ZIMMER BIOMET

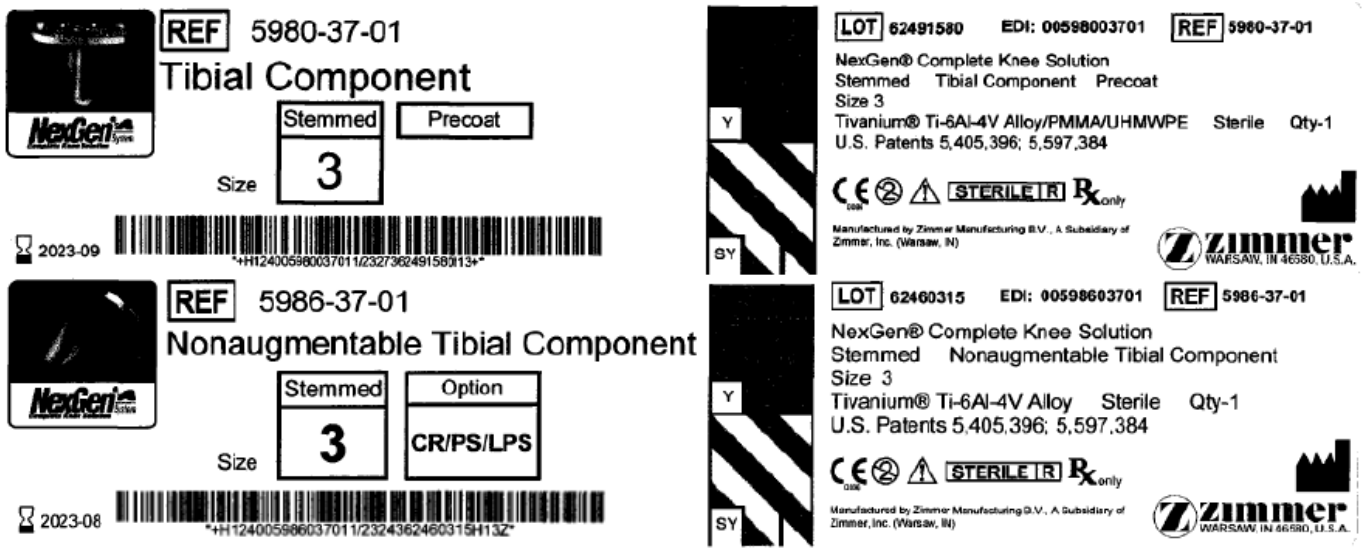
December 18, 2015

To: **Distributors, Sales Representatives, and Distribution Operation Managers**

Subject: **URGENT FIELD SAFETY NOTICE – REMOVAL - LOT SPECIFIC**

Affected Product: **NexGen Precoat Tibial Plate (part: 00-5980-037-01, lot: 62491580)**
NexGen Option Tibial Plate (part: 00-5986-037-01, lot: 62460315)

Zimmer Biomet is initiating a lot specific recall of the NexGen Precoat Tibial Plate and NexGen Option Tibial Plate due to a commingle between the affected lots of the same size tibial components. A field complaint was received indicating the NexGen Option Tibial Plate from lot 62460315 was found in the package for a NexGen Precoat Tibial Plate from lot 62491580. Product from the affected lots was distributed in October 2013.



Product labels

NexGen Precoat Tibial Plate

NexGen Option Tibial Plate

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	Possible delay of surgery to locate another unit	Revision surgery
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	Revision surgery

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. **Locate all affected product identified above and quarantine them immediately.**
3. Carry out a physical count of all affected product in your territory and complete the Inventory Return Certification Form (Attachment 1). Email a completed copy of Attachment 1 to fieldaction.emea@zimmerbiomet.com.
4. Return the recalled product along with the completed Inventory Return Certification Form (Attachment 1). Clearly mark the outside carton of each product return shipment made as "Recall".
5. Please notify Zimmer Biomet of any hospitals to which you have further distributed the affected product. Supply the information for any hospitals that you have identified, as well as the affected surgeons, using an excel spreadsheet. Please return to fieldaction.emea@zimmerbiomet.com.
6. **If after reviewing this notification you have any further questions or concerns please contact your Zimmer Biomet contact person.**

Vigilance 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 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 products. Adverse events may be reported to Zimmer GmbH at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

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ATTACHMENT 1

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Inventory Return Certification Form

Affected Product: NexGen Precoat Tibial Plate (part: 00-5980-037-01, lot: 62491580)
NexGen Option Tibial Plate (part: 00-5986-037-01, lot: 62460315)

Territory Number: _____ Account Number: _____

Account Name: _____

Account Address: _____ Phone Number: _____

Please return the affected products to the following address with a spreadsheet containing item number, lot number, and quantity:

Zimmer Biomet
International Logistics GmbH
Attn: Tim Nowak (Recall Warsaw)
Max-Immelmann-Allee 12
79427 Eschbach Germany

Credit My Account: _____ OR Send a Replacement: _____

An exhaustive search for the affected lots has been performed and all available affected product is being returned to Zimmer Biomet	Check one of the following:			
	Yes		No	

Item No.	Lot No.	No. Returned

Certificate of Acknowledgement:

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

Printed Name: _____ Signature: _____

Title: _____ Telephone: ( ) _____-_____ Date: ___/____/____

Note: This form and affected product must be returned to Zimmer Biomet before this action can be considered closed for your account. It is your responsibility to complete this form and email a copy to: CorporateQuality.PostMarket@ZimmerBiomet.com, in addition to including a copy with your product returns. Clearly mark the outside carton of each product return shipment made as "Recall." Please keep a copy of your completed form for your records.

Please do not return recalled product with other returns.

ZFA 2015-151