

**URGENT MEDICAL DEVICE CORRECTION****September 10, 2019****To:** Hospital/Surgeon Name**Affected Product:** ROSA Brain 3.0**Serial No.:** BRxxxxx

*ROSA Brain 3.0*

Medtech S.A - Zimmer Biomet - is initiating a medical device Field Safety Corrective Action for ROSA Brain 3.0 products. This notice informs you of the issue and the corrective actions Zimmer Biomet is taking.

**Description of the issue:**

**Zimmer Biomet is aware of events where the ROSA Brain 3.0 instrument holder was sent on a trajectory that is not within the intended target.** The robot arm is intended to position the instrument holder on the selected trajectory so that rigid neurosurgical instruments such as drill bit, screwdriver, cannula, etc. - are inserted through the adaptor to perform the intended surgical procedure.

While the incorrect trajectory was detected in all reports received to date (e.g. the robot arm is at an unusual distance from the patient's head, or the instrument is not at the correct position), if it is not corrected, the associated device may be placed incorrectly (e.g. the anchor bolt). Failure of the device to move to the correct trajectory, if not identified by surgical staff, could result in serious injury or death.

Below are the 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
	Surgical delay <30 minutes	Serious injury, brain cognitive injury, or death of the patient
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	Serious injury, brain cognitive injury, or death of the patient

Our records indicate that you may have received one or more of the affected products. The affected units were installed between February 2016 and March 2019.

**Steps that may result in the issue:**

After the registration of the patient within the ROSA Brain 3.0 device, the issue may occur only in the guidance mode (e.g. when the robot arm is on trajectory), when the user selects the optical distance sensor and sends the robot arm on each entry point, and then selects the instrument holder. In such case, the use of the "Undo" button in the Tool installation panel will result in the issue due to a software anomaly.

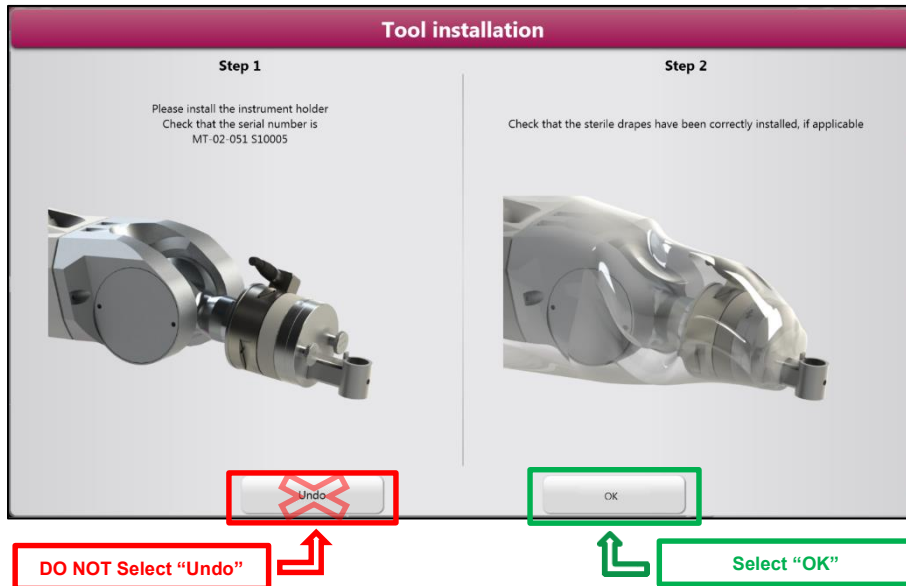
For clarity purposes, the full sequence of events leading to the issue along with the corresponding screenshots is detailed in the **Attachment 2 - Detailed sequence of events.**

**Required actions by users to prevent incorrect instrument configuration:**

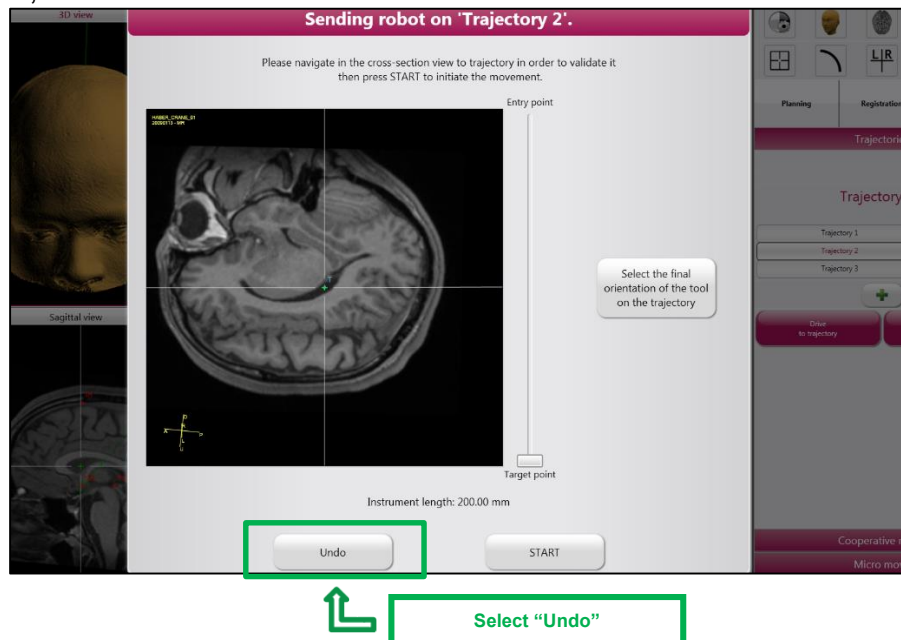
Pending the implementation of a corrective action, Medtech S.A - Zimmer Biomet - advises that the actions detailed on Page 3 of this letter be taken without delay by all users of the ROSA Brain 3.0 device.

## Actions Required By Users (Workaround):

- Once you select the instrument holder, if you would like to Undo your action :
  - DO NOT select "Undo"
  - Select "OK"



- In the next frame, select Undo



**Zimmer Biomet Corrective Action:**

1. Notifying affected customers of the Medical Device Correction. Note that when the workaround described above is followed the ROSA Brain 3.0 device can continue to be used.
2. The instructions on Page 3 of this notification will be provided in a form that can be applied directly to the unit by September 30, 2019 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 a new software version to correct the issue. You will be contacted by October 31, 2019 with additional information regarding this planned update and the estimated timing.

**Transmission of this Medical Device Correction:**

Please advise the appropriate personnel working in your department with the ROSA Brain 3.0 device 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 Attachment 1 – Certificate of Acknowledgement.
  - a. Return a digital copy to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto: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](mailto: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 Attachment 1 – Certificate of Acknowledgement.
  - a. Return a digital copy to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto: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](mailto: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](http://www.fda.gov/medwatch/report.htm)
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: [www.fda.gov/MedWatch/getforms.htm](http://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](mailto:Medtech-CHT@zimmerbiomet.com).

We would like to thank you for your co-operation 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

## ATTACHMENT 1 Certificate of Acknowledgement

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product: ROSA Brain 3.0      Field Action Reference: ZFA2019-00253**

<p style="text-align: center;"><b>Please check one as applicable:</b></p> <p style="text-align: center;"><input type="checkbox"/> Hospital Facility      <input type="checkbox"/> Surgeon</p> <p style="text-align: center;"><b>Do you have affected product in your facility?</b> (Hospital Facility Only: Please mark the appropriate response.)</p> <p><input type="checkbox"/> <b>Yes</b>, we currently have one or more affected items in our facility.</p> <p><input type="checkbox"/> <b>No</b>, we currently have no affected items in our facility.</p>
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By signing below, I acknowledge that the required actions have been taken in accordance with the Medical Device Correction.

**Printed Name:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

**Title:** \_\_\_\_\_ **Telephone:** (    ) \_\_\_\_\_ - \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Facility Name:** \_\_\_\_\_

**Facility Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **ZIP:** \_\_\_\_\_

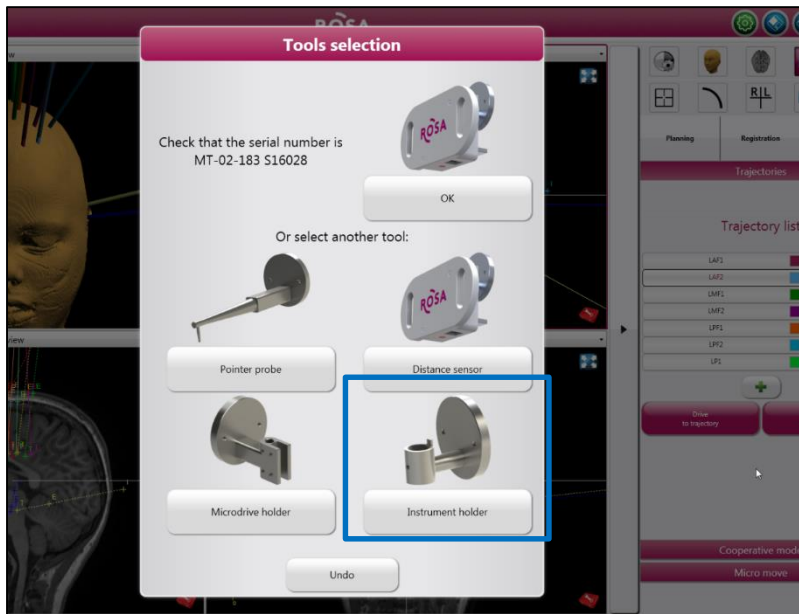
**Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com) or fax to 574-373-3589**

## ATTACHMENT 2

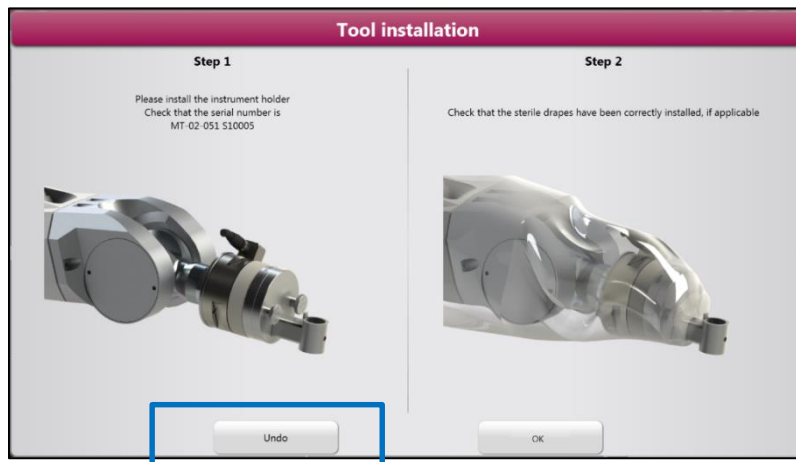
### Detailed sequence of events

The issue may arise if the following steps are performed in order:

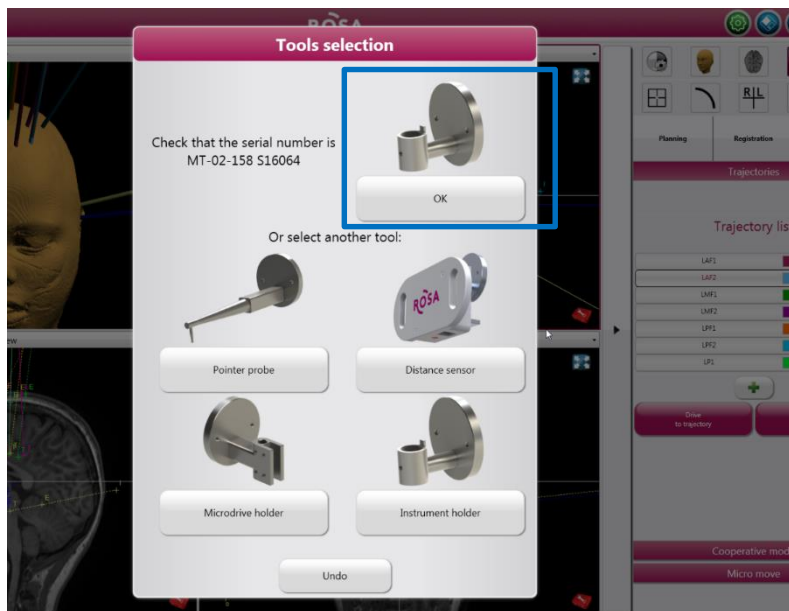
1. Use of the optical distance sensor during guidance mode, e.g. to mark entry points on the patient's head with a skin marker
2. Choosing drive to a trajectory and selection of the instrument holder



3. Installation of the instrument holder on the robot arm
4. Clicking undo on the tool installation frame



5. Choosing drive to a trajectory, then re-selection of the current instrument holder and drive to the trajectory



If the above listed steps are performed, the instrument holder may be sent on a trajectory that is not within the intended target.