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URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Brainlab Spine & Trauma 3D Navigation 1.0: Potential unexpected view representation of an accurately navigated instrument that might result in user misinterpretation under specific circumstances.
Product Reference:	Brainlab Spine & Trauma 3D Navigation 1.0 (subpart of the system "Navigation Software Spine & Trauma 3D, Version 3.0")
Date of Notification:	February 11, 2019
Individual Notifying:	Markus Hofmann, Senior Vigilance Manager
Brainlab Identifier:	CAPA-20190206-002260
Type of action:	Advice regarding use of device; Device modification (SW update)

We are writing to advise you of a display issue with the Brainlab Navigation Software *Spine & Trauma 3D Navigation 1.0.* Under specific circumstances, this issue may display an accurately navigated instrument in an unexpected view representation that is not ideal for the current navigation step.

If this software error occurs, and this unexpected view representation remains undetected by the user, this might cause misinterpretation that could mislead the surgeon during a navigated procedure.

There has been no reported negative impact on patient treatment by any user site due to this issue. The purpose of this Product Notification letter is to provide you with the relevant user information on how this issue occurs and to inform you of the corrective actions Brainlab is taking to address it.

Effect:
In certain occurrences, the affected navigation software application might unexpectedly display an accurately navigated instrument in an axial, coronal/sagittal (ACS) view representation with fixed planes in the image reconstruction (the "not-updated ACS view"), instead of displaying the desirable view representation "Inline View", which is commonly used for navigating invasive instruments at the spine.

This might occur after a "crash restore" or after changing between different navigation workflows during the same patient treatment. Please refer to section Details on next page.

In this not-updated ACS view, intended navigation might be difficult and not always appropriately possible for the user to determine the position of the instrument within the anatomy:

- Navigated instruments could be located outside the displayed anatomical slice, but would be rendered as a projection in this not-updated ACS view.
- This projected rendering could possibly create the incorrect impression that the instrument would be located within the currently displayed anatomical slice.

Brainlab has internally determined that if the unexpected view representation is not detected and the projected rendering is subsequently misinterpreted by the user, this could potentially mislead the surgeon to follow an invasive path other than the one intended.
No such misinterpretation has been reported by any user site.

Expected "Inline View":

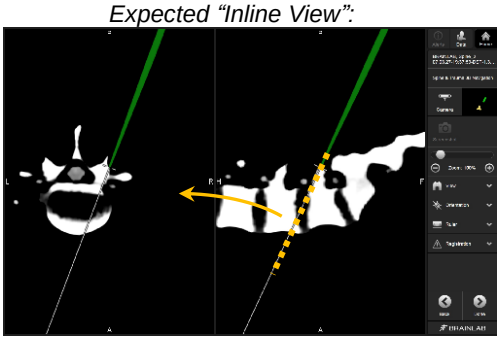


Figure 1 : *Intended and desirable "Inline View" of an instrument position (the dotted line shows the plane of reconstruction for the inline-axial view indicated by the arrow).*
The inline-axial is reconstructed to show the actual anatomical position and direction of the instrument.

"Not-updated ACS view":

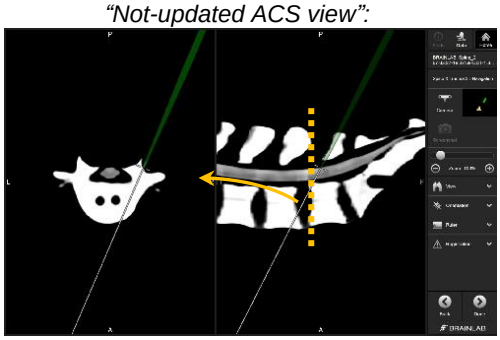


Figure 2*: Unexpected representation of an instrument position (the dotted line shows the plane of reconstruction for the purely axial view indicated by the arrow.)*
The purely axial view is not in line with the instrument, which is ***located behind / before*** *the slice, showing only an overlaid* ***projection*** *of the instrument.*

Details:
In the following, the specific conditions are outlined that cause the affected navigation software to display a different view representation than expected and desired, along with the affected workflows.

Workflow circumstances causing occurrence:

The software **may** display the unexpected view representation if **restarted with a previously registered and verified dataset.**

A restart with a previously registered and verified dataset occurs:

- During a crash restore (e.g., following a system reboot after system freeze, which *is an intended recovery procedure)*, or
- Under specific circumstances, if the user actively switches back and forth to a different navigation workflow within the same treatment for one patient (e.g., after registration, switching to the other workflow that allows for intraoperative screw planning, and then switching back to the original workflow for navigation).

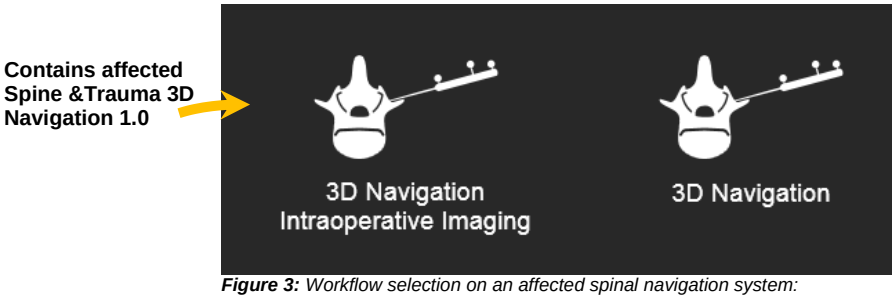


Figure 3: *Workflow selection on an affected spinal navigation system:*
The workflow on the left includes the affected navigation application version 1.0 ("Intraoperative" workflow). If the workflow is changed during a treatment to the workflow on the right – including the navigation application version 2.6 for screw planning – and then switched back to the workflow on the left, the problem can occur in specific cases.

In detail, the issue occurs in the following workflow changes:

- Starting navigation in the "3D Navigation Intraoperative Imaging" workflow, changing the workflow to "3D Navigation" for screw planning and then returning to the initial workflow.
  (*This overall workflow is intended and will be used in remote cases for users who perform intraoperative AIR registrations (e.g., 3D C-arm) using the "Intraoperative" workflow and who desire intraoperative screw planning and also desire to use selected navigation functionality of the affected application afterwards*).
- Starting with the "3D navigation" workflow (AIR App registration only) and changing to "Intraoperative" workflow.
  (*This workflow is not intended*).

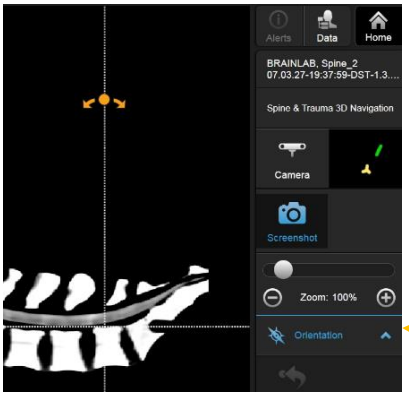
The issue does **not** occur in the following workflows:

- Starting the "3D Navigation Intraoperative Imaging" workflow and staying there.
- Starting with the "3D Navigation Intraoperative Imaging" workflow, changing to "3D Navigation" workflow for re-registration only (such as surface registrations and fluoro match) and then returning to the initial workflow.

For clarity: This issue does **not** occur if there is no software freeze / crash recovery, **and** there is no switch between workflows during navigation for one patient/surgery.

Correction to resolve this view representation issue if it occurs:
Activate the submenu “Orientation.”
The submenu “Orientation” may be closed immediately without applying changes.

This action corrects the view representation issue for all navigated view layouts for the duration of the current patient treatment.



Corrects issue

Retrospective review:
For already-performed treatments potentially affected by the issue, implant positions can be reverified on the standard postoperative implant verification image data (postoperative fluoroscopy, respectively CT). Verification directly after implant placements, usually even before concluding the surgery, is a common standard technique for spinal implant surgeries.

User Corrective Action:

1. Avoid workflow changes with already registered datasets, if possible. If not absolutely necessary (e.g., for intraoperative screw planning), avoid switching between the workflow application selections “3D Navigation Intraoperative Imaging” and “3D Navigation” during one patient treatment.

2. After restarting the application with a previously registered dataset (crash restore or workflow change), **always activate and deactivate the sub-menu “Orientation” once** to ensure that the correct, expected view representations are displayed for the current session.

Please continue to follow the instructions and warnings as described in the user guide. Especially relevant is the following warning in the Brainlab Spine & Trauma 3D Navigation 1.0 Software User Guide:

⚠ **Before beginning any surgical step, always ensure that navigation accuracy can be sufficiently maintained. If a surgical step could easily lead to reference displacement, remount the reference at an optimal position with a reduced possibility of displacement, and then register and verify again. The following methods can be used to ensure accuracy is sufficient:**

- **Landmark verification**
- **Fluoroscopy (compare the instrument location in the fluoro image with the display on the navigation system)**

Brainlab Corrective Action:

1. Existing potentially affected customers receive this product notification information.

2. Brainlab will provide all affected customers with a software revision of Spine & Trauma Navigation Software with the described issue corrected. Brainlab will actively contact you, starting in June 2019 to schedule the update.

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

We sincerely apologize for any inconvenience and thank you in advance for your cooperation.
If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

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Kind Regards,

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Europe: The undersign confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.