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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Knee Navigation System: *Femoral and Tibial Cutting Block Adapter Base* with specific serial numbers might contain parts made from incorrect material and therefore not be suitable for reprocessing
Product Reference:	*Femoral and Tibial Cutting Block Adapter Base* Brainlab Article 41888-04
Date of Notification:	September 23, 2016
Individual Notifying:	Andrea Miller, MDR & Vigilance Manager
Brainlab Identifier:	CAPA-20160914-001734
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 effects Brainlab has determined for specific serial numbers of the *Femoral and Tibial Cutting Block Adapter Base*.

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 one part of the *Femoral and Tibial Cutting Block Adapter Base* with serial numbers ranging from 1267114001 – 1267114070 and with serial number 1308615032 was made from incorrect material (refer to the red marking in Figure 1).

Consequently, neither biocompatibility nor corrosion resistance of these specific products can be ensured.

If corrosion of the *Femoral and Tibial Cutting Block Adapter Base* occurs and is not detected by the user, and the device is used during surgery, corroded particles could, directly or indirectly, enter the patient's body and potentially cause **tissue irritation or a cytotoxic reaction of the patient**.

Corrosion may also impair successful reprocessing of this device part, so that residue from previous surgeries could adhere to the corroded material. If not detected by the user and the device is used during surgery, germs could be transferred to the patient and lead to **infection 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.

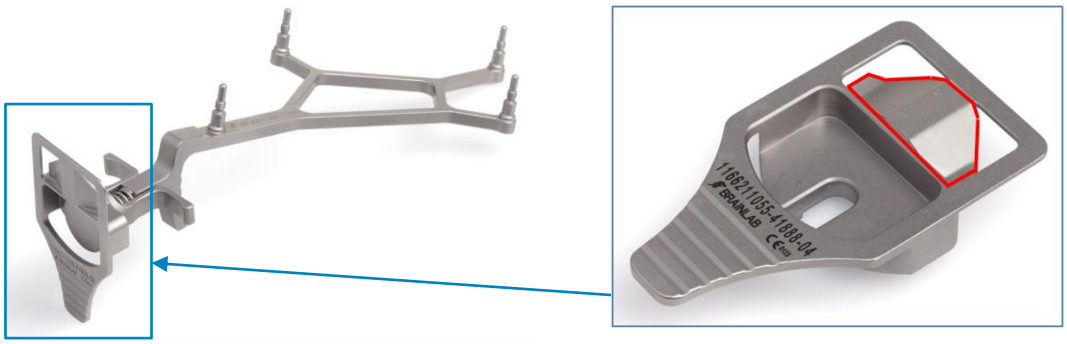

Figure 1: *Femoral and Tibial Cutting Block Adapter Base*,
Brainlab Article 41888-04 (affected part of the device marked red)

Details:

The *Femoral and Tibial Cutting Block Adapter* is used as part of the Brainlab *Knee Navigation System*. It allows the system to track the cutting block during navigation to the planned resection plane. For this, the *Base* plate (see image on the right-hand side of Figure 1), which can be disassembled from the tracking array (see image on the left-hand side of Figure 1), is inserted into the slot of the cutting block.

All parts of the *Femoral and Tibial Cutting Block Adapter Base* are specified to be made from medical grade stainless steel, which is defined as biocompatible according to the relevant standards, and allows full reprocessing of the device.

However, during manufacturing of the *Femoral and Tibial Cutting Block Adapter Base* with serial numbers ranging from 1267114001 – 1267114070 and with serial number 1308615032, one part (the wing-shaped part, see Figure 1) was made from material not specified by Brainlab. Parts made from this incorrect material will not withstand the necessary reprocessing procedures described in Brainlab's *Cleaning, Disinfection and Sterilization Guide*. For this 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. If a *Femoral and Tibial Cutting Block Adapter Base* with corroded parts is used during surgery, the patient could become contaminated with particles of the corroded material, either directly if particles fall into the wound, or indirectly (e.g., by touching the contaminated device with sterile hands or gloves). In the same way, residues from previous surgeries may be transferred to the patient, since corrosion can impair successful reprocessing of the device.

Further, when reprocessing a *Femoral and Tibial Cutting Block Adapter Base* that contains parts made from the incorrect material, corroded particles may be transferred to other devices that are reprocessed within the same cycle.

User Corrective Action:

According to our records, you own at least one potentially affected *Femoral and Tibial Cutting Block Adapter Base* (Brainlab Article 41888-04)**.**

Please identify all *Femoral and Tibial Cutting Block Adapter Bases* with serial numbers ranging from 1267114001 – 1267114070 and with serial number 1308615032, and remove them from clinical use in your hospital.

You are not required to return the affected devices to Brainlab.

Instead, please dispose them according to your local regulations.

You will be provided with a replacement accordingly.

The serial number is engraved on the *Femoral and Tibial Cutting Block Adapter Base* (see Figure 2). The 'xxx' represents a consecutive number that is unique to each article.

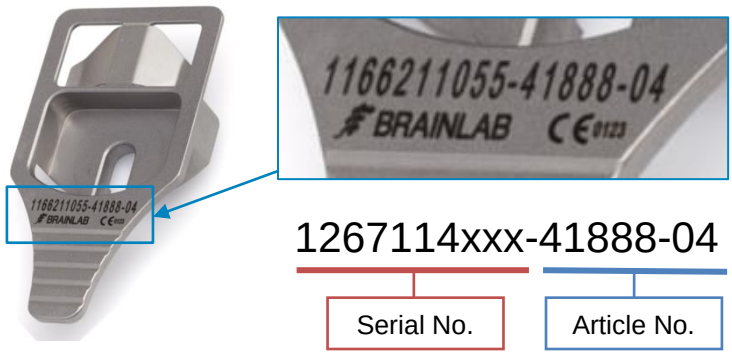

Figure 2: Identify the serial number engraved on the *Femoral and Tibial Cutting Block Adapter Base*

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.

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Brainlab Corrective Action:

1. Brainlab provides existing potentially affected customers with this product notification information.
2. Brainlab will proactively provide replacement hardware for the potentially affected items. Brainlab will contact you starting October 2016 concerning shipment of the replacement 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.

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)

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September 23, 2016
Kind Regards,

[redacted]

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