

Urgent—Medical Device Field Safety Notice (FSN)
Incorrect classification of product release test

November 21, 2018

Dear Sir or Madam,

As the result of internal investigations MED-EL has determined that overall 16 devices have been released and distributed to the field, despite Helium-fine leak test results not being within cochlear implant standards specification (EN45503-2-3, ISO14708-7, AAMI Ci86) of a leak rate below $5 \times 10^{-9} \text{ Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$. The concerned devices are non-conforming and should have not been released.

The products affected are:

Product type	Serial number	Implant status
SONATA	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
CONCERTO	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted
	██████	implanted

The above devices were released before 2013, due to a human error; back then the leak test status was manually set by an operator based on the value of the leakage test result. In 2013 an automated system was implemented for Helium-fine leak testing. This validated system automatically derives a pass/fail decision based on He fine leak measurement data.

MED-EL is therefore voluntarily informing you of a hazard that could occur with the use of such implants. The affected devices are non-conforming products and therefore, over the years following implantation, failure of the device electronics due to accumulation of residual moisture may occur.

The risk of failure due to accumulation of residual moisture is known and the expected harm may include:

- Explantation / re-implantation
- No benefit from the implant
- Painful sensation due to overstimulation, that can be rapidly resolved by removing the audio processor or external coil.

If use of the device is continued regardless of painful sensation, damage of neural tissue and/or pain due to direct current (DC) leakage could occur. However, the likelihood of such event is extremely low and might be prevented by immediately stopping the use of the device.

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

This FSCA includes the following scope and request for actions:

- Immediately informing the concerned clinics about the long term risk via Field Safety Notice (FSN).

Should you receive this letter as a recipient implanted with one of the affected devices, please be aware that no immediate action is required. MED-EL does not recommend a device explantation, as the device may work as intended for years before the electronics may become affected by humidity ingress. Ultimately, accumulation of internal moisture may cause complete failure of the device. Should any uncomfortable or painful sensation be experienced, please stop immediately using the device and contact MED-EL or your local support center for immediate support. MED-EL recommends regular implant checks at least once a year to check the implant status.

Should you have further questions regarding the use of your device, please feel free to contact clinical support at MED-EL or refer to your local support center.

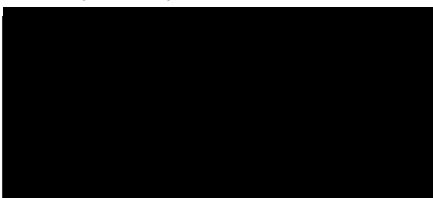
We kindly ask you to report to MED-EL, within 5 working days of receipt that you have received this alert. You may report receipt of this notice to MED EL via scan/email or fax to:

E-mail: FSN@medel.com

Fax: +43 512 288889 690

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

Respectfully,



Martin Herzog

Corporate Director, Quality Assurance