Healthcare facility
Adress

To the attention of the vigilance Safety Officer
and orthopaedic surgery departments.

Valence, March 13th, 2025

Field Safety Corrective Action - RECALL

Reference AMPLITUDE: ISSUE-1045

Single Registration Number (SRN) AMPLITUDE: FR-MF-000003453

Device: EVOK Femoral Stem - Standard Offset - Collarless - Cemented - Taper 12/14 - Size 8

Reference	UDI-DI	Designation	Lot number
1-0196708	03701089549189	EVOK Femoral Stem - Standard Offset - Collarless - Cemented - Taper 12/14 - Size 8	320604 320885 328750 331239 331581 338427 347342 406424 407111 409198 409655 410857

Reason for recall

A potential non-conformity of some EVOK Femoral Stem - Standard Offset - Collarless - Cemented - Taper 12/14 - Size 8 has been identified. A calculation error in the control specifications led to the manufacturing of cemented femoral stems near the tolerance threshold. This calculation error only applies to size 8 cemented femoral stems from the EVOK range. As a result, some femoral stems may be at the tolerance threshold or slightly non-compliant.

As a safety measure, AMPLITUDE has decided to initiate a recall of all size 8 devices on the market.

Potential risks for user and/or patient

Mechanical fatigue tests performed on EVOK cemented femoral stems presenting the worst case of non-compliance did not reveal any risk of breakage. This risk is therefore still assessed as improbable according to the device's risk management file.

No complication linked to an EVOK cemented femoral stem size 8 (reference: 1-0196708) has been reported.

No additional follow-up of implanted patients is recommended. We recommend evaluating the possible occurrence of this event and associated risks during the regular post-operative follow-up of implanted patients.

Actions required

Our traceability data indicates that you have received devices from concerned batches.

We kindly ask you to distribute this notice to the relevant professionals concerned in your Healthcare facility to prevent the use of those impacted devices from your stock. These devices must be identified and quarantined.

Please fill and return the attached return form to AMPLITUDE (Annex 1 of this notice)

Your local representative will contact you to organize the recall of the devices and is available to provide any additional information.

Additional information

Competent Authority has been notified of this recall.

We remind the requirement to report all observed side effect with this device to your local Competent Authority (**Contact to be added**).

We highly appreciate your support and your cooperation to handle this recall. We apologize for the inconvenience caused and we thank you for your understanding.

Mireille LEMERY
Vice-Président Qualité Affaires Réglementaires – correspondant matériovigilance
vigilance@amplitude-ortho.com

Attachment: ANNEX 1 – Customer acknowledgement form

ANNEX 1 – Customer Acknowledgement Form - For Healthcare facility

Field Safety Corrective Action
RECALL

Reference AMPLITUDE: ISSUE-1045
Single Registration Number (SRN) AMPLITUDE: FR-MF-000003453

Device: EVOK Femoral Stem - Standard Offset - Collarless - Cemented - Taper 12/14 - Size 8

Reference	UDI-DI	Designation	Lot number	Quantity
1-0196708	03701089549189	EVOK Femoral Stem - Standard Offset - Collarless - Cemented - Taper 12/14 - Size 8	320604 320885 328750 331239 331581 338427 347342 406424 407111 409198 409655 410857	

☐ I confirm receipt of the Field Safety Notice, I have read and understood its content. The information and required actions were distributed to all relevant people concerned in the Healthcare facility.

☐ I confirm that all inventory locations of my Healthcare facility have been reviewed. I confirm that I have isolated (quarantined) involved devices pending removal, where applicable.

Please fill the table above with the quantities (specify 0 if you have no stock) and return this form at the latest on XX/XX/XX by fax (+33 4 75 41 41 78) or by email (vigilance@amplitude-ortho.com).

Healthcare facility name :
Your name: **Position:** **Date:** **Signature / Stamp:**