Urgent—Medical Device Field Safety Notice (FSN)
Voluntary Field Safety Corrective Action of SONNET Rechargeable Battery Pack Cover Micro Black (Art. No 32221)

October 12, 2016

ADDRESS

Dear *Customer Name*,

MED-EL is voluntarily informing you of a potential hazard that could occur with the use of the SONNET Rechargeable Battery Pack Covers Micro Black you have recently received. MED-EL has determined that the concerned devices are potentially non-conforming and therefore shall not be used. This letter requests your immediate action to identify and return to the manufacturer these SONNET Rechargeable Battery Pack Covers Micro Black. These parts are also included in kit 33635 SONNET Cover Micro (6) Base Col.

The SONNET Rechargeable Battery Pack Cover, please refer to Figure 1, functions as the SONNET audio processor ON/OFF switch when using the rechargeable battery pack.

Figure 1

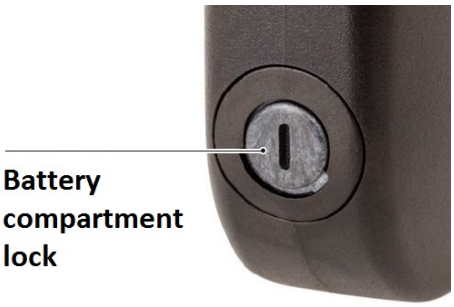

Figure 2

During inspection at MED-EL Headquarters, it was noticed that the battery compartment lock, please refer to Figure 2, was not properly welded to the housing of the SONNET Battery Pack Cover Micro Black. The identified problem affects only this particular batch and colour, which was shipped between 04 and 05 October 2016.

Should a SONNET Rechargeable Battery Pack Cover Micro Black from this batch be used, improper locking of the battery cover could occur. This may allow a child to disassemble the audio processor and to reach small parts, therefore leading to potential for serious injuries. Adult users, handling the device in accordance with the instructions for use, should only observe an inconvenience of having to have their affected SONNET Rechargeable Battery Pack Cover Micro Black exchanged.

MED-EL is informing the corresponding Competent Authority that we are initiating a Field Safety Corrective Action (FSCA) for this device.

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For the return of the involved device(s), please refer to the attached Response Form.

This FSCA includes the following scope and request for actions:

- Immediately informing the concerned recipients about the potential risk.
- Identifying and isolating the affected devices.
- Removing the affected devices from the field by having them returned to the manufacturer.
- A replacement device shall be provided to the concerned recipients as soon as possible.

If you have further questions regarding how to return the affected product or other issues, please contact:

FSN@medel.com

We kindly ask you to report to MED-EL, within 5 working days of receipt that you have received this alert. You may report receipt of this notice to MED EL via scan/email or fax to:

E-mail: FSN@medel.com
Fax: +43 512 288889 690

Mail:
FSN Coordinator
(Office T034)
MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a
6020 Innsbruck, Austria (AT)

We sincerely apologize for any inconvenience this notification may cause and thank you for your quick action to this important notification. We hope this information is of assistance for continued safe use of MED-EL implants and accessories.

Respectfully,

[redacted]