

13 March 2025

To: Hospitals and Surgeons

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

Affected Product: Comprehensive® Shoulder Primary Stem
(5 mm Micro, 6 mm Micro, 7 mm Micro & 7 mm Mini)

See **Attachment 2 – Product scope list** for the affected material and batch numbers.



Figure 1 – The Comprehensive Shoulder Primary Stem (left) did not fit properly due to excess metal that was identified on the inner taper (right).

Biomet Orthopedics is conducting a batch specific medical device Field Safety Corrective Action for ten batches of the Comprehensive Shoulder Primary Stem (5 mm Micro, 6 mm Micro, 7 mm Micro & 7 mm Mini). To date, five product complaints reported that the stem implant did not fit in the inserter or that the inserter could not be detached from the stem. There were no injuries reported associated with the five product complaints received. The internal investigation identified excess metal on the inner taper of the stem due to a chipped manufacturing tool.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Clinically significant extension of surgery to find a replacement.	Clinically significant extension of surgery to find a replacement.
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 September 2023 and October 2024. Local distribution may differ.

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.netherlands@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.

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. 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 per.nl@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,



ATTACHMENT 1 - Certificate of acknowledgement

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Field Safety Corrective Action reference number: ZFA-2024-00214

Affected Product: Comprehensive® Shoulder Primary Stem

(5 mm Micro, 6 mm Micro, 7 mm Micro & 7 mm Mini)

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 disposed 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

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			

Attachment 2 – Product scope list

Material Number	Material Description	Batch Number	UDI Number
113605	Comprehensive Shoulder System, Primary Shoulder Stem, Micro Length, 5 mm, 55 mm Long	66173214	(01)00887868267550(17)330716(10)66173214
		66173215	(01)00887868267550(17)330716(10)66173215
113606	Comprehensive Shoulder System, Primary Shoulder Stem, Micro Length, 6 mm, 55 mm Long	66173216	(01)00887868267567(17)330716(10)66173216
		66173218	(01)00887868267567(17)330716(10)66173218
		66173219	(01)00887868267567(17)330716(10)66173219
113607	Comprehensive Shoulder System, Primary Shoulder Stem, Micro Length, 7 mm, 55 mm Long	66173220	(01)00887868267574(17)330716(10)66173220
		66173221	(01)00887868267574(17)330716(10)66173221
113627	Comprehensive Shoulder System, Mini Humeral Stem, 7 mm, 83 mm Long	65901697	(01)00887868267741(17)330715(10)65901697
		65909480	(01)00887868267741(17)330716(10)65909480
		65915809	(01)00887868267741(17)330715(10)65915809