

07 May 2021

**To:** Hospitals

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

**Affected Product:** ZNN CMN Femoral Nail

**Field Action Reference:** ZFA 2021-00053

Item Number	Lot Number	UDI Number	Description
47-2493-211-11	3020731	(01) 0088902498880 (17) 300131 (10) 3020731	ZNN Cephalomedullary Short Nail 11.5 mm X 21.5 cm 125 CCD Left Ti-6Al-4V Alloy
47-2493-213-11	3025629	(01) 0088902498965 (17) 300131 (10) 3025629	ZNN Cephalomedullary Short Nail 11.5 mm X 21.5 cm 130 CCD Left Ti-6Al-4V Alloy



Zimmer GmbH is conducting a medical device Field Safety Corrective Action (Removal) for the above two lots of ZNN CMN Femoral Nail due to potential commingle between CCD angle 130° and 125°. As a precautionary measure it was decided to remove all potentially affected products from the market.

In case the nail has a bigger/smaller CCD angle, certain difficulty during Lag Screw reaming and placement is expected. The difference in CCD angle could be recognized by the user latest during the assembly of the Lag Screw into the nail under fluoroscopy.

The below two steps in the applicable surgical techniques can potentially assist the user to detect the bigger/smaller CCD angle of the ZNN CMN Nail. As recommended in the applicable surgical techniques (97-2493-005-00 Rev 07, 97-2493-002-00 REV 09, 97-2493-014-00 Rev. 3), during nail assembly step prior to the

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insertion of the nail, confirm also that the lag screw hole in the nail is oriented to guide a lag screw into the femoral head.

During Lag Screw Placement step, position the targeting guide so that the trajectory of the lag screw cannula will place the lag screw in the appropriate position in the femoral head and neck. Pins can be held over the skin in line with the lag screw cannula to help estimate this position and correct CCD angle.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Non-clinically significant extension of surgery time	Clinically significant extension of surgery 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 potentially affected products. The potentially affected units were distributed between July 2020 and March 2021 (Local deployment may differ).

**Hospital Responsibilities:**

1. Review this Field Safety Notice and ensure that potentially affected personnel are aware of the contents.
2. If you have potentially affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all potentially affected product. Your Zimmer Biomet sales representative will remove the potentially affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to [fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com). This form must be returned even if you do not have any potentially affected products at your facility.
4. Retain a copy of the acknowledgement form 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.

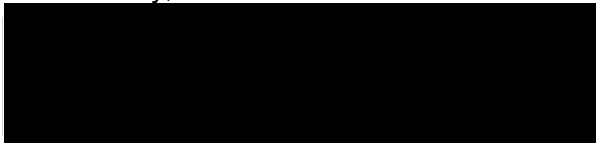
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [winterthur.per@zimmerbiomet.com](mailto:winterthur.per@zimmerbiomet.com) or to your local Zimmer Biomet contact.

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 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,



Francis Moloney, VP QA/RC EMEA



**ATTACHMENT 1  
Certificate of Acknowledgement**

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Potentially affected Product:** ZNN CMN Femoral Nail

**Field Action Reference:** 2021-00053

**Please return the completed form to your Zimmer Biomet contact person:**  
[fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com)

I received and understood the Field Safety Notice.

**Regarding the products:**

All inventories for the potentially affected products have been checked and following products are to be returned:

Product Reference	Lot Reference	Number of products returned

**OR**

The potentially affected products which are unavailable for return have been:

implanted  lost  other: \_\_\_\_\_

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

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

**Printed Name:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

**Date:** \_\_\_/\_\_\_/\_\_\_

**Title:** \_\_\_\_\_ **Telephone:** (    ) \_\_\_\_\_-\_\_\_\_\_

**Facility Name:** \_\_\_\_\_ **Facility Address:**

\_\_\_\_\_

**City:** \_\_\_\_\_ **ZIP:** \_\_\_\_\_ **Country:** \_\_\_\_\_

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