

URGENT MEDICAL DEVICE ADVISORY NOTICE

August 17th, 2016

To: Health Care Professionals

HHE 2016-02 - affected products: All items listed in the below Table 1.

Item	Description	Batches
4711500396-1	OPTIPAC 60 REFOBACIN BONE CEMENT R	A538B08715
4711500396-1	OPTIPAC 60 REFOBACIN BONE CEMENT R	A540B08715
4711500396-1	OPTIPAC 60 REFOBACIN BONE CEMENT R	A601C09945

Table 1: Affected products

Dear Valued Customer,

This Advisory Notice is to inform you about a product non conformity which affects the packaging of the Optipac 60 Refobacin Bone Cement listed above. Our records indicate that you received at least one of the affected batches. We kindly request you to follow the recommendations below.

Biomet France Sarl has initiated this action after having received a complaint indicating that an OPTIPAC 60 REFOBACIN BONE CEMENT R was packaged in an OPTIPAC 40 REFOBACIN BONE CEMENT R folding box.

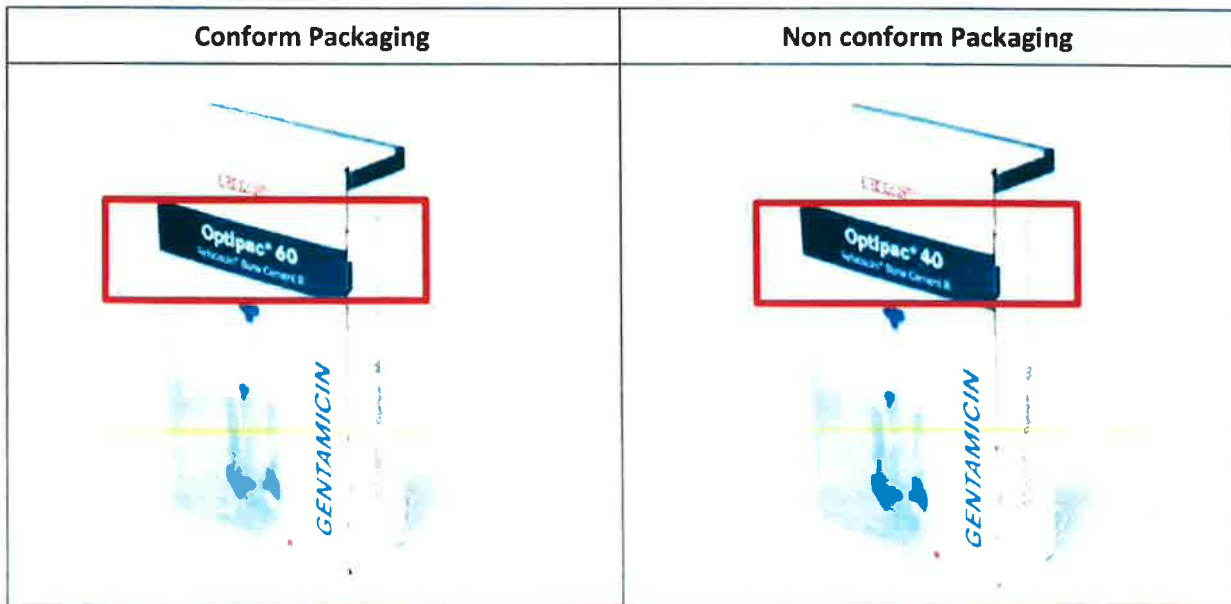




Table 2: Issue description

Investigation revealed that the above non-conformity is solely related to the folding box. Please see above photos. All the labels (internal, external and patient labels) are referring the correct product identification (i.e. Refobacin R 60) and the product inside the box is conforming.

The OPTIPAC 60 REFOBACIN BONE CEMENT R and the OPTIPAC 40 REFOBACIN BONE CEMENT R have the same cement composition and the difference between the two of them is solely the quantity of cement (20 additional grams in the Optipac 60) supplied.

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External label OPTIPAC 60 REFOBACIN BONE CEMENT	Product in the box OPTIPAC 60 REFOBACIN BONE CEMENT
	

If the product is used, no adverse health outcome is expected as the OPTIPAC 60 REFOBACIN BONE CEMENT R and the OPTIPAC 40 REFOBACIN BONE CEMENT R have the same cement composition and the product inside the packaging is conforming to manufacturer specifications.

What we kindly request you to:

1. Read this information carefully and forward to all people within your organization that may utilize this product.
2. Complete and return the attached "Response Form" to Biomet France Sarl or to your local Zimmer Biomet distributor. This confirms that you have received, duly read and understood this Advisory Notice and will fully comply with this notice.

We regret any inconvenience caused by this Advisory notice, and thank you in advance for your support. If you may have any questions regarding this communication, we kindly ask you to contact your local Zimmer Biomet representative.

Yours sincerely,



Florian Bornschein
Management Representative

Biomet Orthopaedics Switzerland GmbH
CH – 8953 Dietikon



Zarko Herzenjak
Managing Director – Plant Director

BIOMET France SARL
Plateau de Lautagne – 26000 Valence France

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ATTACHMENT:

BUSINESS REPLY FORM, Optipac® - HHE 2016-02

Instructions:

1. Complete the Business reply form below
2. Fax to **+33 (0)3 81 32 25 37**, or email a copy to per.fr@zimmerbiomet.com

Health care professional Acknowledgement

I have received and read the Advisory Notice from BIOMET France SARL for the subject. I am informed of the reasons for the Field Action and have informed appropriate health care providers.

Name
Address
Phone number
Signature
Date