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 243 **dated** 29/12/2022 **Regarding NCMDR recall of Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters (Mahurkar QPlus)from (mfr: Covidien LLC).**

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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

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

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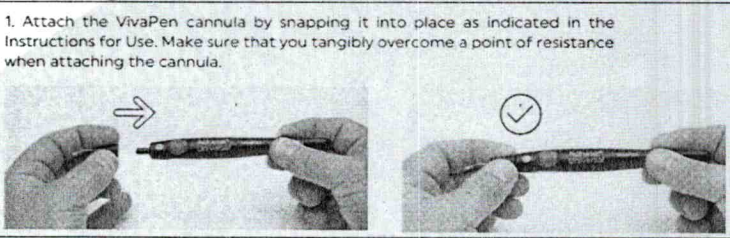
Circular No. 243/ 2022

05-06-1444 H

29 -12-2022

Recall of Dental products - dental material from Ivoclar Vivadent AG.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=18383
Product	VivaPen Snap-On Cannula and Adhese Universal in the Vivapen.
Description	Dental products - dental material.
Manufacturer	Ivoclar Vivadent AG.
The affected products	Product Codes 752382, 752383, 752384, 745762, 745763 all batches
Reason	The affected cannulas may not be reliably fastened to the VivaPen after having attached them.
Action	1. Attach the VivaPen cannula by snapping it into place as indicated in the Instructions for Use. Make sure that you tangibly overcome a point of resistance when attaching the cannula. 2. If you do not feel a "snap" when attaching the cannula, do not use it and discard it. If there are concerns regarding the fit of the cannula, please contact your distributor rep and you will be provided with a free replacement as quickly as possible. 3. Always use the VivaPen with the respective protective sleeve (see Instructions for Use, chapter 2.1.4). 4. Correct use of the protective sleeve will prevent the cannula from coming off inside the patient's mouth and being inhaled or ingested. 5. Sensitize the users/customers to consider the described risk-minimizing measures for all batches of VivaPen cannulas. Please contact the supplier for the necessary information. 6. Return all unused affected items. 7. 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 the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

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