



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

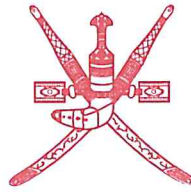
After Compliments,

Please find attached our Circular No. **188** dated **27/11/12** (Regarding Field Safety Notice of MENTOR® Breast Tissue Expanders (CPX4) from (mfr: Johnson & Johnson).

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





Circular No. 188 / 2021

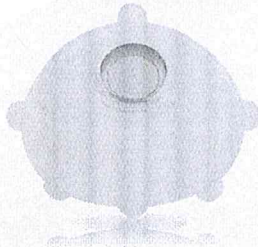
20 -03-1443 H

27 -10-2021

بمقدم بثقة
Moving Forward
with Confidence



Field Safety Notice of MENTOR® Breast Tissue Expanders (CPX4) from Johnson & Johnson.

Source	Johnson & Johnson through their local agent Muscat Pharmacy & Stores LLC.
Product	MENTOR® Breast Tissue Expanders (CPX4)
Description	Breast Tissue Expanders.
Manufacturer	Johnson & Johnson
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	MENTOR® Breast Tissue Expanders (CPX4).
Reason	The Mentor team has learned that some surgeons are not aware of the presence of a magnet in the dome of MENTOR Breast Tissue Expanders (CPX4). Mentor includes contraindications in the Instructions for Use related to other medical devices that could be affected by the magnetic field of these tissue expanders.
Action	1. There is no product deficiency in MENTOR Breast Tissue Expanders and there are no new risks identified. Surgeons should continue to use the CPX4 Tissue Expanders as directed. 2. Local Agent should maintain awareness of this letter to the customers and complete the business reply form. 3. 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