Customer
Address 1
Address 2

Medical Device – Advisory Notice

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

April 8th, 2013,

Name of the product	Reference	Batch
Optipac Refobacin Revision 40	4730501163	103AAH2301

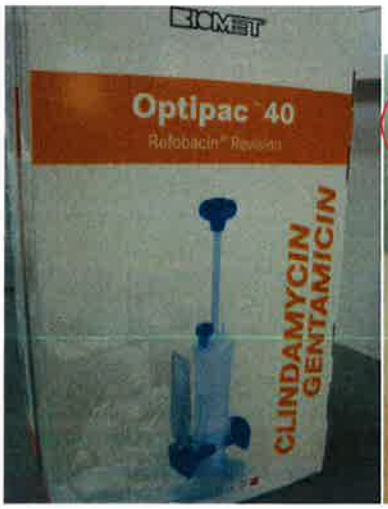
Sir, Madam,

This Advisory Notice is to inform you of a labeling error which affect the Optipac Refobacin Revision 40 listed above. Our records indicate that we have shipped products from the partially affected batch to your hospital. We are kindly requesting that you locate and discontinue use of any of the products from this batch and follow the recommendations listed below. The affected incorrectly labeled products must be returned to Biomet or to your local Biomet Distributor at the address on the cover letter.

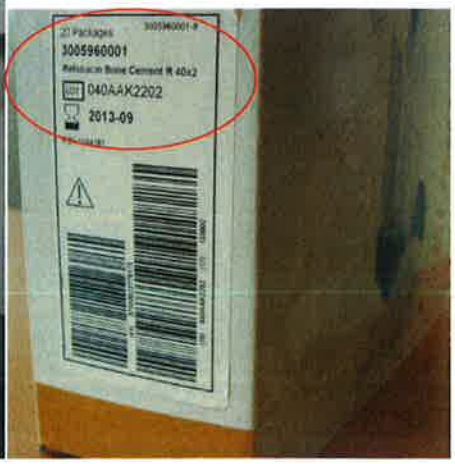
The reason for this action:

Optipac Refobacin Revision 40 is used for stable anchoring of suitable joint prostheses in primary operations, with added protection against infection, particularly in patients over 60 years of age; also in revision operations resulting from aseptic loosening of the prosthesis and infection of the surroundings of the prosthesis by gentamicin and/or clindamycin sensitive strains.
Biomet Orthopaedics Switzerland GmbH is the manufacturer of the Optipac Refobacin Revision 40.

An investigation has highlighted that a limited quantity of pieces of the batch listed above may present, on the individual packaging, an incorrect label which does not match with the product Optipac Refobacin Revision 40, reference 4730501163/batch 103AAH2301, expiry date 2012-07, but with a Refobacin Bone Cement R 40X2, reference 3005960001/batch 040AAK2202, expiry date 2013-09 (see labels below).
The patient labels and the label applied in the breather bag inside the individual box are compliant to the specifications required. The incorrect label is easily detectable as the identification of the product on the label is different from what is indicated on the packaging.



Non Conforming label



It should be noticed that beside the incorrect label on the individual packaging, the product Optipac Refobacin Revision 40 meets the pre-defined specifications of Biomet Orthopaedics Switzerland GmbH, but the product has expired on July 2012 (2012-07). The Refobacin Bone Cement R 40X2 is not affected by this labeling error.

Possible risks:

Following the investigation, it has been estimated that 0, 39 % of the products of the affected batch may present an incorrect label. The probability to use an expired product, by considering the expiry date of September 2013 (2013-09) of the product Refobacin Bone Cement R 40X2, reference 3005960001/batch 040AAK2202, has been assessed as remote.
The risk associated with the use of the expired Optipac Refobacin Revision 40, reference 4730501163/batch 103AAH2301 until September 2013 may be negligible following the outcome of an evaluation conducted on its performance, stability and sterility.

However, as a precautionary measure, Biomet has decided to issue this Advisory Notice to inform our customers of this mislabeling.

Please take due notice of the remaining information for an explanation of this NOTICE.

What we kindly request you to do:

1) To assist us with this action please locate any incorrectly labeled products and remove them from your inventory as soon as possible. Please place any incorrectly labeled affected products in a quarantine area pending return to Biomet or to your local Biomet distributor. The products that are confirmed adequately labeled should have been used or scrapped by you as the product has expired since 2012-07.

2) Please discontinue the use of any product identified as incorrectly labeled.

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 affected products may have been transferred.

4) Sign and return the enclosed "Fax-back form", and indicate the number of incorrectly labeled products that you would like to return. This fax-back form confirms that you have received, duly read, understand and will fully comply with this notice.

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

We would like to apology 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,

Florian Bornschein
Management Representative

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Quality and Regulatory Director

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