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



سلطنة عُمان وزارة الصحة لمديرية العامة للصيدلة والرقابة الدوائية 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 123 dated 13/6/23 Regarding NCMDR Recall of Single Use Repositionable Clip HX-202LR/HX-202UR from (mfr: Olympus).

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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Circular No.

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13 -06-2023

Recall of Single Use Repositionable Clip HX-202LR/HX-202UR from Olympus.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19541
Product	Single Use Repositionable Clip HX-202LR/HX-202UR.
Description	Medical instruments for use in humans - general instruments.
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Material ID: N4508930; Material Description: HX-202LR.A (EN); Lot Number: 25K, 26K, 27K, 28K Material ID: N4509030; Material Description: HX-202LR.B (EN); Lot Number: 26K, 27K, 29K, 2YK Material ID: N4509130; Material Description: HX-202LR.A (EN); Lot Number: 24K, 25K, 26K, 27K, 28K, 29K, 2XK Material ID: N4509230; Material Description: HX-202UR.B (EN); Lot Number: 24K, 25K, 26K, 27K, 29K, 2XK, 2ZK, 31K, 32K
Reason	Clips fail to achieve their expected function or deploy incorrectly, potentially causing harms to patients.
Action	 Cease use of product and quarantine any affected product. Olympus will issue a Return Material Authorization to return any affected product. 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 Rubaie

Director General





ص.ب: ۳۹۳ مسقط - الرمز البريدي: ۱۰۰ - هاتف: ۲۲۳۰۷۱۱۱ - فاکس: Ρ.Ο. Box: **393** Muscat - Postal Code: **100** - Tel: **22357111** - Fax: **22358489**