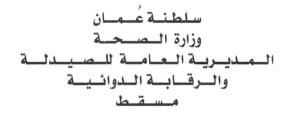
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







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 206 dated 14/11/2022 Regarding NCMDR recall of 3MTM Steri-DrapeTM Surgical Drapes from (mfr: 3M Health Care).

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





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



سلطنة عُـمان وزارة الـصـحـة الـمـديـريـة الـعـامـة للـصـيـدلـة والـرقـابـة الـدوائـيـة مـسـقـط

Circular No. 206/2022

Moving Forward with Confidence

20 -04-1444 H

14 -11-2022

Recall of 3MTM Steri-DrapeTM Surgical Drapes from 3M Health Care.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17319
Product	3MTM Steri-DrapeTM Surgical Drapes.
Description	Drape, surgical, general-purpose, single use.
Manufacturer	3M Health Care.
Local agent	Waleed Pharmacy & Stores L.L.C
	Catalogue numbers 1000; Lot number: 33HECP
	Catalogue numbers 1010; Lot number: 33HJNT, 33KM9K, 33KPJY
The affected	Catalogue numbers 1020; Lot number: 33JXEM, 33KL5W, 33KLMN
products	Catalogue numbers 1021; Lot number: 33H9HW
	Catalogue numbers 1060; Lot number: 33K9TF
	Catalogue numbers 1061; Lot number: 33KJTC.
	The liner on the adhesive component of the affected drapes is difficult to remove without
Reason	damaging the product and may render the product unusable. In addition, there is an increase
-	in reported adhesive related skin injuries for these affected lots.
Action	1. Please identify the affected product listed above and immediately cease use of affected
	models and lots of 3M TM Steri-Drape TM Surgical Drapes.
	2. Please discard all remaining affected product listed above per facility procedures.
	3. Contact the local agent for remedial action.
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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



