

URGENT MEDICAL DEVICE CORRECTION

January 6, 2020

To: Hospital/Surgeon Name

Affected Product: ROSA Brain 3.0 and/or ROSA One 3.1 Brain application

Serial No.: Bxxxxxx



ROSA Brain 3.0 and ROSA One Application-Brain

Medtech S.A - Zimmer Biomet - is initiating a medical device Field Safety Corrective Action for Brain 3.0 and ROSA One 3.1 Brain application products. This notice informs you of the issue and the corrective actions Zimmer Biomet is taking. Our records indicate that you have received or use at least one of the affected products.

Description of the issue:

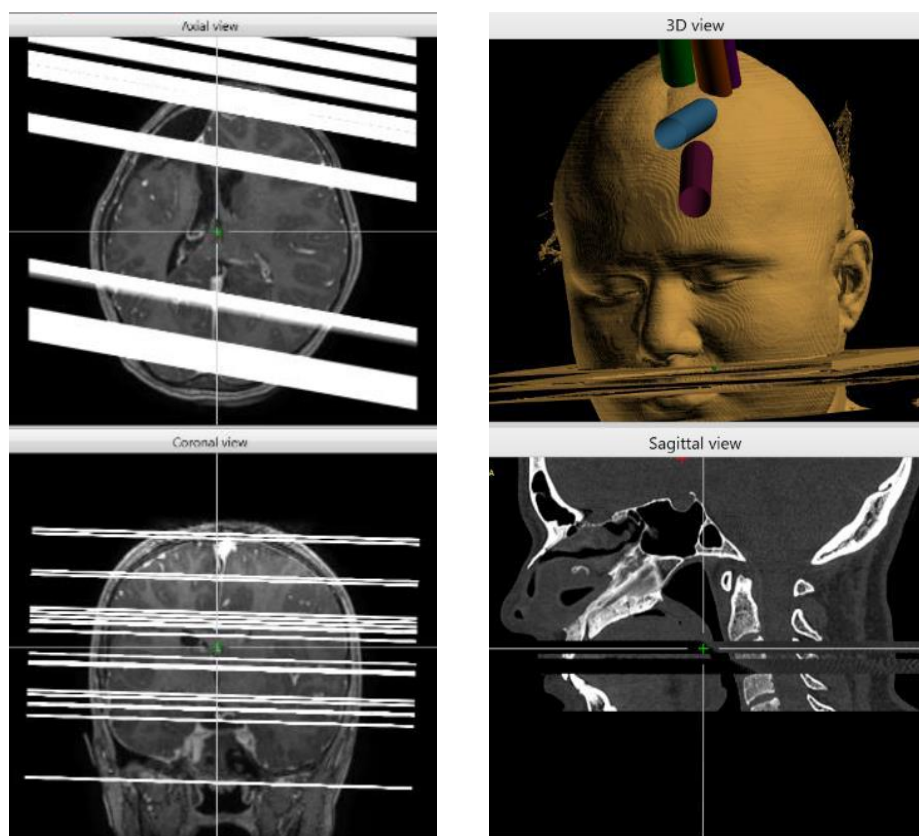
Zimmer Biomet is aware of events where some cross-sectional images from the image acquisitions of the patient's head are not reconstructed/displayed properly in two and three dimension views when using ROSA Brain software, potentially compromising the surgery planning.

The ROSA Brain system is an image-guided device that assists the surgeon in planning the position of instruments or implants on preoperative or intraoperative images. It provides a stable, accurate and reproducible mechanical guidance in accordance with the planning. An image acquisition of the patient's head (MRI / CT or 2D X-Ray images) is performed prior to surgery and loaded into the device. In the preoperative phase, the surgeon carries out the surgical planning on the patient images using the ROSA Brain software.

Failure of the device to properly display the medical images could compromise the preoperative planning phase. If such issue was not identified by surgical staff during preoperative planning prior to surgery, this could result in postponed, cancelled or aborted surgery.

This issue has resulted in three medical device reports (MDRs) being reported and in all of these cases, there were artifacts found in the original CT/MRI scan. The data from the scans were not properly read by the ROSA Brain software and therefore led to incorrect image display and reconstruction. The issue is highly detectable by the user and affects only the information displayed to the user. There is no impact on the geometry / topology of the reconstruction, and consequently distances, trajectories and device accuracy are not affected. In all of the reported cases, this issue was discovered prior to surgery.

Examples of the issue are provided below:



Examples of Reconstruction and Display Issues

Below are the risks associated with this issue.

Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	None / Additional CT or MRI scan / Surgical delay <30 min	If discovered after surgery has started, cancellation of the surgery
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	None	None

Actions Required By Users:

Your device can continue to be used, as long as the recommendations below are followed:

While the current Instructions For Use do not require the images to be reviewed with ROSA Brain software prior to surgery, they adequately describe the standard workflow and indicate that the image acquisition of the patient’s head (MRI / CT or 2D X-Ray images) is performed prior to surgery, and is then loaded into the device and used by the surgeon in the preoperative phase to carry out the surgical planning.

Due to this potential image management issue, **Zimmer Biomet recommends that images be reviewed using the ROSA Brain software prior to surgery.** If an issue is detected with the reconstruction and display of the images using the ROSA software, and if the artifacts are located in the Region Of Interest and prevent the surgical planning, then the surgery might have to be cancelled or converted to traditional surgery. However, if the artifacts are not located inside the Region Of Interest and if the surgery planning is successful, the affected device can continue to be used.

Zimmer Biomet Corrective Action:

1. Notifying affected customers of the Medical Device Correction.
2. Instructions regarding review of the images using the ROSA Brain software prior to surgery will be added directly to the ROSA unit by January 31, 2020 through a visit to your site by a Zimmer Biomet engineer or shipping to you with instructions for applying to the unit.
3. A Zimmer Biomet engineer will be deployed to your site to implement the updated ROSA software to address this issue, once it is available. It is estimated that these updates will begin approximately in May 2020 and be completed by September 2020.



Transmission of this Medical Device Correction:

Please advise the appropriate personnel working in your department with the ROSA system of the content of this letter.

Risk Manager Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Complete the enclosed Certificate of Acknowledgement.
 - a. Return a digital copy to CorporateQuality.PostMarket@zimmerbiomet.com.
 - b. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your facilities documentation.
3. If you have further questions or concerns after reviewing this notice, please call Perry Twyford at 281-389-3236 between 9:00 am and 6:00pm EST, Monday through Friday. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow up schedule.
3. Complete the enclosed Certificate of Acknowledgement.
 - a. Return a digital copy to CorporateQuality.PostMarket@zimmerbiomet.com
 - b. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your documentation.
4. If you have further questions or concerns after reviewing this notice, please call Perry Twyford at 281-389-3236 between 9:00 am and 6:00pm EST, Monday through Friday. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

- This medical device correction was reported to the U.S. Food and Drug Administration.
- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing Medtech-CHT@zimmerbiomet.com.



We would like to thank you for your cooperation in advance, and regret any inconveniences caused by this correction.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Escapule'.

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director