

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Use of Brainlab Skull Reference Base in combination with KLS Martin Cross-Drive screws

Product Reference: Brainlab Skull Reference Base (Art. No. 52121B)
Brainlab Skull Reference Base (Art. No. 52129 & 52129A)
Brainlab Disposable Self-Tapping Screw 1.5 X 6MM (Art. No. 52128)
KLS Martin Cross-Drive Screw 1.5x6mm (Art. No. 25-678-06)

Date of Notification: July 20, 2011

Individual Notifying: [REDACTED], Regulatory Affairs Manager

Brainlab Identifier: 11-06-08.RYO.1

Type of action: Advice regarding use of device.



We are writing to advise you regarding the use of the Brainlab Disposable Self-Tapping Screw 1.5 X 6MM (Art. No. 52128) / KLS Martin Cross-Drive Screw 1.5x6mm (Art. No. 25-678-06) in combination with the Brainlab Skull Reference Base (Art. No. 52121B, 52129, 52129A).

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:

Applying too much torque or tensile force to the head of the screw during insertion and fixation of the Skull Reference Base may cause the screw head to deform or to shear off. In such case, the screw can no longer be removed using the specified screwdriver or parts of the screw may remain inside the patient's skull bone.

Particularly this might happen when,

- applying too much torque while screwing the screw completely into the bone. This may occur when either no pre-drilling or pre-drilling using any other than the specified KLS Martin drill bit is performed
- fastening the tube fixation nut too tightly e.g. by using an additional forceps, thus exceeding the maximum tensile force of the screw
- using any other than the screws specified by Brainlab in combination with the Skull Reference Base



Figure 1: Skull Reference Base 52129A



Figure 2: Skull Reference Base 52121B, 52129

User Corrective Action:

1. Ensure to follow the instructions attached to this Field Safety Notice when using the Skull Reference Set.
2. From now on please ensure to only use the following compatible skull screw type:
KLS Martin maxDrive® Drill-Free Screws 1.5x6mm (KLS Art. No. 25-878-06-09), (Brainlab Art. No. 52170)
and the corresponding screwdrivers and drill bits.

Brainlab Corrective Action:

1. Existing potentially affected customers with above-mentioned Skull Reference Base versions receive this product notification letter.
2. Depending on the used Skull Reference Base version these customers receive the attached update to the Instructions for Use BL-IL-52121B_52129-Rev1.0 or BL-IL-60903-79-Rev2.0 regarding safe use of the Skull Reference Array kit.

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) or by

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

20, 2011

Kind Regards,



Regulatory Affairs Manager

[\[redacted\]@Brainlab.com](mailto: [redacted]@Brainlab.com)

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