ZIMMER BIOMET

December 12, 2019

**To:** Distributors, Sales Representatives, and Distributor Operation Managers

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

**Affected Product:** OPTIPAC

See **Attachment 2 – List of Products in Scope**

*Figure 1 : Optipac system*


*Figure 2 : Breather bag of the Optipac*

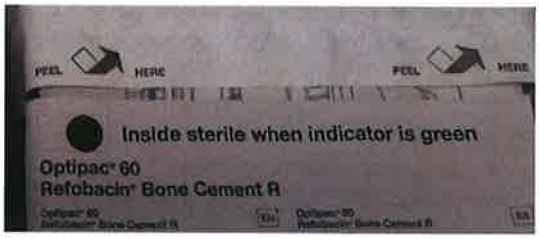


*Figure 3 : Packaging detail - sterile dot*

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.

*Figure 4 : Sterile dot before exposure*

*Figure 5 : Sterile dot after exposure*



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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).

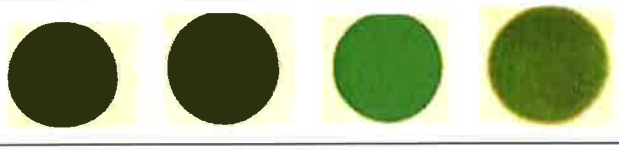

*Figure 6 : Sterile dot color variation depending on the environmental conditions*

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

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

**Your Responsibilities**

1. Review this notification and ensure that affected team members are aware of the contents.
2. Inform your customers with the Field Safety Notice for surgeons/ hospitals.
3. Ensure documentation from customers as requested.
4. 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.
5. Retain a copy of the acknowledgement form with your Field Action records for the event of a compliance audit of your facility's documentation.

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6. If you have further questions or concerns after reviewing this notice, please 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,

Yannick BOSSERT
QARC Director EMEA West

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# ATTACHMENT 1

**Certificate of Acknowledgement:**

By signing below, I acknowledge that I have received, read, and understand the contents of this Field Action communication. All required activities are complete or are being completed.

**Printed Name:** _____ **Signature:** _____

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

**Facility Name:** _____

**Facility Address:** _____

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

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

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# ATTACHMENT 2
## Affected Product List

| 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*