ZIMMER BIOMET

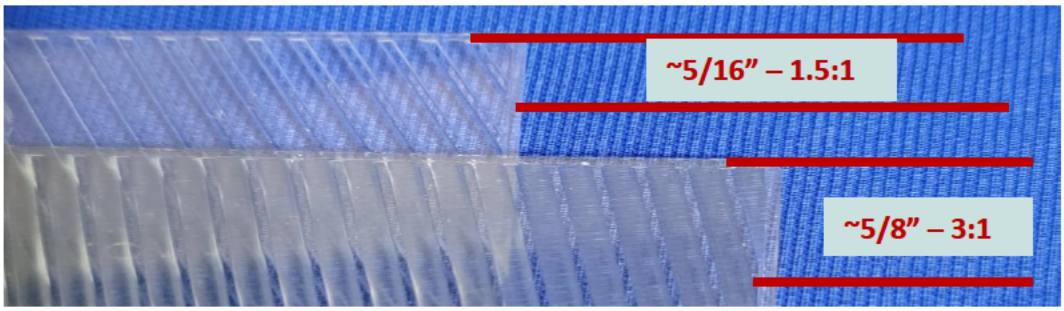
11 January 2024

To: Hospitals

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

Affected Product: Dermacarriers™ II Skin Graft Carriers, 3:1 Ratio

Material / Item Number	Batch / Lot Number	UDI Number
00-2195-013-00	65292843	(01)00889024378780(17)261016(10)65292843
00-2195-013-00	65390419	(01)00889024378780(17)270118(10)65390419



Zimmer Surgical, Inc. is conducting a batch/lot specific medical device Field Safety Corrective Action for two batches/lots of the Dermacarriers™ II Skin Graft Carriers, 3:1 ratio. The two impacted batches/lots of the 3:1 ratio Dermacarriers were manufactured using the mold for the 1.5:1 ratio Dermacarriers. As a result, the package label and the ratio text identify the product as a 3:1 ratio. However, the ridge pattern is a 1.5:1 ratio. The issue was identified through the six received complaints for the issue.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Tissue damage, minor. Health Care Professional determines the graft is usable as is and reports no additional harm.	Injury (Moderate - Surgical intervention) due to additional unplanned graft deemed necessary.
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.	Injury (Moderate - Surgical intervention) due to scarring from additional unplanned graft.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between February 2023 and October 2023. Local deployment may differ.

The affected devices are distributed as 20-pack boxes and may be located within your inventory as a 20-pack box or individual units.

Hospital Responsibilities:

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have affected product(s) at your facility, immediately locate and quarantine affected product(s) 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 product from your facility.
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.ch@zimmerbiomet.com. This form shall be returned even if you do not have affected products at your facility. Upon receipt of the affected product(s), Zimmer Biomet will credit your account. Please return a copy of the completed response form along with your returned product to ensure proper credit, and mark "RECALL" on the outside of the returned cartons.
5. Retain a copy of the **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 Field Safety 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.CH@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.

Sincerely,

[redacted]

Francis Moloney, VP QA/RC EMEA

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ATTACHMENT 1 – Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Dermacarriers™ II Skin Graft Carriers, 3:1 Ratio
Field Safety Corrective Action Reference Number: ZFA2023-00275

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.

Note: Any product not available for return is considered dispositioned at your location and unavailable for use.

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

Complete the table below for all affected products returned. If additional space is needed, please provide a spreadsheet and return it with this form. **Do not return products with other returns.**

Material / Item Number	Batch / Lot Number	Quantity Returned	Unit of Measure (Boxes of Pieces)
00-2195-013-00	65292843		
00-2195-013-00	65390419		

Hospital Acknowledgement

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

Printed Name: _____ **Signature:** _____

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

Facility Name: _____ **Facility Account Number:** _____

Facility Address: _____

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