URGENT: MEDICAL DEVICE REMOVAL

Single Use Mechanical Lithotriptor V

Product Name	Model/Catalog Number	Lot Number(s)	UDI PI
Single Use Mechanical Lithotriptor V	BML-V442QR-30	33K-39K, 3XK, 3YK, 3ZK, 41K-44K	04953170218422

Table 1: Impacted product

Date: December 16, 2024

Attention: Endoscopy Department/Risk Management,

Dear Healthcare Professional:

Olympus is initiating a product removal 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 the BML-V442QR-30. The complaint data analysis found that distal tip tearing 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.

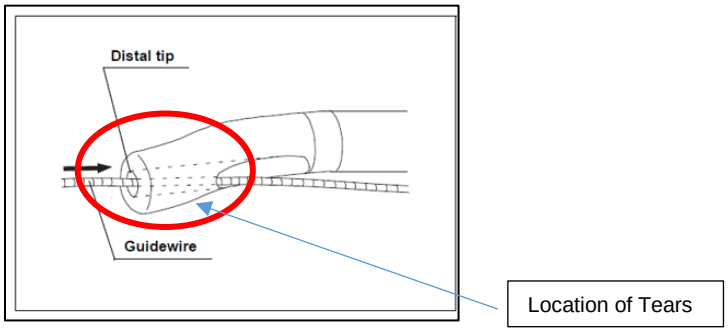


Figure 1. Location of distal tip tear

Risk to Health:

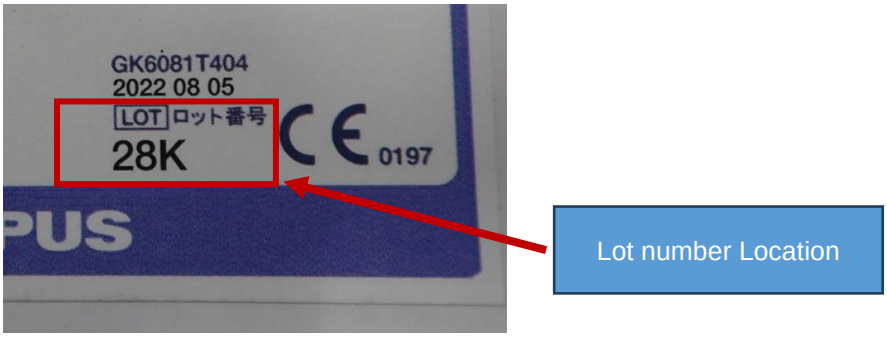
A distal tip tear can lead to potential patient harms. Depending on when a torn distal tip is identified, it could lead to a delay in initiating an ERCP procedure, or if noticed during the ERCP, it could prolong the surgery, due to the need to replace the device in both instances. If there is no alternative 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.



2. **Cease usage of the impacted lot numbers with immediate effect.**
3. If you have affected products in your inventory, please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this letter through our Olympus web portal:
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0464"
    c. Complete the form as instructed.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests you to report any complaints, including incorrect product found in packaging, 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 directly by phone at (647) 999-3203 or by e-mail Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Actions Lead, Americas