September 22, 2020

To : Healthcare facilities

Subject : **URGENT FIELD SAFETY NOTICE – REMOVAL**

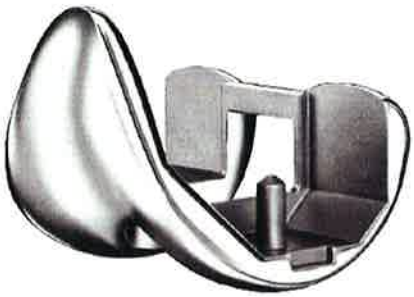
Reference: **FA 2020-01**

Affected Products: **FIRST® Femur Cemented**

Dear Madam, Dear Sir,

Symbios Orthopédie SA is conducting a voluntary medical device Field Safety Corrective Action (removal) for seven (7) lots. Please find below the affected lots:

Product name	Product reference	Lot number
FIRST Femur Cemented F1/LEFT	5002 1031	1025491B+
FIRST Femur Cemented F1/RIGHT	5002 1021	1077661-
FIRST Femur Cemented F1/LEFT	5002 1031	1096641-
FIRST Femur Cemented F1/LEFT	5002 1031	1121291-
FIRST Femur Cemented F2/L	5002 1032	1122221-
FIRST Femur Cemented F1/RIGHT	5002 1021	P015493B-
FIRST Femur Cemented F1/LEFT	5002 1031	P015714A-



Picture 1: FIRST® Femur Cemented product

Symbios Orthopédie SA was informed through ANSM who transferred to Symbios a customer complaint of a potential mix-up related to the above lots. The affected products of the above lots are suspected to have a physical product not matching the box label.

The potential risks associated to the issue are the following:

Risks		
Immediate health consequences that may result from use of or exposure to the product issue	Most probable	Highest severity
	Slight delay during the surgery (< 30 min) after discovery of the issue and replacement of the product.	Aborted surgery due to the absence of a replacement device to complete the surgery.
Long-term health consequences that may result from use of or exposure to the product issue	Most probable	Highest severity
	None.	Potential complication due to extension of anesthesia.

As a precautionary measure, Symbios Orthopédie SA has decided to recall the potentially affected products. Our records indicate that you may have received one or more of these product lots. To date, no adverse health outcome has been reported.

Your Responsibilities:

1. Review this notification and ensure affected team members are aware of the content.
2. Immediately locate and quarantine affected product(s) in your inventory.
3. Complete **Annex 1 – Certificate of Acknowledgement** hereafter.
    a. Return a digital copy to regulatory@symbios.ch as soon as possible and provide the original copy to your local Symbios contact. **This certificate must be returned even if you do not have any affected products in your facility**.
    b. Retain a copy of the Certificate of Acknowledgement with your records in the event of a compliance audit of your documentation.

Once the digital copy of certificate of acknowledgement will be received, Symbios Orthopédie SA will organize the return of the product and its replacement at our expense.

Other Information

This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Symbios Orthopédie SA informed of any adverse events associated with these identified product lots or any other Symbios Orthopédie SA products by emailing regulatory@symbios.ch or to your local Symbios contact.

The undersigned confirms that this notice has been delivered to the relevant Competent Authorities.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this Field Safety Corrective Action.

Sincerely,

Nicolas Guignet
Regulatory Affairs & Quality Assurance Vice President

symbios

Annex 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED - URGENT ACTION NEEDED

Affected product: FIRST® Femur Cemented **Field Action reference: FA 2020-01**

Please tick the relevant box:

☐ **Yes**, we currently have one or more affected products in stock at our facility.
[If so, please fill in the table below.]

☐ **No**, we do not have any affected product in stock in our facility.

Identified impacted product lots:

Product name	Product reference	Lot number	Quantity

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

Name: _____ **Signature:** _____

Title: _____ **Tel:** _____ **Date:** ___/___/_____

Name of healthcare facility: _____

City: _____ **Region:** _____ **Postcode:** _____

Once the digital copy of this certificate of acknowledgement will be sent to regulatory@symbios.ch, Symbios will organize the return of the product(s) and the replacement at our expense.

Note: This form must be returned to Symbios Orthopédie SA before this action can be considered closed for your account. It is important that you complete this form and email a copy to: regulatory@symbios.ch in addition to including a copy with your product returns.