

June 8, 2017

To: Risk Managers / Surgeons

Subject: **URGENT MEDICAL DEVICE RECALL REMOVAL – Lot Specific**

Affected Product: Affixus Hip Fracture Nail

Zimmer Biomet is conducting a voluntary medical device field action for the Affixus Hip Fracture Nail due to issues with the nail not properly engaging with the targeting jig. An investigation into the nail/targeting jig assembly, showed that certain specifications were undersized causing interference to the fit of the nail onto the targeting jig which can result in a surgical delay. The complaint rate for a delay in surgery is 0.012% which exceeds Zimmer Biomet’s estimated occurrence rate.

Refer to **Attachment 2 – Affected Product List** for the affected items and descriptions. The lots included in this field action are all lots that begin with a “D” (eg. DPFBWY) **Note: Affected products can potentially be in DePuy labeled boxes.** Be sure to check all inventories of these Affixus HFN products.



Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	User dissatisfaction	Surgical delay, greater than 30 minutes
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	None	None

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of August 2010 and April 2017.

Surgeon Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. Your Zimmer Biomet sales representative will remove the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
 - a. Return a digital copy to fieldaction.eire@zimmerbiomet.com.
 - b. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your facilities documentation.
5. If after reviewing this notice you have further questions or concerns please contact your Zimmer Biomet representative.

Other Information

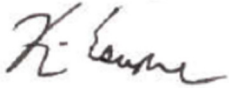
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

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

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

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

Sincerely,



Kevin W. Escapule
Post Market Surveillance and Regulatory Compliance Director



ATTACHMENT 1

Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Field action Notice.

Hospital Facility

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.uk@zimmerbiomet.com.

An exhaustive search for the affected lots has been performed and all available affected product is being returned to Zimmer Biomet; any product not returned or found in inventory are considered consumed and unavailable for use.	Check one of the following:		
	Yes		No

Item Number	Lot Number	Quantity to be Returned

Attachment 2

Affected Product List – Lots affected all begin with a “D”

Item Number	Description
814309180	HFN 125 DEG 9MM X 180MM
814311180	HFN 125 DEG 11MM X 180MM
814313180	HFN 125 DEG 13MM X 180MM
814509180	HFN 130 DEG 9MM X 180MM
814511180	HFN 130 DEG 11MM X 180MM
814513180	HFN 130 DEG 13MM X 180MM
814309260	HFN RH 125 DEG 9MM X 260MM
814309280	HFN RH 125 DEG 9MM X 280MM
814309300	HFN RH 125 DEG 9MM X 300MM
814309320	HFN RH 125 DEG 9MM X 320MM
814309340	HFN RH 125 DEG 9MM X 340MM
814309360	HFN RH 125 DEG 9MM X 360MM
814309380	HFN RH 125 DEG 9MM X 380MM
814309400	HFN RH 125 DEG 9MM X 400MM
814309420	HFN RH 125 DEG 9MM X 420MM
814309440	HFN RH 125 DEG 9MM X 440MM
814309460	HFN RH 125 DEG 9MM X 460MM
814311260	HFN RH 125 DEG 11MM X 260MM
814311280	HFN RH 125 DEG 11MM X 280MM
814311300	HFN RH 125 DEG 11MM X 300MM
814311320	HFN RH 125 DEG 11MM X 320MM
814311340	HFN RH 125 DEG 11MM X 340MM
814311360	HFN RH 125 DEG 11MM X 360MM
814311380	HFN RH 125 DEG 11MM X 380MM
814311400	HFN RH 125 DEG 11MM X 400MM
814311420	HFN RH 125 DEG 11MM X 420MM
814311440	HFN RH 125 DEG 11MM X 440MM
814311460	HFN RH 125 DEG 11MM X 460MM
814313260	HFN RH 125 DEG 13MM X 260MM
814313280	HFN RH 125 DEG 13MM X 280MM
814313300	HFN RH 125 DEG 13MM X 300MM
814313320	HFN RH 125 DEG 13MM X 320MM
814313340	HFN RH 125 DEG 13MM X 340MM

Item Number	Description
814313360	HFN RH 125 DEG 13MM X 360MM
814313380	HFN RH 125 DEG 13MM X 380MM
814313400	HFN RH 125 DEG 13MM X 400MM
814313420	HFN RH 125 DEG 13MM X 420MM
814313440	HFN RH 125 DEG 13MM X 440MM
814313460	HFN RH 125 DEG 13MM X 460MM
814409260	HFN LH 125 DEG 9MM X 260MM
814409280	HFN LH 125 DEG 9MM X 280MM
814409300	HFN LH 125 DEG 9MM X 300MM
814409320	HFN LH 125 DEG 9MM X 320MM
814409340	HFN LH 125 DEG 9MM X 340MM
814409360	HFN LH 125 DEG 9MM X 360MM
814409380	HFN LH 125 DEG 9MM X 380MM
814409400	HFN LH 125 DEG 9MM X 400MM
814409420	HFN LH 125 DEG 9MM X 420MM
814409440	HFN LH 125 DEG 9MM X 440MM
814409460	HFN LH 125 DEG 9MM X 460MM
814411260	HFN LH 125 DEG 11MM X 260MM
814411280	HFN LH 125 DEG 11MM X 280MM
814411300	HFN LH 125 DEG 11MM X 300MM
814411320	HFN LH 125 DEG 11MM X 320MM
814411340	HFN LH 125 DEG 11MM X 340MM
814411360	HFN LH 125 DEG 11MM X 360MM
814411380	HFN LH 125 DEG 11MM X 380MM
814411400	HFN LH 125 DEG 11MM X 400MM
814411420	HFN LH 125 DEG 11MM X 420MM
814411440	HFN LH 125 DEG 11MM X 440MM
814411460	HFN LH 125 DEG 11MM X 460MM
814413260	HFN LH 125 DEG 13MM X 260MM
814413280	HFN LH 125 DEG 13MM X 280MM
814413300	HFN LH 125 DEG 13MM X 300MM
814413320	HFN LH 125 DEG 13MM X 320MM
814413340	HFN LH 125 DEG 13MM X 340MM

Attachment 2

Affected Product List – Lots affected all begin with a “D”

Item Number	Description
814413360	HFN LH 125 DEG 13MM X 360MM
814413380	HFN LH 125 DEG 13MM X 380MM
814413400	HFN LH 125 DEG 13MM X 400MM
814413420	HFN LH 125 DEG 13MM X 420MM
814413440	HFN LH 125 DEG 13MM X 440MM
814413460	HFN LH 125 DEG 13MM X 460MM
814509260	HFN RH 130 DEG 9MM X 260MM
814509280	HFN RH 130 DEG 9MM X 280MM
814509300	HFN RH 130 DEG 9MM X 300MM
814509320	HFN RH 130 DEG 9MM X 320MM
814509340	HFN RH 130 DEG 9MM X 340MM
814509360	HFN RH 130 DEG 9MM X 360MM
814509380	HFN RH 130 DEG 9MM X 380MM
814509400	HFN RH 130 DEG 9MM X 400MM
814509420	HFN RH 130 DEG 9MM X 420MM
814509440	HFN RH 130 DEG 9MM X 440MM
814509460	HFN RH 130 DEG 9MM X 460MM
814511260	HFN RH 130 DEG 11MM X 260MM
814511280	HFN RH 130 DEG 11MM X 280MM
814511300	HFN RH 130 DEG 11MM X 300MM
814511320	HFN RH 130 DEG 11MM X 320MM
814511340	HFN RH 130 DEG 11MM X 340MM
814511360	HFN RH 130 DEG 11MM X 360MM
814511380	HFN RH 130 DEG 11MM X 380MM
814511400	HFN RH 130 DEG 11MM X 400MM
814511420	HFN RH 130 DEG 11MM X 420MM
814511440	HFN RH 130 DEG 11MM X 440MM
814511460	HFN RH 130 DEG 11MM X 460MM
814513260	HFN RH 130 DEG 13MM X 260MM
814513280	HFN RH 130 DEG 13MM X 280MM
814513300	HFN RH 130 DEG 13MM X 300MM
814513320	HFN RH 130 DEG 13MM X 320MM
814513340	HFN RH 130 DEG 13MM X 340MM
814513360	HFN RH 130 DEG 13MM X 360MM
814513380	HFN RH 130 DEG 13MM X 380MM

Item Number	Description
814513400	HFN RH 130 DEG 13MM X 400MM
814513420	HFN RH 130 DEG 13MM X 420MM
814513440	HFN RH 130 DEG 13MM X 440MM
814513460	HFN RH 130 DEG 13MM X 460MM
814515320	HFN RH 130 DEG 15MM X 320MM
814515360	HFN RH 130 DEG 15MM X 360MM
814515400	HFN RH 130 DEG 15MM X 400MM
814515440	HFN RH 130 DEG 15MM X 440MM
814609260	HFN LH 130 DEG 9MM X 260MM
814609280	HFN LH 130 DEG 9MM X 280MM
814609300	HFN LH 130 DEG 9MM X 300MM
814609320	HFN LH 130 DEG 9MM X 320MM
814609340	HFN LH 130 DEG 9MM X 340MM
814609360	HFN LH 130 DEG 9MM X 360MM
814609380	HFN LH 130 DEG 9MM X 380MM
814609400	HFN LH 130 DEG 9MM X 400MM
814609420	HFN LH 130 DEG 9MM X 420MM
814609440	HFN LH 130 DEG 9MM X 440MM
814609460	HFN LH 130 DEG 9MM X 460MM
814611260	HFN LH 130 DEG 11MM X 260MM
814611280	HFN LH 130 DEG 11MM X 280MM
814611300	HFN LH 130 DEG 11MM X 300MM
814611320	HFN LH 130 DEG 11MM X 320MM
814611340	HFN LH 130 DEG 11MM X 340MM
814611360	HFN LH 130 DEG 11MM X 360MM
814611380	HFN LH 130 DEG 11MM X 380MM
814611400	HFN LH 130 DEG 11MM X 400MM
814611420	HFN LH 130 DEG 11MM X 420MM
814611440	HFN LH 130 DEG 11MM X 440MM
814611460	HFN LH 130 DEG 11MM X 460MM
814613260	HFN LH 130 DEG 13MM X 260MM
814613280	HFN LH 130 DEG 13MM X 280MM
814613300	HFN LH 130 DEG 13MM X 300MM
814613320	HFN LH 130 DEG 13MM X 320MM
814613340	HFN LH 130 DEG 13MM X 340MM

Attachment 2

Affected Product List – Lots affected all begin with a “D”

Item Number	Description
814613360	HFN LH 130 DEG 13MM X 360MM
814613380	HFN LH 130 DEG 13MM X 380MM
814613400	HFN LH 130 DEG 13MM X 400MM
814613420	HFN LH 130 DEG 13MM X 420MM
814613440	HFN LH 130 DEG 13MM X 440MM
814613460	HFN LH 130 DEG 13MM X 460MM
814615320	HFN LH 130 DEG 15MM X 320MM
814615360	HFN LH 130 DEG 15MM X 360MM
814615400	HFN LH 130 DEG 15MM X 400MM
814615440	HFN LH 130 DEG 15MM X 440MM
816709165	HFN 125 DEG 9MM X 165MM
816710165	HFN 125 DEG 10MM X 165MM
816712165	HFN 125 DEG 12MM X 165MM
816809165	HFN 130 DEG 9MM X 165MM
816810165	HFN 130 DEG 10MM X 165MM
816812165	HFN 130 DEG 12MM X 165MM
816709260	HFN RH 125 9MM X 260MM 1.5M
816709280	HFN RH 125 9MM X 280MM 1.5M
816709300	HFN RH 125 9MM X 300MM 1.5M
816709320	HFN RH 125 9MM X 320MM 1.5M
816709340	HFN RH 125 9MM X 340MM 1.5M
816709360	HFN RH 125 9MM X 360MM 1.5M
816709380	HFN RH 125 9MM X 380MM 1.5M
816709400	HFN RH 125 9MM X 400MM 1.5M
816710260	HFN RH 125 10MM X 260MM 1.5M
816710280	HFN RH 125 10MM X 280MM 1.5M
816710300	HFN RH 125 10MM X 300MM 1.5M
816710320	HFN RH 125 10MM X 320MM 1.5M
816710340	HFN RH 125 10MM X 340MM 1.5M
816710360	HFN RH 125 10MM X 360MM 1.5M
816710380	HFN RH 125 10MM X 380MM 1.5M
816710400	HFN RH 125 10MM X 400MM 1.5M
816712260	HFN RH 125 12MM X 260MM 1.5M
816712280	HFN RH 125 12MM X 280MM 1.5M
816712300	HFN RH 125 12MM X 300MM 1.5M

Item Number	Description
816712320	HFN RH 125 12MM X 320MM 1.5M
816712340	HFN RH 125 12MM X 340MM 1.5M
816712360	HFN RH 125 12MM X 360MM 1.5M
816712380	HFN RH 125 12MM X 380MM 1.5M
816712400	HFN RH 125 12MM X 400MM 1.5M
816809260	HFN LH 125 9MM X 260MM 1.5M
816809280	HFN LH 125 9MM X 280MM 1.5M
816809300	HFN LH 125 9MM X 300MM 1.5M
816809320	HFN LH 125 9MM X 320MM 1.5M
816809340	HFN LH 125 9MM X 340MM 1.5M
816809360	HFN LH 125 9MM X 360MM 1.5M
816809380	HFN LH 125 9MM X 380MM 1.5M
816809400	HFN LH 125 9MM X 400MM 1.5M
816810260	HFN LH 125 10MM X 260MM 1.5M
816810280	HFN LH 125 10MM X 280MM 1.5M
816810300	HFN LH 125 10MM X 300MM 1.5M
816810320	HFN LH 125 10MM X 320MM 1.5M
816810340	HFN LH 125 10MM X 340MM 1.5M
816810360	HFN LH 125 10MM X 360MM 1.5M
816810380	HFN LH 125 10MM X 380MM 1.5M
816810400	HFN LH 125 10MM X 400MM 1.5M
816812260	HFN LH 125 12MM X 260MM 1.5M
816812280	HFN LH 125 12MM X 280MM 1.5M
816812300	HFN LH 125 12MM X 300MM 1.5M
816812320	HFN LH 125 12MM X 320MM 1.5M
816812340	HFN LH 125 12MM X 340MM 1.5M
816812360	HFN LH 125 12MM X 360MM 1.5M
816812380	HFN LH 125 12MM X 380MM 1.5M
816812400	HFN LH 125 12MM X 400MM 1.5M