Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمـان وزارة الصحـة مركز سلامة الـدواء مسقط

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 67 dated 19/5/2024 Regarding NCMDR Recall of VicrylTM, VicrylTM Plus, PdsTM, PdsTM Plus, MonocrylTM And MonocrylTM Plus Sutures from (mfr: Ethicon Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information





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Circular No. 67/2024

م فرق المرابعة المرا

روية عمان

11-11-1445 H **19** -05-2024

Recall of VicrylTM, VicrylTM Plus, PdsTM, PdsTM Plus, MonocrylTM And MonocrylTM Plus Sutures from Ethicon Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21042
Product	Vicryl™, Vicryl™ Plus, Pds™, Pds™ Plus, Monocryl™ And Monocryl™ Plus Sutures.
Description	Antibacterial Suture.
Manufacturer	Ethicon Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	VICRYL TM (polyglactin 910) Suture and VICRYL TM Plus Antibacterial (polyglactin 910) Suture PDS TM II (polydioxanone) Suture and PDS TM Plus Antibacterial (polydioxanone) Suture MONOCRYL TM (poliglecaprone 25) Suture and MONOCRYL TM Plus Antibacterial (poliglecaprone 25) Suture. PDS TM II (polydioxanone) Suture PRODUCT CODE: W9125H, W9101H PRODUCT LOTS: UAMRRP, UAMLPS PDS TM Plus Antibacterial (polydioxanone) Suture; PRODUCT CODE: PDP148H PRODUCT LOTS: TLMJBS. TLMJBR
Reason	It has been identified a manufacturing issue on a specific packaging machine that resulted in a hole in the primary packaging of above-mentioned products.
Action	 Please quarantine and return above-mentioned unused sutures. 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 Rubare Control Superior General



