

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Spine & Trauma Navigation System: *Instrument Star Unit ML (Calibration with ICM4)* with specific serial numbers might have pins made of an incorrect material, not suitable for sterilization processes

Product Reference: Brainlab Article 55830-25A: *Instrument Star Unit ML (Calibration with ICM4)*

Date of Notification: November 15, 2013

Individual Notifying: [REDACTED] MDR & Vigilance Manager

Brainlab Identifier: **CAPA-20130627-000492**

Type of Action: Device component exchange; advice regarding use of device


www.brainlab.com

We are writing to advise you of the following potential effect that might occur with the Brainlab Article 55830-25A, *Instrument Star Unit ML (Calibration with ICM4)* with specific serial numbers.

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:

Brainlab has determined that pins of the *Instrument Star Unit ML (Calibration with ICM4)* with specific serial numbers might have been made of an incorrect material that is not suitable for the necessary disinfection and sterilization of the product (please see Figure 1 and Figure 2).

Consequently, the biocompatibility of these specific products cannot be ensured. Pins made of this incorrect material will not withstand the necessary reprocessing procedures described in the Brainlab *Cleaning, Disinfection and Sterilization Guide*. The prescribed reprocessing procedures will cause visible corrosion of pins made of this incorrect material. Please refer to the Appendix for the corresponding serial numbers of the potentially affected products. One or multiple pins of each product might be affected.

If this corrosion occurs and is not detected by the user, and the device is used during surgery, corroded particles of the pin could, directly or indirectly, enter the patient's body, potentially leading to **infection and serious injury of the patient**.

Brainlab has not received any reports of such corroded products having been used in surgery, nor of any effects on patients, due to this issue.

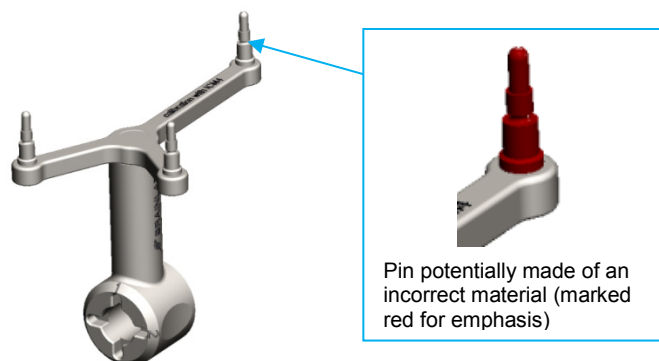


Figure 1: Brainlab *Instrument Star Unit ML (Calibration with ICM4)*

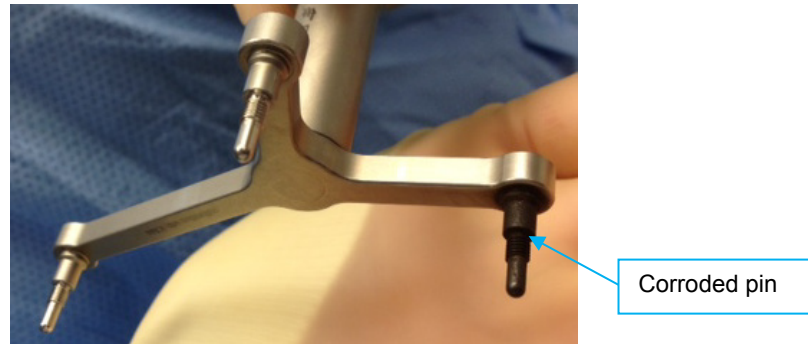


Figure 2: Brainlab *Instrument Star Unit ML* showing described effect: one corroded pin after reprocessing due to the incorrect material.

Details:

The Brainlab *Instrument Star Unit ML (Calibration with ICM4)* enables usage of manually calibrated Brainlab instruments or third-party instruments with the Brainlab Spine & Trauma Navigation System. It has an interface for receiving dedicated instruments, e.g., awls, probes or chisels.

All parts of the *Instrument Star Unit ML* are intended to be made of medical grade stainless steel, which is defined as biocompatible according to the relevant standards.

When manufacturing specific *Instrument Star Unit MLs*, a material not specified by Brainlab was used for a number of pins. For the incorrectly used material, neither biocompatibility nor corrosion resistance can be ensured.

Reprocessing (i.e., disinfection and sterilization) before clinical use will cause this incorrect material to visibly corrode. Although it is not intended for direct patient contact, if an *Instrument Star Unit ML* with corroded pins is used during surgery, a contamination of the patient with particles of the corroded material could occur, either directly or indirectly.

User Corrective Action:

According to our records you are the owner of at least one *Instrument Star Unit ML (Calibration with ICM4)* (Brainlab Article 55830-25A) with a potentially affected serial number.

Please refer to the Appendix for a list of potentially affected serial numbers.

Please identify all *Instrument Star Units ML* with any of the serial numbers identified in the Appendix, and remove them from clinical use in your hospital.

You will be provided with a replacement accordingly.

The serial number is engraved on the array of the *Instrument Star Unit ML* (please see Figure 3). The 'xxx' represents a consecutive number that is unique to each article.

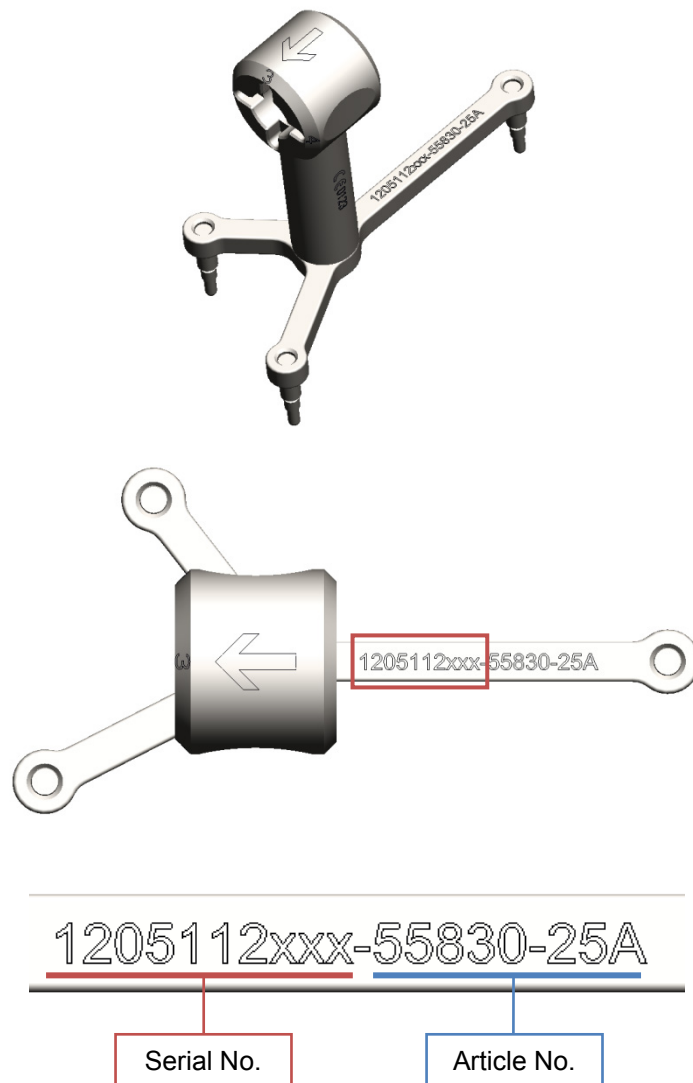


Figure 3: Identify the serial number engraved on the *Instrument Star Unit ML*.

Please continue to always follow the instructions in the relevant user manuals:

- After cleaning and disinfection, ensure that each instrument is clean and undamaged.
- Check the functionality and check for corrosion.
- Do not use damaged or corroded instruments.
- If you are not sure of an instrument's suitability for use, contact Brainlab support.

Brainlab Corrective Action:

1. Existing potentially affected customers receive this product notification letter.
2. Brainlab will actively provide replacement hardware for the potentially affected items.

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 44 or +1 800 597 5911 (for US customers)

E-mail: support@brainlab.com (for US customers: us.support@brainlab.com)

Fax: Brainlab AG: + 49 89 99 15 68 33

Address: Brainlab AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

November 15, 2013

Kind regards,



MDR & Vigilance Manager

brainlab.vigilance@brainlab.com

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



Appendix:

Serial numbers of potentially affected *Instrument Star Unit ML (Calibration with ICM4)* (Article No. 55830-25A):

Serial numbers
1205112004
1205112006
1205112010
1205112011
1205112013
1205112014
1205112015
1205112016
1205112017
1205112018
1205112019
1205112020
1205112021
1205112023
1205112025
1205112026
1205112027
1205112029
1205112030
1205112032
1205112034
1205112045

