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 228 **dated** 26/10/2023 **Regarding NCMDR Recall of Zimmer® Dermatome Blades 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

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
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سلطنة عُمان
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Circular No. 228 / 2023

12 -04-1445 H
26 -10-2023

Recall of Zimmer® Dermatome Blades from Zimmer Biomet.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19738
Product	Zimmer® Dermatome Blades.
Description	Skin graft blades.
Manufacturer	Zimmer Biomet.
Local agent	Mosaic International LLC.
The affected products	Model: 00-8800-000-10 Refer to the attachment for affected product list
Reason	Potentially skin grafts being thin and non-uniform when using the above affected blades, which may result in the need for additional harvests to adequately cover the area.
Action	1. Immediately locate and quarantine affected product in your inventory and return them. 2. 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

NHP

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

September 5, 2023

To: Distributors, Sales Representatives, and Distributor Operation Managers

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: Zimmer® Dermatome Blades (00-8800-000-10)

See Attachment 2 – Affected Product List for a list of affected lots

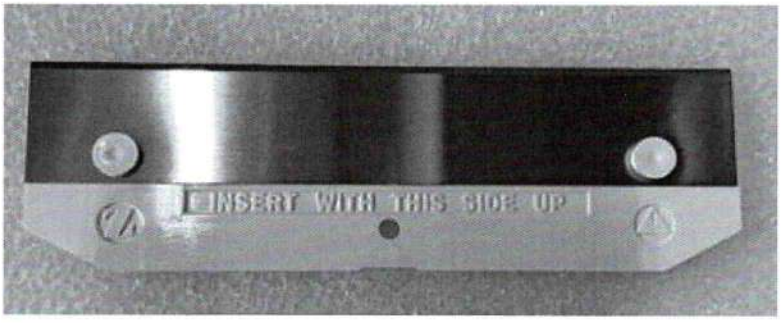

Figure 1: Dermatome Blade

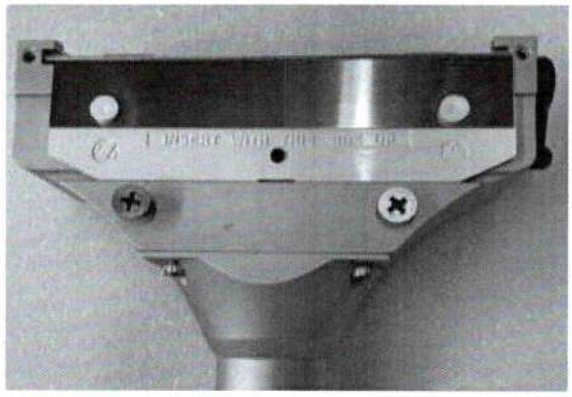

Figure 2: Dermatome Blade assembled in Dermatome Handpiece

Zimmer Biomet is conducting a lot specific medical device recall for the Zimmer® Dermatome Blades (00-8800-000-10) listed in **Attachment 2 – Affected Product List.** There have been 38 complaints received related to skin grafts being thin and non-uniform when using the affected blades. The issue would be identified at the time of use and may result in the need for additional harvests to adequately cover the area. The trade-off of incomplete coverage versus having additional grafts is at the discretion of the health care provider based on the condition of the graft, overall patient condition, and severity of the need for the graft.

The investigation identified an assignable cause within the manufacturing process, which was present for a defined amount of time and has been corrected for subsequent lots.

The affected devices are distributed as 10-pack boxes of blades and may be located within your inventory as a 10-Pack box or individual blades

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	Tissue damage, moderate
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	Tissue damage, moderate (scarring at unplanned additional harvest locations)

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between March 2023 and August 2023.

ZIMMER BIOMET

Your Responsibilities

1. Review this notification and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your territory.
   a. Complete **Attachment 1 – Inventory Return Certification Form** for each return and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form must be returned even if you do not have affected products available to return in your territory.
   b. For International Returns, request an IRA by emailing zimmerbiometintlirarequests@zimmerbiomet.com
   c. Include a hardcopy of **Attachment 1** in each carton of your return shipment for immediate processing.
   d. Mark "RECALL" on the outside of the returned cartons
4. Return the **Additional Accounts** form to CorporateQuality.PostMarket@zimmerbiomet.com.
   a. Review the list of hospitals included with the email notification sent to your facility, which includes a list of hospitals that have already been notified of this recall.
   b. Identify whether there are any additional hospitals that Zimmer Biomet has *not* notified and list these accounts on the Additional Accounts form. Please provide the form in **Excel format**.
   c. If there are no additional accounts to notify, please indicate that there are no additional accounts, or indicate "None" or "NA" on the form.
5. Retain a copy of your Inventory Return Certification and product return forms for your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

This recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Call: 1-800-332-1088 to request a reporting form
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing product.experience@zimmerbiomet.com.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed. The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

ZIMMER BIOMET

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

Stephanie Leppo
Quality Associate Director

ZIMMER BIOMET

ATTACHMENT 1 - Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: Zimmer® Dermatome Blades (00-8800-000-10) **ZFA Number: ZFA 2023-00208**

Territory Number: _____ **Account Number:** _____

Account Name: _____

Account Address: _____

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Zimmer Biomet
Product Service Department
ATTN: RECALLS
1777 West Center Street
Warsaw, IN 46580

OR

Zimmer GmbH
Biomet Global Supply Chain Center B.V.
Hazeldonk 6530
Dock 20
Breda 4836 LD, Netherlands

	Check one of the following:	
This is the final return for the entire territory. **An exhaustive search has been performed for the affected products.**	**Yes** ☐	**No** ☐

Note: Any product not returned or found in your territory is considered consumed and unavailable for use.

☐ **Credit My Account**

Item Number	Lot Number	UDI Number	Quantity Returned	Unit of Measure (Boxes or Blades)

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to CorporateQuality.PostMarket@zimmerbiomet.com with this form.

Certificate of Acknowledgement:

By signing below, I acknowledge that I have received, read, and understand the contents of this recall communication. All required activities are complete or are being completed.

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** ( ) _____ **Ext.** _____ **Date:** _____

Note: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com.

Please do not return affected product with other returns.

ZIMMER BIOMET

ATTACHMENT 2 - Affected Product List

Affected Product: Zimmer® Dermatome Blades (00-8800-000-10)

Note: The affected devices are distributed as 10-pack boxes of blades and may be located within your inventory as a 10-Pack box or individual blades

Item Number	Lot Number	Individual Blade UDI Number	10-Pack Box UDI Number
00880000010	65599469	(01)00889024375895(17)280205(10)65599469	(01)00889024380318(17)280205(10)65599469
00880000010	65620875	(01)00889024375895(17)280206(10)65620875	(01)00889024380318(17)280206(10)65620875
00880000010	65621233	(01)00889024375895(17)280207(10)65621233	(01)00889024380318(17)280207(10)65621233
00880000010	65630969	(01)00889024375895(17)280209(10)65630969	(01)00889024380318(17)280209(10)65630969
00880000010	65647382	(01)00889024375895(17)280212(10)65647382	(01)00889024380318(17)280212(10)65647382
00880000010	65648460	(01)00889024375895(17)280213(10)65648460	(01)00889024380318(17)280213(10)65648460
00880000010	65709066	(01)00889024375895(17)280214(10)65709066	(01)00889024380318(17)280214(10)65709066
00880000010	65925347	(01)00889024375895(17)280219(10)65925347	(01)00889024380318(17)280219(10)65925347
00880000010	65925348	(01)00889024375895(17)280220(10)65925348	(01)00889024380318(17)280220(10)65925348
00880000010	65935737	(01)00889024375895(17)280221(10)65935737	(01)00889024380318(17)280221(10)65935737
00880000010	65935738	(01)00889024375895(17)280223(10)65935738	(01)00889024380318(17)280223(10)65935738
00880000010	65952857	(01)00889024375895(17)280319(10)65952857	(01)00889024380318(17)280319(10)65952857
00880000010	65952858	(01)00889024375895(17)280424(10)65952858	(01)00889024380318(17)280424(10)65952858
00880000010	65972711	(01)00889024375895(17)280430(10)65972711	(01)00889024380318(17)280430(10)65972711
00880000010	65972712	(01)00889024375895(17)280503(10)65972712	(01)00889024380318(17)280503(10)65972712
00880000010	65988623	(01)00889024375895(17)280507(10)65988623	(01)00889024380318(17)280507(10)65988623
00880000010	65952862	(01)00889024375895(17)280426(10)65952862	(01)00889024380318(17)280426(10)65952862
00880000010	65988624	(01)00889024375895(17)280509(10)65988624	(01)00889024380318(17)280509(10)65988624
00880000010	65989036	(01)00889024375895(17)280514(10)65989036	(01)00889024380318(17)280514(10)65989036
00880000010	65989037	(01)00889024375895(17)280516(10)65989037	(01)00889024380318(17)280516(10)65989037
00880000010	66000975	(01)00889024375895(17)280520(10)66000975	(01)00889024380318(17)280520(10)66000975
00880000010	66000976	(01)00889024375895(17)280523(10)66000976	(01)00889024380318(17)280523(10)66000976
00880000010	66002852	(01)00889024375895(17)280528(10)66002852	(01)00889024380318(17)280528(10)66002852
00880000010	65952860	(01)00889024375895(17)280530(10)65952860	(01)00889024380318(17)280530(10)65952860
00880000010	66002853	(01)00889024375895(17)280610(10)66002853	(01)00889024380318(17)280610(10)66002853
00880000010	66014333	(01)00889024375895(17)280613(10)66014333	(01)00889024380318(17)280613(10)66014333
00880000010	66014332	(01)00889024375895(17)280617(10)66014332	(01)00889024380318(17)280617(10)66014332
00880000010	66038885	(01)00889024375895(17)280624(10)66038885	(01)00889024380318(17)280624(10)66038885
00880000010	66172214	(01)00889024375895(17)280628(10)66172214	(01)00889024380318(17)280628(10)66172214
00880000010	66049031	(01)00889024375895(17)280710(10)66049031	(01)00889024380318(17)280710(10)66049031
00880000010	66078057	(01)00889024375895(17)280724(10)66078057	(01)00889024380318(17)280724(10)66078057
00880000010	66049032	(01)00889024375895(17)280719(10)66049032	(01)00889024380318(17)280719(10)66049032