



نتقدم بثقة  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Oman Vision

To:

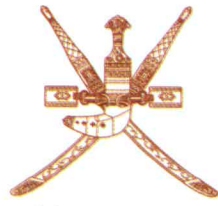
**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (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 91 dated 11/5/2023 Regarding NCMDR Recall of Distal Cover MAJ-2315 from (mfr: Olympus).

Copy to:

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



Circular No. 91 / 2023

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11 -05-2023

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### Recall of Distal Cover MAJ-2315 from Olympus.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19530">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19530</a>
Product	Distal Cover MAJ-2315.
Description	Duodenoscope.
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Single Use Distal Cover MAJ-2315 Used with: EVIS EXERA III Duodenovideoscope TJF-Q190V, EVIS LUCERA Elite Duodenovideoscope TJF-Q290V, Duodenovideoscope TJF-Q170V Material ID: N5786100 Material Description: MAJ-2315 Single Use Distal Cover UDI: 04953170403019 Lot Number: Lower than H2530
Reason	May cause mucosal injury, become cracked and/or detach from the endoscope during use.
Action	1. Immediately locate and no longer use the MAJ-2315 with the original design Olympus will issue a Return Material Authorization to return any affected product at no charge to you. 2. Contact the local agent for remedial action.
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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General

