ZIMMER BIOMET

May 23, 2016

To: **Hospitals and Surgeons**

Subject: **URGENT FIELD SAFETY NOTICE - REMOVAL**

FSN/FSCA: **FA 2016-05**

Affected Product: **Zimmer Natural Nail® Cephalomedullary Nail (ZNN CMN Nails)**

Dear Sirs,

Zimmer GmbH is initiating a voluntary removal of the two specific lots of ZNN CMN Nails as indicated in below table 1.

Product	Material Number	Lot Number
ZNN CMN Nail 11.5mmX30cm 130 L(Left)	47-2493-303-11	2840845
ZNN CMN Nail 13mmX30cm 125 R (Right)	47-2493-300-13	2840846

Table 1: Material and Lot numbers affected

During monitoring of the product a comingle between the two specific lots has been identified.

The ZNN CMN Nail with 11.5 mm diameter, length 30 cm, CCD angle 130, left leg (Material 47-2493-303-11 and lot 2840845) is placed in the box of a ZNN CMN Nail with 13 mm diameter, length 30 cm, CCD angle 125 and right leg (Material number 47-2493-300-13 and lot 284046) and vice versa.

Zimmer® Natural Nail® System Cephalomedullary Nail (CMN)

Picture 1: Illustration of the ZNN CMN

Our records indicate that you may have received one or more of the affected products.

Risks
The issue is detectable due to diameter difference, CCD Angle and the laser marking on the product which indicates the Item-Number, Lot and Leg Side. In case of use of the incorrectly packaged product, following risks have been identified.

1) If the surgeon discovers the issue prior implantation, a potential slight delay in the surgery time might occur until a new product is available.
2) If the issue is detected, but no other correct device is available a new surgical approach or a postponing of the surgery would become necessary. The delay of surgery might be >30 min. As a consequence of such the infection risk for patient would increase.
3) If the wrong diameter/leg side/angle is used and especially if the bigger implant is used, bone fracture might occur during insertion. This would induce a change of the surgical approach and also prolongation of the surgery.
4) No long range health consequences are expected as the issues with the product comingle would be detected during surgery. Surgery completion with the incorrect implant is not possible because of the difference in the CCD angle, which would be detectable due to the bone geometry and due to a potential cut out of the lag screw.

Your Responsibilities

1. Review the notification immediately and ensure affected personnel are aware of the contents without delay.
2. Assist your Zimmer Biomet sales representative with the quarantine of any device mentioned in table 1.
3. Your Zimmer Biomet sales representative will remove the affected device, if any, from your facility.
4. Complete the Certification of Acknowledgement from (Attachment 1) and return to fieldaction.emea@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**

Vigilance/ Reporting Information

This voluntary notification will be reported to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local health authority in your country.

Please keep Zimmer GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

Kind regards,

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Anne-Catherine Morancy Meister
PMS Manager

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Attachment 1
Certificate of Acknowledgement

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Please email or fax the completed form to your local Zimmer Biomet contact

Fax / Email _____ / _____

By signing below, I acknowledge that I have received and understand the content of the Urgent Field Safety Notice – Removal, and that the required actions have been taken in accordance with the notice:

1. Return parts in inventory
2. Fill the list below
3. Sign the form

Product reference	Quantity to return

Printed Name:_____

Signature:_____

Hospital Name: _____

Hospital Address:_____

Phone Number:_____

Please maintain a copy of your completed form with your internal records.