ZIMMER BIOMET

March 03, 2022

Nextremity Solutions – Nextra® Hammertoe Correction System

Dear Valued Customer,

Zimmer Biomet is committed to the quality of our product offerings and patient safety. In an effort to serve you and your patients, it is our promise to support you at all times, including during unexpected events, such as a Field Safety Corrective Action.

Enclosed is a product communication from one of our Foot and Ankle suppliers, Nextremity Solutions®. While the accompanying product action is being initiated by Nextremity Solutions®, your relationship is with Zimmer Biomet. We value your business and want to assure you that we stand behind you and we are committed to providing safe and effective treatment solutions for your patients. It is for that reason we ask for your immediate attention and response to the attached Nextremity request.

To make this as seamless as possible for you, we ask that you follow without delay the directions in the enclosed Field Safety Notice. You may direct any questions regarding the Field Safety Corrective Action to fieldaction.uk@zimmerbiomet.com. We are working very closely with Nextremity Solutions® to handle this event in a way that will minimize the impact to the patient and you. Thank you for your patience and cooperation in assisting us to properly complete the necessary process for this action.

Sincerely,

NextremitySolutions®

**March 03, 2022**

## URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)

**Affected Product:** Nextra® Hammertoe Correction System

Dear Hospital and/or Surgeon,

The purpose of this letter is to advise you that Nextremity Solutions is voluntarily recalling the manufacturing lots of product listed in Table 1 below. These products are part of the Nextra® Hammertoe Correction System which is indicated for small bone reconstruction limited to inter-digital repair and fusion of the lesser toes.

**Table 1**

| SKU | Product Description | Manufacturing Lot |
|---|---|---|
| NX-4532K | 4.5 Middle 3.2 Proximal Kit | 168117318B |
| NX-4532K-SC | 4.5 Middle and 3.2 Proximal Saw Cut | 168117318C |
| NX-3532K | 3.5 Middle 3.2 Proximal Kit | 168125017A |
| NX-3532K-SC | 3.5 Middle and 3.2 Proximal Saw Cut | 168125017B |
| NX-4532K | 4.5 Middle and 3.2 Proximal Kit | 168125017C |
| NX-4532K-SC | 4.5 Middle and 3.2 Proximal Saw Cut | 168125017D |
| NX-DR | Nextra Driver | 168A27917C |

Distribution records indicate that the products were shipped to you between June 2018 and October 2021.

**Reason for voluntary Field Safety Corrective Action (removal):**
The product listed in Table 1 contains a reversible driver designed to engage with both pieces of the two-part Nextra implant construct. The proximal end of the driver in the affected product (Table 1) is oversized in varying degrees, making it difficult to fully connect with and remove from the proximal Nextra implant. Figure 1 below depicts the Nextra reversible driver and identifies the proximal end.

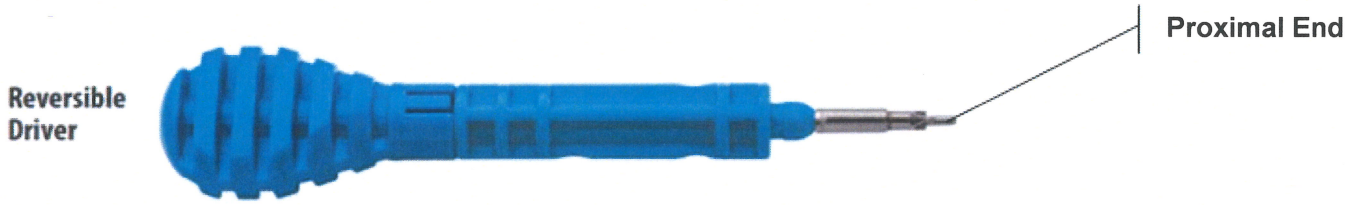


**Figure 1. Reversible Nextra Driver (Above)**

Nextremity Solutions is aware of certain complaints related to the issue which resulted in a surgical delay of greater than 30 minutes, use of an alternate surgical approach, in-situ removal of the implant, and difficulty inserting the implant.

**Risks:**
The issue can result in surgical delay, use of an alternative surgical approach, in-situ removal of the implant, and difficulty inserting the implant.

**How to recognize the issue:**
The problem can be recognized by observing the lot number on the kit, or individually packaged driver. If the lot number on the kit or on individually packaged driver matches any of the lot numbers in Table 1, the driver is affected by the issue.

**Field Safety Corrective Action (removal) instructions:**
Nextremity Solutions products with the referenced part and lot number should not be used and should be quarantined and returned to Zimmer Biomet for return to Nextremity Solutions.

**Your Responsibilities:**

1. Review this notification and ensure that affected personnel are aware of its 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. Complete **Attachment 1 – Medical Device Field Safety Corrective Action Return Response** and send to fieldaction.uk@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of your **Medical Device Field Safety Corrective Action Return Response** 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 by Zimmer Biomet distributed product by emailing per.uk@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. Your urgent cooperation is needed. 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,

[redacted]

NextremitySolutions®

## ATTACHMENT 1 MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION RETURN RESPONSE

Acknowledgement and Receipt Form

**Immediate Response Required-Time Sensitive Action Needed**

**Affected product:** Nextra® Hammertoe Correction System

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

**Regarding the parts**:

☐ A thorough search has been performed for the affected products and the below are available for return.
All products that are not available (for return) have been implanted or used: ☐ Yes ☐ No

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

| Item Number | Lot Number | UDI Number | Quantity Returned |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to fieldaction.uk@zimmerbiomet.com with this form.

By signing below, I acknowledge that I have received, read, and understand the contents of this recall 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:** _____ **Tel:** (___)_____ **Ext.:** _____ **Date:** _____

**Facility Name**: _____

**Facility Address**: _____

**City:** _____ **State:** _____ **ZIP:** _____

**Note:** This form will 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.uk@zimmerbiomet.com.