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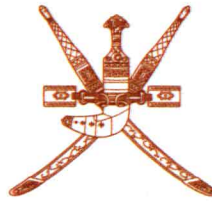
**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (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 154 dated 24/7/2023 Regarding NCMDR recall of Fusion Lithotripsy Extraction Baskets from (mfr: Cook Medical Europe Limited).

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. 154/2023

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24 -07-2023

نتقدم بثقة  
Moving Forward  
with Confidence



### Recall of Fusion Lithotripsy Extraction Baskets from Cook Medical Europe Limited

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19632">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19632</a>
Product	Fusion Lithotripsy Extraction Baskets.
Description	Endotherapy stone removal basket.
Manufacturer	Cook Medical Europe Limited.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	UDI: 10827002482774, 10827002482781 Reference number: FS-LXB-3X6 Lot number: W4635963.
Reason	The above device was manufactured and distributed with nonconforming. This manufacturing nonconformance can appear in the field as inability to advance or retract the basket, or the drive wire breaking or separating from handle (with or without mechanical lithotripsy).
Action	1. Quarantine the above device and return it to the Cook Medical. 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

