October 24, 2018

To: Surgeons/Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD ACTION - REMOVAL**

Affected Product: Antegrade Femoral Connecting Bolt

Reference: ZFA2017-298

Item Number: 14-442093

Affected Lot List					
034150	**100734**	**185050**	**185070**	**305380**	**321540**
354450	**370490**	**401040**	**413040**	**426760**	**627490**
629930	**629950**	**639280**	**764450**	**844240**	**975460**

Zimmer Biomet is conducting a medical device Field Safety Corrective Action (removal) for specific production lots of the Antegrade Femoral Connecting Bolt. Zimmer Biomet has received reports of connecting bolt fractures during insertion of the femoral nail. The scope of this removal is isolated to product manufactured between 2008 and 2010. If the bolt were to fracture during use, which would be easily recognized, the highest severity risk was identified as a surgical delay greater than 30 minutes and potential for foreign body retention.

The affected devices may have been shipped as a single finished device or through an instrument kit. The table below contains the item number that would have been used to order.

Item Number	Description
14-442093	Antegrade Femoral Connecting Bolt
14-442000S	Antegrade Femoral Nail Instrument Kit
979195	Phoenix Antegrade Nail System Loaner Kit

All Antegrade Femoral Connecting Bolts contain an item and lot number marked on the neck of the device. Reference figure 1 for the location of the laser marking.

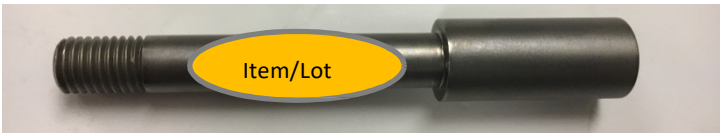

Figure 1

You may have received one or more of the affected devices, which were distributed between January 2009 and September 2017 (local deployment might differ).

Surgeon/ Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected instrument(s) at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected instrument(s) from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com. This form must be returned **even if you do not have affected products at your facility**.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

Other Information

This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.nl@zimmerbiomet.com or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field action.

Sincerely,
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_____
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ATTACHMENT 1

Certificate of Acknowledgement

Field Action Reference: ZFA 2017-298

Affected Product: Antegrade Fem Connecting Bolt (Instrument)

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

[ ] **Hospital Facility** [ ] **Surgeon** *(Please check one as applicable)*

Printed Name:_____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: fieldaction.netherlands@zimmerbiomet.com.

Even if you have no product to return, this form must be completed, signed and returned.

All inventories for the affected products have been checked and following products are to be returned:

Product Reference	Lot Reference	Number of products returned

OR

The affected products which are unavailable for return have been: discarded lost other:_____

Comments (if needed):_____