

10 August, 2018

**To:** Surgeons/ Hospitals

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

**Affected Product:** Zimmer® Natural Nail® System Tibial Nail – Yellow 8.3 mm

Item Number	Lot Number	UDI Number
47249534008	61169228R	(01)00889024097551(10)61169228R(17)19059

Zimmer Biomet is conducting a lot specific medical device field action for the Zimmer® Natural Nail® System Tibial Nail – Yellow 8.3 mm. A field complaint investigation confirmed that the item is labeled as an 8.3mm, but it is actually a Zimmer® Natural Nail® System Tibial Nail- Yellow 12 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
	Extension of surgery less than 30 minutes to look for replacement part	Extension of surgery more than 30 minutes to look for replacement part
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	Malunion/non-union leading to revision surgery

Our records indicate that you may have received one or more of the affected products. The affected units were distributed on November 7, 2016 from the manufacturer. The timeframe here above relate to the distribution dates of the manufacturing site. Please refer to your local Zimmer Biomet representative for further information.

### Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the 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 – 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 affected products at your facility.



4. Retain a copy of the acknowledgement form with your field 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 notice, please contact your Zimmer Biomet representative.

**Surgeon Responsibilities:**

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to [fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com).
4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this 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 action.

Sincerely,



## ATTACHMENT 1

### Certificate of Acknowledgement

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

**Affected Product:** Zimmer® Natural Nail® System Tibial Nail – Yellow 8.3 mm

**Field Action Reference: ZFA2018-00270**

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

[ ] Hospital Facility [ ] Surgeon (Please check one as applicable)

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

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

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

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

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

**Note:** This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to:  
[fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com).

**Even if you have no product to return, this form must be completed, signed and returned.**

**Choose the following options:**

☐ All received products were used (implanted)

*Or complete the chart below for remaining products:*

Product Reference	Lot Reference	Number of products returned

**Comments (if needed):** \_\_\_\_\_