ZIMMER BIOMET

July 06, 2016

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

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

FSN/FSCA: **FA 2016-08**

Affected Product:

Avenir® Müller Stem 6 Lateral uncemented- REF: 01.06010.106, LOT: 4023094

Avenir® Müller Stem 4 Standard uncemented- REF: 01.06010.004, LOT: 4022860

Dear Sirs,

Zimmer GmbH is initiating a voluntary removal of two lots Avenir Müller Stems (combination material number/ lot number is indicated above) that may be in your inventories. The Avenir Müller Stem 6 lateral uncemented might be placed in the packaging of the Avenir Müller Stem 4 standard uncemented and vice versa.

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

Risks

1) A slight delay in the surgery time might occur if after the discovery of the issue prior implantation, a new product has been made available to finalize the surgery accordingly.
2) If no similar implant is available, the doctor might choose a one size bigger stem and further raps the bone for preparation which induces a delay in surgery. Potentially the length of the new implant size might create the dissymmetry in patient's leg.
3) The surgeon might have to change the surgical approach and chose a different product conducting to a delay during the surgery or even interrupt / postpone the surgery if there is no appropriate available solution.
4) The surgeon might use a standard stem instead of a lateral stem. For the standard stem the offset is 6mm smaller and therefore an increased laxity of the hip might result. This could conduct to a risk of luxation, pain or revision surgery.

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 1). Email a completed copy of Attachment 1 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 1) 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/ Reporting 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 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]

ZIMMER BIOMET

Attachment 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Inventory Return Certification Form

FSN/FSCA: FA 2016-08

Affected Product:

Avenir® Müller Stem 6 Lateral uncemented- REF: 01.06010.106, LOT: 4023094

Avenir® Müller Stem 4 Standard uncemented- REF: 01.06010.004, LOT: 4022860

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 products are 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 2016-08

ZIMMER BIOMET

July 06, 2016

To: **Hospitals and Surgeons**

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

FSN/FSCA: **FA 2016-08**

Affected Product:

Avenir® Müller Stem 6 Lateral uncemented- REF: 01.06010.106, LOT: 4023094

Avenir® Müller Stem 4 Standard uncemented- REF: 01.06010.004, LOT: 4022860

Dear Sirs,

Zimmer GmbH is initiating a voluntary removal of two lots Avenir Müller Stems (as indicated above) that may be in your inventories. The Avenir Müller Stem 6 lateral uncemented might be placed in the packaging of the Avenir Müller Stem 4 standard uncemented and vice versa.

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

Risks

1) A slight delay in the surgery time might occur if after the discovery of the issue prior implantation, a new product has been made available to finalize the surgery accordingly.
2) If no similar implant is available, the doctor might choose a one size bigger stem and further rasp the bone for preparation which induces a delay in surgery. Potentially the length of the new implant size might create the dissymmetry in patient's leg.
3) The surgeon might have to change the surgical approach and chose a different product conducting to a delay during the surgery or even interrupt / postpone the surgery if there is no appropriate available solution.
4) The surgeon might use a standard stem instead of a lateral stem. For the standard stem the offset is 6mm smaller and therefore an increased laxity of the hip might result. This could conduct to a risk of luxation, pain or revision surgery.

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 affected device.
3. Your Zimmer Biomet sales representative will remove the affected device, if any, from your facility.
4. Complete the Certification of Acknowledgement from (Attachment 1) 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/ Reporting 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 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,

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Attachment 1
Certificate of Acknowledgement

FSN/FSCA: FA 2016-08

Affected Product:

Avenir® Müller Stem 6 Lateral uncemented- REF: 01.06010.106, LOT: 4023094

Avenir® Müller Stem 4 Standard uncemented- REF: 01.06010.004, LOT: 4022860

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 received	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.