Date: 19-Dec-2024

Olympus reference: QIL FY25-EMEA-24-FY25-012 BML-V442QR-30 Distal Tip Tear

URGENT: FIELD SAFETY NOTICE

RE: Single Use Mechanical Lithotriptor V

Attention: Endoscopy Department, Risk Management, Material Manager

Material ID	Model/Catalog Number	Product Name	Lot Number(s)	UDI PI
N2303230	BML-V442QR-30	Single Use Mechanical Lithotriptor V	33K, 34K, 35K, 36K, 37K, 38K, 39K, 3XK, 3YK, 3ZK, 41K, 42K, 43K, 44K	04953170218422

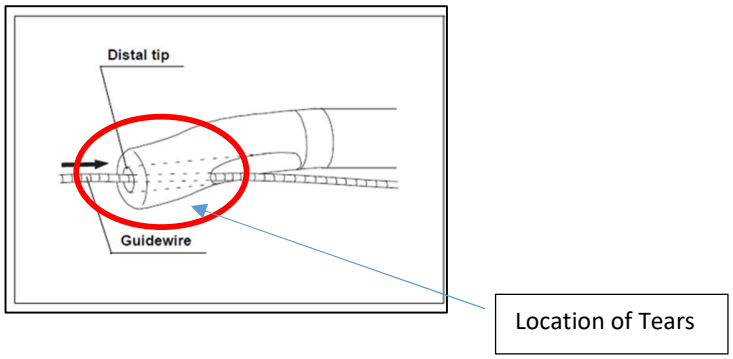
Table 1: Impacted Product

Dear Healthcare Professional,

Olympus is initiating a product removal Field Action for specific lots of the BML-V442QR-30, Single Use Mechanical Lithotriptor V. The Mechanical Lithotriptor is a single use device used with an Olympus endoscope to perform endoscopic mechanical lithotripsy to crush calculi (stones) inside the bile duct. Our records indicate that your facility has purchased one or more of the affected products.

Reason for Action:

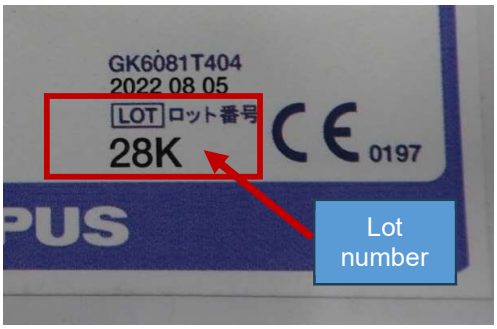
Olympus has identified an increase in complaints for BML-V442QR-30. The complaint data analysis found that distal tip tearing (see Figure 1) of the Mechanical Lithotriptor V had increased beginning with the production of lot 33K. Olympus has identified 296 complaints for the BML-V442QR-30 globally between June 1, 2021, through July 31, 2024. There were 169 reportable malfunctions, and there was one report of a serious injury in relation to this issue. Olympus' investigation confirmed that the issue is limited to the lots included in this letter, and there is an ongoing investigation of this issue to prevent further occurrence. The image with an example of the distal tip tear is below:



Risk to Health:
A distal tip tear can lead to potential patient harms. Depending on when a torn distal tip is identified, it could lead to a delay in initiating an ERCP procedure, or if noticed during the ERCP, it could prolong the surgery, due to the need to replace the device in both instances. If there is no alternative device replacement available, it could potentially result in the cancellation of the procedure. Potential consequences of a torn distal tip also include injury to the bile or pancreatic duct and bowel perforation. In the event either of these occur, appropriate medical intervention/management should be based on the clinical circumstance.

Actions Required:
Olympus requires you to take the following actions:

1. Examine your inventory for the impacted Single Use Mechanical Lithotriptor V lot numbers (Table 1) and quarantine any affected devices. The lot number can be located on the package as follows:



2. **Cease usage of the impacted lot numbers with immediate effect.**
3. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this letter by completing and returning the enclosed Reply Form to your local Olympus representative *[local facility method/contact] by [X date]*.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Your National Competent Authority is aware of the actions described in this letter.

Olympus requests that you report any complaints, including incorrect product found in packaging, to *[local facility complaint reporting contact]*. Adverse events experienced with the use of this product may also be reported *[local competent authority]* by *[method].*

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].*

Sincerely,
Name
Olympus title

REPLY FORM – QIL FY25-EMEA-24-FY25-012 BML-V442QR-30 Distal Tip Tear

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.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* by date *XXX*.