ZIMMER BIOMET

06 October 2025

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION (REMOVAL)**

Affected Product: ZipTight™, Acute AC Joint Implant, Single Ziploop®

Material Number	Batch Number	UDI Number
904834	0002587666	(01)00880304478404(17)290130(10)0002587666

Complaint package without the slotted button assembly

Conforming Package with the slotted button assembly

Figure 1: Packaged Product Reported in Complaints (shown in red) versus Conforming Package (shown in green).

Biomet Sports Medicine is conducting a medical device Field Safety Corrective Action for one batch of the ZipTight, Acute AC Joint Implant, Single Ziploop. Seven product complaints have been received with no patient impact, reporting that the slotted button assembly was missing, as shown in Figure 1 above.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	No patient, user, or other stakeholder harm occurs.	Clinically insignificant extension of surgery to find a replacement device.
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.	None.

Our records indicate that you may have received one or more of the affected products. The affected products were distributed between June and July 2025.

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Hospital Responsibilities

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. Immediately locate and quarantine any affected product in your inventory. Your Zimmer Biomet sales representative may assist with removing the affected product(s) from your facility.
3. If any affected product has been further distributed, provide your customer(s) with this Field Safety Notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send it to fieldaction.gscc@zimmerbiomet.com. This form must be returned even if you do not have any affected product available for return.
5. Retain a copy of **Attachment 1 - Certificate of Acknowledgement** with your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Other Information

This Field Safety Corrective Action was reported to all relevant Competent Authorities and Notified Bodies as required under the applicable regulations for Medical Devices per Regulation (EU) 2017/745 and guidance MDCG 2023-3. The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies. Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing ProductComplaintGSCC@zimmerbiomet.com.

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

Sincerely,

ZIMMER BIOMET

ATTACHMENT 1 - Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Field Safety Corrective Action reference number: ZFA-2025-00166
Affected Product: ZipTight™, Acute AC Joint Implant, Single Ziploop®

Do you have affected product(s) in your facility?
☐ Yes, we currently have one or more affected products in our facility.
☐ No, we currently have no affected items in our facility.
Note: *Any product not available for return is considered dispositioned under your distributorship and unavailable for use.*

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 Number	Batch Number	Quantity Returned
904834	0002587666	

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.

Facility Name					
Facility Address					
Post Code		**City**		**Country**	
Printed Name					
Title					
Date		**Signature**			