

April xx, 2021

To: Hospitals and Surgeons

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

Reference: **ZFA 2021-00063**

Affected Product: ROSA One 3.1 Brain application – endoscopy mode

| Serial Number | UDI Number |
|---------------|------------|
| BSXXXXXX | XXXXXXX |



ROSA One 3.1 Brain Application

Medtech S.A - Zimmer Biomet - is initiating a medical device Field Safety Corrective Action (Correction) for ROSA One 3.1 Brain application products. This Field Safety Notice informs you of the issue and the corrective actions Zimmer Biomet is taking.

Description of the issue:

Medtech S.A - Zimmer Biomet has become aware of an event where a software anomaly affecting the endoscopy module of ROSA One 3.1 Brain application led to a transient deactivation of the security zone followed by an unexpected blockage of the robot arm.

The ROSA One 3.1 Brain application system is an image-guided device that assists the surgeon in planning the position of instruments and/or implants on preoperative or intraoperative images. It provides a stable, accurate and reproducible mechanical guidance in accordance with the planning.

The robot arm is intended to position the instrument holder on the selected trajectory so that rigid neurosurgical instruments such as drill bit, cannula, endoscope, etc. - are inserted through the adaptor to perform the intended surgical procedure.

When using the ROSA device in endoscopy, the surgeon manipulates the endoscope through the ROSA “cooperative mode” feature inside a defined security zone until a satisfactory image is obtained. Therefore, the endoscope is guided manually through the cavities (e.g. brain ventricles), trying to keep the region of interest in the most appropriate part of the field of view, enabling proper positioning of the surgical tools, if any.

While the deactivation of the security zone was not detected in the sole complaint report received to date, the subsequent blockage of the robot arm followed by an impact of the endoscope with the skull bone, led the user to switch to traditional surgery.

No adverse consequence for the patient has been reported to date.

If the deactivation of the security zone is not detected by surgical staff during surgery, this could result in a robot arm blockage, difficulties to withdrawn the endoscope from the patient’s head, or serious injury or death.

Below are the potential risks associated with this issue and the steps that may result in this issue occurring.

| | | |
|--|---|------------------|
| Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue. | Most Probable | Highest Severity |
| | Delay <30 minutes, Delay >30 minutes | Nerve injuries |
| Describe long range health consequences (injuries or illness) that may result from use of or exposure to the device issue. | Most Probable | Highest Severity |
| | No injuries expected | Nerve injuries |

Steps that may result in the issue:

- The device is used in endoscopy mode.
- The user handles the endoscope in the security zone, in cooperative mode, near the security zone limits.
- The software detects an issue with the cooperative mode, displays a warning message, and the cooperative mode stops (as specified – mitigation).
- The issue occurs when the cooperative mode resumes with the security zone deactivated and the arm speed set to “Slow” (which is a higher speed than initially selected by the user).

Pending the implementation of a corrective action, Medtech S.A - Zimmer Biomet - advises that **the endoscopy module of the ROSA One 3.1 Brain application software shall not be used for surgery.**

Zimmer Biomet Corrective Action:

1. Notifying affected customers of the Medical Device Field Safety Corrective Action.
2. A Zimmer Biomet engineer will be deployed to your site to deactivate the endoscopy module on your ROSA One 3.1 Brain application unit. Removal of the endoscope calibration files stops the end user from being able to execute the endoscopy surgical option and removes all the identified above risks. You will be contacted by the 30th of April, 2021 with additional information regarding this planned update and the estimated timing.
3. A Zimmer Biomet engineer will then be deployed to your site to implement a new software version to correct the issue. You will be contacted by the 31st of May, 2021 with additional information regarding this planned update and the estimated timing.

Transmission of this Medical Device Field Safety Corrective Action:

Please advise the appropriate personnel working in your department with the ROSA One 3.1 Brain application system of the content of this Field Safety Notice.

Hospital Responsibilities:

1. Review this Field Safety Notice and ensure affected personnel are aware of the contents.
2. Complete **Attachment 1 – Certificate of Acknowledgement** and send to Medtech_FSCA@zimmerbiomet.com.
3. Retain a copy of the acknowledgement form with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
4. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your 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. Complete **Attachment 1 – Certificate of Acknowledgement** and send to Medtech_FSCA@zimmerbiomet.com.
4. Retain a copy of the Certificate of Acknowledgement with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

Other Information

This 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 as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this units or any other Zimmer Biomet product by emailing Medtech-CHT@zimmerbiomet.com. or to your local Zimmer Biomet contact.

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

The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies.

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



Sincerely,

████████████████████
Interim QA Vice President

ATTACHMENT 1 Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: ROSA One 3.1 Brain application**Field Action Reference: ZFA-2021-00063**

Please return the completed form to your Zimmer Biomet contact person or by e-mail
Medtech_FSCA@zimmerbiomet.com

I received and understood the Field Safety Notice.

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

Hospital Facility **Surgeon** *(Please check one as applicable)*

Printed Name: _____ **Signature:** _____ **Date:** ____/____/____

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

Facility Name: _____ **Facility Address:** _____

City: _____ **ZIP:** _____ **Country:** _____