

Customer  
Address 1  
Address 2

Medical Device – Advisory Notice

Attention: Hospital Director, Risk Management, Medical Device Vigilance Coordinator

July, 17<sup>th</sup> 2014,

Name of the product	Reference	Batch
CALCIBON PASTE 5G	3030050001	P015105/1
CALCIBON PASTE 10G	3030100001	P015210/1

Dear Sir, Madam,

This Advisory Notice is to inform you of a bar code error located on the label (both outside packaging and patient label) in relation to the following products :

CALCIBON PASTE 5G Ref: 3030050001 Batch: P015105/1  
CALCIBON PASTE 10G Ref: 3030100001 Batch: P015210/1

Our records indicate that we may have shipped certain products from this batch to your hospital.

**The reason for this action:**

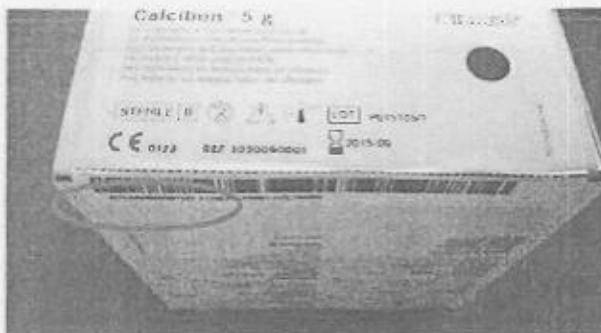
An investigation has revealed that:

1. The products with batch number P015105/1 have an incorrect EAN code written under the barcode: the printed EAN refers to Calcibon 20g instead of Calcibon 5g. When scanning the barcode, it appears the reference 3030200001 (Calcibon 20 g) instead of 3030050001 (Calcibon 5g) .
2. The patient labels indicate REF 3030100001 (Calcibon 10g), Lot, P015105/1 instead of REF 3030050001 (Calcibon 5g), Lot, P015105/1.
3. The products with batch number P015210/1 have an incorrect EAN code written under the barcode: the printed EAN refers to Calcibon 20g instead of Calcibon 10 g. When scanning the barcode, it appears the reference 3030200001 (Calcibon 20 g) instead of 3030100001 (Calcibon 10g)

It should be noted that the affected product is manufactured in accordance with pre-defined specifications and all necessary regulatory information on the label (batch number, item part and expiry date) are correct.

See pictures below:

- Incorrect EAN code on the top label:



Picture 1

- Incorrect reference patient label



Picture 2



**Possible risks:**

No adverse health outcome has been identified as the affected products are still in accordance with pre-defined specifications. In addition, the identification on the top label of the affected products are still correct and the traceability is maintained as batch numbers are correct both on top labels and patient labels.

**What we kindly request you to do:**

1. We kindly ask you to look at your inventory if you have performed a scan of the bar code. If you did, please make the appropriate change in your system.
2. In case you want to perform a product exchange, products can be returned to your local Biomet distributor at the address on the cover letter.
3. Please give this information to each person in your organization that uses or orders these products. Additionally, please ensure that a copy of this letter is provided to any other organization to which the products may have been transferred.

We thank you in advance for your attention to this matter.

We would like to apologize for this issue and any inconvenience caused by this matter.

If you have any questions regarding this communication, we kindly ask you to contact your local Biomet representative.

Yours sincerely

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Management Representative of Biomet Orthopaedics Switzerland GmbH

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Biomet France

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