

October 12, 2018

To: Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE - REMOVAL (update)**

Affected Product: Affixus Hip Fracture Nail

See Attachment 2 for a list of affected product



This is a follow up to the medical device field safety corrective action notification dated July 31, 2018. Zimmer Biomet has since identified additional lot numbers that are within the scope of this issue. The added part and lot combinations are listed in Attachment 2 of this letter.

Zimmer Biomet is conducting a lot-specific medical device field safety corrective action for Affixus Hip Fracture Nail due to the set screw not being able to advance or reverse from the original position in the nail.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between 03/13/2018 and 08/29/2018 (local deployments 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 fieldaction.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 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 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,

A handwritten signature in black ink, appearing to read 'K. Escapule', written over a horizontal line.

Kevin W. Escapule
Post Market Surveillance and Regulatory Compliance Director



ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Affixus Hip Fracture Nail

Field Action Reference: ZFA 2018-00344

Notification Date: October 12, 2018

By signing below, I acknowledge that the required actions have been taken in accordance with this field action 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	Lot	Description
814311280	790170	Affixus® Hip Fracture Nail Right 125° 11 mm x 280 mm
814311340	944450	Affixus® Hip Fracture Nail Right 125° 11 mm x 340 mm
814311360	688290	Affixus® Hip Fracture Nail Right 125° 11 mm x 360 mm
814311420	017270	Affixus® Hip Fracture Nail Right 125° 11 mm x 420 mm
814313180	500880	Affixus® Hip Fracture Nail Right 125° 13 mm x 180 mm
814313260	813260	Affixus® Hip Fracture Nail Right 125° 13 mm x 260 mm
814313280	813300	Affixus® Hip Fracture Nail Right 125° 13 mm x 280 mm
814313360	645770	Affixus® Hip Fracture Nail Right 125° 13 mm x 360 mm
814313380	813390	Affixus® Hip Fracture Nail Right 125° 13 mm x 380 mm
814313440	051080	Affixus® Hip Fracture Nail Right 125° 13 mm x 440 mm
814313460	017310	Affixus® Hip Fracture Nail Right 125° 13 mm x 460 mm
814409300	790790	Affixus® Hip Fracture Nail Left 125° 9 mm x 300 mm
814409340	971050	Affixus® Hip Fracture Nail Left 125° 9 mm x 340 mm
	645800	
814409400	767720	Affixus® Hip Fracture Nail Left 125° 9 mm x 400 mm
	097150	
814409420	790820	Affixus® Hip Fracture Nail Left 125° 9 mm x 420 mm
814409440	900270	Affixus® Hip Fracture Nail Left 125° 9 mm x 440 mm
814411300	971270	Affixus® Hip Fracture Nail Left 125° 11 mm x 300 mm
	133240	
814411320	813600	Affixus® Hip Fracture Nail Left 125° 11 mm x 320 mm
814411360	519470	Affixus® Hip Fracture Nail Left 125° 11 mm x 360 mm
814411400	530100	Affixus® Hip Fracture Nail Left 125° 11 mm x 400 mm
	646600	
814411420	813860	Affixus® Hip Fracture Nail Left 125° 11 mm x 420 mm
	813680	
814411440	646640	Affixus® Hip Fracture Nail Left 125° 11 mm x 440 mm
	646630	
814411460	285050	Affixus® Hip Fracture Nail Left 125° 11 mm x 460 mm
	287410	
814413340	155980	Affixus® Hip Fracture Nail Left 125° 13 mm x 340 mm
	156040	
814413400	646680	Affixus® Hip Fracture Nail Left 125° 13 mm x 400 mm
814413420	762730	Affixus® Hip Fracture Nail Left 125° 13 mm x 420 mm
814509180	609650	Affixus® Hip Fracture Nail 130° 9 mm x 180 mm

	609640	
814509300	128150	Affixus® Hip Fracture Nail Right 130° 9 mm x 300 mm
	971560	
814509360	646750	Affixus® Hip Fracture Nail Right 130° 9 mm x 360 mm
814509400	900740	Affixus® Hip Fracture Nail Right 130° 9 mm x 400 mm
814509420	503950	Affixus® Hip Fracture Nail Right 130° 9 mm x 420 mm
	503960	
814509440	503970	Affixus® Hip Fracture Nail Right 130° 9 mm x 440 mm
	472970	
814509460	017420	Affixus® Hip Fracture Nail Right 130° 9 mm x 460 mm
	960610	
814511180	156970	Affixus® Hip Fracture Nail 130° 11 mm x 180 mm
	504010	
	504000	
	503990	
	503980	
	130940	
130930		
814511280	353610	Affixus® Hip Fracture Nail Right 130° 11 mm x 280 mm
814511340	371200	Affixus® Hip Fracture Nail Right 130° 11 mm x 320 mm
814511360	696380	Affixus® Hip Fracture Nail Right 130° 11 mm x 360 mm
	097190	
814511380	519620	Affixus® Hip Fracture Nail Right 130° 11 mm x 380 mm
	519630	
	813210	
814511400	245530	Affixus® Hip Fracture Nail Right 130° 11 mm x 400 mm
	017490	
814511420	171860	Affixus® Hip Fracture Nail Right 130° 11 mm x 420 mm
	171870	
814513180	097180	Affixus® Hip Fracture Nail 130° 13 mm x 180 mm
	188350	
	290690	
	188370	
	970530	
	970580	
970510		
814513400	773050	Affixus® Hip Fracture Nail Right 130° 13 mm x 400 mm
814513420	418360	Affixus® Hip Fracture Nail Right 130° 13 mm x 420 mm
814513440	017710	Affixus® Hip Fracture Nail Right 130° 13 mm x 440 mm

814513460	901520	Affixus® Hip Fracture Nail Right 130° 13 mm x 460 mm
814609280	091560	Affixus® Hip Fracture Nail Left 130° 9 mm x 280 mm
814609300	371540	Affixus® Hip Fracture Nail Left 130° 9 mm x 300 mm
814609320	721080	Affixus® Hip Fracture Nail Left 130° 9 mm x 320 mm
814609400	812930	Affixus® Hip Fracture Nail Left 130° 9 mm x 400 mm
	812750	
	812920	
814609460	245470	Affixus® Hip Fracture Nail Left 130° 9 mm x 460 mm
814611300	157410	Affixus® Hip Fracture Nail Left 130° 11 mm x 300 mm
	171840	
814611320	900100	Affixus® Hip Fracture Nail Left 130° 11 mm x 320 mm
814611340	157430	Affixus® Hip Fracture Nail Left 130° 11 mm x 340 mm
	587790	
	944920	
814611360	629800	Affixus® Hip Fracture Nail Left 130° 11 mm x 360 mm
814611380	609690	Affixus® Hip Fracture Nail Left 130° 11 mm x 380 mm
814611400	759180	Affixus® Hip Fracture Nail Left 130° 11 mm x 400 mm
814611420	712240	Affixus® Hip Fracture Nail Left 130° 11 mm x 420 mm
	812340	
814613360	091850	Affixus® Hip Fracture Nail Left 130° 13 mm x 360 mm
814613380	145040	Affixus® Hip Fracture Nail Left 130° 13 mm x 380 mm
814613400	543380	Affixus® Hip Fracture Nail Left 130° 13 mm x 400 mm
814613420	482820	Affixus® Hip Fracture Nail Left 130° 13 mm x 420 mm
814615360	791930	Affixus® Hip Fracture Nail Left 130° 15 mm x 360 mm
816709165	816520	Affixus® Hip Fracture Nail 125° 9 mm x 165 mm
	063610	
	063630	
816710165	945090	Affixus® Hip Fracture Nail 125° 10 mm x 165 mm
	945230	
816712165	145060	Affixus® Hip Fracture Nail 125° 12 mm x 165 mm
	901690	
	901680	
816810165	558270	Affixus® Hip Fracture Nail 130° 10 mm x 165 mm
	558260	
816812165	901770	Affixus® Hip Fracture Nail 130° 12 mm x 165 mm