

16 January 2025

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (CORRECTION)**

Affected Product: Optipac® (see Attachment 2 - Affected Product List)

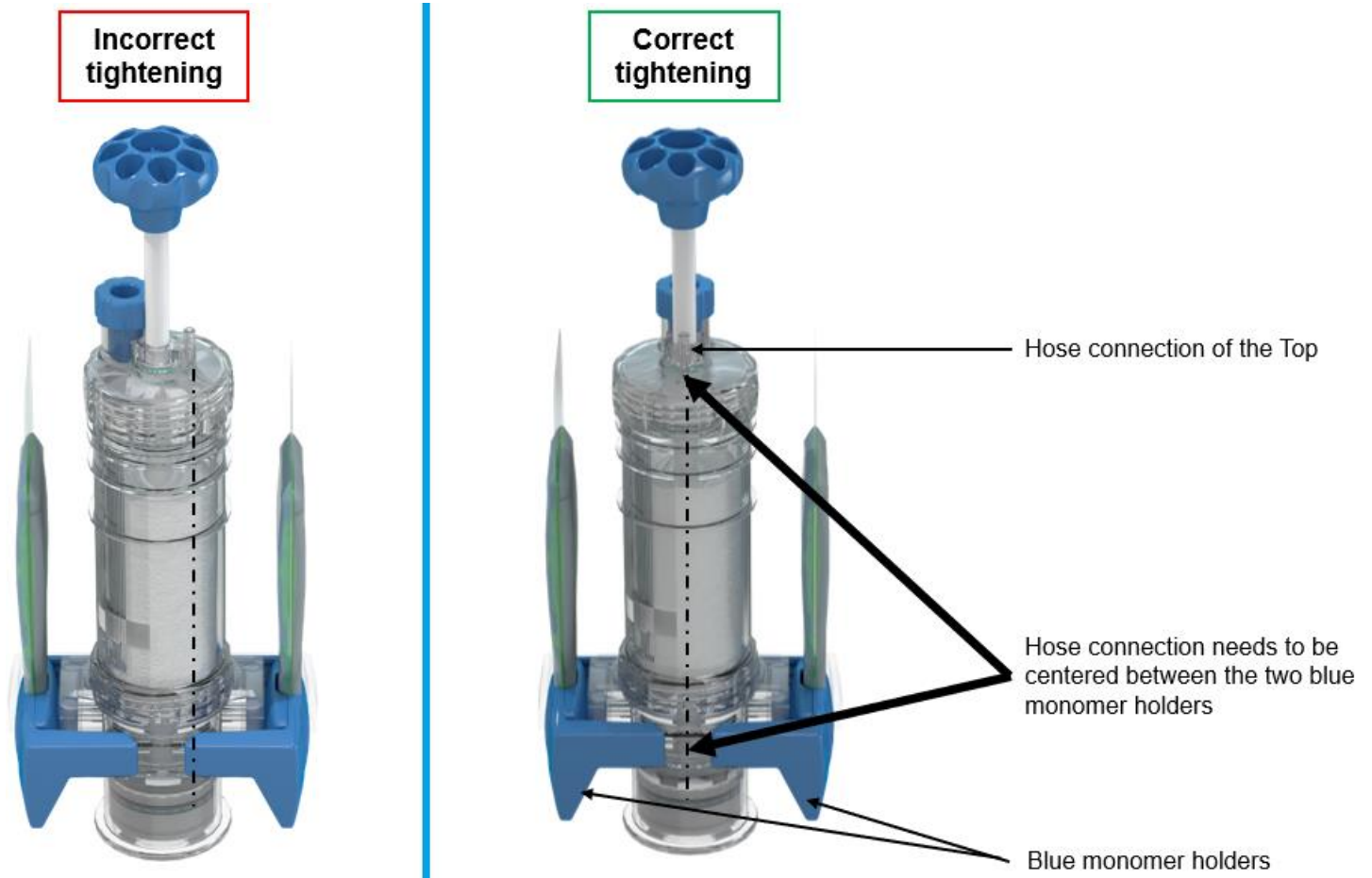


Figure 1: Incorrect tightening and correct tightening

Biomet France is conducting a medical device Field Safety Corrective Action (correction) for certain Optipac products due to an increased number of product complaints where it was reported that during the process of preparation, the monomer liquid does not enter into the cylinder once the blue monomer holders are pushed towards the middle of the cylinder. To date, no adverse events have been reported.

Following investigation, the issue can be linked to an incomplete tightening of the mixing rod when it is assembled with the cylinder during use. It can lead to an incomplete vacuum within the system, which can prevent the complete release of the monomer in the cylinder. The product cannot be used when the monomer liquid has not entered the cylinder, and it must be discarded after such occurrence. The above **figure 1** shows both the “incorrect tightening” and the “correct tightening” of the Optipac product.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Non-clinically significant increase of the surgical time.	Non-clinically significant increase of the surgical time.
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.

The current Instruction for Use (IFU) states “Screw the mixing rod on the cylinder and tighten firmly”. Please see **Attachment 2 - Affected Product List** for the applicable IFU versions.

By means of this Field Safety Notice, we inform you that we are conducting an update on the applicable IFUs to describe the assembling process in more detail. The IFU updates are estimated to be available in Q3 2025.

Scheduled update on the applicable IFU’s

The section “Process of preparation”, will include a new picture that illustrates the correct assembly, together with explanatory notes. Below you will find an extract of the scheduled update.

- *Screw the mixing rod on the cylinder and **tighten firmly**.*
- **Note 1:** *Make sure that the hose connection is centered between the two blue monomer holders as illustrated in figure aside (**Figure 2**).*
- **Note 2:** *An incorrect assembly can lead to a non-functional device due to air leakage. In such case, the monomer liquid may not enter (or partially enter) inside the cylinder.*

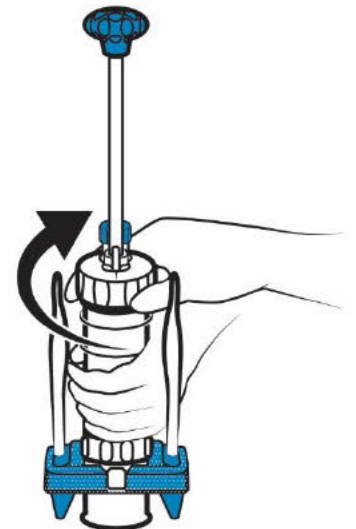


Figure 2: IFU illustration

Our records indicate that you may have received one or more of the affected products listed in **Attachment 2 - Affected Product List**. As Optipac has an 18-month sterile time, non-expired products were distributed since July 2023.

In the meantime, until the scheduled IFU updates are implemented, manufacturing of the affected products listed in **Attachment 2 - Affected Product List** will continue with their current IFU versions. Those newly manufactured products will be distributed with their current IFU versions and are therefore also affected by this Field Safety Notice.

Hospital responsibilities:

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If any affected product has been further distributed, provide your customer(s) with this Field Safety Notice and ensure documentation.
3. Complete **Attachment 1 - Certificate of acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com. This form must be returned even if you do not have any affected product currently available.
4. Retain a copy of **Attachment 1 - Certificate of acknowledgement** with your records in the event of a compliance audit of your facility.
5. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Surgeon responsibilities:

1. Review this Field Safety Notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
3. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Other information

This Field Safety Corrective Action was reported to all relevant Competent Authorities and Notified Bodies as required under the applicable regulations for Medical Devices per Regulation (EU) 2017/745 and guidance MDCG 2023-3. The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies. Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

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

We would like to thank you for your co-operation in advance and regret any inconvenience caused by this Field Safety Corrective Action.

Sincerely,



ATTACHMENT 1 - Certificate of acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Optipac®
Field Safety Corrective Action reference number: ZFA-2024-00248

Hospital Acknowledgement

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

Printed name		Title	
Facility name		Telephone number	
Facility address		ZIP / Post code	
City		Country	
Signature		Signing date <i>DD-MMM-YYYY</i>	

ATTACHMENT 2 - Affected Product List

Material number	Material description	Current version of Instruction for Use	Updated version of Instruction for Use
110035374	Optipac 40 Biomet Bone Cement R	Reference: 9878300190 IFU updated: 2019/10 Index: 03	Reference: 9878300190 Index: 04
110035375	Optipac 60 Biomet Bone Cement R	Reference: 9878300190 IFU updated: 2019/10 Index: 03	Reference: 9878300190 Index: 04
110035376	Optipac 80 Biomet Bone Cement R	Reference: 9878300190 IFU updated: 2019/10 Index: 03	Reference: 9878300190 Index: 04
4710500394-3	Optipac 40 Refobacin Bone Cement R	Reference: 9878300160 IFU updated: 2022/12 Index: 04	Reference: 9878300160 Index: 05
4711500396-3	Optipac 60 Refobacin Bone Cement R	Reference: 9878300160 IFU updated: 2022/12 Index: 04	Reference: 9878300160 Index: 05
4712500398-3	Optipac 80 Refobacin Bone Cement R	Reference: 9878300160 IFU updated: 2022/12 Index: 04	Reference: 9878300160 Index: 05
4720502083-3	Optipac 40 Refobacin Plus Bone Cement	Reference: 9878300170 IFU updated: 2019/10 Index: 03	No IFU update will occur as the product was discontinued in May 2024.
4721502084-3	Optipac 60 Refobacin Plus Bone Cement	Reference: 9878300170 IFU updated: 2019/10 Index: 03	No IFU update will occur as the product was discontinued was May 2024.
4722502117-3	Optipac 80 Refobacin Plus Bone Cement	Reference: 9878300170 IFU updated: 2019/10 Index: 03	No IFU update will occur as the product was discontinued was May 2024.