ZIMMER BIOMET

18 September 2023

To: Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE**

Affected Product: Zimmer® Dermatome Blades (see **Attachment 2** for the affected product list)

Figure 1
Dermatome Blade

Figure 2
Dermatome Blade assembled in Dermatome Handpiece

Zimmer Surgical, Inc. is conducting a batch/lot specific medical device Field Safety Corrective Action for the Zimmer® Dermatome Blades 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 batches/lots.

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 May 2023 and August 2023. Local deployment may differ.

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

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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, immediately locate and quarantine affected product in your inventory.
   a. Your Zimmer Biomet sales representative may remove and return the affected product from your facility on your behalf.
   b. Alternatively, you may directly return all affected products from your facility.
      i. Complete **Attachment 1 – Certificate of Acknowledgement** for each return and send to fieldaction.netherlands@zimmerbiomet.com.
      ii. Include a hardcopy of **Attachment 1 – Certificate of Acknowledgement** in each carton of your return shipment for immediate processing.
      iii. Mark "RECALL" on the outside of the returned cartons.
3. If the product has been further distributed, provide your customers with the Field Safety Notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com. This form shall be returned even if you do not have affected products at your facility. Upon receipt of the affected product, Zimmer Biomet will credit your account. Please return a copy of the completed response form along with your returned product to ensure proper credit.
5. Retain a copy of **Attachment 1 – Certificate of Acknowledgement** 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 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 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.nl@zimmerbiomet.com.

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.

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ATTACHMENT 1 – Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: Zimmer® Dermatome Blades
Field Safety Corrective Action Reference Number: ZFA2023-00208

Do you have affected product in your facility? (Please mark the appropriate response.)

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

If you selected **Yes**, please mark the appropriate response below:

☐ My Zimmer Biomet Sales Representative will return the affected items from our facility.

☐ Our facility will return the affected items directly.

Please return the affected product to the appropriate address below with a spreadsheet containing the material/item number, batch/lot number and quantity in the correct unit of measure.

Zimmer Biomet Nederland B.V.
(Warehouse BeNeLux)
Hazeldonk 6526
4836 LD Breda, Netherlands

Material/Item Number	Batch/Lot Number	Quantity Returned	Unit of Measure (boxes or blades)

Complete this table for all affected items returning. Do not return affected products with other returns. If additional space is needed, please provide a spreadsheet and return it to fieldaction.netherlands@zimmerbiomet.com with this form.

All products that are not available for return have been implanted or used: ☐ Yes ☐ No ☐ Unknown
Any product not returned or found in your facility is considered dispositioned on your location and unavailable for use.

Certificate of Acknowledgement

By signing below, I acknowledge that I have received, read and understood the contents of this Field Safety Notice and that all the required actions have been taken accordingly.

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

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

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ATTACHMENT 2 - Affected Product List

Affected Product: Zimmer® Dermatome Blades

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.

Material/Item Number	Batch/Lot Number	Individual Blade UDI Number	10-Pack Box UDI Number
00-8800-000-10	65599469	(01)00889024375895(17)280205(10)65599469	(01)00889024380318(17)280205(10)65599469
00-8800-000-10	65620875	(01)00889024375895(17)280206(10)65620875	(01)00889024380318(17)280206(10)65620875
00-8800-000-10	65621233	(01)00889024375895(17)280207(10)65621233	(01)00889024380318(17)280207(10)65621233
00-8800-000-10	65630969	(01)00889024375895(17)280209(10)65630969	(01)00889024380318(17)280209(10)65630969
00-8800-000-10	65647382	(01)00889024375895(17)280212(10)65647382	(01)00889024380318(17)280212(10)65647382
00-8800-000-10	65648460	(01)00889024375895(17)280213(10)65648460	(01)00889024380318(17)280213(10)65648460
00-8800-000-10	65709066	(01)00889024375895(17)280214(10)65709066	(01)00889024380318(17)280214(10)65709066
00-8800-000-10	65925347	(01)00889024375895(17)280219(10)65925347	(01)00889024380318(17)280219(10)65925347
00-8800-000-10	65925348	(01)00889024375895(17)280220(10)65925348	(01)00889024380318(17)280220(10)65925348
00-8800-000-10	65935737	(01)00889024375895(17)280221(10)65935737	(01)00889024380318(17)280221(10)65935737
00-8800-000-10	65935738	(01)00889024375895(17)280223(10)65935738	(01)00889024380318(17)280223(10)65935738
00-8800-000-10	65952857	(01)00889024375895(17)280319(10)65952857	(01)00889024380318(17)280319(10)65952857
00-8800-000-10	65952858	(01)00889024375895(17)280424(10)65952858	(01)00889024380318(17)280424(10)65952858
00-8800-000-10	65972711	(01)00889024375895(17)280430(10)65972711	(01)00889024380318(17)280430(10)65972711
00-8800-000-10	65972712	(01)00889024375895(17)280503(10)65972712	(01)00889024380318(17)280503(10)65972712
00-8800-000-10	65988623	(01)00889024375895(17)280507(10)65988623	(01)00889024380318(17)280507(10)65988623
00-8800-000-10	65952862	(01)00889024375895(17)280426(10)65952862	(01)00889024380318(17)280426(10)65952862
00-8800-000-10	65988624	(01)00889024375895(17)280509(10)65988624	(01)00889024380318(17)280509(10)65988624
00-8800-000-10	65989036	(01)00889024375895(17)280514(10)65989036	(01)00889024380318(17)280514(10)65989036
00-8800-000-10	65989037	(01)00889024375895(17)280516(10)65989037	(01)00889024380318(17)280516(10)65989037
00-8800-000-10	66000975	(01)00889024375895(17)280520(10)66000975	(01)00889024380318(17)280520(10)66000975
00-8800-000-10	66000976	(01)00889024375895(17)280523(10)66000976	(01)00889024380318(17)280523(10)66000976
00-8800-000-10	66002852	(01)00889024375895(17)280528(10)66002852	(01)00889024380318(17)280528(10)66002852
00-8800-000-10	65952860	(01)00889024375895(17)280530(10)65952860	(01)00889024380318(17)280530(10)65952860
00-8800-000-10	66002853	(01)00889024375895(17)280610(10)66002853	(01)00889024380318(17)280610(10)66002853
00-8800-000-10	66014333	(01)00889024375895(17)280613(10)66014333	(01)00889024380318(17)280613(10)66014333
00-8800-000-10	66014332	(01)00889024375895(17)280617(10)66014332	(01)00889024380318(17)280617(10)66014332
00-8800-000-10	66038885	(01)00889024375895(17)280624(10)66038885	(01)00889024380318(17)280624(10)66038885
00-8800-000-10	66172214	(01)00889024375895(17)280628(10)66172214	(01)00889024380318(17)280628(10)66172214
00-8800-000-10	66049031	(01)00889024375895(17)280710(10)66049031	(01)00889024380318(17)280710(10)66049031
00-8800-000-10	66078057	(01)00889024375895(17)280724(10)66078057	(01)00889024380318(17)280724(10)66078057
00-8800-000-10	66049032	(01)00889024375895(17)280719(10)66049032	(01)00889024380318(17)280719(10)66049032