**Healthcare facility**
Address

To the attention of the vigilance Safety Officer
and orthopedic surgery departments

Valence, November 18th 2019

Ref. AMPLITUDE: COMP-1044

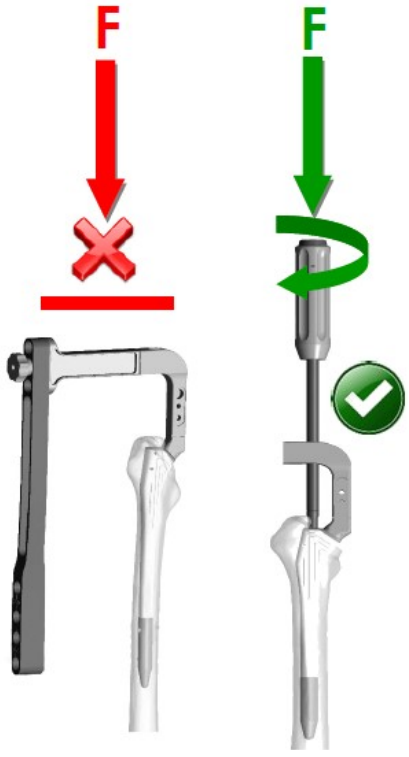
Objet : **Urgent FIELD SAFETY NOTICE - Advisory Notice**
OPTIMAL® stem – Locking version

*Reason of the advisory notice:*
The company AMPLITUDE has decided to issue an Advisory Notice regarding the locking of OPTIMAL® stems. This decision follows feedback from field related to difficulties during locking phase of OPTIMAL® stems. The purpose of this notice is to inform you of recommendations to be followed during this step of the surgical technique.

## 1 STEM IMPACTION AND ORIENTATION

When implanting the stem, **do not impact the frame while it is mounted on the stem** as this may **jeopardise the alignment of the drilling barrels** (drill bits) with the holes in the stem.

The frame **must be disassembled** after the trials on the back table and re-assembled after stem impaction. **Striking force should only be applied through the provided impactor.**

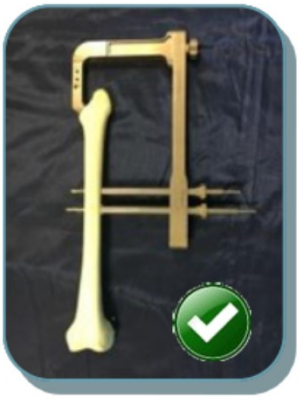


AMPLITUDE

## 2 USE THE TWO DRILL BITS TO MAKE THE HOLES
## AVOID PUTTING PRESSURE ON THE FRAME DURING DRILLING

It is **essential to use both drill bits from the instrumentation set** to make the holes where the threaded pins will be inserted. Leave drill bit No. 1 in place to stiffen the construct proximally and drill the second hole using drill bit No. 2, making sure to cross both cortices each time. Leave drill bit No. 2 in place while assembling the first threaded pin.

**Avoid putting pressure** on the frame during drilling as this could misalign the drill bit and jeopardise the frame's correct alignment.



These recommendations are included in the surgical technique

*Circumstances and risks for the user and/or the patient:*

In cases where the recommendations would not be followed, there is a risk that the OPTIMAL® stem may be drilled beside the locking holes.

If it is detected during the surgery, additional drilling will be required in order to lock the threaded pin into the locking holes of the OPTIMAL® stem. It would generate an increase of surgical time and in some cases the incision should be enlarged.

In cases where this would be detected after the surgery, (on post-operative X-rays), if the threaded pins are not locked into the holes of the stem, there is an increased risk of instability of the stem, which could require a revision surgery.

In very rare cases where the stem should have been damaged by the offset drilling, there is a risk of stem breakage in the distal area.

*Concerned devices:*

The traceability data indicates that you are a user of OPTIMAL® stems. The involved instrument set is:

| Reference REF | Designation |
|---|---|
| 2-0199963 | Instrument set for OPTIMAL® stem |

AMPLITUDE

*What you must do:*

Please circulate this notice to the related individuals in your healthcare facility.

We also remind you that any adverse event experienced using these devices must be declared to the Competent Authority and your local representative.

*Other information*

The French competent authority is advised about this Advisory Notice

The instrument sets are inspected at each return to Amplitude in order to guarantee that they comply with the specifications. If you suspect or become aware of a failure or a deterioration, please contact our sales department without delay.

Our sales department is at your disposal if you need any further information.

We thank you for your help and your cooperation in the implementation of this Advisory Notice. We apologize for the inconvenience and thank you for your comprehension.

Mireille LEMERY
Vice-President Quality and Regulatory Affairs
*vigilance@amplitude-ortho.com*