August 11, 2015

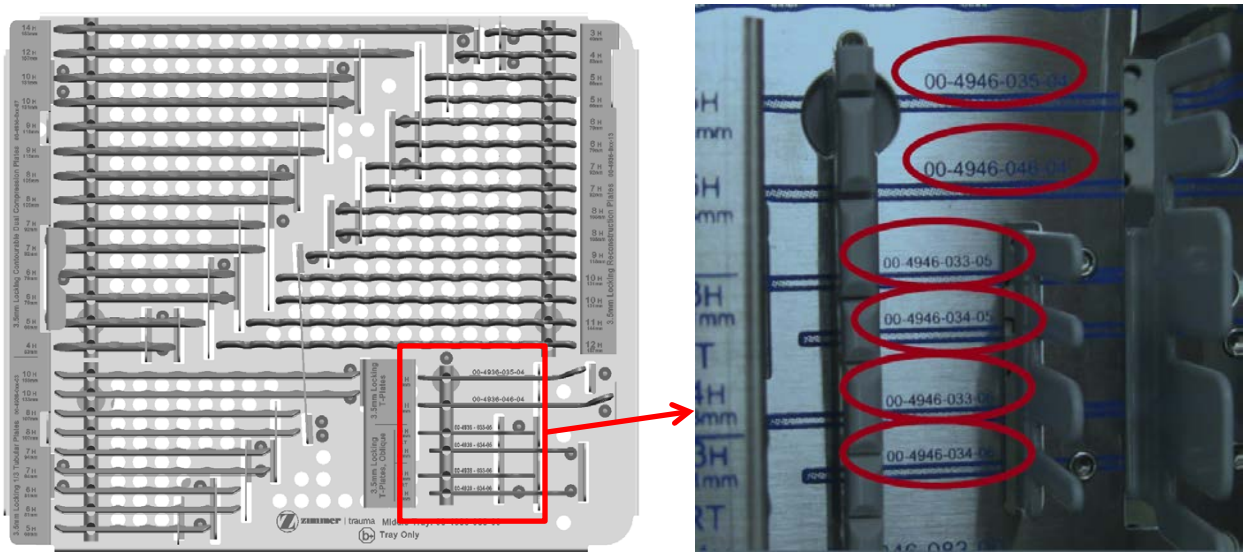
To: **Risk Managers and Surgeons**

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

Affected Product: **Zimmer Universal Locking System 3.5 mm Stainless Steel Base and Trays.**

Part Number: 00-4836-080-00; Lot 56555128

Zimmer Biomet is initiating a voluntary recall of one lot of the Zimmer Universal Locking System 3.5 mm Stainless Steel Base and Trays, as it was found through review of open Complaints and stock investigations that a single lot of Zimmer Universal Locking System 3.5 mm Stainless Steel Base and Trays has incorrect silk screening as applied by the supplier. The T-plate catalog numbers noted in the tray are listed as the 00-4946-xxx-xx series (titanium plates); however, the correct numbers should be 00-4936-xxx-xx (stainless steel plates). Zimmer Biomet is recalling all product from this lot. The affected lot was distributed from May 2014 through April 2015.



Zimmer Universal Locking System 3.5 mm Stainless Steel Base and Trays affected silk screening

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	Incorrect part observed by technician or part loader prior to use in OR; or by nurse or physician in OR prior to implantation. If used transiently in OR and then recognized by surgical team, then this modest patient exposure is unlikely to incite an inflammatory response if then removed from surgical field.	Incorrect part not noted and used in surgery (implanted and retained in patient) causing tissue irritation or corrosion and subsequent inflammatory reaction from mixing of different metals (e.g. galvanic corrosion).

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 term health consequences are expected from transient tissue exposure.	Patient allergic reaction from bio incompatibility may incite sufficient tissue or metal response to require reoperation and 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 product from lot 56555128.
3. Your Zimmer Biomet sales representative will remove the affected trays, if any, from your facility.
4. Complete the Acknowledgement of Responsibility Form (Attachment 1) and return to corporatequality.postmarket@zimmerbiomet.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 a.m. through 5 p.m. EST.**

Other Information

This voluntary recall will be 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 Biomet 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.

Attachment 1

Certificate of Acknowledgement:

Affected Product: Zimmer Universal Locking System 3.5 mm Stainless Steel Base and Trays.
PN 00-4836-080-00, lot number 56555128

By signing below, I acknowledge that I have read the Urgent Medical Device Recall Notice and that the required actions have been taken in accordance with the Recall notice.

Printed Name:_____ Signature:_____

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

Hospital Name: _____ Address:_____

Hospital Phone Number: _____

Note: It is important that you complete this form and email a copy to: CorporateQuality.PostMarket@zimmerbiomet.com. Please keep a copy for your records in the event of an audit.

ZFA 2015-101