Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat



وزارة الصح التمديرية التعامية لل والرقابة الدوائ

Circular No. 200 / 2022

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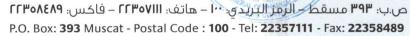
Recall of Fogarty Arterial Embolectomy Catheters, Fogarty Fortis Arterial Embolectomy Catheters, and Fogarty Riliary Ralloon Probesfrom Edwards Lifesciences Services CmhH

Biliary Balloon Probesfrom Edwards Lifesciences Services GmbH.	
Source	GHC- Gulf Health Council
Product	Fogarty Arterial Embolectomy Catheters, Fogarty Fortis Arterial Embolectomy Catheters, and Fogarty Biliary Balloon Probes.
Manufacturer	Edwards Lifesciences Services GmbH.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	Thrombectomy balloon catheter: 120803FP, 120404FP, 120403FP, 120804FP, 120806FP, 120602FP, 120805FP, 120807FP, 120803FSP, 120403FSP, 120404FFP, 120804FFP. Biliary drainage catheter: 410235FP, 410236FP, 410405FP Fogarty® Arterial Embolectomy Catheters Pouch-Pack: 120803FP, 120404FP, 120403FP, 120804FP, 120806FP, 120805FP, 120807FP, 120803FSP, 120403FSP. Fogarty® FORTIS Arterial Embolectomy Catheters Pouch-Pack: 120404FFP, 120804FFP Fogarty® Biliary Balloon Probes - Pouch Pack: 410235FP, 410236FP, 410405FP.
Reason	Edwards Lifesciences is voluntarily recalling certain lots of abovementioned products due to inability to inflate the balloon or maintain balloon integrity because some catheters are exhibiting latex deterioration in the balloon. The root cause was identified that storage of these devices was in the same room as high energy ionizing radiation sources. For product currently under Edwards' control, stop shipment has been placed. This product within Edwards control will be reworked to include instructions on the appropriate storage of the device.
Action	<ol> <li>Do not store above mentioned products in rooms with high energy ionizing radiation sources that could generate ozone (e.g. Fluoroscopy machines, X-ray machines, UV lights, HVAC sanitation equipment, etc.).</li> <li>If the customer has devices that have been exposed to the equipment described above, the affected inventory needs to be returned to Edwards.</li> <li>If the customer has devices that have not been exposed to the equipment above, these devices can be used as per the IFU.</li> <li>Contact the local agent for remedial action.</li> </ol>
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="Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie DIRECTOR GENERAL

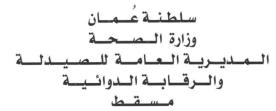






## Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







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. 200 dated 31/10/2002 Regarding GHC recall of Fogarty Arterial Embolectomy Catheters, Fogarty Fortis Arterial Embolectomy Catheters, and Fogarty Biliary Balloon Probes from (mfr: Edwards Lifesciences Services GmbH).

## 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



