



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. 81/22 dated 26/4/22 Regarding NCMDR FSCA of Original and Essential Kit Pedicle Screw systems from (mrf: Safe Orthopaedics).

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: ٢٢٣٥٧٨٨٩ - فاكس: ٢٢٣٥٨٤٨٩

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Circular No. 81 / 2022

رؤية عمان 2040
Forward with Confidence

24 -09-1443 H

26 -04-2022

Field Safety Corrective Action of Original and Essential Kit Pedicle Screw systems from Safe Orthopaedics

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=16092
Product	Original and Essential Kit Pedicle Screw systems.
Description	Medical instruments for use in humans - bone surgery.
Manufacturer	Safe Orthopaedics.
The affected products	All.
Reason	A clear indication was missing on our surgical guides distributed together with our Pedicle Screw instrumentation kits: Original and Essential.
Action	1. Safe Orthopaedics sales representative will personally explain to you this improvement and deliver the new version of the Surgical Guide released in February 2022. 2. Contact the local agent for remedial action.
Product Picture	<p>SCREW INSERTION</p> <p>1</p> <p>Insert the universal handle on the preloaded screwdriver, in a straight or T-position.</p> <p>Screw down the screw into the pedicle. If using a guide wire, remove it when the screw is partially inserted.</p> <p>Choose the round shape hole on the side of the universal handle for T-position.</p> <p>Optional: the ratchet module can be used in a straight or a T-position.</p> <p>Choose the rectangular shape hole on the side of the universal handle for T-position with the ratchet.</p> <p>FSN2022-01 Germany EN Page 1 of 2</p>
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 Rubaia
DIRECTOR GENERAL



