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.** 128 **dated** 28/7/22 **Regarding NCMDR Recall of CoolSculpting® parallel plate applicators from (mfr: ZELTIQ Aesthetics, Inc. (ZELTIQ) / Abbvie).**

**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

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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سلطنة عُمان
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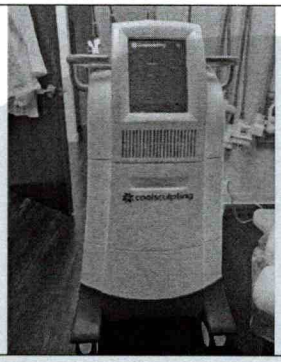
# Circular No. 128/ 2022

29 -12-1443 H

28 -07-2022

**Recall of CoolSculpting® parallel plate applicators from ZELTIQ Aesthetics, Inc. (ZELTIQ) / Abbvie.**

| | |
|---|---|
| Source | GHC- Gulf Health Council |
| Product | CoolSculpting® parallel plate applicators. |
| Manufacturer | ZELTIQ Aesthetics, Inc. (ZELTIQ) / Abbvie. |
| The affected products | (CoolCore, CoolCurve, CoolCurve+, CoolMax, and CoolFit). |
| Reason | The CoolSculpting ® applicators are used to deliver the cooling treatment to the patient. ZELTIQ is voluntarily discontinuing and recalling the abovementioned medical device due to the observance of a slightly increased rate of Paradoxical Hyperplasia (PH) (visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment and may require surgical intervention for correction). This voluntary discontinuation and recall do not affect the CoolSculpting® control units, cooling cup applicators (CoolMini, CoolAdvantage, CoolAdvantage Petite, and CoolAdvantage Plus) or surface applicators (CoolSmooth and CoolSmooth Pro) or the CoolSculpting® Elite system and associated family of Elite applicators. |
| Action | 1. The healthcare providers will be required to cease use of parallel plate applicators.<br>2. All affected products will be returned to AbbVie or its distributors.<br>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**

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