ZIMMER BIOMET

December 08, 2015

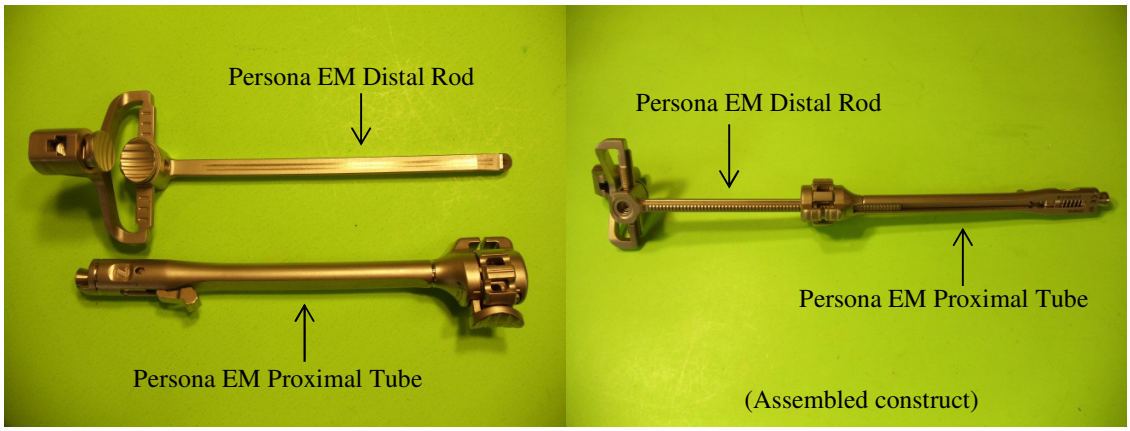
To: **Risk Managers**

Subject: **URGENT FIELD SAFETY NOTICE – REMOVAL - LOT SPECIFIC**

Affected Product: **Persona EM Proximal Tube, 42-5399-001-00, and Persona EM Distal Rod, 42-5399-002-00**

Affected lots of 42-5399-001-00	Affected lots of 42-5399-002-00
62137111	62137112
62156913	62156914
62222598	62222599

Zimmer Biomet is initiating a lot specific recall of the Persona EM Proximal Tube and Persona EM Distal Rod. During a complaint investigation it was identified that the previous version of the instruments may not properly mate with the current version. Affected devices were distributed between the dates of July 2012 and December 2012.



Persona EM Proximal Tube and Persona EM Distal Rod

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	Minor Delay of Surgery (< 5 minutes)
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	None

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative with the quarantine of any affected product.
3. Your Zimmer Biomet sales representative will remove the recalled product from your facility.
4. Complete the Certificate of Acknowledgement Form (Attachment 1) and return to fieldaction.emea@zimmerbiomet.com
5. Include a completed Certificate of Sterilization (Attachment 2) with units being returned to Zimmer Biomet.
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.

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 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 1

Certificate of Acknowledgement:

Affected Product: **Persona EM Proximal Tube p/n: 42-5399-001-00 and Persona EM Distal Rod p/n: 42-5399-002-00**

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

Fax / Email _____ / _____

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. Please keep a copy of your completed form for your records.

Please do not return recalled product with other returns.

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ATTACHMENT 2

CERTIFICATE OF STERILIZATION

Persona EM Proximal Tube (p/n: 42-5399-001-00) and
Persona EM Distal Rod (p/n: 42-5399-002-00)

By signing below, I acknowledge that the instrumentation being returned to Zimmer Biomet, Inc. has been clean and sterilized prior to being returned.

Describe the method of disinfecting: _____

Printed Name: _____ Signature: _____

Title: _____ Telephone: ( ) _____-_____

Date: ____/____/____

Territory Number: _____

Account Name: _____

Note: Please ensure this form is included with the returned parts.

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