



Healthcare facility
Address

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

Valence, January 31st, 2019

Ref. : AMPLITUDE CC 19-01-012

Subject: Advisory Notice
EVOK[®] Femoral stem Standard Offset Collarless and Collared - size 8

Reason of the advisory notice:

During an internal file review, an error regarding the weight restriction has been identified in the IFU and on the labels of the EVOK[®] femoral stem standard offset collarless and collared size 8. The tests performed allowed to define a weight restriction of 85kg, although the information on the IFU and labels specified a maximum weight of 89kg. The incorrect weight restriction has also been communicated on support documents like the surgical technique and X-Ray templates.

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

Whereas no breakage has been recorded, there is a risk of early breakage in case the EVOK[®] femoral stem standard offset collarless and collared size 8 is implanted into a patient with a weight over 85kg.

Concerned devices:

The traceability data indicates that you were provided the concerned device:

Reference	Designation
1-0192008	EVOK [®] Femoral stem Standard Offset Collarless - HA Coated –Taper 12/14 size 8
1-0192108	EVOK [®] Femoral stem Standard Offset Collared - HA Coated –Taper 12/14 size 8

What you must do:

- Please circulate this notice to the related individuals in the hospital.
- Follow the recommendation of the maximum patient weight of 85kg, described in this notice.
- Return the attached back form, after completion
- We remind you that any adverse event experienced using these devices must be declared to the Competent Authority and your local representative.



In the case a EVOK[®] femoral stem standard offset collarless and collared size 8 has been implanted in your healthcare facility, we recommend to check the patient weight and to adapt the follow-up taking into account the risk identified into this safety notice.

Our commercial department will contact you to provide the updated support documents.

Other information

The French competent authority is advised about 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


Attached : Return form

BACK FORM
Advisory Notice - CC-19-01-012

EVOK[®] femoral stem standard offset - Size 8

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I acknowledge receipt and taken into account the field safety notice regarding the weight restriction of the EVOK[®] femoral stem standard offset size 8.

 **Not recommended for patients over 85kg / Non recommandée pour des patients de plus de 85kg**

I will undertake the actions described in the received safety notice.

Name :

Function :

Date :

Signature :

Please return this form as soon as possible by fax (+33 (0)4-75-41-41-78) or by email (vigilance@amplitude-ortho.com)