AMPLITUDE

Healthcare Facility
Address

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

Valence, July 26th 2019

Ref. AMPLITUDE: COMP-1163

Object: **BATCH RECALL**
SATURNE® tripolar cup - Cemented - AMPLITUDE

Reason for recall
Following feedback from a Healthcare facility, we identified the presence of SATURNE® tripolar cup size 46 inside a box with labels specifying size 48. The most probable cause is a mix-up between 2 batches during the packaging phase. The investigation reveals that a batch of size 46 and a batch of size 48 are partially impacted by this error. The size information engraved on the cup is correct.

Circumstances and risks for the user and/or the patient
In case of a device labelled with the incorrect size, the size difference will be detected during the handling of the cup using the impactor tip. It would generate an increase of surgical time, in order to procure a cup of the planned size in stock at the Healthcare facility or to ream at the upper diameter if no other cup of the planned size is available.

Concerned device
The traceability data indicates that you were provided products from the concerned batches:

Reference REF	Designation	Batch LOT
1-0106248	SATURNE® tripolar cup - Cemented Size 48	276713
1-0106246	SATURNE® tripolar cup - Cemented Size 46	276711

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What you must do

- Please circulate this notice to the related individuals in order to prevent the use of those devices in the Healthcare facility.
- Hold the devices concerned by this recall in quarantine.
- Return these devices to Amplitude.

We 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 recall procedure.

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

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