

August 22, 2018

To: Hospitals and Surgeons

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

Reference: ZFA2018-00413

Affected Product: Affixus® Hip Fracture Nail

See **Attachment 2 – Affected Product List**



Zimmer Biomet is conducting a lot specific medical device field action (removal) for the Affixus® Hip Fracture Nail due to complaints indicating that when the product was opened in surgery, the sterile packaging was already open. The investigation determined that while this product was packaged correctly at the time of manufacture, approximately 20% of the affected product was opened by Zimmer Biomet for an unrelated inspection and was inadvertently distributed after December 28, 2017 without the intended rework. As can be observed in the photo above, it is highly detectable at the point of use that the sterile barrier is not intact for the subset of product that exhibits this condition.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Delay in surgery less than 30 mins to retrieve another part	Delay in surgery greater than 30 mins to retrieve another part
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	Loss of sterile barrier leading to infection; Patient wound is prepared for specific size device; however, because sterile size is unavailable, the next closest size is used leading to malunion

Our records indicate that you may have received one or more of the affected products. While the subset of product potentially exhibiting this condition was distributed after December 28, 2017; the affected lot numbers were distributed between July 2017 and July 2018 (from the legal manufacturer. Local deployment might vary).

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fielddaction.emea@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the Certificate of 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.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fielddaction.emea@zimmerbiomet.com.
4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
6. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

Other Information

This 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.

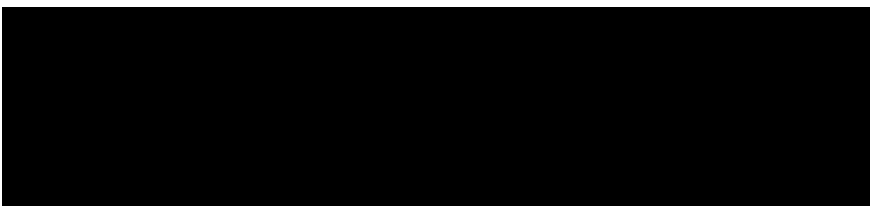
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

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,





ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Affixus® Hip Fracture Nail

Field Action Reference: ZFA 2018-00413

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

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

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City: _____ **ZIP:** _____ **Country:** _____

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.emea@zimmerbiomet.com.

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

Choose the following options:

All received products were used (implanted)

Or complete the chart below for remaining products:

Product Reference	Lot Reference	Number of products returned

Comments (if needed): _____

ATTACHMENT 2

Affected Product List

Item Number	Lot Number	Item Description	Item Number	Lot Number	Item Description
814309180	177830	Affixus® Hip Fracture Nail 125° 9 mm x 180 mm	814311180	129900	Affixus® Hip Fracture Nail 125° 11mm x 180mm
814309180	177890	Affixus® Hip Fracture Nail 125° 9 mm x 180 mm	814311180	129910	Affixus® Hip Fracture Nail 125° 11mm x 180mm
814309180	177910	Affixus® Hip Fracture Nail 125° 9 mm x 180 mm	814311180	287720	Affixus® Hip Fracture Nail 125° 11mm x 180mm
814309180	177920	Affixus® Hip Fracture Nail 125° 9 mm x 180 mm	814311180	287740	Affixus® Hip Fracture Nail 125° 11mm x 180mm
814309180	177820	Affixus® Hip Fracture Nail 125° 9 mm x 180 mm	814311340	288670	Affixus® Hip Fracture Nail Right 125° 11 mm x 340 mm
814309180	244120	Affixus® Hip Fracture Nail 125° 9 mm x 180 mm	814311340	244090	Affixus® Hip Fracture Nail Right 125° 11 mm x 340 mm
814309180	287770	Affixus® Hip Fracture Nail 125° 9 mm x 180 mm	814311360	244170	Affixus® Hip Fracture Nail Right 125° 11 mm x 360 mm
814309260	450640	Affixus® Hip Fracture Nail Right 125° 9 mm x 260 mm	814311380	244180	Affixus® Hip Fracture Nail Right 125° 11 mm x 380 mm
814309300	219750	Affixus® Hip Fracture Nail Right 125° 9 mm x 300 mm	814311420	289160	Affixus® Hip Fracture Nail Right 125° 11 mm x 420 mm
814309300	450750	Affixus® Hip Fracture Nail Right 125° 9 mm x 300 mm	814311420	369250	Affixus® Hip Fracture Nail Right 125° 11 mm x 420 mm
814309300	244110	Affixus® Hip Fracture Nail Right 125° 9 mm x 300 mm	814311420	369260	Affixus® Hip Fracture Nail Right 125° 11 mm x 420 mm
814309320	450770	Affixus® Hip Fracture Nail Right 125° 9 mm x 320 mm	814311440	369280	Affixus® Hip Fracture Nail Right 125° 11 mm x 440 mm
814309320	450790	Affixus® Hip Fracture Nail Right 125° 9 mm x 320 mm	814311460	436200	Affixus® Hip Fracture Nail Right 125° 11 mm x 460 mm
814309340	584910	Affixus® Hip Fracture Nail Right 125° 9 mm x 340 mm	814313180	558020	Affixus® Hip Fracture Nail Right 125° 13 mm x 180 mm
814309340	616470	Affixus® Hip Fracture Nail Right 125° 9 mm x 340 mm	814313180	244220	Affixus® Hip Fracture Nail Right 125° 13 mm x 180 mm
814309340	244100	Affixus® Hip Fracture Nail Right 125° 9 mm x 340 mm	814313260	343500	Affixus® Hip Fracture Nail Right 125° 13 mm x 260 mm
814309360	219760	Affixus® Hip Fracture Nail Right 125° 9 mm x 360 mm	814313280	369340	Affixus® Hip Fracture Nail Right 125° 13 mm x 280 mm
814309380	436160	Affixus® Hip Fracture Nail Right 125° 9 mm x 380 mm	814313300	616680	Affixus® Hip Fracture Nail Right 125° 13 mm x 300 mm
814309440	289130	Affixus® Hip Fracture Nail Right 125° 9 mm x 440 mm	814313300	616780	Affixus® Hip Fracture Nail Right 125° 13 mm x 300 mm
814309460	369120	Affixus® Hip Fracture Nail Right 125° 9 mm x 460 mm	814313360	136750	Affixus® Hip Fracture Nail Right 125° 13 mm x 360 mm
814311180	178050	Affixus® Hip Fracture Nail 125° 11mm x 180mm	814313400	584890	Affixus® Hip Fracture Nail Right 125° 13 mm x 400 mm
814311180	178060	Affixus® Hip Fracture Nail 125° 11mm x 180mm	814313440	678960	Affixus® Hip Fracture Nail Right 125° 13 mm x 440 mm
814311180	178070	Affixus® Hip Fracture Nail 125° 11mm x 180mm	814313440	678970	Affixus® Hip Fracture Nail Right 125° 13 mm x 440 mm

Item Number	Lot Number	Item Description	Item Number	Lot Number	Item Description
814409260	679000	Affixus® Hip Fracture Nail Left 125° 9 mm x 260 mm	814413360	369410	Affixus® Hip Fracture Nail Left 125° 13 mm x 360 mm
814409300	201230	Affixus® Hip Fracture Nail Left 125° 9 mm x 300 mm	814509320	201440	Affixus® Hip Fracture Nail Right 130° 9 mm x 320 mm
814409300	201240	Affixus® Hip Fracture Nail Left 125° 9 mm x 300 mm	814511180	244300	Affixus® Hip Fracture Nail 130° 11 mm x 180 mm
814409300	500030	Affixus® Hip Fracture Nail Left 125° 9 mm x 300 mm	814511180	244320	Affixus® Hip Fracture Nail 130° 11 mm x 180 mm
814409300	679050	Affixus® Hip Fracture Nail Left 125° 9 mm x 300 mm	814511180	436430	Affixus® Hip Fracture Nail 130° 11 mm x 180 mm
814409320	558060	Affixus® Hip Fracture Nail Left 125° 9 mm x 320 mm	814511180	136520	Affixus® Hip Fracture Nail 130° 11 mm x 180 mm
814409440	584790	Affixus® Hip Fracture Nail Left 125° 9 mm x 440 mm	814511320	616240	Affixus® Hip Fracture Nail Right 130° 11 mm x 320 mm
814409440	584810	Affixus® Hip Fracture Nail Left 125° 9 mm x 440 mm	814511320	616250	Affixus® Hip Fracture Nail Right 130° 11 mm x 320 mm
814409460	584760	Affixus® Hip Fracture Nail Left 125° 9 mm x 460 mm	814511340	369640	Affixus® Hip Fracture Nail Right 130° 11 mm x 340 mm
814409460	584770	Affixus® Hip Fracture Nail Left 125° 9 mm x 460 mm	814511360	343590	Affixus® Hip Fracture Nail Right 130° 11 mm x 360 mm
814411260	244270	Affixus® Hip Fracture Nail Left 125° 11 mm x 260 mm	814511360	343610	Affixus® Hip Fracture Nail Right 130° 11 mm x 360 mm
814411260	679300	Affixus® Hip Fracture Nail Left 125° 11 mm x 260 mm	814511400	343630	Affixus® Hip Fracture Nail Right 130° 11 mm x 400 mm
814411320	679160	Affixus® Hip Fracture Nail Left 125° 11 mm x 320 mm	814513360	436470	Affixus® Hip Fracture Nail Right 130° 13 mm x 360 mm
814411340	244280	Affixus® Hip Fracture Nail - Left 125° 11mm x 340mm	814513360	616630	Affixus® Hip Fracture Nail Right 130° 13 mm x 360 mm
814411340	558120	Affixus® Hip Fracture Nail - Left 125° 11mm x 340mm	814513360	616640	Affixus® Hip Fracture Nail Right 130° 13 mm x 360 mm
814411340	558130	Affixus® Hip Fracture Nail - Left 125° 11mm x 340mm	814609360	616460	Affixus® Hip Fracture Nail Left 130° 9 mm x 360 mm
814411360	244290	Affixus® Hip Fracture Nail Left 125° 11 mm x 360 mm	814611360	289190	Affixus® Hip Fracture Nail Left 130° 11 mm x 360 mm
814411360	343530	Affixus® Hip Fracture Nail Left 125° 11 mm x 360 mm	814611380	287810	Affixus® Hip Fracture Nail Left 130° 11 mm x 380 mm
814411360	343550	Affixus® Hip Fracture Nail Left 125° 11 mm x 360 mm	814611380	343660	Affixus® Hip Fracture Nail Left 130° 11 mm x 380 mm
814413260	679240	Affixus® Hip Fracture Nail Left 125° 13 mm x 260 mm	814611400	500220	Affixus® Hip Fracture Nail Left 130° 11 mm x 400 mm
814413340	369380	Affixus® Hip Fracture Nail Left 125° 13 mm x 340 mm	814615360	436650	Affixus® Hip Fracture Nail Left 130° 15 mm x 360 mm
814413340	436290	Affixus® Hip Fracture Nail Left 125° 13 mm x 340 mm	816709165	694950	Affixus® Hip Fracture Nail 125° 9 mm x 165 mm
814413360	369400	Affixus® Hip Fracture Nail Left 125° 13 mm x 360 mm			