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

سلطنة عُمان
وزارة الصحة
المديرية 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.285. dated 25/12/23 Regarding NCMDR recall of Multiple products by Karl Storz from (mfr: Karl Storz Endoscopy UK Ltd).

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. 285 / 2023

11 -06-1445 H
25 -12-2023

Recall of Multiple products by Karl Storz from Karl Storz Endoscopy UK Ltd

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19826
Product	Multiple products by Karl Storz.
Description	Medical instruments for use in humans.
Manufacturer	Karl Storz Endoscopy UK Ltd.
Local agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	Commercial name(s): BEYER Antrum Punch, Antrum Punch, 65°, 11 cm, Sphenoid Punch, 30°, 11 cm, Sphenoid Punch, 3.2 x 4 mm, Sphenoid Punch, 30°, 1.6 x 2 mm, Galea Spring Hook, 31 cm, Uvula Retractor, Optical Biopsy and Grasping Forceps, Grasping Forceps, flexible, 1 mm, Optical Scissor, Working Insert, with steering lever Device Model/Catalogue/part numbers : 615000; 615010; 615025; 648500; 648523; 662797; 723014; 723400; 11003MB; 11540OS; 26161UH Affected serial or lot numbers: all
Reason	It was found that there is not insufficient evidence to show that the reprocessing method of the products was adequately validated.
Action	1. Immediately quarantine, discontinue use and return the affected devices to Karl Storz representative. 2. 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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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