Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 179 **dated** 30/12/2024 **Regarding SFDA Recall of Single Use Mechanical Lithotriptor V from (mfr: Olympus).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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سلطنة عُمان
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Circular No. 179 **/ 2024**

28 -06-1446 H
30 -12-2024

Recall of Single Use Mechanical Lithotriptor V from Olympus.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/222
Product	Single Use Mechanical Lithotriptor V.
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Material ID: N2303230. Model/Catalog Number: BML-V442QR-30. Lot Number(s): 33K, 34K, 35K, 36K, 37K, 38K, 39K, 3XK, 3YK, 3ZK, 41K, 42K, 43K, 44K. UDI PI: 04953170218422.
Reason	Distal tip tearing of the Mechanical Lithotriptor V had increased beginning with the production of lot 33K.
Action	1. Cease usage of the impacted lot numbers with immediate effect. 2. If you have affected products in your inventory, please contact Olympus distributor with regard to return of affected products, refer to the attachment for more details.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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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

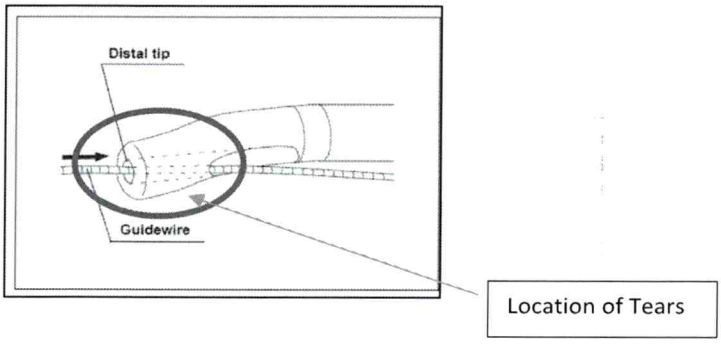
Table 1: Impacted Product

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:



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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 ra@olympus-mea.com
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 any complaints, including incorrect product found in packaging, to *ra@olympus-mea.com*. Adverse events experienced with the use of this product may also be reported *ra@olympus-mea.com*

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact ra@olympus-mea.com

Sincerely,
Fadila Ezzahid
Regional Quality Assurance & Regulatory Affairs Specialist Middle East & Africa
Olympus MEA FZ-LLC, P.O. Box: 33607 Dubai
Registration No. 93456 (Dubai Development Authority)
Dubai Science Park - Laboratory Complex - Dubai - United Arab Emirates

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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 ra@olympus-mea.com by date *16 January 2025*.