June 09, 2022

To: Distributors

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.

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.

Your Responsibilities

1. Review this Field Safety Notice and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine all affected product in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your territory.
   a. Complete **Attachment 1 – Inventory Return Certification Form** and send to fieldaction.gscc@zimmerbiomet.com. This form must be returned even if you do not have affected products available to return in your country.
   b. Include a hardcopy of **Attachment 1** in each carton of your return shipment for immediate processing.
   c. Mark “RECALL” on the outside of the returned cartons.
4. Retain a copy of your **Inventory Return Certification** and product return forms for your records in the event of a compliance audit of your facility.
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 - Inventory Return Certification Form
IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

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

Country: _____ **Account Number:** _____

Account Name: _____

Account Address: _____

Please return all affected products to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Zimmer GmbH
Biomet Global Supply Chain Center B.V.
Hazeldonk 6530 - Dock 20
Breda 4836 LD, Netherlands

This is the final return for the entire territory.	Check one of the following:	
An exhaustive search has been performed for the affected products.	Yes ☐	No ☐

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

☐ Credit My Account ☐ Send a Replacement

Item Number	Lot Number	Quantity Returned

Complete the above table for all the affected items to be returned or provide a spreadsheet with the return of this form if the above table has not enough space to list all products. **Please do not return affected product with other returns.**

Certificate of Acknowledgement

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

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** (____)_____ **Ext.:** _____ **Date:** _____

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