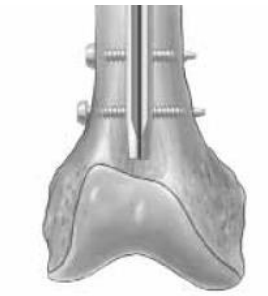
April 29, 2015

To: **Risk Managers and Surgeons**

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: **4.5mm Cortical Screws listed as compatible with the M/DN system (see Attachment 1 for a complete list) all lots manufactured prior to December, 2014.**

Zimmer is initiating a voluntary recall of the 4.5mm Cortical Screws listed as compatible with the M/DN system as it was found through review of the Design History Files that the entire scope of 4.5mm Cortical Screws listed as compatible with the M/DN system is not compatible with the M/DN system. The compatibility issue can only occur at worst case print specification wherein multiple features are at Maximum Material Condition (meaning the hole in the nail would need to be as small as possible and the outside diameter of the screw would need to be as large as possible). Zimmer has received one complaint that could potentially be attributed to the incompatibility of the 4.5 screws. No injury or harm has been reported to the patient as a result of the incident described in the complaint. The estimated occurrence rate is 0.00033%. Zimmer is recalling non-expired and unconsumed affected product. Affected devices were distributed from January 2006 through February, 2015.



Distal Screws in M/DN nail

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	Screw would bind upon entering the nail and have to be removed during the surgery.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	No ill health expected.	Difficulty of removal of the screw after fracture healing.

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 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 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 Number	Description
00-2253-020-45	INTERLOCKING IM SCREW 4.5MM DIA X 20MM
00-2253-022-45	INTERLOCKING IM SCREW 4.5MM DIA X 22.5MM
00-2253-025-45	INTERLOCKING IM SCREW 4.5MM DIA X 25MM
00-2253-027-45	M/DN Intramedullary Fixation 4.5mm Dia. Cortical Screw
00-2253-030-45	INTERLOCKING IM SCREW 4.5MM DIA X 30MM
00-2253-032-45	INTERLOCKING IM SCREW 4.5MM DIA X 32.5MM
00-2253-035-45	INTERLOCKING IM SCREW 4.5MM DIA X 35MM
00-2253-037-45	INTERLOCKING IM SCREW 4.5MM DIA X 37.5MM
00-2253-040-45	INTERLOCKING IM SCREW 4.5MM DIA X 40MM
00-2253-042-45	INTERLOCKING IM SCREW 4.5MM DIA X 42.5MM
00-2253-045-45	INTERLOCKING IM SCREW 4.5MM DIA X 45MM
00-2253-047-45	INTERLOCKING IM SCREW 4.5MM DIA X 47.5MM
00-2253-050-45	INTERLOCKING IM SCREW 4.5MM DIA X 50MM
00-2253-052-45	INTERLOCKING IM SCREW 4.5MM DIA X 52.5MM
00-2253-055-45	INTERLOCKING IM SCREW 4.5MM DIA X 55MM
00-2253-057-45	INTERLOCKING IM SCREW 4.5MM DIA X 57.5MM
00-2253-060-45	INTERLOCKING IM SCREW 4.5MM DIA X 60MM
00-2253-062-45	INTERLOCKING IM SCREW 4.5MM DIA X 62.5MM
00-2253-065-45	INTERLOCKING IM SCREW 4.5MM DIA X 65MM
00-2253-067-45	INTERLOCKING IM SCREW 4.5MM DIA X 67.5MM
00-2253-070-45	INTERLOCKING IM SCREW 4.5MM DIA X 70MM
00-2253-072-45	INTERLOCKING IM SCREW 4.5MM DIA X 72.5MM
00-2253-075-45	INTERLOCKING IM SCREW 4.5MM DIA X 75MM
00-2253-077-45	INTERLOCKING IM SCREW 4.5MM DIA X 77.5MM
00-2253-080-45	INTERLOCKING IM SCREW 4.5MM DIA X 80MM
00-2253-082-45	INTERLOCKING IM SCREW 4.5MM DIA X 82.5MM
00-2253-085-45	INTERLOCKING IM SCREW 4.5MM DIA X 85MM
00-2253-087-45	INTERLOCKING IM SCREW 4.5MM DIA X 87.5MM
00-2253-090-45	INTERLOCKING IM SCREW 4.5MM DIA X 90MM

Attachment 2

Acknowledgement of Responsibility:

Affected Product: 4.5mm Cortical Screws listed as compatible with the M/DN systems (see Attachment 1 for a complete list)

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: _____ Address:_____

Hospital Phone Number: _____

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 2015-28