

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطِنَة اَمَانَة
وَزَارَة الصِّحَة
وَالرِّقَابَة الدَّوْلِيَّة
مَسْقَط

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 Regarding NCMDR Field Safety Notice 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

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سلطنة عمان
وزارة الصحة
المديرية العامة للأدوية
والرقابة الدوائية
مسقط

Circular No. 131 / 2020

20 -11-1441 H

12 -07-2020

Field Safety Notice of Aequalis Ascend Flex Stem Implants from Tornier Inc.

Source	NCMDR - National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=15204
Product	Aequalis Ascend Flex Stem Implants- Aequalis Ascend Flex Cemented Humeral Stem - Uncoated shoulder humeral stem prosthesis
Manufacturer	Tornier Inc
The affected products	Multiple catalogue numbers as attached.
Reason	The manufacturer advises that during shipping, it is possible for the Aequalis Ascend Flex humeral stem to become unseated or otherwise move within its internal packaging restraints. Movement within the packaging may cause the product to rub against the Polyethylene Terephthalate Glycol (PETG) blister shipping container causing the transfer of PETG material from the blister container to the stem. PETG material on the stem is detectable by visual inspection and will appear as a white film or white particles to the unaided eye.
Action	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 contact E-mail Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL



Medical Devices Sector

قطاع الأجهزة الطبية

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

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TGA Recall

Reference Number: mdprc 049 11 19 002

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Date submitted: 5/16/2020

Manufacturer:	Tornier Inc
Device Type:	Aequalis Ascend Flex Stem Implants
Description:	Aequalis Ascend Flex Cemented Humeral Stem - Uncoated shoulder humeral stem prosthesis
Medical Device Identifier:	Multiple Catalogue Numbers
Reason of Field Safety Corrective Action:	The manufacturer advises that during shipping, it is possible for the Aequalis Ascend Flex humeral stem to become unseated or otherwise move within its internal packaging restraints. Movement within the packaging may cause the product to rub against the Polyethylene Terephthalate Glycol (PETG) blister shipping container causing the transfer of PETG material from the blister container to the stem. PETG material on the stem is detectable by visual inspection and will appear as a white film or white particles to the unaided eye.
Remedy Action:	The manufacturer is advising customers to: 1) To ensure backup stem product is available in the operating room or is easily accessible prior to beginning surgery. 2) 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. 3) If no packaging material is visible on the stem, you may proceed with the implantation procedure. The manufacturer is not advising any additional follow-up for patients implanted with the affected devices.

	Swissmedic update action:
	suspension of implantations of Aequalis Ascend Flex humeral stems We will of course inform you as soon as possible, once the additional tests have been completed, of the follow-up to be given both for resuming implantations and if necessary for monitoring implanted patients.

	Swissmedic update action:
	If any of the Ascend Flex humeral stem devices in current packaging are still in your hospital, we would ask you to complete the attached form confirming you have received this notification. You will be contacted to arrange return and to exchange devices concerned by this notice which are still present in your facility.
Athorized Representative/Importer/Distributor:	Cure Development International Ltd
Report Source:	http://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2019-RN-01666-1
Source Ref. Number:	RC-2019-RN-01666-1, Vk_20191107_21
SFDA Comments:	SFDA urges all hospitals that have devices subjected to recall, to contact the company.

TORNIER



Attachment A:
List of affected Products

Product Description	Catalog Numbers	Product Description	Catalog Numbers	
Standard PTC Humeral stem	DWF601A	Long PTC Humeral stem	DWF619A	
	DWF601B		DWF619B	
	DWF601C		DWF619C	
	DWF602A	Standard Cemented Humeral stem	DWF702A	
	DWF602B		DWF702B	
	DWF602C		DWF702C	
	DWF603A		DWF703A	
	DWF603B		DWF703B	
	DWF603C		DWF703C	
	DWF604A		DWF704A	
	DWF604B		DWF704B	
	DWF604C		DWF704C	
	DWF605A		DWF705A	
	DWF605B		DWF705B	
	DWF605C		DWF705C	
	DWF606A		DWF706A	
	DWF606B		DWF706B	
	DWF606C		DWF706C	
	DWF607A		DWF707A	
	DWF607B		DWF707B	
	DWF607C		DWF707C	
	DWF608A		DWF708A	
	DWF608B		DWF708B	
	DWF608C		DWF708C	
	DWF609A		DWF709A	
	DWF609B		DWF709B	
	DWF609C		DWF709C	
Long PTC Humeral stem	DWF611A		Long Cemented Humeral stem	DWF712A
	DWF611B			DWF712B
	DWF611C			DWF712C
	DWF612A	DWF713A		
	DWF612B	DWF713B		
	DWF612C	DWF713C		
	DWF613A	DWF714A		
	DWF613B	DWF714B		
	DWF613C	DWF714C		
	DWF614A	DWF715A		
	DWF614B	DWF715B		
	DWF614C	DWF715C		
	DWF615A	DWF716A		
	DWF615B	DWF716B		
	DWF615C	DWF716C		
	DWF616A	DWF717A		
	DWF616B	DWF717B		
	DWF616C	DWF717C		
	DWF617A	DWF718A		
	DWF617B	DWF718B		
DWF617C	DWF718C			
DWF618A	DWF719A			