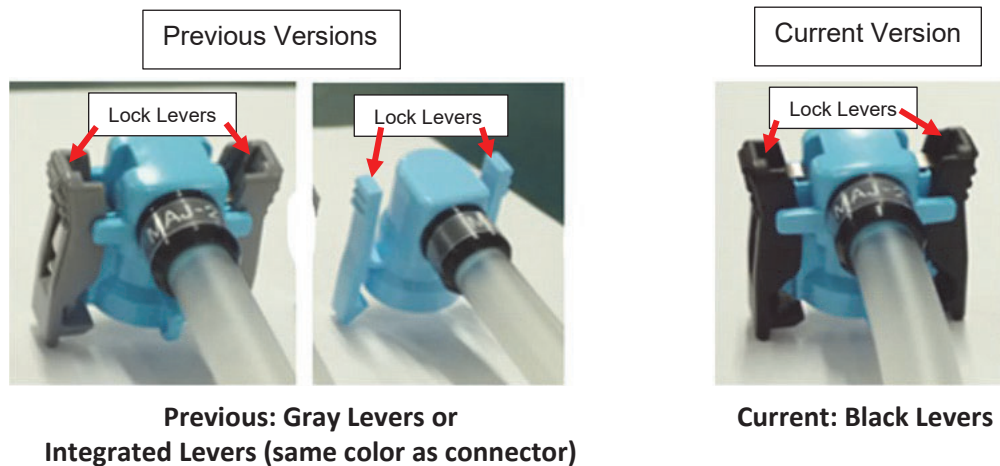
Olympus is writing to inform you of a Medical Device Removal pertaining to a subset of Endoscope Reprocessor Connecting Tubes. These products are designed to be used when reprocessing Olympus endoscopes using the Olympus Endoscope Reprocessor. The connecting tubes are compatible with the OER-ELITE Endoscope Reprocessor.

Background:

At market launch in September 2020, the initial design (Version 1) of the reprocessor connecting tube incorporated a “separate” type of connector, meaning that the connector body and the lock levers (identified in image below) were separate components. It was later identified through internal testing that the lock lever may disengage and detach from the connecting tube body if pressed outward. This subsequently led to a design change in November 2021 (Version 2) to an “integrated” type of connector, in which the connector body and lock levers are a single component. These connecting tube versions are depicted in the image below.

Reason for Action:

Olympus identified through a complaint review that Version 2 of the connecting tubes may fail prematurely. Specifically, the lock levers have detached and broken earlier than expected in some instances. The current connecting tube design addresses the issues identified for Version 1 and Version 2. Olympus will therefore be removing the previous versions of connecting tubes (Version 1 and Version 2) from the market and replacing them with the current version.



Since the products' launch in September of 2020, Olympus has received 1,182 complaints potentially related to broken lock levers. No serious injuries have been reported related to this issue.

Risk to Health:

Use of an affected Endoscope Reprocessor Connecting Tube may result in the lock lever disengaging or breaking during endoscope reprocessing. If the connecting tube disconnects from the Endoscope Reprocessor, the reprocessing cycle may not be completed as intended. In such cases, the endoscope may require reprocessing to be restarted with a functioning connecting tube or manual disinfection. This failure mode may lead to a delay in initiating treatment if clinical procedures must be postponed while the endoscope is properly reprocessed.

Actions Required:

Our records indicate that your facility has received one or more units affected. These products may have been included with your OER-ELITE. Olympus requires you to take the following actions:

1. Examine your inventory and your OER-ELITE and identify which connecting tube version(s) you have, based on the images above. The current version has black lock levers. The previous versions have gray lock levers or integrated lock levers, which are the same color as the rest of the connector.
 - a. If you have sufficient quantities of the current version (black) to support your reprocessing needs, stop using the previous version and set aside for return. You may proceed with using the current version, only.
 - b. If you have insufficient quantities of the current version (black) available, and you do not have another method of endoscope reprocessing readily available, you may continue using the

previous version(s) consistent with the Instructions for Use, which require users to inspect the connecting tube prior to use. Transition to the current version as soon as possible by placing an order through Customer Service at 1-800-848-9024, option 2.

2. When you obtain sufficient quantities of the current version (black) to support your reprocessing needs, stop using the previous version and only use the current version going forward.
 - a. To return the previous version of the connector, please contact Customer Service at 1-800-848-9024 option 2, to obtain a Return Material Authorization. To expedite processing, please have the quantity for each lot, the corresponding PO# and/or account number, if available. Olympus will issue a credit to your facility upon return of your affected product.
3. Even if you no longer have this product, Olympus requests that you acknowledge receipt of this letter through the Olympus web portal:
 - a. Go to <https://olympusamerica.com/recall>
 - b. Enter the recall number "0497"
 - c. Complete the form as instructed.
4. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests that you report any complaints of device damage or failure 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 by phone at (647) 999-3203 or by email at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Sr. Manager
Field Corrective Action, Americas

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Attachment 1 – Models and Lot Numbers
Distributed in the U.S. between Oct-2020 to Feb-2026

Product Name	Model/Catalog Number	Lot Numbers	UDI DI
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CONNECTING TUBE	MAJ-2138	See below	04953170404184
CONNECTING TUBE	MAJ-2330	See below	04953170404207

Lot Numbers					
	11A	21A	31A	41A	51A
	12A	22A	32A	42A	
	13A	23A	33A	43A	
	14A	24A	34A	44A	
	15A	25A	35A	45A	
	16A	26A	36A	46A	
	17A	27A	37A	47A	
	18A	28A	38A	48A	
09A	19A	29A	39A	49A	
0XA	1XA	2XA	3XA	4XA	
0YA	1YA	2YA	3YA	4YA	
0ZA	1ZA	2ZA	3ZA	4ZA	