

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلْطَنَة عُومَان
وَزَارَة الصِّحَّة
وَالرِّقَابَة الدَّوْلِيَّة
مُسَقَط

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. 48..... dated 21/5/11.... Regarding recall of Pilling CLEAR
ADVANTAGE® Disposable Aortic Punch from Teleflex Medical

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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سلطنة عمان
وزارة الصحة
الديرة العامة للأدوية
والرقابة الدوائية
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Circular No. 48 / 2020

07-07-1441 H

02-03-2020

Ref:2020/35

Recall of Pilling CLEAR ADVANTAGE® Disposable Aortic Punch from Teleflex Medical

Source of Recall	NCMDR National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15079
Product	Pilling CLEAR ADVANTAGE® Disposable Aortic Punch
Manufacturer	Teleflex Medical
Local Agent	Muscat Pharmacy & Store L.L.C
The affected products	Product No.: 353440, DP-28K, MDP-28K, DP-36K, MDP-36K, DP-40K, MDP-40K, DP-44K, MDP-44K, DP-48K, MDP-48K, DP-52K, MDP-52K, DP-56K, MDP-56K, DP-60K, MDP-60K
Reason for Recall	There is a potential for the device packaging to become compromised; thus, the sterility of the device cannot be guaranteed. If device sterility is compromised and the product is used it could lead to contamination and infection which could compromise anastomosis and contribute to wound infection
Action	1. Check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately. 2. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) 3. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) 4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product
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 Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

