AMPLITUDE

AMPLITUDE GmbH
Am Neuen Graben 15
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To the attention of the Director

Valence, 29 September 2017

Réf. AMPLITUDE : COMP-0567 (EN)

Objet : **RECALL**
GENERIC® femoral stem - AMPLITUDE

Dear Partner,

AMPLITUDE initiates a batch recall.

Reason for recall
It has been reported to Amplitude that a GENERIC® femoral stem cemented taper 10/12 size 4 was found in a box labelled "size 3". The origin of this incident is a mix-up between two batches of different stem sizes during the manufacturing process. The investigation shows that a size 3 femoral stem's batch and a size 4 femoral stem's batch are partially impacted by this non conformity. The information engraved on the femoral stem regarding the size is correct.

Circumstances and risks for the user and/or the patient
Although no clinical consequence were reported relating to this event, the circumstances or the risks for the patients might be.
If the error is identified before implantation:

- Surgery delay if another implant with the right size is available,
- Surgery delay if the operative preparation can be changed and adjusted to the available implants,
- Postoperative instability related to the impossibility to restore the articulation center with the available femoral stems and the available femoral heads.

If the error is not identified before implantation:

- Surgery delay if the femoral stem height difference can be maked up by femoral heads with different neck lengths,
- Postoperative instability related to the impossibility to restore the articulation center with the available femoral stems and the available femoral heads,
- Femur breakage related to an excessive impaction in cases where the surgeon might try to position the stem at the expected level of the resection plan by an over impaction.

If the error is not identified during the surgery:

- Postoperative instability related to a wrong restoration of the articulation center,
- A sinked down position of the femoral stem inside the femur related to a too thick cemented coat.

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Concerned devices

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

Reference REF	Designation	Batch number LOT
1-0100203	GENERIC® femoral stem - cemented taper 10/12 size 3	259789
1-0100204	GENERIC® femoral stem - cemented taper 10/12 size 4	259252

The communication for the users is detailed in the attached safety notice mail template.

As part of the safety notice procedure and according to contractual arrangements, we ask you to:

- Conduct local regulatory notification to the competent authority. Deliver the FSCA form if applicable (Europe),
- Inform the healthcare facilities using the attached mail if applicable.

We thank you to acknowledge receipt of this mail by sending back the attached form fully completed to AMPLITUDE Regulatory Affairs department.

The French Health Agency (ANSM) has been informed of this safety information.

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 it may cause and thank you for your understanding.

[redacted]

vigilance@amplitude-ortho.com

Attachments :

- Acknowledge receipt form,
- FSN mail template in English.