

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

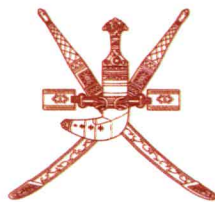
After Compliments,

Please find attached our Circular No 244 dated 29/12/2022 Regarding NCMDR recall of Novafil Monofilament Polybutester Suture, Sofsilk Coated Braided Silk Suture from (mfr: Covidien LLC).

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





Circular No. 244/ 2022

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29 -12-2022

نتقدم بثقة
Moving Forward
with Confidence



Recall of Novafil Monofilament Polybutester Suture, Sof silk Coated Braided Silk Suture from Covidien LL

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=17363
Product	Novafil Monofilament Polybutester Suture, Sof silk Coated Braided Silk Suture.
Description	Non-absorbable sutures.
Manufacturer	Covidien LLC.
The affected products	Novafil Monofilament Polybutester Suture: Product Description 8886 4400-13 NOVAFIL 6-0 BLU 45CM SBE2; Model Number: 8886440013; Lot #D2A0461Y Sof silk Coated Braided Silk Suture: Product Description: SS-745 SOFSILK* 3-0 BLK 75CM C12 X36 and VS-870 SOFSILK* 5-0 BLK 75CM CV23 X36; Model Numbers: SS745 and VS870; Lot # D1M2971FY, D1M2873Y.
Reason	Manufacturing errors in the packaging of the listed non-absorbable sutures may cause a gap or wrinkle in the breather pouch seal resulting in a sterile barrier breach.
Action	1. Identify and quarantine all unused and non-expired affected non-absorbable sutures. 2. Return all unused and non-expired affected product in your inventory to Medtronic. 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

