



April 2, 2015

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL - LOT SPECIFIC**

Affected Product: NexGen CRA/LCCK/RHK 5mm Distal Femoral Augment, Size F

Catalog Number: 00-5990-036-10 Lot Number: 62815809

Zimmer is initiating a voluntary lot specific recall of the NexGen CRA/LCCK/RHK 5mm Distal Femoral Augment, Size F due to the affected lot being packaged without the locking screw. The affected lot was distributed from December 3, 2014 through December 23, 2014.

The locking screw packaged with the augment is used to fix the augment to the femoral component.



NexGen 5mm Distal Femoral Augment, Size F

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	Short delay (less than 30 minutes) while bone cement hardens if used to fix augment in place.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	None

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer sales representative with the quarantine of any affected product.
3. Your Zimmer sales representative will remove the recalled product from your facility.
4. Complete the Acknowledgement of Responsibility Form (Attachment 1) and return to corporatequality.postmarket@zimmer.com.



5. If after reviewing this notification you have further questions or concerns please call the customer call center at 1-877-946-2761 between 8:00 am and 5:00pm 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 informed of any adverse events associated with this device or any other Zimmer product. Adverse events may be reported to Zimmer at zimmer.per@zimmer.com.



ATTACHMENT 1

Acknowledgement of Responsibility:

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

Printed

Name: _____ Signature: _____

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

Hospital Name and Address: _____

Please do not return recalled product with other returns.

ZFA 2015-30