



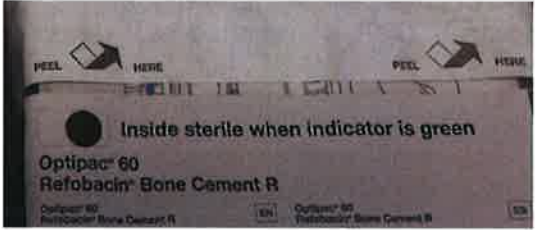
December 12, 2019

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE - CORRECTION**



Affected Product: OPTIPAC

See Attachment 2 – List of Products in Scope

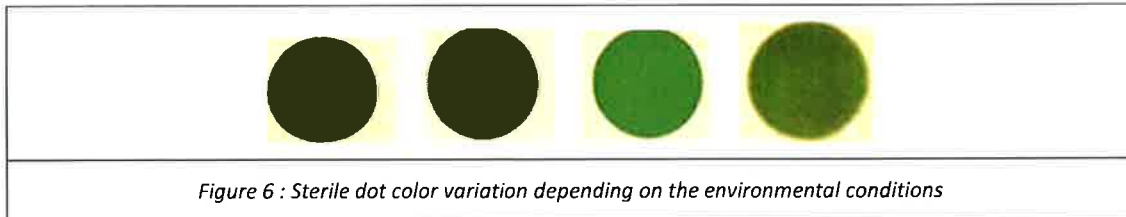
		
<p><i>Figure 1 : Optipac system</i></p>	<p><i>Figure 2 : Breather bag of the Optipac</i></p>	<p><i>Figure 3 : Packaging detail - sterile dot</i></p>

Biomet France Sarl and Biomet Orthopedics Switzerland GmbH are conducting jointly a Field Safety Corrective Action for certain Optipac products. Some color variations (different shade of green) of the sterile dot were reported through product complaints. To date, no adverse events have been reported. By means of this Field Safety Notice, we would like to inform the users that color variations in the sterile dots do not imply the product's sterility is affected, and that the products can continue to be used within their sterility date. This Field Safety Notice does not require return of any products.

Sterile dots are visual indicators indicating that the products were exposed to ethylene oxide sterilization process. They are not utilized as an ultimate quality control parameter for the sterilization process of our Optipac products. Initially, the sterile dot is purple, and it turns green after exposure.

	
<p><i>Figure 4 : Sterile dot before exposure</i></p>	<p><i>Figure 5 : Sterile dot after exposure</i></p>

A color variation (different shades of green as described in Figure 6) can be observed depending on sterilization conditions and also on the environmental conditions (temperature, relative humidity, contact with disinfectant vapor, exposure to light).



In accordance with the applicable procedures, all applicable sterilization criteria (physical parameters and biological indicators) are checked prior to the release of the product to the market. The sterilization process itself is validated and under control. No clinically relevant patient risk is expected from this issue.

Patient risks identified:

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>None</i>	<i>Insignificant extension of surgery (less than 30 min)</i>
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>None</i>	<i>None</i>

Our records indicate that you may have received one or more of the products in scope of this Field Safety Notice.

Hospitals Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. Forward the FSN to all those who need to be aware of the described issue
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send it to fieldaction.eire@zimmerbiomet.com. This form will need to be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your Field Action records for the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative or send your questions to fieldaction.eire@zimmerbiomet.com.



Other Information

This medical device Field Action is reported to all relevant Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.ie@zimmerbiomet.com.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your assistance. We regret any inconvenience caused by this correction.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Yannick Bossert', written over a horizontal line.

Yannick BOSSERT
QARC Director EMEA West



**ATTACHMENT 1
Certificate of Acknowledgement**

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Optipac

Field Action Reference: ZFA-2019-00325

Please check one as applicable:

Hospital Facility Surgeon

Do you have stock of affected product at your facilities?
(Hospital Facility Only: Please mark the appropriate response.)

Yes, we currently have one or more affected items in stock at our facilities.

No, we currently have no affected items in stock at our facilities.

By signing below, I acknowledge that the required actions have been taken in accordance with this Field Safety Notice.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** () _____ - _____ **Date:** ___/___/___

Facility Name: _____

Facility Address: _____

City: _____ **State:** _____ **ZIP:** _____

Note: This form will be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to fieldaction.eire@zimmerbiomet.com.

ATTACHMENT 2

List of Products in Scope

Item Number	Lot Number	Item Description
110035374	All lot numbers	OPTIPAC 40 BIOMET BONE CEMENT R
110035375	All lot numbers	OPTIPAC 60 BIOMET BONE CEMENT R
110035376	All lot numbers	OPTIPAC 80 BIOMET BONE CEMENT R
4709500392-3	All lot numbers	OPTIPAC KNEE REFOBACIN BONE CEMENT R
4710500394-3	All lot numbers	OPTIPAC 40 REFOBACIN BONE CEMENT R
4711500396-3	All lot numbers	OPTIPAC 60 REFOBACIN BONE CEMENT R
4712500398-3	All lot numbers	OPTIPAC 80 REFOBACIN BONE CEMENT R
4719502082-3	All lot numbers	OPTIPAC KNEE REFOBACIN PLUS BONE CEMENT
4720502083-3	All lot numbers	OPTIPAC 40 REFOBACIN PLUS BONE CEMENT
4721502084-3	All lot numbers	OPTIPAC 60 REFOBACIN PLUS BONE CEMENT
4722502117-3	All lot numbers	OPTIPAC 80 REFOBACIN PLUS BONE CEMENT
4740500394-3	All lot numbers	OPTIPAC HIPSET REFOBACIN BONE CEMENT R

Table 1: Biomet France Sarl products

Item Number	Lot Number	Item Description
4710500394-1	All lot numbers	OPTIPAC-S 40 REFOBACIN BONE CEMENT R
4711500396-1	All lot numbers	OPTIPAC-S 60 REFOBACIN BONE CEMENT R
4712500398-1	All lot numbers	OPTIPAC-S 80 REFOBACIN BONE CEMENT R
4740500394-1	All lot numbers	OPTIPAC SOFTPAC HIPSET

Table 2: Biomet Orthopedics Switzerland GmbH products

