

## FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

**Subject:** Fixation of iMRI Registration Matrix for GE might not be rigid, potentially affecting the accuracy displayed in the navigation.

**Product Reference:** iMRI Registration Matrix for GE

**Date of Notification:** August 28, 2015

**Individual Notifying:** [REDACTED], Manager MDR & Vigilance

**Brainlab Identifier:** CAPA-20150821-001476

**Type of action:** Device component exchange; advice regarding use of device.



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We are writing to advise you of the following potential effect Brainlab has detected for the Brainlab iMRI Registration Matrix GE. This Notification letter is to provide you with corrective action information, and to inform you of the actions Brainlab is taking to address this issue.

### Effect:

The **Brainlab iMRI Registration Matrix for GE** enables automatic image registration for navigation of intraoperatively acquired MR image data sets from a GE scanner. For imaging and registration the Registration Matrix is suspended above the patient by the Rail Adapters, which are intended to hold the matrix and a Flex Coil above the patient.

It has been detected that the fixation between Registration Matrix and Rail Adapters (see *Figure 1*) may not always prevent slipping.

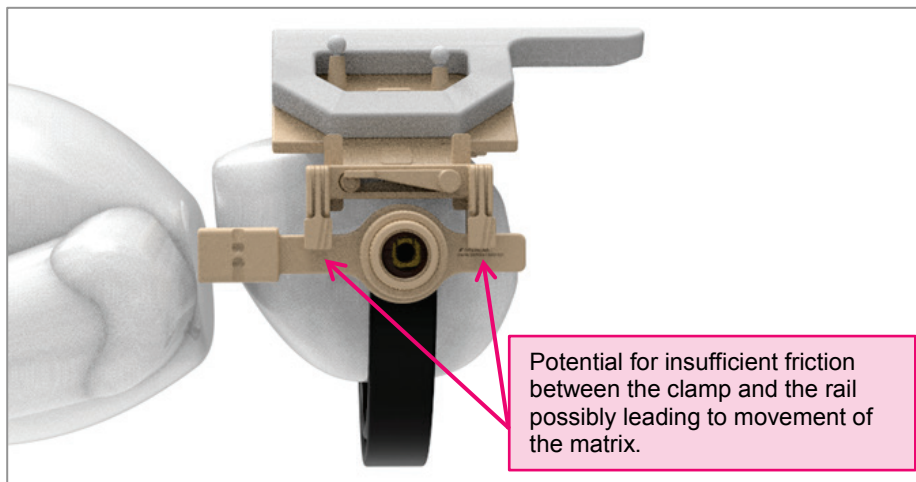


Figure 1: Brainlab iMRI Registration Matrix for GE

The friction between the rail clamps and the rails, without the necessary caution, may not always secure the device in its intended position, when high forces are applied on the Registration Matrix. This could be the case, among other possible scenarios,

- Due to vibrations during transportation on an uneven floor
- When applying tension on the Flex Coil cable
- When docking the patient table to the end stop during transfer from scanner to the OR table

As a result, movement of the Registration Matrix (containing the MR and infrared markers required for navigation) relative to the GE Skull Clamp, and thus to the patient's head, might occur.

If a very large movement occurs, specifically a significant rotational movement, the upper part of the registration matrix (weight ~1,3 kg) could potentially hit the patient's face, leading to a physical trauma and, in a worst case scenario, to **serious injury of the patient**.

With smaller movements, specifically those between performing the MR scan and the automatic registration performed by navigation, the MR dataset potentially cannot be accurately matched with the actual patient anatomy. The result of the automatic registration must always be verified by the user to ensure that the accuracy is appropriate for the planned procedure. It is likely that in most cases any shift of the upper part of the iMRI Registration Matrix is significant enough to be easily recognized during verification. However, if an inaccurate registration is not detected during user verification, a significant deviation may be added to the instrument positions virtually displayed by the Brainlab navigation in the region of interest and could mislead the user regarding clinical decisions, which could ultimately lead to **ineffective treatment, serious injury or even death of the patient.**

#### User Corrective Action:

With immediate effect, when using the iMRI Registration Matrix for GE please adhere to the following instructions:

#### 1) Handle the iMRI Registration Matrix for GE with extreme care

- **Do not apply high forces** on the Registration Matrix, e.g., by leaning on the upper part of the matrix or applying tension on the cable of the Flex Coil.
- **Reduce transportation distances** with the iMRI Registration Matrix for GE and a patient involved to a minimum.
- **Avoid any vibrations or shocks** during transportation e.g., due to an uneven floor or when hitting the end stop during transfer from scanner to OR table.
- If possible **perform automatic registration** of intraoperatively acquired MR images **before locking the transport** table into its end position (due to additional shocks when locking).

#### 2) Usage of additional drapes to increase friction

To increase the friction and therefore the stability of the fixation of iMRI Registration Matrix for GE, please **always use 2 layers of drape between rail clamps and rails** (as shown in figure 2).

**Only use textile drapes or “Spun-Melt-Spun-drapes / SMS-drapes”** (drapes made of a combination of spunbond and meltblown nonwovens) for this purpose. Do not use foil drapes, as they do not provide adequate friction.

Use the drapes between the rail clamps and the rails during any procedure where patient treatment is involved, including during transportation and scanning and also if working in a non-sterile field. You can use small pieces of drape, only covering the clamping surface not covering the patient.

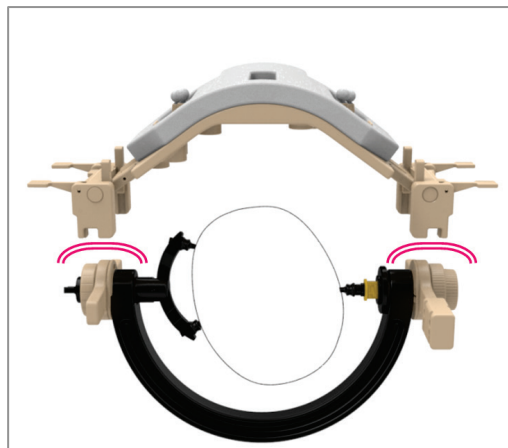


Figure 2: Use 2 layers of drape between rail connector and rail

### 3) Carefully verify the result of the automatic registration

After performing automatic registration of intraoperatively acquired MR images the result must be carefully verified:

- Verify registration accuracy by holding the pointer or Softouch to various anatomical landmarks and verifying their position in the navigation software.
- Verify the accuracy at least at the following landmarks and regions:
  1. Move the pointer around the **corner line of the craniotomy**. Additionally, move the pointer along the bone outside of the craniotomy.
  2. If accessible verify in **multiple widely distributed areas**, e.g., on both sides of the face, at the top of the head, in or near to the region of interest.
  3. To detect rotational and translational errors verify **significant landmarks all over the patient's head** as accessible. Recommended landmarks are:
    - Tragus left and right
    - Inion (postero-inferior part of skull)
    - Bregma (top of skull)
    - Typical landmarks are also nasion or lateral canthi
- For each verification point, compare the position of the pointer on the patient to the position displayed on the navigation system.
- The accuracy in the region of interest may differ from the accuracy verified on the skin / bone surface. During surgery, continuously recheck accuracy using anatomic landmarks as you reach the area of interest.



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**Please carefully decide if the determined accuracy is suitable for the current procedure.**

#### **In General:**

**Always ensure that the iMRI Registration Matrix for GE is correctly assembled.**

**Always use the appropriate spacer(s) if the width of the matrix is adjusted.**

Refer to the according instructions in the Brainlab Instrument User Guide and in the Instruction Leaflet "Automatic Image Registration System for GE".

#### **Brainlab Corrective Action:**

1. Existing potentially affected customers receive this product notification letter.
2. Brainlab will provide revised hardware to affected customers in order to resolve this issue for the *iMRI Registration Matrix for GE* after availability.  
Brainlab will actively contact you starting January 2016 to schedule the exchange of hardware.

**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.

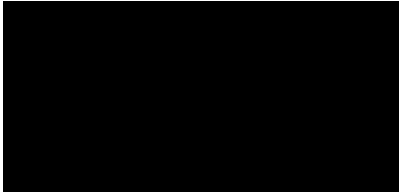
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August 28, 2015

Kind Regards,



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

