

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: New sterilization instructions for the Brainlab Offset Cup Impactor Universal

Product Reference: Brainlab Offset Cup Impactor Universal (Art. no. 52856/52856A)

Date of Notification: December 22, 2016

Individual Notifying: Markus Hofmann, Senior MDR & Vigilance Manager

Brainlab Identifier: CAPA-20161213-001829

Type of action: Advice regarding use of device.


www.brainlab.com

We are writing to advise you of the following potential effect that has been detected for the sterilization of the Brainlab Offset Cup Impactor Universal. 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 Offset Cup Impactor Universal** in combination with the Brainlab Navigation Software Hip enables navigated positioning of an acetabular cup implant through a small incision. The device is provided non-sterile and must be sterilized prior to surgical use.

It has been detected that, when the Brainlab Offset Cup Impactor Universal (blue handle) is reprocessed in a Sterilization Tray as described in the current Brainlab Cleaning, Disinfection and Sterilization Guide (Revision 5.2 and previous) the device may not be determined as sterile. **The required sterility assurance level (SAL) of 10^{-6} can only be achieved if the device is individually wrapped for sterilization.**

Please note that the above is only applicable for the Brainlab Offset Cup Impactor Universal with the blue plastic handle. Versions with a metal handle are not affected by this Field Safety Notice / Product Notification.

If a non-sterile Brainlab Offset Cup Impactor Universal is used during a surgical procedure to implant an acetabular cup, contaminated residues on the product surface could, directly or indirectly, enter the patient's body, potentially leading to infection.

Brainlab has not received any reports of effects on patients, due to this issue.



Figure 1: Brainlab Offset Cup Impactor Universal (Art. No. 52856 / 52856A)

User Corrective Action:

With immediate effect, the **Brainlab Offset Cup Impactor Universal (blue handle) must be sterilized in an individually wrapped configuration.**

Do not sterilize the Brainlab Offset Cup Impactor Universal with blue handle in instrument trays as this may result in a non-sterile device.

Immediately inform those responsible for sterilization of the devices to utilize the updated instructions.

Please continue to use the following Steam Sterilization Parameters for sterilization of the Brainlab Offset Cup Impactor Universal (blue handle):

Cycle type	Sterilization temperature	Sterilization time	Drying time
Prevacuum	134°C (274°F)	At least 18 min	At least 30 min
Prevacuum	135°C (275°F)	At least 3 min	At least 60 min

Additionally, please continue to always follow the other instructions in the relevant Brainlab Cleaning, Disinfection and Sterilization Guide.

Brainlab Corrective Action:

- Existing potentially affected customers receive this product notification letter.
- These customers receive the attached update to the Instructions for Use (BL-IL-60960-69ML Rev. 1) regarding sterilization instructions for Brainlab Offset Cup Impactor Universal.

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 (until Dec 31, 2016) / +49 89 99 15 68 1044 (as of Jan 01, 2017) 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 (until Dec 31, 2016) / + 49 89 99 15 68 5033 (as of Jan 01, 2017)


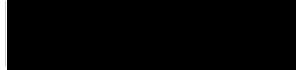
Address: Brainlab AG (headquarters):

Kapellenstrasse 12, 85622 Feldkirchen, Germany (until Dec 31, 2016)

Olof-Palme-Strasse 9, 81829 München, Germany (as of Jan 01, 2017)

December 22, 2016

Kind regards,

Markus Hofmann

Senior MDR & Vigilance Manager

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

