ZIMMER BIOMET

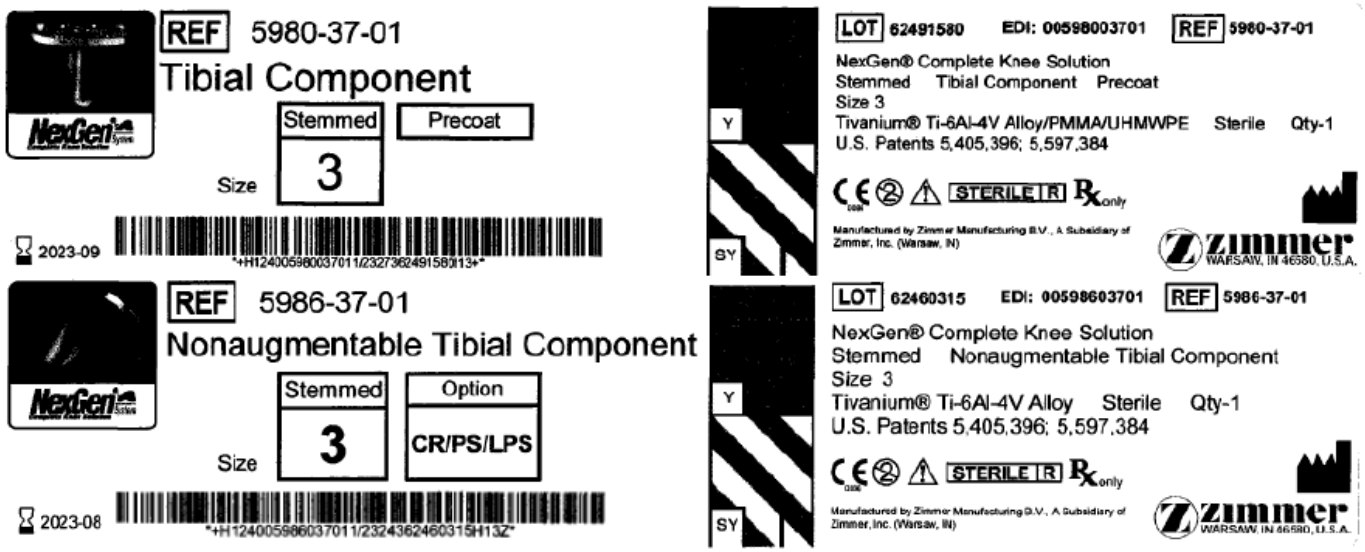
December 18, 2015

To: **Risk Managers and Surgeons**

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. 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.
5. **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

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)

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.

Printed Name: _____

Signature: _____

Hospital Name: _____

Hospital Address: _____

Phone Number: _____

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

ZFA 2015-151