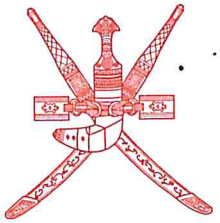
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
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. 167/2020 **dated** 3/9/2020 **Regarding NCMDR Recall of Profemur Modular Femoral Neck Long (Ti) from (mfr: Microport Orthopedics).**

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**

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

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سلطنة عمان
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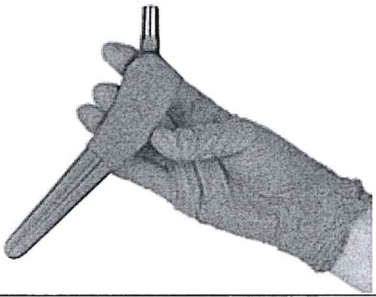
Circular No. 167 / 2020

14 -1-1442 H

03 -09-2020

Recall of Profemur Modular Femoral Neck Long (Ti) from Microport Orthopedics.

Source	NCMDR- National Centre Medical Device Reporting http://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2020-RN-00693-1
Product	Profemur Modular Femoral Neck Long (Ti).
Description	Profemur Long and X-Long Titanium Modular Necks.
Manufacturer	Microport Orthopedics.
The affected products	Item numbers: PHA01204, PHA01214, PHA01224, PHA01234, PHA01244, PHA01254, PHA01264, PHAO1206, PHAO1236 and PHAO1256
Reason	MicroPort Orthopedics continues to receive reports of fracture for the Profemur Long and X-Long Titanium Modular Necks. A potential fracture cannot be detected during surgery, by visual inspection or any other diagnostic technique. Should a fracture occur, the patient may experience sudden pain, instability and difficulty walking/performing common tasks. Due to the sudden pain and loss of mobility, it is expected the patient will recognize immediately the device is not functioning properly and seek medical attention. A fractured femoral neck will need revision surgery to correct.
Action	1. MicroPort Orthopedics does not recommend prophylactic revision surgery, but does advise that HCP's continue to monitor patients according to standard follow up protocol Customers should inform MicroPort Orthopedics of any adverse events immediately. 2. 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

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ - فاكس: ٢٢٣٥٧١١١ - هاتف: ١٠٠ - الرمز البريدي: ٣٩٣ مسقط - ص.ب
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