



March 10, 2015

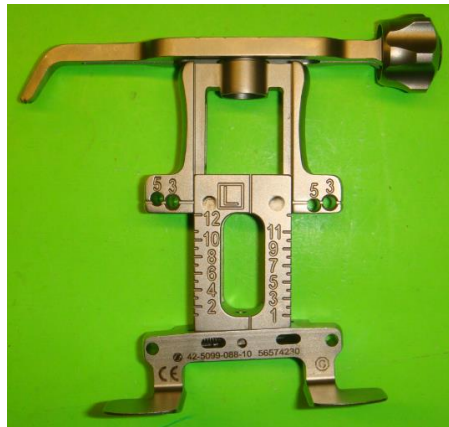
To: Risk Managers and Surgeons

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

Affected Product: **Persona Anterior Referencing Locking Boom Femoral Sizer (Instrument)**

Catalog Number: **42-5099-088-10**

Zimmer is initiating a voluntary lot specific recall of the Zimmer Persona Anterior Referencing Locking Boom Femoral Sizer produced by one supplier due to motion in the assembly. You are receiving this letter because our records indicate that you may have received the affected product. Records indicate that the affected product was distributed from May 1, 2014 through January 23, 2015.



Persona Anterior Referencing Locking Boom Femoral Sizer

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	No immediate health consequences.	Erroneous anterior femoral bone resection Improper femoral component size
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	No long range health consequences.	Femoral fracture due to notching the femur Risk of instability or stiffness

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. **If after reviewing this notification you have further questions or concerns please call the customer call center at 1-877-946-2761. Hours of operation are Monday through Friday, 8:00 a.m. through 5:00 p.m. 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

Part
42-5099-088-10

Lots		
56573342	56574505	56574999
56574229	56574818	56575000
56574230	56574819	56575020
56574301	56574820	56575021
56574349	56574861	56575072
56574374	56574862	56575105
56574375	56574863	
56574504	56574998	



Attachment 2

Acknowledgement of Responsibility:

Affected Product: Persona Anterior Referencing Locking Boom Femoral Sizer

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

Printed
Name: _____ Signature: _____

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

If you are signing on behalf of a medical facility or hospital, please also provide the following information:

Hospital Name: _____

Hospital Address: _____

Note: It is important that you complete this form and email a copy to:
CorporateQuality.PostMarket@Zimmer.com Please keep a copy for your records.

ZFA 2015-13
