

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
الديرة العامة للصيد
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. 229.... dated 09/12/2020 Regarding NCMDR Recall of Hysteromat E.A.S.I. from (mfr: Karl Storz Endoscopy UK Ltd).

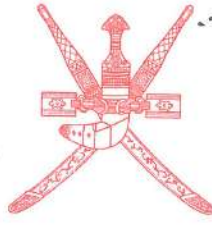
Copy to:

- 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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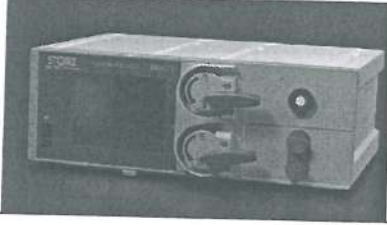
سلطنة عمان
وزارة الصحة
الديرة العامة للأدوية
والعقاقير والمواد الطبية
مسقط

Circular No. 229/2020

23 -04-1442 H

09 -12-2020

Recall of Hysteromat E.A.S.I. from Karl Storz Endoscopy UK Ltd.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15444
Product	HYSTEROMAT E.A.S.I.
Description	Suction/irrigation pump.
Manufacturer	Karl Storz Endoscopy UK Ltd
Local agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	Article number: 26340020-1 Serial number: all.
Reason	The pressure value displayed by the device could differ from the actual intracavitary pressure value.
Action	1. Do not use the Hysteromat E.A.S.I. anymore. Remove the pumps so that they are inaccessible to users. The application stop is initially valid for 6 months — you will receive information on how to proceed within this period. 2. 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 an E-mail: Med-device@moh.gov.om



Dr. Mohammed Hamdan Al Rubaie

Director General