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May 20th, 2014

To the attention of head of vigilance and the orthopedic surgery department

Ref. AMPLITUDE : AQ 14 0130

Subject: **Batch recall**
Cotyle double mobilité SATURNE – AMPLITUDE

As part of the routine controls of the microbiology load prior sterilization, our contract laboratory issued results with lack of accuracy for part of the production of SATURNE dual-mobility acetabular cups.

As a consequence we can not check if the critical specification to guaranty the sterility was verified or not.

This is the reason for recall of the following batches :

Reference	Designation	Batch number	Expiry date
1-0103358	Cotyle double mobilité SATURNE de reconstruction HAP sans ciment Taille 58	202269	2019-03

We identified your hospital have some of these products on stock.

Please forward this mail to the related departments and check your stock. The concerned products must be put in quarantine and returned to the distributor AMPLITUDE GmbH.

The competent authorities are informed about this recall.

We remind you that any adverse event when using these devices must be declared to the BfArM national competent authority.

We apology for the inconvenience and thank you for your cooperation.

[REDACTED]
Quality Management
Customer Service