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. 20 **dated** 23/01/20 **Regarding NCMDR Recall of Recall of Mini Compress, Compress device used in hip prothesis. from (Mfr: Zimmer)**

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. 20 / 2020

Ref: 10 /2020

27 -05-1441 H

23 -01-2020

Recall of Mini Compress, Compress device used in hip prothesis from Zimmer

Source of Recall	**NCMDR** National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=15017
Product	Mini Compress, Compress device used in hip prosthesis.
Manufacturer	Zimmer Biomet Inc
Local Agent	SURGITECH EQUIPMENT LLC
The affected products	Multiple Lot numbers of the affected device are provided in the attached
Reason for Recall	Elevated levels of bacterial endotoxin and residual debris remain on the devices due to the cleaning issue.
Action	1. Kindly check your stock, contact your local agent for remedial action 2. Quarantine affected device.
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

NHP

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

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

ZIMMER BIOMET

December 15, 2019

To Whom It May Concern:

Purpose of this declaration document is to confirm that according to our records Saudi Arabia received below listed products affected by Recall Number Z-0520-2020 initiated by Zimmer Biomet, Inc. on August 21, 2019 impacting COMP RVRS Shoulder Baseplates, including Custom Products.

Material	Material Description	Batch	Quantity
115330	COMP RVRS SHDR GLEN BSPLT +HA	182250	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	182250	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	038040	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	130310	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	130270	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	239970	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	518600	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	811210	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	348150	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	348150	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	348150	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	272120	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	272120	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	549330	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	549330	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	549330	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	507410	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	507410	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	507410	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	507410	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	230220	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	661470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	661470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	661470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	661470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	094170	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	094170	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951830	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951830	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951830	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951830	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951830	1

ZIMMER BIOMET

115330	COMP RVRS SHDR GLEN BSPLT +HA	951830	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951830	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951780	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951780	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951780	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	951780	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	415470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	415470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	415470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	415470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	415470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	415470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	415470	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	588310	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	588310	1
115330	COMP RVRS SHDR GLEN BSPLT +HA	415470	7
115330	COMP RVRS SHDR GLEN BSPLT +HA	588310	2

We are currently identifying affected hospitals and will return the available items to our distribution items or/and scrap the items before end of March 2020, according to the deadline appointed by Zimmer Biomet, Inc. The acknowledgment forms received from the hospitals will be shared with SFDA, or else subject hospitals that will not respond will be escalated to SFDA.

If you need any additional clarification, please contact lea.atallah@zimmerbiomet.com.
Thank you.

Lea Atallah
Quality & Regulatory Affairs Manager MEA

Lea Atallah

Digitally signed by Lea Atallah
Date: 2019.12.15 12:47:52 +02'00'

ZIMMER BIOMET

December 15, 2019

To Whom It May Concern:

Purpose of this declaration document is to confirm that according to our records Saudi Arabia received below listed products affected by Recall Number Z-0530-2020 initiated by Zimmer Biomet, Inc. on August 21, 2019 impacting BALL NOSE GUIDE WIRE 80CM, 100CM. Item Nos. 281001080, 281001100.

Material	Material Description	Batch	Quantity
281001080	BALL NOSE GUIDE WIRE 80CM	270171	6
281001100	BALL NOSE GUIDE WIRE 100CM	830520	6

We are currently identifying affected hospitals and will return the available items to our distribution items or/and scrap the items before end of March 2020, according to the deadline appointed by Zimmer Biomet, Inc. The acknowledgment forms received from the hospitals will be shared with SFDA, or else subject hospitals that will not respond will be escalated to SFDA.

If you need any additional clarification, please contact lea.atallah@zimmerbiomet.com.
Thank you.

Lea Atallah
Quality & Regulatory Affairs Manager, MENA

ZIMMER BIOMET

December 15, 2019

To Whom It May Concern:

Purpose of this declaration document is to confirm that according to our records Saudi Arabia received below listed products affected by Recall Number Z-0531-2020 initiated by Zimmer Biomet, Inc. on August 21, 2019 impacting 2.0MM BALL NOSE GUIDE WIRE, Item Nos. 281017006 - Product Usage: These instruments and delivery systems are used to facilitate implantation of orthopedic medical devices.

Material	Material Description	Batch	Quantity
281017006	2.0MM BALL NOSE GUIDE WIRE	260821	2

We are currently identifying affected hospitals and will return the available items to our distribution items or/and scrap the items before end of March 2020, according to the deadline appointed by Zimmer Biomet, Inc. The acknowledgment forms received from the hospitals will be shared with SFDA, or else subject hospitals that will not respond will be escalated to SFDA.

If you need any additional clarification, please contact lea.atallah@zimmerbiomet.com.
Thank you.

Lea Atallah
Quality & Regulatory Affairs Manager, MENA