

September 14, 2015

To: Risk Managers and Surgeons

Subject: URGENT FIELD SAFETY NOTICE - CORRECTION

FSN/FSCA: FA 2015-05

**Affected Product: Zimmer Natural Nail CM Long- Cephalomedullary Nails
See Attachment 1 for Item Numbers – All Lots**

As a part of a quality improvement initiative, Zimmer GmbH conducted an internal review of packaging design verification and testing, according to the current packaging test standards.

During this review, it was identified that a subset of above referenced products manufactured and packaged from July 2009 to July 2015, required additional testing to ensure that product packaging met the established requirements for sterile barrier integrity.

The Cephalomedullary Nails are packaged in a double sterile barrier packaging, that includes the placement of the product in a protective pouch and then into two sterile barrier trays (inner and outer). In approximately 5% of the tested samples, the outer tray was found to be compromised, but there were no records which suggested that the sterility of the inner tray was affected. To date no complaints have been received alleging compromised packaging.

The affected item numbers (all lots) are listed on Attachment 1. Our records indicate that you may have received one or more of the affected products from this packaging configuration. Affected devices were distributed from December 2009 through July 2015.

In the event of any damage to the carton box and/or to the outer tray, it is very likely that it is detected prior to the surgery. The package insert (instructions for use) provided with the device or device system contains a section on sterility. It instructs the user to inspect the package and not use the device if any seal or cavity is damaged. Accordingly, all affected products should be visually inspected for damage and returned if damage is noted. For reference purposes please see below images.

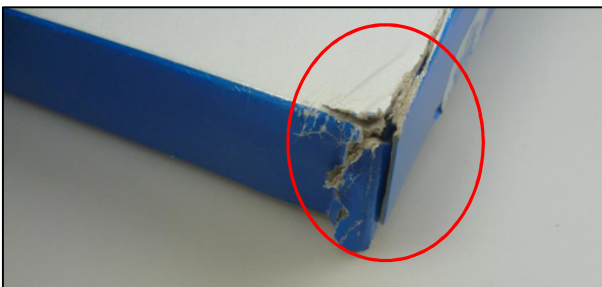


Fig 1. Carton box damage



Fig. 2 Outer tray damage

Risks

- If a damaged outer tray is detected during surgery, it may result in a slight delay in surgery to obtain another implant.
- In the unlikely event that a compromised packaging is not detected, prior or during a surgery by the user, it may lead to periprosthetic infection. This may result in revision or multi-stage revision to treat the infection.

Your Responsibilities

1. Review the notification immediately and ensure affected personnel are aware of the contents without delay.
2. Locate immediately any affected products in your inventory.
3. Use the visual aids provided in this notice and inspect the product's package as described in the package insert and ensure there is no damage to the outer tray.
4. If damage to the outer tray is observed, do not use the product. Please quarantine the product and contact your Zimmer Biomet representative for return of the damaged product via Product Experience Report (PER).
5. If solely the carton-box is damaged the device can be used as sterility is maintained by means of the double-barrier.
6. Complete and return Attachment 2, Certificate of Acknowledgement to fieldaction.emea@zimmerbiomet.com. Keep a copy of your completed response with your records in the event of an audit.
7. If after reviewing this notification you have questions concerning this notification, please contact your local Zimmer Biomet representative.

Vigilance Information

This voluntary notification will be reported to the U.S. Food and Drug Administration and 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 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,

Matthias Bürger
Vice President
Quality Assurance and Regulatory Compliance – EMEA

ATTACHMENT 1

Item Number	Name
47-2493-481-10	ZNN CMN Nail 10mmX48cm 125 L
47-2493-480-10	ZNN CMN Nail 10mmX48cm 125 R
47-2493-483-10	ZNN CMN Nail 10mmX48cm 130 L
47-2493-482-10	ZNN CMN Nail 10mmX48cm 130 R
47-2493-485-10	ZNN CMN Nail 10mmX48cm 135 L
47-2493-484-10	ZNN CMN Nail 10mmX48cm 135 R
47-2493-481-11	ZNN CMN Nail 11.5mmX48cm 125 L
47-2493-480-11	ZNN CMN Nail 11.5mmX48cm 125 R
47-2493-483-11	ZNN CMN Nail 11.5mmX48cm 130 L
47-2493-482-11	ZNN CMN Nail 11.5mmX48cm 130 R
47-2493-485-11	ZNN CMN Nail 11.5mmX48cm 135 L
47-2493-484-11	ZNN CMN Nail 11.5mmX48cm 135 R
47-2493-481-13	ZNN CMN Nail 13mmX48cm 125 L
47-2493-480-13	ZNN CMN Nail 13mmX48cm 125 R
47-2493-483-13	ZNN CMN Nail 13mmX48cm 130 L
47-2493-482-13	ZNN CMN Nail 13mmX48cm 130 R
47-2493-485-13	ZNN CMN Nail 13mmX48cm 135 L
47-2493-484-13	ZNN CMN Nail 13mmX48cm 135 R
47-2493-463-13	ZNN CMN Nail 13mmX46cm 130 L
47-2493-461-10	ZNN CMN Nail 10mmX46cm 125 L
47-2493-460-10	ZNN CMN Nail 10mmX46cm 125 R
47-2493-463-10	ZNN CMN Nail 10mmX46cm 130 L
47-2493-462-10	ZNN CMN Nail 10mmX46cm 130 R
47-2493-465-10	ZNN CMN Nail 10mmX46cm 135 L
47-2493-464-10	ZNN CMN Nail 10mmX46cm 135 R
47-2493-461-11	ZNN CMN Nail 11.5mmX46cm 125 L
47-2493-460-11	ZNN CMN Nail 11.5mmX46cm 125 R
47-2493-463-11	ZNN CMN Nail 11.5mmX46cm 130 L
47-2493-462-11	ZNN CMN Nail 11.5mmX46cm 130 R
47-2493-465-11	ZNN CMN Nail 11.5mmX46cm 135 L
47-2493-464-11	ZNN CMN Nail 11.5mmX46cm 135 R
47-2493-461-13	ZNN CMN Nail 13mmX46cm 125 L
47-2493-460-13	ZNN CMN Nail 13mmX46cm 125 R
47-2493-462-13	ZNN CMN Nail 13mmX46cm 130 R
47-2493-465-13	ZNN CMN Nail 13mmX46cm 135 L
47-2493-464-13	ZNN CMN Nail 13mmX46cm 135 R
47-2493-441-10	ZNN CMN Nail 10mmX44cm 125 L

Item Number	Name
47-2493-442-10	ZNN CMN Nail 10mmX44cm 130 R
47-2493-445-10	ZNN CMN Nail 10mmX44cm 135 L
47-2493-444-10	ZNN CMN Nail 10mmX44cm 135 R
47-2493-441-11	ZNN CMN Nail 11.5mmX44cm 125 L
47-2493-440-11	ZNN CMN Nail 11.5mmX44cm 125 R
47-2493-443-11	ZNN CMN Nail 11.5mmX44cm 130 L
47-2493-442-11	ZNN CMN Nail 11.5mmX44cm 130 R
47-2493-445-11	ZNN CMN Nail 11.5mmX44cm 135 L
47-2493-444-11	ZNN CMN Nail 11.5mmX44cm 135 R
47-2493-441-13	ZNN CMN Nail 13mmX44cm 125 L
47-2493-440-13	ZNN CMN Nail 13mmX44cm 125 R
47-2493-443-13	ZNN CMN Nail 13mmX44cm 130 L
47-2493-442-13	ZNN CMN Nail 13mmX44cm 130 R
47-2493-445-13	ZNN CMN Nail 13mmX44cm 135 L
47-2493-444-13	ZNN CMN Nail 13mmX44cm 135 R
47-2493-421-10	ZNN CMN Nail 10mmX42cm 125 L
47-2493-420-10	ZNN CMN Nail 10mmX42cm 125 R
47-2493-423-10	ZNN CMN Nail 10mmX42cm 130 L
47-2493-422-10	ZNN CMN Nail 10mmX42cm 130 R
47-2493-425-10	ZNN CMN Nail 10mmX42cm 135 L
47-2493-424-10	ZNN CMN Nail 10mmX42cm 135 R
47-2493-421-11	ZNN CMN Nail 11.5mmX42cm 125 L
47-2493-420-11	ZNN CMN Nail 11.5mmX42cm 125 R
47-2493-423-11	ZNN CMN Nail 11.5mmX42cm 130 L
47-2493-422-11	ZNN CMN Nail 11.5mmX42cm 130 R
47-2493-425-11	ZNN CMN Nail 11.5mmX42cm 135 L
47-2493-424-11	ZNN CMN Nail 11.5mmX42cm 135 R
47-2493-421-13	ZNN CMN Nail 13mmX42cm 125 L
47-2493-420-13	ZNN CMN Nail 13mmX42cm 125 R
47-2493-423-13	ZNN CMN Nail 13mmX42cm 130 L
47-2493-422-13	ZNN CMN Nail 13mmX42cm 130 R
47-2493-425-13	ZNN CMN Nail 13mmX42cm 135 L
47-2493-424-13	ZNN CMN Nail 13mmX42cm 135 R
47-2493-401-10	ZNN CMN Nail 10mmX40cm 125 L
47-2493-400-10	ZNN CMN Nail 10mmX40cm 125 R
47-2493-403-10	ZNN CMN Nail 10mmX40cm 130 L
47-2493-402-10	ZNN CMN Nail 10mmX40cm 130 R

Item Number	Name
47-2493-440-10	ZNN CMN Nail 10mmX44cm 125 R
47-2493-443-10	ZNN CMN Nail 10mmX44cm 130 L
47-2493-401-11	ZNN CMN Nail 11.5mmX40cm 125 L
47-2493-400-11	ZNN CMN Nail 11.5mmX40cm 125 R
47-2493-403-11	ZNN CMN Nail 11.5mmX40cm 130 L
47-2493-402-11	ZNN CMN Nail 11.5mmX40cm 130 R
47-2493-405-11	ZNN CMN Nail 11.5mmX40cm 135 L
47-2493-404-11	ZNN CMN Nail 11.5mmX40cm 135 R
47-2493-401-13	ZNN CMN Nail 13mmX40cm 125 L
47-2493-400-13	ZNN CMN Nail 13mmX40cm 125 R
47-2493-403-13	ZNN CMN Nail 13mmX40cm 130 L
47-2493-402-13	ZNN CMN Nail 13mmX40cm 130 R
47-2493-405-13	ZNN CMN Nail 13mmX40cm 135 L
47-2493-404-13	ZNN CMN Nail 13mmX40cm 135 R
47-2493-381-10	ZNN CMN Nail 10mmX38cm 125 L
47-2493-380-10	ZNN CMN Nail 10mmX38cm 125 R
47-2493-383-10	ZNN CMN Nail 10mmX38cm 130 L
47-2493-382-10	ZNN CMN Nail 10mmX38cm 130 R
47-2493-381-11	ZNN CMN Nail 11.5mmX38cm 125 L
47-2493-380-11	ZNN CMN Nail 11.5mmX38cm 125 R
47-2493-383-11	ZNN CMN Nail 11.5mmX38cm 130 L
47-2493-382-11	ZNN CMN Nail 11.5mmX38cm 130 R
47-2493-381-13	ZNN CMN Nail 13mmX38cm 125 L
47-2493-380-13	ZNN CMN Nail 13mmX38cm 125 R
47-2493-383-13	ZNN CMN Nail 13mmX38cm 130 L
47-2493-382-13	ZNN CMN Nail 13mmX38cm 130 R
47-2493-361-10	ZNN CMN Nail 10mmX36cm 125 L
47-2493-360-10	ZNN CMN Nail 10mmX36cm 125 R
47-2493-363-10	ZNN CMN Nail 10mmX36cm 130 L
47-2493-362-10	ZNN CMN Nail 10mmX36cm 130 R
47-2493-361-11	ZNN CMN Nail 11.5mmX36cm 125 L
47-2493-360-11	ZNN CMN Nail 11.5mmX36cm 125 R
47-2493-363-11	ZNN CMN Nail 11.5mmX36cm 130 L
47-2493-362-11	ZNN CMN Nail 11.5mmX36cm 130 R
47-2493-361-13	ZNN CMN Nail 13mmX36cm 125 L
47-2493-360-13	ZNN CMN Nail 13mmX36cm 125 R
47-2493-363-13	ZNN CMN Nail 13mmX36cm 130 L

Item Number	Name
47-2493-405-10	ZNN CMN Nail 10mmX40cm 135 L
47-2493-404-10	ZNN CMN Nail 10mmX40cm 135 R
47-2493-340-10	ZNN CMN Nail 10mmX34cm 125 R
47-2493-343-10	ZNN CMN Nail 10mmX34cm 130 L
47-2493-342-10	ZNN CMN Nail 10mmX34cm 130 R
47-2493-341-11	ZNN CMN Nail 11.5mmX34cm 125 L
47-2493-340-11	ZNN CMN Nail 11.5mmX34cm 125 R
47-2493-343-11	ZNN CMN Nail 11.5mmX34cm 130 L
47-2493-342-11	ZNN CMN Nail 11.5mmX34cm 130 R
47-2493-341-13	ZNN CMN Nail 13mmX34cm 125 L
47-2493-340-13	ZNN CMN Nail 13mmX34cm 125 R
47-2493-343-13	ZNN CMN Nail 13mmX34cm 130 L
47-2493-342-13	ZNN CMN Nail 13mmX34cm 130 R
47-2493-321-10	ZNN CMN Nail 10mmX32cm 125 L
47-2493-320-10	ZNN CMN Nail 10mmX32cm 125 R
47-2493-323-10	ZNN CMN Nail 10mmX32cm 130 L
47-2493-322-10	ZNN CMN Nail 10mmX32cm 130 R
47-2493-321-11	ZNN CMN Nail 11.5mmX32cm 125 L
47-2493-320-11	ZNN CMN Nail 11.5mmX32cm 125 R
47-2493-323-11	ZNN CMN Nail 11.5mmX32cm 130 L
47-2493-322-11	ZNN CMN Nail 11.5mmX32cm 130 R
47-2493-321-13	ZNN CMN Nail 13mmX32cm 125 L
47-2493-320-13	ZNN CMN Nail 13mmX32cm 125 R
47-2493-323-13	ZNN CMN Nail 13mmX32cm 130 L
47-2493-322-13	ZNN CMN Nail 13mmX32cm 130 R
47-2493-301-10	ZNN CMN Nail 10mmX30cm 125 L
47-2493-300-10	ZNN CMN Nail 10mmX30cm 125 R
47-2493-303-10	ZNN CMN Nail 10mmX30cm 130 L
47-2493-302-10	ZNN CMN Nail 10mmX30cm 130 R
47-2493-301-11	ZNN CMN Nail 11.5mmX30cm 125 L
47-2493-300-11	ZNN CMN Nail 11.5mmX30cm 125 R
47-2493-303-11	ZNN CMN Nail 11.5mmX30cm 130 L
47-2493-302-11	ZNN CMN Nail 11.5mmX30cm 130 R
47-2493-301-13	ZNN CMN Nail 13mmX30cm 125 L
47-2493-300-13	ZNN CMN Nail 13mmX30cm 125 R
47-2493-303-13	ZNN CMN Nail 13mmX30cm 130 L
47-2493-302-13	ZNN CMN Nail 13mmX30cm 130 R

Item Number	Name
47-2493-362-13	ZNN CMN Nail 13mmX36cm 130 R
47-2493-341-10	ZNN CMN Nail 10mmX34cm 125 L
47-2493-325-10	ZNN CMN Nail 10mmX32cm 135 L
47-2493-325-11	ZNN CMN Nail 11.5mmX32cm 135 L
47-2493-325-13	ZNN CMN Nail 13mmX32cm 135 L
47-2493-304-10	ZNN CMN Nail 10mmX30cm 135 R
47-2493-304-11	ZNN CMN Nail 11.5mmX30cm 135 R
47-2493-304-13	ZNN CMN Nail 13mmX30cm 135 R
47-2493-324-10	ZNN CMN Nail 10mmX32cm 135 R
47-2493-324-11	ZNN CMN Nail 11.5mmX32cm 135 R
47-2493-324-13	ZNN CMN Nail 13mmX32cm 135 R
47-2493-345-10	ZNN CMN Nail 10mmX34cm 135 L
47-2493-345-11	ZNN CMN Nail 11.5mmX34cm 135 L
47-2493-345-13	ZNN CMN Nail 13mmX34cm 135 L
47-2493-365-10	ZNN CMN Nail 10mmX36cm 135 L
47-2493-365-11	ZNN CMN Nail 11.5mmX36cm 135 L

Item Number	Name
47-2493-305-10	ZNN CMN Nail 10mmX30cm 135 L
47-2493-305-11	ZNN CMN Nail 11.5mmX30cm 135 L
47-2493-305-13	ZNN CMN Nail 13mmX30cm 135 L
47-2493-365-13	ZNN CMN Nail 13mmX36cm 135 L
47-2493-344-10	ZNN CMN Nail 10mmX34cm 135 R
47-2493-344-11	ZNN CMN Nail 11.5mmX34cm 135 R
47-2493-344-13	ZNN CMN Nail 13mmX34cm 135 R
47-2493-364-10	ZNN CMN Nail 10mmX36cm 135 R
47-2493-364-11	ZNN CMN Nail 11.5mmX36cm 135 R
47-2493-364-13	ZNN CMN Nail 13mmX36cm 135 R
47-2493-385-10	ZNN CMN Nail 10mmX38cm 135 L
47-2493-385-11	ZNN CMN Nail 11.5mmX38cm 135 L
47-2493-385-13	ZNN CMN Nail 13mmX38cm 135 L
47-2493-384-10	ZNN CMN Nail 10mmX38cm 135 R
47-2493-384-11	ZNN CMN Nail 11.5mmX38cm 135 R
47-2493-384-13	ZNN CMN Nail 13mmX38cm 135 R

Attachement 2

Certificate of Acknowledgement

Fax back to: Zimmer GmbH at +41 52 244 86 76

FSN/FSCA: FA 2015-05
Affected Product: Zimmer Natural Nail CM Long – Cephalomedullary Nails

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

Printed Name: _____

Signature: _____

Hospital Name: _____

Hospital Address: _____

Phone Number: _____

Please email the completed form to and to fieldaction.emea@zimmerbiomet.com.
Please maintain a copy of your completed form with your internal records.

ZFA 2015-100