



Amplitude GmbH • Am Neuen Graben 15 • 55576 Zotzenheim

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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

Amplitude GmbH  
Am Neuen Graben 15  
55576 Zotzenheim  
Telefon 0 67 01 / 20 55 20  
Telefax 0 67 01 / 20 55 21

Geschäftsführer  
Dr. Werner Seibel  
Olivier Jallabert  
info@amplitude-ortho.de  
www.amplitude-ortho.de

Bankverbindung:  
Mainzer Volksbank  
BIC: MVBMD55XXX  
IBAN:  
DE52551900000787305010

HRB Nr. 43090  
Amtsgericht Mainz  
Str.: 08 650 05760  
USt.-ID: DE273212918