March 20, 2015

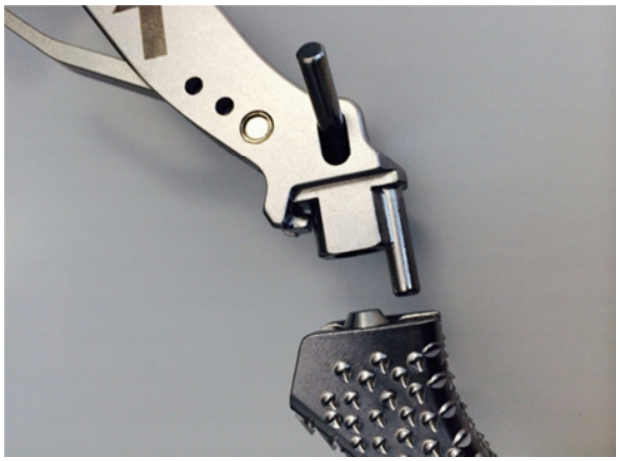
To: **Risk Managers and Surgeons**

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

Affected Product: **Anatomical Shoulder Handle for Rasp**
Item: 01.04233.000; Lots: 13838644,13870129, 13878179

Zimmer is initiating a voluntary recall of three lots of the Anatomical Shoulder Handle for Rasp due to difficulties to attach of the Anatomical Shoulder Rasps (high resistance) or, once attached, due to difficulties to remove the handle (seizing up of the two components).

Zimmer received complaints between April 2014 and August 2014 for this issue. Analysis of returned devices and product in inventory determined that the cone geometry was not within the tolerance for the affected lots. You are receiving this letter because our records indicate that you may have received the affected products between July 2013 and September 2014.



Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	If the instrument cannot be used, a slight delay (<15 minutes) in the surgery time may result to obtain another device.	If no other devices are available, the operation could be subject to cancelation.
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.	A potential infection of the patient due to a lack of sterility caused by rupturing of the users-gloves may not be excluded due to an attempt to release or connect the holding mechanism of the handle.

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 fieldaction.emea@zimmer.com.
5. **If after reviewing this notification you have further questions or concerns please contact your Zimmer contact person.**

Vigilance Information

This voluntary notification will be reported to the local Competent Authorities within EU.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 to the local health authority in your country.

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, or to your local Zimmer representative.

Kind regards,

_____

[redacted]
Vice President
Quality Assurance and Regulatory Affairs – EMEA

ATTACHMENT 1

Confirmation for Receipt of Urgent Safety Notification
FSN/FSCA: FA 2015-01

Please complete and sign this document to confirm the receipt of this Notification

Please send this form to your local Zimmer contact.

Fax / Email: _____ _____

Do not hesitate to contact Zimmer if you need further details.

This document confirms that you have received the Urgent Safety Notice on the product

Anatomical Shoulder Handle for Rasp (Item: 01.04233.000; Lots: 13838644, 13870129, 13878179).

I confirm that the relevant information was given to me by Zimmer, for the protection of the interests and safety of patients.

_____
Hospital/Clinic name and address

_____
Printed Name of Surgeon

_____
Signature and Date