

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سِلاطِنَةُ عُومَانِ  
وَزَارَةُ الصِّحَّةِ  
وَالرِّيَاةِ الْعَامَّةِ وَالصِّدْقِ  
وَالرَّقَابَةِ الدَّوْلِيَّةِ  
مَسْقَط

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. 10.6..... dated 27/5/2012 Regarding BD PCEA Patient Controlled Epidural Analgesia) Administration Sets recall of (Mfr: Becton Dickinson (BD) )

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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وَزارة الصِّحة  
المديرية العامة للصِّحة  
والرقابة الدوائية  
مسقط

Circular No. 106 / 2020

04 - Shwal - 1441 H

27 - May - 2020

Field Safety Corrective Actions (FSCA) of BD PCEA Patient Controlled Epidural Analgesia) Administration Sets from: Becton Dickinson (BD)

Source	Becton Dickinson (BD) www.fda.gov/medwatch
Product	BD PCEA (Patient Controlled Epidural Analgesia) Administration Sets
Manufacturer	Becton Dickinson (BD)
The affected products	19016079 – 19036183 - 19045426
Reason	The potential to leak between the connection of the male luer and the yellow striped tubing this leak may be observed while priming or during use the most likely health consequence associated with a leak in APCEA administration set would be inadequate pain control for the patient due to an under infusion of medication.
Action	Please take your necessary actions regarding withdrawing mentioned above if you have it. Stop using the product and contact the local agent to take the necessary if you have it.
Product image	
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 contact E-mail <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

Directorate General of Pharmaceutical Affairs & Drug Control  
Sultanate of Oman

