ZIMMER BIOMET

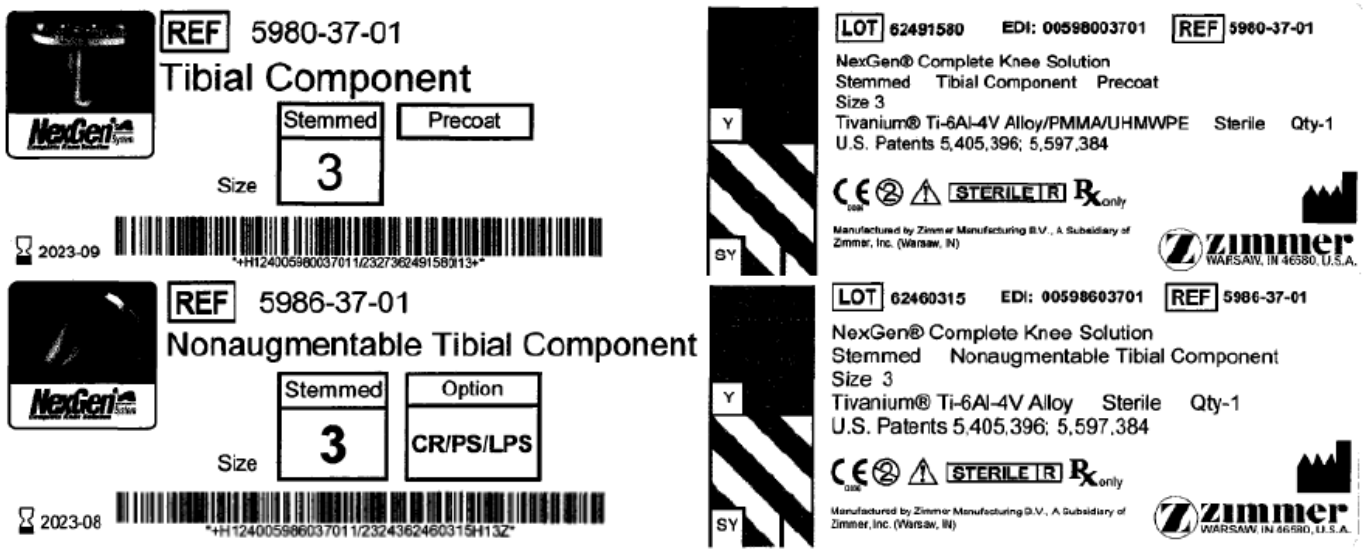
December 03, 2015

To: **Risk Managers and Surgeons**

Subject: **URGENT MEDICAL DEVICE RECALL – 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. Assist your Zimmer Biomet sales representative with the quarantine of any affected product.
3. Your Zimmer Biomet sales representative will remove the recalled product from your facility.
4. Complete the Certificate of Acknowledgement Form (Attachment 1) and return to corporatequality.postmarket@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please call the customer call center at 1-800-348-2759 between 8:00 am and 8:00 pm EST.**

Other Information

This voluntary recall was reported to the U.S. Food and Drug Administration.

MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online:www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at zimmer.per@zimmer.com.

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ATTACHMENT 1

Certificate of Acknowledgement:

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

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

Printed
Name: _____ Signature: _____

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

Facility Name: _____

Facility Address: _____

City: _____ State: _____ ZIP: _____

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