ZIMMER BIOMET

30, September, 2016

To: Risk Managers and Surgeons

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

FSN/FSCA: **ZFA 2016-180**

Affected Product: NexGen LPS Femoral – Lot Specific

Item Number	Lot Number	UDI Number
00-5964-017-51	63329529	(01) 00889024001152 (17) 260430 (10) 63329529
00-5964-017-51	63342469	(01) 00889024001152 (17) 260430 (10) 63342469
00-5964-017-51	63342472	(01) 00889024001152 (17) 260430 (10) 63342472
00-5964-017-52	63329533	(01) 00889024001169 (17) 260430 (10) 63329533
00-5964-017-51	63329527	(01) 00889024001152 (17) 260430 (10) 63329527

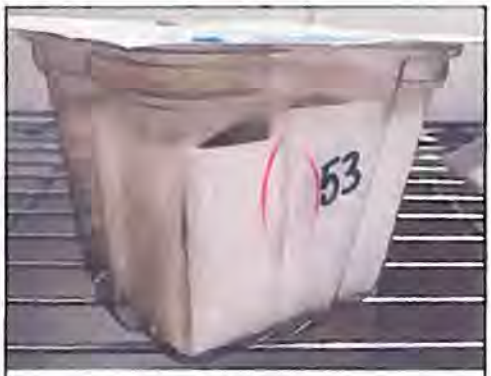

Figure 1. Failure Example

Zimmer Biomet is conducting a medical device recall for the NexGen LPS Femoral, part number 00-5964-017-51/52, and lot numbers 63329529, 63342469, 63342472, 63329533, and 63329527. There is a possibility that the protective foam insert used during the packaging of the affected products is undersized, which may cause a breach in the inner cavity during transportation. Zimmer Biomet has received no complaints regarding a breach in the inner cavity of the affected products.

Our records indicate you may have received one or more of the affected products. The affected products were distributed between the dates of 25 April 2016 and 18 May 2016.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	None	None
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	None	Periprosthetic infection occurs with a risk for revision or multi-stage revision for treatment.

Your Responsibilities:

1. Review this notification immediately and ensure affected personnel are aware of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow up schedule.
3. Assist your Zimmer Biomet sales representative with the quarantine of any device mentioned above.
4. Your Zimmer Biomet sales representative will remove the affected device, if any, from your facility.
5. Complete the Certification of Acknowledgement from (Attachment 1) and return a digital copy to fieldaction.emea@zimmerbiomet.com. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your documentation.
6. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**

Vigilance/ Reporting 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 or any relevant requirements 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 zimmer.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

Sincerely,

[redacted]

ZIMMER BIOMET

ATTACHMENT 1
Certificate of Acknowledgement

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

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

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

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.