Healthcare Facility
Address

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

Valence, September 26th 2019

Ref. AMPLITUDE: ISSUE-0584

Object: **BATCH RECALL**
SCORE® tibial baseplate - Cemented - AMPLITUDE

Reason for recall
During internal review, it has been detected that a baseplate with a small scratch on the polished surface was released on the market. The root cause is attributed to a human error during handling of non-conformities. The investigation reveals that only one part of the batch is impacted by this non-conformity (other parts are compliant).

Circumstances and risks for the user and/or the patient
There is a risk of premature wear of the inlay which may lead to revision.

In case of implantation, no specific patient follow-up is recommended.

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

Reference REF	Designation	Batch LOT
1-0200503	SCORE tibial baseplate for mobile bearing insert – Cemented – Size 3	292399

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.

AMPLITUDE

Other information
The national competent authority is advised about this recall procedure.

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

[redacted]