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

سلطنة عُمان
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 164 **dated** 30/7/2023 **Regarding NCMDR Recall of Internal Fixation Devices from (mfr: Zimmer Biomet).**

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

ISO 9001:2015 CERTIFIED QUALITY MANAGEMENT SYSTEMS

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

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

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 164 / 2023

12 -01-1445 H

30 -07-2023

Recall of Internal Fixation Devices from Zimmer Biomet.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19627
Product	Zimmer® Periarticular Locking Plate System, Distal Lateral Femoral Plate – Right - 6 Holes – 159 mm Length.
Description	Internal Fixation Devices.
Manufacturer	Zimmer Biomet.
Local agent	Mosaic International LLC
The affected products	Material/Item Number: 00-2357-101-06 Batch/Lot Number: 64254511, 64296571, 65379087, 65379093, 65379096 UDI Number: (01)00890240559 40(10)64254511, (01)00890240559 40(10)64296571, (01)00890240559 40(10)65379087, (01)00890240559 40(10)65379093, (01)00890240559 40(10)65379096 The affected products were distributed between July 2019 and February 2023.
Reason	A possible thread form issue of the locking holes that could result in locking screws that would not properly mate with the plate.
Action	1. Quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility. 2. Surgeon should review the attachment for awareness of the contents. 3. Contact the 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 the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

ZIMMER BIOMET

11 July 2023

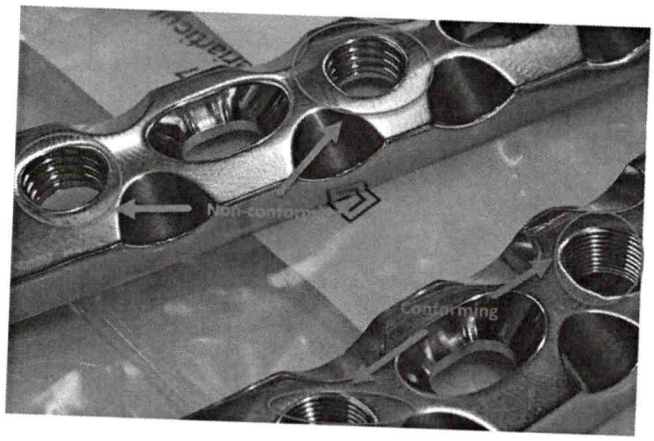
To: Hospitals and Surgeons

Subject: URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Affected Product: Zimmer® Periarticular Locking Plate System
Distal Lateral Femoral Plate – Right - 6 Holes – 159 mm Length

Material/Item Number	Batch/Lot Number	UDI Number
00-2357-101-06	64254511	(01)0089024055940(10)64254511
00-2357-101-06	64296571	(01)0089024055940(10)64296571
00-2357-101-06	65379087	(01)0089024055940(10)65379087
00-2357-101-06	65379093	(01)0089024055940(10)65379093
00-2357-101-06	65379096	(01)0089024055940(10)65379096

Zimmer Inc. is conducting a batch/lot specific medical device Field Safety Corrective Action (removal) for certain batches/lots of the 6 holes Distal Lateral Femoral Plate with a 159 mm length, which is part of the Zimmer® Periarticular Locking Plate System (ZPLP). This Field Safety Corrective Action is due to a possible thread form issue of the locking holes, that could result in locking screws that would not properly mate with the plate. The improperly mated screw may not be readily recognizable by the user since the screw may not correctly lock. The issue was discovered through a complaint investigation.



The affected devices may have been received as a single finished device or in an instrument kit with material/item 00-2358-010-05 (Distal Lateral Femoral Plate and Jig Case).

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None.	Clinically insignificant extension of surgery.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None.	Loss of fixation occurs resulting in medical intervention, such as revision surgery.

Our records indicate that you may have received one or more of the affected products. The affected products were distributed between July 2019 and February 2023.

ZIMMER BIOMET

Hospital Responsibilities

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. If the product has been further distributed, provide your customers with the Field Safety Notice for hospitals and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement Form** and send to fieldaction.export@zimmerbomet.com. This form must be returned even if you do not have affected products at your facility.
5. Retain a copy of the **Attachment 1 – Certificate of Acknowledgement Form** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Surgeon Responsibilities

1. Review this Field Safety Notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement Form** and send to fieldaction.export@zimmerbiomet.com.
4. Retain a copy of the **Attachment 1 – Certificate of Acknowledgement Form** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your local Zimmer Biomet representative.

Other Information

This medical device Field Safety Corrective Action was reported to all relevant Competent Authorities and related Notified Bodies as required under the applicable regulations for Medical Devices per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.export@zimmerbiomet.com or to your local Zimmer Biomet representative.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation and regret any inconvenience caused by this Field Safety Corrective Action.

Sincerely,

Francis Moloney

Francis Moloney, VP QA/RC EMEA

ZIMMER BIOMET

ATTACHMENT 1 - Certificate of Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Zimmer® Periarticular Locking Plate System, Distal Lateral Femoral Plate Right 6 Holes 159mm Length

Field Safety Corrective Action Reference: ZFA2023-00060

☐ A thorough search has been performed for the affected products and the below are available for return.

Note: All products that are not available for return will be considered as dispositioned on your location.

All products that are not available for return have been implanted or used: ☐ Yes ☐ No ☐ Unknown

Material/Item Number	Batch/Lot Number	Quantity returned

Complete this table for all affected items returned or provide a spreadsheet with the return of this form if the table above has not enough space to list all products. **Do not return affected products with other returns.**

Certificate of Acknowledgement

By signing below, I acknowledge that I have received, read and understood the contents of Field Safety Notice communication. All required activities are complete or are being completed.

Printed Name:_____ **Signature:**_____

Title:_____ **Telephone:**_____ **Date:**_____

Facility Name:_____

Facility Address:_____

City:_____ **Country:**_____ **ZIP/Post Code:**_____

Please return the completed form to your Zimmer Biomet contact or by e-mail to fieldaction.export@zimmerbiomet.com.