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. 181 **dated** 29/6/12 **Regarding NCMDR Recall of Genesis II Constrained Insert from (mfr: Smith & Nephew 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**

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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Circular No. 181 / 2020

11 -02-1442 H

24 -09-2020

Recall of Genesis II Constrained Insert from Smith & Nephew inc.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15364
Product	Genesis II Constrained Insert Size 1-2 18 MM.
Description	Knee Implants and components used to repair damaged/degenerative parts of the knee joint.
Manufacturer	Smith & Nephew inc.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	Product Number (Batch Number): 71420966 (18JT09702)
Reason	The affected devices' anterior locking detail does not meet its design specifications, which could result in the articular insert failing to properly mate with a tibial baseplate.
Action	1. Return affected unused devices to your local agent. 2. Contact local agent for remedial action.
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 an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

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

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 034 09 20 000 **Back**
Date submitted: 9/27/2020

Manufacturer:	Smith & Nephew inc
Device Type:	Genesis II Constrained Insert Size 1-2 18 MM
Description:	Knee Implants and components used to repair damaged/degenerative parts of the knee joint.
Medical Device Identifier:	Product Number (Batch Number): 71420966 (18JT09702)
Reason of Field Safety Corrective Action:	The affected devices' anterior locking detail does not meet its design specifications, which could result in the articular insert failing to properly mate with a tibial baseplate.
Remedy Action:	Return affected unused devices to your national Smith+Nephew agency/distributor.
Athorized Representative/Importer/Distributor:	Smith & Nephew inc
Report Source:	NCMDR
Source Ref. Number:	F22642A0DF2D9
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	**Smith & Nephew.pdf**

View History