

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلغة
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..... dated ^{4/2020} ^{1/1/2020} regarding TGA recall OF Aequalis Ascend Flex Stem Implants (Mfr: Tornier Inc)

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

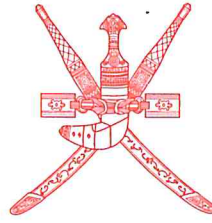
Directorate General of Pharmaceutical Affairs
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MUSCAT

Circular No. 4 / 2020

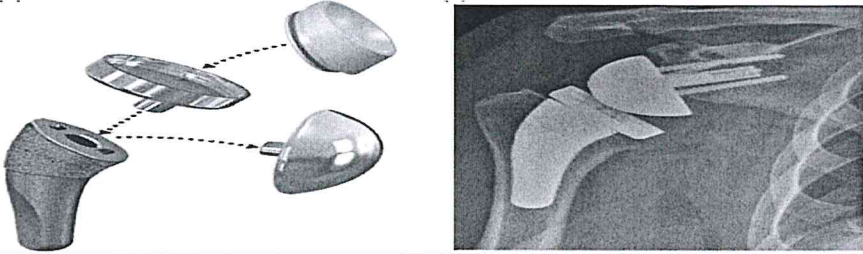
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Recall of Aequalis Ascend Flex Stem Implants from Tornier Inc

Source of Recall	TGA Recall
Product	Aequalis Ascend Flex Stem Implants-uncoated humeral shoulder prothesis
Manufacturer	Tornier Inc
The affected products	Multiple Catalogue Numbers
Reason for Recall	white film or white particles appear can be detectable by visual inspection and unaided eye
Action	<ol style="list-style-type: none">1. Kindly check your stock, contact your local agent for remedial action2. To ensure backup stem product is available in the operating room or is easily accessible prior to beginning surgery.3. Visually examine the stem after removing the stem from its packaging. If white film or particles are seen on the stem, immediately remove the implant and anything it touches from the sterile field. Replace the stem with a backup stem that lacks visible white film or particles.4. If no packaging material is visible on the stem, you may proceed with the implantation procedure.
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 Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

