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



سلطنة عُـمان وزارة الـصحـة الـمديـريـة العامـة للـصيـدلـة والـرقـابـة الـدوائـيـة مـسـقـط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

رونة عنمان

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. 165. dated 7/9/22. Regarding NCMDR Recall of YelloPort Elite Universal Seal from (mfr: Surgical Innovations Limited).

Copy to:

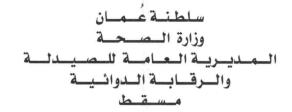
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





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





Circular No. 165/2022

07 -09-2022

0 10-02-1444 H

Recall of YelloPort Elite Universal Seal from Surgical Innovations Limited.



NCMDR- National Center for Medical Devices Reporting- SFDA Source https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17252 Product YelloPort Elite Universal Seal. Description Trocars, Abdominal, Laparoscopic. Manufacturer Surgical Innovations Limited. The affected Part No. EA512US products All Lots. During the manufacturing process, there is a risk of the formation of a hole in the sterile packaging Reason which typically forms near the pre-sealed area at the bottom of the sterile packaging of the YelloPort Elite Universal Seals. 1. All product still in stock at end users must be returned to the Distributor. 2. Replacement devices, as appropriate, which do not have this issue, will be provided by Action Surgical Innovations. Contact the local agent for remedial action. 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 comments

Ph. Ahmed Saif Al Harbi

Acting Director General





E-mail: Med-device@moh.gov.om

