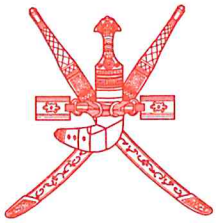
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs
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.....31..... dated .....24/03/19..... regarding the recall of Edwards Lifesciences's Swan-Ganz Thermodilution Catheters due to incorrect assembly causing reversal of lumens.

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

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

Sultanate of Oman
Ministry of Health
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سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
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Circular No. 31 / 2019

17 -07-1440 H
24 -03-2019

Edward Lifesciences Recalls Swan-Ganz Thermodilution Catheter due to incorrect assembly causing reversal of Lumens

The US Food & Drug Administration (FDA) has issued a Medical Device Alert informing that Edwards Lifesciences is recalling 131F7, 131F7J, 131F7P, 131VF7P, 151F7 Swan-Ganz Thermodilution Catheters manufactured December 26, 2017, to April 19, 2018 due, to incorrect assembly and reversal of the catheter tubes (lumens). If the lumens are reversed the clinician may note inaccurate pulmonary artery and central venous pressure values and waveforms. This may result in unintended treatment, which may result in adverse health consequences.

The inaccurate waveforms and pressure values may also misguide a physician during placement of the catheter, increasing the risk of blood vessel perforation. This exposes the patient to a reasonable likelihood of a serious adverse health consequence or death.

The recalled product and lot numbers are:

- Edwards Lifesciences Swan-Ganz Thermodilution Catheter
- Model Numbers: 131F7, 131F7J, 131F7P, 131VF7P, 151F7
- Lot Numbers: 61321177, 61176373, 61227528, 61321254, 61176369, 61176314, 61176370, 61176367, 61176374, 61321241, 61311580
- Manufacturing Dates: December 26, 2017, to April 19, 2018
- Distribution Dates: January 20, 2018, to August 20, 2018
- Devices Recalled in the U.S.: 1,426

Kindly check your stock and return the available quantity, if any, to the manufacturer/local agent.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above device or any other medical device to:

Director of Medical Device Control
Directorate General of Pharmaceutical Affairs & Drug Control
Ministry of Health, PO Box 393, Muscat, PC-100, Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

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