

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Brainlab Navigation System Spine & Trauma 3D:
Potentially unstable fixation of DrapeLink Registration Kit (for C-arm Ziehm Vision RFD) with specific serial numbers

Product Reference: Brainlab DrapeLink Registration Kit for C-arm Ziehm Vision RFD:
Adapter Left / Right; Brainlab Article no. 19154-03 and 19154-04

Date of Notification: November 16, 2017

Individual Notifying: Julia Mehlretter, Manager MDR & Vigilance

Brainlab Identifier: CAPA-20171107-002023

Type of action: Advice regarding use of device; Device modification

We are writing to advise you of the following potential effect that has been detected for your *Brainlab DrapeLink Registration Kit for C-arm Ziehm Vision RFD* that is used with *Brainlab Navigation System Spine & Trauma 3D*.

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 *DrapeLink Registration Kit for C-arm Ziehm Vision RFD* allows the integration of *Ziehm Vision RFD C-arms* for automatic registration of intraoperatively acquired fluoroscopic 3D images, enabling their use with navigation. As part of the integration, the Brainlab *DrapeLink C-arm Array (Left/Right)* is mounted to the corresponding *Brainlab DrapeLink Adapter (Left/Right)*, which is attached to the C-arm (refer to Figure 1, the adapter is marked by a red arrow).

Brainlab has determined that due to a human error at a Brainlab supplier an unknown number of items within one specific production lot of *Brainlab DrapeLink Adapters (Left/Right)* were not manufactured according to defined specifications.

According to our records you (hospital name) own the following affected part(s):

Brainlab DrapeLink Adapter Right	Serial number: XXXXXXXX-19154-03
Brainlab DrapeLink Adapter Left	Serial number: XXXXXXXX-19154-04

For a complete list of affected serial numbers refer to section "User corrective actions" below.

With immediate effect, do not use *Brainlab DrapeLink Adapters* with an affected Serial number for clinical use.

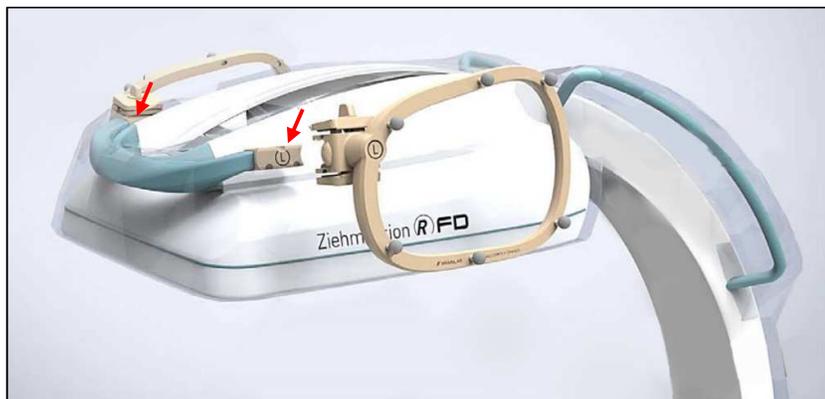


Figure 1: Brainlab DrapeLink Registration Kit for C-arm Ziehm Vision RFD with the potentially affected DrapeLink Adapter indicated by red arrows

Due to this manufacturing error the required reproducible rigid fixation between DrapeLink C-arm Array and Adapter cannot be ensured in all cases.

This can lead to the following effects:

- A potentially inaccurate initial registration of the C-arm image dataset, caused by a deviation of the DrapeLink C-arm Array position during the patient scan compared to the DrapeLink C-arm Array position during C-arm calibration.
- A potentially inaccurate registration of a subsequently acquired image dataset (intraoperative update) after an accurate initial registration of a first dataset, caused by a later movement of the DrapeLink C-arm Array during surgery.

Such inaccurate registrations are visible to the user in the mandatory accuracy verification step, displayed by the software directly after the registration process.

Registration results performed with incorrectly manufactured adapters can range between being accurate and deviating by several millimeters, depending on the movement of the array on the C-arm. Carefully performed accuracy verification in all directions (by holding the tip of the pointer to several anatomical landmarks and verifying their position in the software) will reveal potential navigation inaccuracies.

If clinically acceptable accuracy was verified and approved after registration, no further negative effects on navigation accuracy of this image dataset will occur due to this error. Potential movement of the array position after a scan was performed has no influence on navigation results of this scan.

Only in the case where a registration deviation occurred, exceeding clinically acceptable limits for the specific surgery, and was not detected during the mandatory accuracy verification by the user, **the resulting deviation of instrument positions displayed in the navigation software could mislead the user in regard to clinical decisions.**

User Corrective Action:

According to our records, you own at least one potentially affected Brainlab DrapeLink Adapter.

Potentially affected are:

Article	Serial numbers from to	
Brainlab DrapeLink Adapter Right Art. No. 19154-03	<u>7459216001</u>	- <u>7459216027</u>
	<u>1356916001</u>	- <u>1356916013</u>
Brainlab DrapeLink Adapter Left Art. No. 19154-04	<u>7459316001</u>	- <u>7459316027</u>
	<u>7714816001</u>	- <u>7714816017</u>

Please identify all Brainlab DrapeLink Adapters with the serial numbers specified above and **ensure that they are no longer clinically used at your hospital.**

Please do not dispose of the affected item.

A Brainlab Customer Support Representative will contact you to arrange a service visit to collect and replace the potentially affected item.

Brainlab will determine if your adapter was incorrectly manufactured and inform you of the results.

The serial number (followed by the article number) is engraved on the Brainlab DrapeLink Adapter (see Figure 2 and 3). **Please note that both Left and Right Adapters have different**

serial numbers. Each adapter has to be verified individually. It is likely that only one – either the left or right – adapter bears an affected serial number.

Adapters with other (non-affected) serial numbers can still be used. In case of doubt, please contact your local Brainlab Customer Support Representative to e.g., discuss a new OR setup.

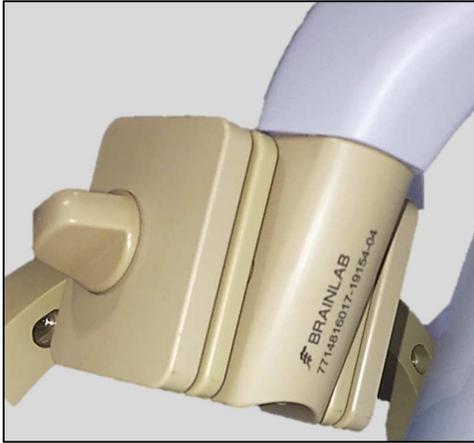


Figure 2: Serial number visible on Brainlab DrapeLink Adapter Right (with DrapeLink C-arm Array attached)



Figure 3: Serial number visible on Brainlab DrapeLink Adapter Left

Please continue to always follow the instructions and warnings as described in the relevant user guides:

- Ensure that the Locking Screw of the DrapeLink C-arm Array is tightened properly before navigation is performed.
- The system automatically detects the position of the reference array and registration kit when a new 3D scan is acquired. Nevertheless, registration accuracy must be verified by holding the tip of the pointer to at least three anatomical landmarks and verifying their position in the software.
- Inform Brainlab about all events when the flat-panel housing or handle is opened or replaced for service reasons.
- Yearly inspection and calibration of the C-arm with DrapeLink C-arm Arrays is recommended to maintain its accuracy.

Brainlab Corrective Action:

1. Existing potentially affected customers receive this product notification information.
2. Brainlab will proactively provide replacement hardware for the potentially affected items. Brainlab will actively contact you immediately to schedule the exchange of hardware including a Brainlab service visit for calibration.

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.

Customer Hotline:

+49 89 99 15 68 1044 or +1 800 597 5911 (for US customers)



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November 16, 2017

Kind Regards,

A handwritten signature in black ink, appearing to read "Julia Mehtretter".

Julia Mehtretter
Manager MDR & Vigilance

brainlab.vigilance@brainlab.com

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