October 04, 2024

URGENT: MEDICAL DEVICE REMOVAL

MAJ-1555 Single Use Biopsy Valve

Product Name	Model Number	Lot Numbers	UDI PI
Single Use Biopsy Valve	MAJ-1555	1YH	14953170247573
		1ZH	
		21H	
		22H	
		23H	
		24H	

Attention: Endoscopy Department, Risk Management

Dear Healthcare Provider:

Olympus is writing to inform you of a Field Corrective Action pertaining to the MAJ-1555 Single Use Biopsy Valve. This product is intended to be attached to the instrument channel port of the compatible endoscopes and to prevent reflux of body fluids.

Reason for Action:

Olympus has become aware that the lots identified above may be missing product identification and an expiration date on the sterile packaging. The information that may be missing are the sterile and manufacturing lot numbers, and expiration dates. This information is clearly printed and can be found on the outer box or zipper bag label. The affected lots were distributed from March 2022 to December 2022. Olympus has not received any complaints associated with this issue.

Olympus recommends that you do not use any of these products if you are unable to determine the expiration date.

Risk to Health:

The inability to confirm the expiration date on the product could result in use of product beyond its intended shelf life, which could, in rare cases, result in an infection.

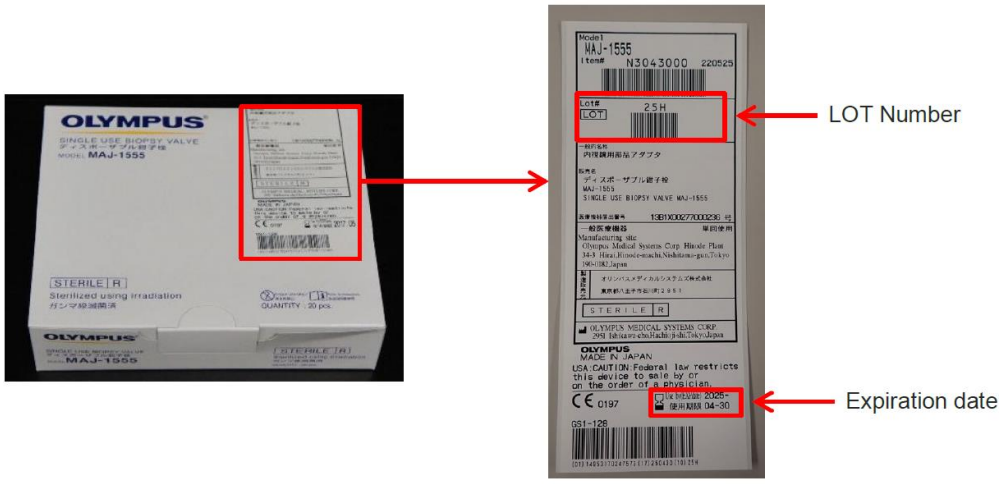
Actions Required:

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

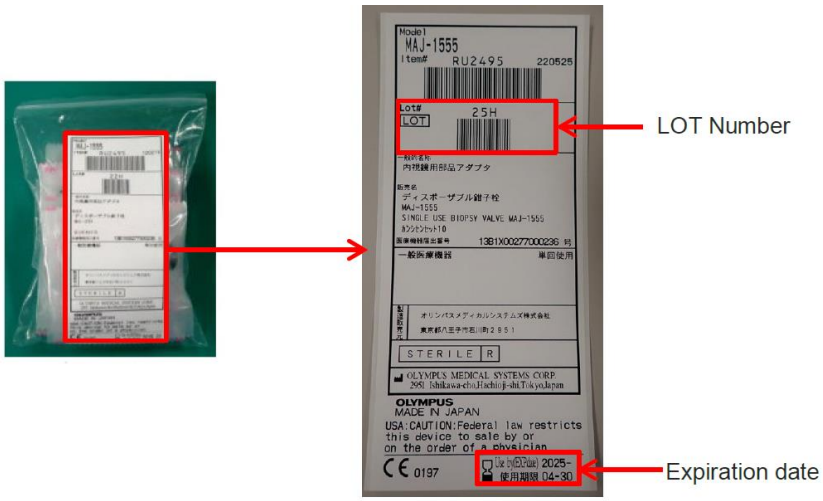
1. Carefully read the content of this notification.
2. Inspect your inventory and identify any MAJ-1555 devices with the lot number(s) specified above. Please check all areas of the hospital to determine if any of these devices remain in inventory.
3. If you have the affected lots in stock, inspect the sterile packages to confirm the sterile lot, manufacturing lot and expiration date are clearly printed as illustrated below.

4. The information missing from the sterile packages can be found on the outer box or zip bag as illustrated below:

Carton Box



Zipper Bag



5. In the event the sterile package is missing the sterile lot, manufacturing lot and/or expiration date, maintain the outer box or zip bag for your future reference. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification.

6. Olympus further recommends that you do not use any of these products if you are unable to determine the expiration date. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization for the affected product for which you are unable to determine the expiration date. Olympus will issue a credit to your facility upon return of your affected product.
7. Olympus requests that you acknowledge receipt of this letter. 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 "**0459**"
    c. Complete the form as instructed.
8. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including those related to missing product identification information, to the Olympus 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 email at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow,
Field Corrective Actions Lead, Americas