

Montbonnot, on the 13 April 2017

URGENT INFORMATION NOTICE

Objective: **Safety Information for the Ankle Arthrodesis Nail 611AFN**

Our Ref.: **FA-TOF-2016-033**

Person responsible for follow-up: **Alice SIAUD-SIMOENS – 04 56 52 43 28**

Safety Information

Batches concerned: Drill MJU777 batches 11D463 and 12E794

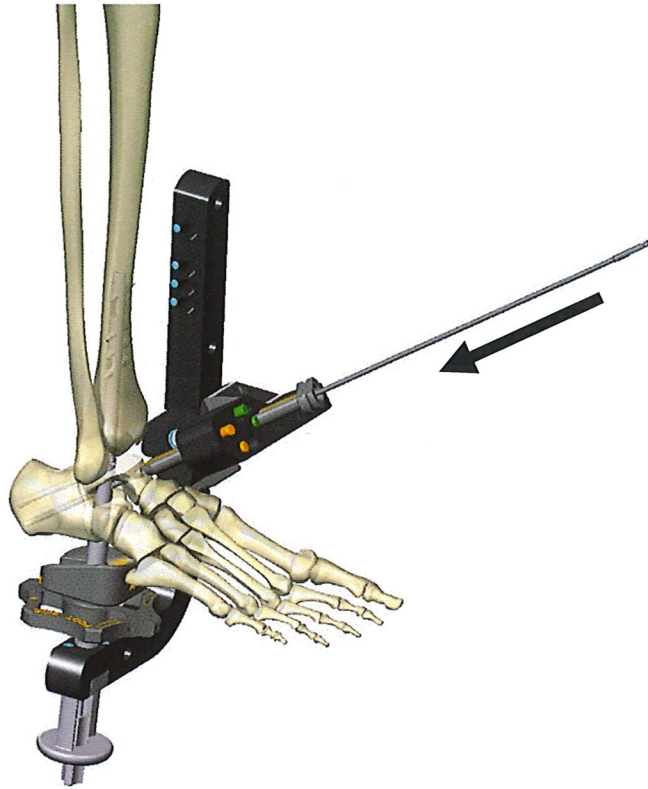
Dear Sir or Madam,

The purpose of this letter is to inform you of a voluntary safety corrective action relating to the use of the drill Reference MJU777 used during 611AFN Ankle Arthrodesis Nail surgery.

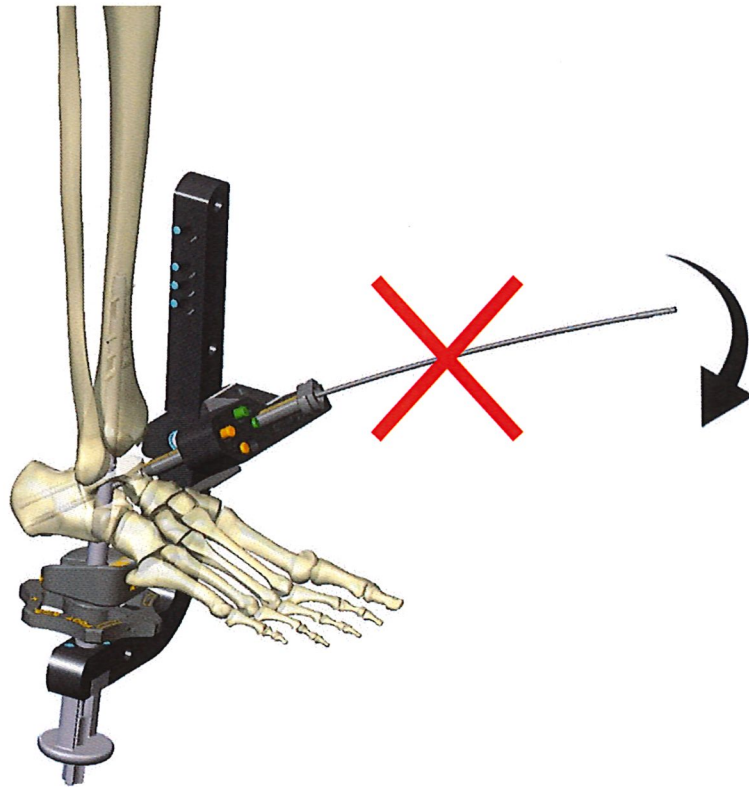
Although the drill reference MJU777 is guided during drilling by a guide reference MJU775, isolated cases of drill breakage have been reported.

Internal tests have made it possible to reproduce this dysfunction, highlighting the importance of respecting the surgical technique in order to avoid any risk of breakage.

We therefore remind you to correctly apply the drilling force in the axis of the drill as shown after.



Drill straight in the axis: ✓



Caution: Do not bend when drilling: ✗

Finally, in order to optimize the drilling technique, we decided to modify the cutting angle of our drills.

You will be informed in the near future of the availability of the replacement part. Our customer service will then contact you to organize the return and the exchange of the devices present in your establishment.

The competent authorities and the customers affected by this action have been informed.

Our records indicate that you have received the products listed above.
Thank you for completing the attached form confirming that you have received and distributed this security information.

Action to be taken by the user

Insofar as your establishment has the devices concerned, we ask you to:

- Distribute this notice to all parties concerned,
- To remain vigilant internally in relation to this recommendation,
- To inform us of any adverse effects and / or to report them to the Competent Authorities according to the regulations in force and in accordance with MEDDEV 2.12-1.

For further information, please contact:

Sylvie SAINT-PREUX
Lower Extremities Sr. International Product Manager
+ 33 (0)6 10 43 46 79

Thank you for your cooperation and the trust you have shown in our Company, please receive, Madam, Sir, our sincere greetings.



Maud ANDRIOLLO
Vigilance Correspondent



FA TOF 2016 033 - Safety information

Acknowledgment of receipt

Please complete this acknowledgment of receipt and return it to us within the next **15 days**
By fax at 04.76.61.35.33 or by email alice.siaud-simoens@wright.com

Establishment/Name of the company _____

NAME: _____

Position: _____

Address: _____

Telephone n°: _____

My inventory was checked and the results are as follows (please tick the appropriate box)

Yes, I have in my possession product (s) concerned in my inventory.

Product Description	Reference	Batch	Quantity
Drill	MJU777	11D463	
Drill	MJU777	12E794	

No, I do not have in my possession products concerned in my inventory.

By completing and returning this form, I confirm that I have received and read this security notice.

Date : _____

Signature : _____