Reference: 2024-X003M

18 December 2024

URGENT: MEDICAL DEVICE REMOVAL
Product: Single Use Mechanical Lithotriptor V

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

Table 1: Impacted product

Attention: **Endoscopy Department, Risk Management, Material Manager**

Dear Healthcare Professional/Provider:

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.

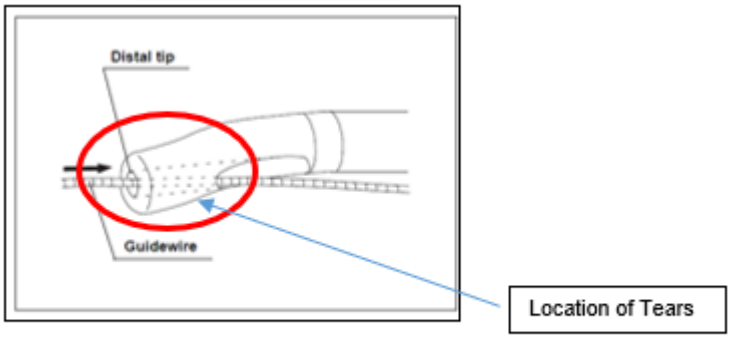

Figure 1. Example of distal tip tear

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.

Action steps to be taken by end user:

Our records indicate that your facility has purchased one of the affected products. **Olympus requests 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. Olympus requests that you acknowledge receipt of this letter. Indicate on the Response Form that you have received and understood this notification by filling out and returning the completed enclosed Response Form to us.
4. Olympus will contact you to arrange for return of your device to Olympus, and we will issue credit to your facility.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests that you report complaints, and adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this matter. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact for enquiries
Regulatory Affairs and Quality Assurance Department
Email : mes-ra.oml@olympus.com
Tel : (603) 7650 8990
Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai

……

Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd

RESPONSE FORM

Medical Device Recall - Acknowledgement and Receipt

Response is required

[Name & Address of Hospital/Medical Facility]
[Dept/Attn]

PRODUCT NAME: Single Use Mechanical Lithotriptor V

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

Please distribute this information to the appropriate personnel at your facility including surgeons who may have received the product which is the subject of this recall notice.

I have read and understand the recall instructions provided in the **18 December 2024** letter.

Yes ☐ No ☐

Any adverse incidents associated with recalled product?

Yes ☐ No ☐

If yes, please explain: _____

Check the applicable boxes below:

☐ I DO NOT have affected device remaining. All have been used or discarded.

☐ I DO have the affected device, which I will return to Olympus.

Lot Number: _____ Quantity to be Returned (UOM): _____

Name: _____

Designation: _____

…… ……

Signature & Company Stamp Date

Please send the completed and signed Response Form to Regulatory Affairs Department to
[Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com]

2024-X003M.r1

Final Audit Report 2024-12-18

Created:	2024-12-17 (Australian Western Standard Time)
By:	Seo Ching Yeoh (seoching.yeoh@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAUsK_MskkG8PYbnXAeL5cIO8TMVoQZ2j3

"2024-X003M.r1" History

Document created by Seo Ching Yeoh (seoching.yeoh@olympus.com)
2024-12-17 - 10:00:12 PM GMT+8- IP address: 165.225.113.31

Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature
2024-12-17 - 10:06:35 PM GMT+8

Email viewed by Hideki Nagai (hideki.nagai@olympus.com)
2024-12-18 - 7:11:44 AM GMT+8- IP address: 104.47.56.126

Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)
Signature Date: 2024-12-18 - 7:13:13 AM GMT+8 - Time Source: server- IP address: 165.225.230.122

Agreement completed.
2024-12-18 - 7:13:13 AM GMT+8