ZIMMER BIOMET

May X, 2016

To: **Hospitals and Surgeons**

Subject: **URGENT FIELD SAFETY NOTICE - REMOVAL**

FSN/FSCA: **FA 2016-03**

Affected Product: **Zimmer Biomet / Normed Fender Titanium Plates**

Dear Sirs,

As a precautionary measure, Zimmer GmbH is initiating a voluntary recall of Fender Titanium Plates that may be in your inventories. Please see attachment 1 for the involved part numbers.

The Fender System 3.5 / 4.0, Titanium plating system is intended for temporary epiphysiodesis and growth control.

During monitoring of the products a potential risk was recently identified. Indeed the screw head might go through the bore hole of the plate, due to a potential tolerance issue during the manufacturing. If the screw head would slip through the plate's hole, the plate might become loose and the system does not work as intended.

Our records indicate that you may have received one or more of the potentially affected products.

	
Picture 1: Fender Titanium Plate	*Picture 2: Fender System (yellow) Size 3.5, Fender System (silver) Size 4.0.*

Risk

- If an affected product is used, the issue might be noticed intra operatively by the surgeon, and a new available system must be used which creates a potential slight delay in the surgery time.
- For the Fender Titanium Plates already implanted, the standard protocol for follow up of patients (for example X-rays controls) applies. The plates are intended to be removed within short term as soon as the intended correction in the patient is reached.
- If the standard protocol for follow up would show that the screw head went through the hole of the plate, the surgeon must assess the situation and if adequate, the system must be removed with or without replacement. In case of a replacement, the Zimmer Biomet/ Normed system is however currently not available till further notice.

- As the issue might not systematically occur, no preventive removal of the implanted systems is recommended.

Your Responsibilities

1. Review the notification immediately and ensure affected personnel are aware of the contents without delay.
2. Assist your Zimmer Biomet sales representative with the quarantine of any device mentioned in attachment 1.
3. Your Zimmer Biomet sales representative will remove the affected device, if any, from your facility.
4. Complete the Certification of Acknowledgement from (Attachment 2) and return to fieldaction.emea@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**

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 or any relevant requirements to the local health authority in your country.

Please keep Zimmer Biomet GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

Kind regards,

_____

[redacted]

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Attachment 1

Product Scope

Device Name	Ref. No.
FENDER TITAN PLATE 12 MM, SYSTEM 3,5 ONE SIDE ONLY	**36.10.012**
FENDER TITAN PLATE 10 MM, SYSTEM 3.5 DOUBLE-SIDE	**36.10.110**
FENDER TITAN PLATE 12 MM, SYSTEM 3,5 DOUBLE-SIDE	**36.10.112**
FENDER TITAN PLATE 16 MM, SYSTEM 4,0 ONE SIDE ONLY	**36.15.016**
FENDER TITAN PLATE 14 MM, SYSTEM 4,0 DOUBLE-SIDE	**36.15.114**
FENDER TITAN PLATE 16 MM, SYSTEM 4,0 DOUBLE-SIDE	**36.15.116**

ZIMMER BIOMET

Attachment 2
Certificate of Acknowledgement

FSN/FSCA: FA 2016-03

Affected Product: Zimmer Biomet / Normed Fender Titanium Plates

Please email or fax the completed form to your local Zimmer Biomet contact

Fax / Email _____ / _____

By signing below, I acknowledge that I have received and understand the content of the Urgent Field Safety Notice – Removal, and that the required actions have been taken in accordance with the notice:

1. Return parts in inventory
2. Fill the list below
3. Sign the form

Product reference	Quantity to return

☐ All parts received were implanted.

Printed Name:_____

Signature:_____

Hospital Name: _____

Hospital Address:_____

Phone Number:_____

Please maintain a copy of your completed form with your internal records.

May XX, 2016

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

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Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. **Locate all affected product identified above 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 fieldaction.emea@zimmerbiomet.com
4. Return any affected product within your possession and from hospital accounts within your territory. Clearly mark the outside of all return packages, "Recall," and include a copy of the Inventory Return Certification form (Attachment 2) with your return shipment(s).
5. Provide an additional accounts form to fieldaction.emea@zimmerbiomet.com for any hospitals to which you provided affected product that Zimmer Biomet has not already notified.
6. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**

Vigilance Information

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

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Please keep Zimmer Biomet GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

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ATTACHMENT 2

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Inventory Return Certification Form

Affected Product: Zimmer Biomet / Normed Fender Titanium Plates

Territory Number: _____ **Account Number:** _____

Account Name: _____

Account Address: _____ **Phone Number:** _____

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

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

Credit My Account: _____ **OR** **Send a Replacement:** _____

An exhaustive search for the affected lots has been performed and all available affected product is being returned to Zimmer Biomet. If No, please specify: _____	Check one of the following:			
	Yes		No	

Item No.	Lot No.	Qty to be. Returned

Certificate of Acknowledgement:

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 Biomet before this action can be considered closed for your account. It is your responsibility to complete this form and email a copy to: fieldaction.emea@zimmerbiomet.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.

FA 2016-03