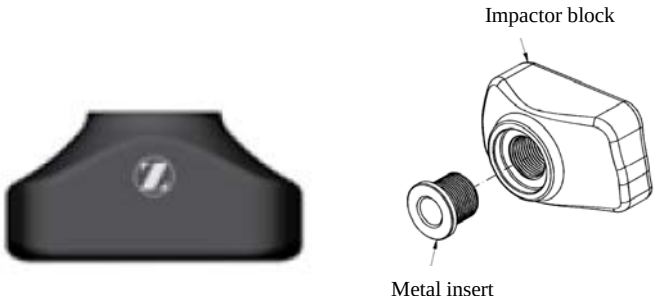
April 30, 2015

To: **Risk Managers and Surgeons**

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

Affected Product: **PRI Femoral Impactor Head, 00-5901-032-00 (see Attachment 1 for a list of affected lots)**

Zimmer is initiating a voluntary lot specific recall of the PRI Femoral Impactor Head instruments supplied by Flextronics due to the potential for uncured adhesive between the metal threaded insert and the impactor block to leak out of the assembled part following the autoclave sterilization process. The substance was identified as Master Bond epoxy, which serves as a secondary locking mechanism to fix the metal insert to the impactor head. Complaints for foreign material on the impactor block have been received. The affected lots were supplied by Flextronics and distributed from Zimmer, Inc., from February 2014 through March 19, 2015.



PRI Femoral Impactor Head

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	Biologic Response
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	Biologic Response

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 2) and return to corporatequality.postmarket@zimmer.com.
5. Include a completed Certificate of Sterilization (Attachment 3) with units being returned to Zimmer.
6. **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 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

Affected lots of 00-5901-032-00				
56572845	56574197	56574534	56574775	56575838
56573249	56574198	56574535	56575827	56575839
56573282	56574325	56574536	56575828	56575840
56573283	56574326	56574604	56575829	56576089
56573284	56574327	56574605	56575830	56576090
56573285	56574328	56574606	56575831	56576091
56574130	56574329	56574607	56575832	56576421
56574135	56574530	56574608	56575833	56576429
56574136	56574531	56574617	56575836	56576431
56574137	56574532	56574714	56575837	56576544
56574196	56574533	56574774		

ATTACHMENT 2

Acknowledgement of Responsibility:

Affected Product: PRI Femoral Impactor Head

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: _____

Note: This form and affected product must be returned to Zimmer 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@Zimmer.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 2015-42

ATTACHMENT 3

CERTIFICATE OF STERILIZATION

PRI Femoral Impactor Head: 00-5901-032-00

By signing below, I acknowledge that the instrumentation being returned to Zimmer, Inc. has been clean and sterilized prior to being returned.

Describe the method of disinfecting: _____

Printed Name: _____ Signature: _____

Title: _____ Telephone: ( ) _____-_____

Date: ____/____/____

Territory Number: _____

Account Name: _____

Note: Please ensure this form is included with the returned parts.