June 10, 2015

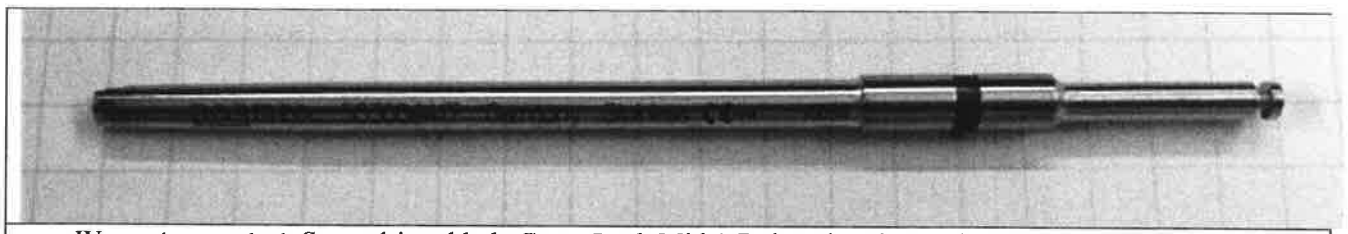
To: **Surgeons and Risk Managers**

Subject: URGENT FIELD SAFETY NOTICE

FSN/FSCA: **FA 2015-04**
Affected Product: **Screwdriver blade Cross-Lock Mid 1.7, dental-end; Lot (16688) Item (503004417)**

Zimmer GmbH is initiating a voluntary recall on behalf of Normed Medizin-Technik GmbH of 1 lot of the Screwdriver blade Cross-Lock Mid 1.7.

Internal investigation found that the Screwdriver blade (2.3 mm) was mislabeled. Following inspection of the product, it was determined that they were erroneously marked as Screwdriver blade Cross-Lock Mid 1.7, dental-end; Lot (16688), Item (503004417). You are receiving this letter because our records indicate that you may have received the affected products from 26.Feb.2015, through 16.Mar.2015.



Wrong laser-etched: Screwdriver blade Cross-Lock Mid 1.7, dental-end; Lot (16688) Item (503004417)

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 wrong screwdriver blade will be detected before use, no immediate health consequences (injuries or illnesses) may result from use or exposure to the device issue. Another screwdriver blade can be used.	If the wrong screwdriver blade will be detected before use, the surgeon will try to complete the surgery with another screwdriver blade. A slight delay of the operation time might occur.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	If the wrong screwdriver blade will be detected before use, no long range health consequences (injuries or illnesses) may result from use or exposure to the device issue.	If the wrong screwdriver blade will be detected before use, the surgeon will try to complete the surgery with another screwdriver blade. A slight delay of surgery time might occur. No long range health consequences may result from use or exposure to the device issue.

Your Responsibilities

1. Review the notification and ensure that relevant 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.

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 Winterthur.Reporting@zimmer.com, or to your local Zimmer representative.

Kind regards

Arne Briest
Safety Officer for Medical Devices
(SIBA, MPG Artikel 30)
© Normed Medizin-Technik GmbH

Marion Bavand
Deputy Safety Officer for Medical Devices
(Stv. SIBA, MPG Artikel 30)
© Normed Medizin-Technik GmbH
Postmarket Surveillance Manager
Zimmer GmbH

ATTACHMENT 1

Acknowledgement of Responsibility
Confirmation for Receipt of Urgent Field Safety Notifice
FSN/FSCA: FA 2015-04

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

Screwdriver blade Cross-Lock Mid 1.7, dental-end; Lot (16688) Item (503004417)

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