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

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 200 / 2022

05 -04-1444 H

31 -10-2022

Recall of Fogarty Arterial Embolectomy Catheters, Fogarty Fortis Arterial Embolectomy Catheters, and Fogarty 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, 120602FP, 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	1. 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.). 2. If the customer has devices that have been exposed to the equipment described above, the affected inventory needs to be returned to Edwards. 3. If the customer has devices that have not been exposed to the equipment above, these devices can be used as per the IFU. 4. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

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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**

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Directorate General of Pharmaceutical Affairs & Drug Control

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