



**Healthcare Facility**  
Address

*L.R.A.R. N°xx xxx xxx xxxx x*

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

Valence, February 17<sup>th</sup> 2020

Ref. AMPLITUDE - ISSUE-0633

Object : **FSN – Advisory Notice**  
EXTREME® Femoral stem – AMPLITUDE

Reason for advisory notice

Following feedback from a Healthcare facility, we identified a possible conflict between the EXTREME® Epiphyseal-Metaphyseal section and the assembly screw on the prosthesis EXTREME®. That conflict appears in the rare case when both parts have dimensions at the limit of their tolerance, that do not ensure an optimal locking of the diaphyseal nail in rotation, as only the morse taper will provide that function.

Circumstances and risks for the user and/or the patient

Whereas no associated patient issue was reported, it could induce for the patient the following consequences:

If the conflict is detected during the surgery (impossibility to insert the assembly screw, impossibility to assembly the locknut or if the rotation of the diaphyseal nail is not secured with the Epiphyseal-Metaphyseal section:

- An extended surgery time if one other device with the same size is available in the hospital,
- An extended surgery time if the preparation must be modified and adapted with another available device.

If the conflict is not detected during the surgery, the rotation between the diaphyseal nail and the Epiphyseal-Metaphyseal section could induce the non-fixation of the device to the proximal part of the bone, a bad restoration of the articular center that creates a premature wear of the insert/acetabular cup and/or femoral fracture due to rotation of the proximal part.

No specific follow-up is recommended for the patient. We recommend a particular attention regarding this event and the associated risks during the post-operative follow-up of the implanted patients.

Concerned device

The traceability data indicates that you implanted the concerned device(s):

Reference REF	Designation	Batch :
1-0107201	EXTREME Epiphyseal-Metaphyseal section with assembly screw and locknut - HA coated - cementless - size 1	All batches with an expiry date before 08/2024.
1-0107202	EXTREME Epiphyseal-Metaphyseal section with assembly screw and locknut - HA coated - cementless - size 2	
1-0107203	EXTREME Epiphyseal-Metaphyseal section with assembly screw and locknut - HA coated - cementless - size 3	
1-0107204	EXTREME Epiphyseal-Metaphyseal section with assembly screw and locknut - HA coated - cementless - size 4	

What you must do

- Read carefully this advisory notice.
- Please circulate this notice to the related individuals in the Healthcare facility.
- Report to us all the event that could be associated to this event via the following address: [vigilance@amplitude-ortho.com](mailto:vigilance@amplitude-ortho.com)

The French Competent Authority is advised about this action.

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

We apologize for the inconvenience and thank you for your comprehension.

Mireille LEMERY

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[vigilance@amplitude-ortho.com](mailto:vigilance@amplitude-ortho.com)