June 09, 2022

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Affected Product: NCB Femoral Screw

Item Number	Item Description	Lot Number	UDI Number
02.03150.038	NCB SCREW 5.0 L = 38	3101299	(01) 00889024295759 (10) 3101299

Zimmer GmbH is conducting a medical device Field Safety Corrective Action (removal) for one lot of the NCB Femoral Screws. The product in scope is part of a mix-up with a NCB Humeral Screw that differs in dimensions and therefore it has been decided to remove the affected lot from the market.

The product packaging of the affected lot shows a product of NCB Femoral Screws with a diameter of 5.0 mm and a length of 38 mm. Instead, the product within the packaging is a NCB Humeral Screw with a diameter of 4.0 mm and a length of 40 mm.

The longer screw length can be identified prior to implantation through a screw length identification check performed by the surgical staff as per standard procedure. In case the incorrect screw is used for implantation, absence of the expected resistance and/or inter-fragmentary compression will be recognized by the surgeon due to the smaller diameter of the screw compared to the drilled diameter in the bone.

The affected products were delivered non-sterile and the table below will help to identify the affected products.

Type of product receipt	Outer label information	Product laser marking (small on screw top surface)	Actual inner product size
With packaging pouch	Item Number: 02.03150.038 Lot Number: 3101299 Diameter: 5mm. Length: 38mm.	UDI Number: (01)00889024296213 Lot Number: (10)3101354	Diameter: 4 mm. Length: 40 mm.
In kit without packaging pouch	N/A	UDI Number: (01)00889024296213 Lot Number: (10)3101354	Diameter: 4 mm. Length: 40 mm.

ZFA2022-00080

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 insignificant extension of surgical time.	*Clinically insignificant extension of surgical time.*
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 March 2022 and April 2022. Local deployment may differ.

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, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. If the product has been further distributed, provide your customers with the Field Safety Notice for hospitals and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.gscc@zimmerbiomet.com.
5. This form must be returned even if you do not have affected products at your facility.
6. Retain a copy of the **Certificate of Acknowledgement** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
7. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your 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. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.gscc@zimmerbiomet.com.
4. Retain a copy of the **Certificate of Acknowledgement** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

Other Information

This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as 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 GSCC.Supplier.Quality@zimmerbiomet.com or to your local Zimmer Biomet contact.

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 in advance and regret any inconveniences caused by this Field Safety Corrective Action.

Sincerely,

xxx

ZIMMER BIOMET

ATTACHMENT 1- Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: NCB Femoral Screw
Field Safety Corrective Action Reference: ZFA2022-00080

Please return the completed form to your Zimmer Biomet contact person or by e-mail to:
fieldaction.gscc@zimmerbiomet.com

Regarding the parts:

☐ A thorough search has been performed for the affected products and the below are available for return.
Please provide a spreadsheet with the return of this form if the below table has not enough space to list all products.

Item Number	Lot Number	Quantity Returned

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

All products that are not available (for return) will be considered as dispositioned on your location and therefore physical unavailable unless otherwise specified.

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

[ ] **Hospital Facility** [ ] **Surgeon** *(Please check one as applicable)*

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) _____-_____ **Date:** _____/_____/_____

Facility Name: _____

Facility Address: _____

City: _____ **Country:** _____ **ZIP:** _____

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