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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Spine & Trauma 3D: Potentially incorrect “fluoro match registration”
Product Reference:	Navigation Software Spine & Trauma 3D 2.0
Date of Notification:	November 18, 2013
Individual Notifying:	[redacted], MDR & Vigilance Manager
Brainlab Identifier:	CAPA-20131104-000565
Type of action:	Advice regarding use of device; Device modification

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We are writing to advise you of the following effect that has been identified for Brainlab Navigation Software Spine & Trauma 3D 2.0, when using the “fluoro match registration” function. The purpose of this Product Notification letter is to provide you with corrective action information and to advise you of the action Brainlab is taking to address the issue.

Effect:

The “**fluoro match registration**” function of the Navigation Software Spine & Trauma 3D 2.0 allows the user to intraoperatively match e.g., CT data sets to the current patient anatomy visible on fluoroscopic images, used by the navigation software during spinal surgeries to display the position and orientation of instruments.

For this registration function **in combination with a digitally integrated C-arm**, the software algorithm may not find an adequate match between the intraoperatively acquired 2D fluoroscopic images and the preoperative CT or other compatible 3D datasets. If such an incorrect match would occur, the display of instruments by the navigation system would be shifted compared to the actual patient anatomy.

The result of the match must always be verified by the user via both visual verification and physical verification on anatomical landmarks as required by the software and as described in the Software User Guide. If an incorrect match would occur and not be detected during user verification, deviation of the position information in the navigation software could mislead the user regarding clinical decisions. This could ultimately lead to **ineffective treatment, serious injury or even death of the patient.**

Details:

Due to a software anomaly the intraoperative 2D fluoroscopic images are not correctly processed, causing a low contrast of the images. For this reason, the software algorithm may not find a correct match between the low-contrast 2D fluoroscopic images and the segmented area of the 3D dataset. Alternatively, it may incorrectly match the segmented area to the Spine Reference X-Clamp, visible on the fluoroscopic images.

This potential error only occurs with digital C-arm integrations (applicable for various Ziehm, Philips and Siemens models), using a network cable connection between the C-arm and navigation system. C-arms integrated via analog video signals are not affected by this issue.

User Corrective Action:

Brainlab will provide a software update to affected customers with this issue resolved. As a temporary solution, until the software update has been implemented, users of the Navigation Software Spine & Trauma 3D 2.0 shall adhere to the following:

<u>Modification of C-arm configurations:</u>

1. If possible: Use **analog image transfer** between C-arm and Brainlab Navigation System. Please consult your local Brainlab Customer Support Representative for this modification.
2. If possible: Adjust the **image size** of your C-arm to **8bit**.
   Please follow the instructions provided with your C-arm and if required consult the C-arm manufacturer.

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Measures when performing a Fluoro match registration

In order to reduce the probability that the algorithm results in an inaccurate match, please adhere to the following:

- Perform the preoperative CT scans according to the descriptions in the Brainlab scan protocol.
- Set the threshold so that a smooth bone surface is displayed. The quality of the chosen bone threshold influences the accuracy of the matching result. Refer to section "Bone Threshold" in your Software User Guide.
- Use the Radiolucent Spine Reference Clamp instead of the Spine Reference X-Clamp.
- Make sure that no additional objects (e.g., wires, retractors, instruments, etc.) are within the field of view of the C-arm.

Attention! These measures do not ensure that the match found by the software algorithm is always correct. They only affect the probability of an incorrect match.

In general:

Always make sure to perform **careful accuracy verification** according to the instructions in the Software User Guide:

- Always verify registration accuracy by holding the pointer or instrument tip to at least three anatomical landmarks and verifying their position in the software.
- Verify that the registration is at the correct level on the patient and data set.
- Accuracy must be checked on the treated bone structure.

If the accuracy is insufficient, it is recommended to repeat registration (e.g., repeat matching, re-acquire fluoro images). It is not recommended to proceed to navigation with low accuracy.

If in doubt, please discontinue the use of "fluoro match registration" and contact your Brainlab Customer Support Representative to discuss alternatives.

Brainlab Corrective Action:

- Existing potentially affected Spine & Trauma 3D 2.0 customers receive this product notification information.
- Brainlab will provide a software update with this issue solved to affected customers. Tentative planned timeline for availability: January 2014.

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 co-operation. If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

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November 18, 2013

Kind Regards,

[redacted]

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