



نتقدم بثقة  
Moving Forward  
with Confidence



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 40 dated 24/3/2024 Regarding NCMDR Recall of Sofsluk sutures within Mölnlycke® Procedure Trays from (mfr: Mölnlycke Health Care AB).

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



**DSC**  
مركز سلامة الدواء  
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩  
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489  
✉ @DSCPHO Email: dscpho@moh.gov.om



Circular No. 40/2024

13 -09-1445 H  
24 -03-2024

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Recall of Sofslik sutures within Mölnlycke® Procedure Trays from Molnlycke Health Care AB.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=20953">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=20953</a>
Product	Sofslik sutures within Mölnlycke® Procedure Trays.
Description	Procedure Trays.
Manufacturer	Molnlycke Health Care AB.
Local agent	Al Zahrawi Medical Supplies LLC.
The affected products	Suture Sofsilks coated 2 No needle 2x150c Mölnlycke component code: 2301764-00 Included in various Mölnlycke® Procedure Trays MATERIAL: 97050213-08 BATCH: 23233690, 23233691, 23233694
Reason	The above affected devices were sterilized with gamma doses that exceeded the range approved or were exposed to more than the approved number of Ethylene Oxide- (EO) sterilization cycles. The expected impact on the tensile strength of these sutures will develop overtime throughout their labelled shelf life.
Action	1. Identify and isolate the unused Mölnlycke® Procedure Trays. 2. Discard the affected Sofslik sutures. 3. 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General

