June 17, 2015

To: **Distributors, Sales Representatives, and Distribution Operation Managers**

Subject: **URGENT FIELD SAFETY NOTICE**

Affected Product: **Java Hook Implants, Instruments, and Containers (See Attachment 1 for a complete list)**

Zimmer is initiating a voluntary recall of all part and lot numbers of Java Hook implants, instruments and containers due to lack of a steam sterilization validation to support the sterilization parameters stated in the Instructions For Use (IFU) (030EAN0000T and 030EAN0000I). The affected implants, instruments and containers were distributed throughout Europe, Asia-Pacific, and South America from November 21, 2003 through April 21, 2015.

Java Hook Implants and Instruments Containers

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	None
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	The patient may develop an infection that is successfully treated.	The patient may develop an infection that is not able to be successfully treated, patient develops sepsis/multiple organ failure which could potentially lead to patient death.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. **Locate all affected product identified in Attachment 1 and quarantine them immediately.**
3. Carry out a physical count of all affected product in your territory and complete the Inventory Return Certification Form (Attachment 2). Email a completed copy of Attachment 2 to dorothee.fleuri@zimmer.com
4. Return the recalled product along with the completed Inventory Return Certification Form (Attachment 2). Clearly mark the outside carton of each product return shipment made as "Recall."
5. Please notify your local Zimmer representative of any hospitals that you have further distributed the affected product to. Supply the information for any hospitals that you have identified, as well as the affected surgeons.
6. **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 these devices or any other Zimmer product. Adverse events may be reported to Zimmer at qualitycompliance@zimmer.com, or to your local Zimmer representative.

ATTACHMENT 1

Part Number	Lot Number	Name
SN2030-0-00001	"all"	Blocker
SN2030-0-30055	"all"	Straight rod Dia. 5,5 Lg.300
SN2030-0-40055	"all"	Straight rod Dia. 5,5 Lg.400
SN2030-0-50001	"all"	Pedicle Hook
SN2030-0-50010	"all"	Large Lamina Hook
SN2030-0-50011	"all"	Narrow Lamina Hook
SN2030-0-50012	"all"	Right Offset Lamina Hook
SN2030-0-50013	"all"	Left Offset Lamina Hook
SN2030-0-50014	"all"	5mm Right Offset Lamina Hook
SN2030-0-50015	"all"	5mm Left Offset Lamina Hook
SN2030-0-50016	"all"	Reduced Lamina Hook
SN2030-0-50020	"all"	Right Angled Thoracic Hook
SN2030-0-50021	"all"	Left Angled Thoracic Hook
SN2030-0-50022	"all"	Straight Thoracic Hook
SN2030-0-51001	"all"	Straight domino Dia. 5,5
SN2030-0-51002	"all"	Offset domino Dia. 5,5
SN2030-0-61001	"all"	Straight domino Dia. 6.0mm
SN2030-0-61002	"all"	Offset domino Dia. 6.0mm
SN2030-0-61003	"all"	Straight domino Dia. 5,5 / 6.0 mm
SN2030-0-61004	"all"	Offset domino Dia. 5,5 / 6.0 mm
SN2030-1-00100	"all"	Lamina Preparation Instrument
SN2030-1-00110	"all"	Pedicle Preparation Instrument
SN2030-1-00200	"all"	Hook Holding Forceps
SN2030-1-00300	"all"	Hook Persuader
SN2030-1-00400	"all"	Hook Impactor
SN2030-2-00005	"all"	Ø 5,5 Hook Implant & Instrument Tray

ATTACHMENT 2

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Inventory Return Certification Form

Affected Product: **Java Hook Implants, Instruments, and Containers.**

Territory Number: _____ Account Number: _____

Account Name: _____

Account Address:_____Phone Number: _____

Please return the affected product to the following address with a spreadsheet containing part number, lot number, and quantity:

Zimmer International Logistics GmbH
Attn:Tim Nowak
Max-Immelmann-Allee 12
79427 Eschbach Germany

An exhaustive search has been performed for the affected products and thereafter the status of affected products	Check one of the following:			
	Yes		No	

Please indicate for each part number the quantity and status

1- Implants

Part Number	Quantity returned	Quantity destroyed	Quantity implanted	Quantity lost

2-Instruments

Part Number	Quantity returned	Quantity destroyed	Quantity lost

3-Containers

Part Number	Quantity returned	Quantity destroyed	Quantity lost

Acknowledgement of Responsibility:

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

Printed Name:_____ Signature:_____

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

Note: This form and affected product must be returned to Zimmer before this action can be considered closed for your account. It is your responsibility to complete this form and email a copy to: dorothee.fleuri@zimmer.com, in addition to including a copy with your product returns. Clearly mark the outside carton of each product return shipment made as "Recall." Please keep a copy of your completed form for your records.

Please do not return recalled product with other returns.

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