

URGENT FIELD SAFETY NOTICE

RE: MAJ-1555 Single Use Biopsy Valve

Attention: Operating Room Director, Risk Management Department

Material ID	Product Name	Model Number	Lot Numbers	UDI PI
N3043000	Single Use Biopsy Valve	MAJ-1555	1YH	14953170247573
			1ZH	
			21H	
			22H	
			23H	

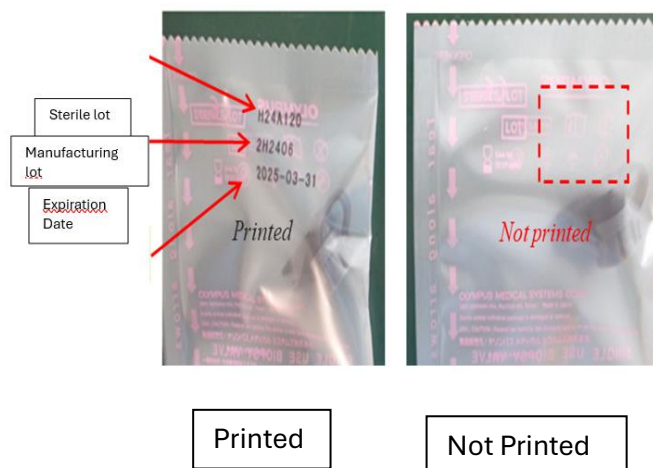
Dear Healthcare Professional:

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 May 2023. 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 Olympus representative with regard to return and reimbursement procedure. Olympus will issue a credit to your facility upon return of your affected product.
7. If you have further distributed this product, identify your customers, and forward them this notification.
8. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative ra@olympus.co.uk latest by 05/11/2024.

BSI and the Medicines and Healthcare products Regulatory Agency (MHRA) is aware of the actions described in this letter.

Olympus requests that you report any complaints, including those related to MAJ-1555, to concerns@olympus.com. Adverse events experienced with the use of this product may also be reported Medicines and Healthcare products Regulatory Agency (MHRA) online.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact ra@olympus.co.uk / Olympus directly at 01702 616333 from Monday through Friday.

Sincerely,

Charlotte Bell

Charlotte Bell
FSCA & QA Projects Lead/Region UI



REPLY FORM: QIL FSN FY25-EMEA-18-FY23-OSTA-04-MAJ-1555

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

Insert description of the product names and model numbers of the affected products

Catalog #	Serial / Lot #	Date Shipped	Qty Shipped to your facility	Qty remaining in Stock

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
		Click or tap to enter a date.
<i>Name</i>	<i>Signature</i>	<i>Date (YYYY-MM-DD)</i>

Please send the completed form to ra@olympus.co.uk by date 05/11/2024.