MED-EL

Reliability Report Q1 2021
MED-EL Cochlear Implant Systems

March 2021

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Introduction

There are many things you should think about when choosing a cochlear implant system for yourself or your child. One important factor is the reliability performance of the cochlear implant and the sound processor. The more reliable a cochlear implant system proves to be, the higher the chances for it to provide benefit to you over a longer time span and the safer it is; as each surgical intervention, e.g. for replacing a defective implant, poses a certain, although relatively low risk to your health.

The purpose of this document is to provide a comprehensive overview of the current reliability performance of MED-EL Cochlear Implant Systems. This document not only contains a description of the methodology applied at MED-EL for calculating reliability data, but also provides detailed information on all current and previous generations of cochlear implants and sound processors.

As reliability data permanently change over time, it is important to always use the latest data available to obtain an accurate picture of the system performance. MED-EL updates its reliability data regularly, and these updates can be found easily on the International Website at the following hyperlink: www.medel.com/int/reliability-reporting. As print brochures may be outdated easily with such short update cycles, please make sure to always also check the Website for potential updated information.

Methodology

This section describes the methodology for the calculation of the reliability performance for implantable components and non-implantable components of cochlear implant systems. The information given here tries to be as detailed as necessary to understand the data shown in the 'Data' section. For more information please be referred to the documents listed in the 'Literature' section at the end.

The methodology used at MED-EL and laid out on the next pages, is exceeding the requirements of the family of standards on active implantable medical devices, ISO 14708, and the standard on reliability reporting of cardiac pacemakers, ISO 5841-2:2014, which was for many years the only standard available to describe long-term reliability performance of active implantable medical devices. It also exceeds the requirements suggested for publishing reliability data of cochlear implants in clinical journals, first developed by a European group of surgeons in 2005, described by G. O'Donoghue (2005) in an Editorial to Otology & Neurotology and later published by Battmer et al (2010). It meets important parts of the requirements of the US standard ANSI/AAMI CI86:2017, for example reporting on all explanted devices and on external components of the cochlear implant system.

Implantable Components

MED-EL is legally obliged to establish and to maintain a database containing information on all cochlear implants which are built, sold, shipped, and implanted. The information collected ranges from details of production and results of production tests to details of implantation surgery. Whenever new information on a specific cochlear implant becomes known at MED-EL's Quality Management group, the record in the database gets updated.

If a cochlear implant does not provide benefit to the patient anymore, according to its intended use, and for whatever reason, the clinician together with the patient may decide to remove the device from the patient's head. In some cases, such a decision will only happen after consulting the manufacturer and after having conducted various in-vivo tests.

Failure Categorization

The removed implant together with the clinician's report usually gets sent back to the manufacturer where it is carefully analyzed and tested with the aim to identify the root cause for the failure. Each returned implant undergoes root cause analysis. To assign the correct failure category, the failure mode (= 'what' failed) and the failure mechanism (= 'how' did the failure happen) must be identified.

In general, MED-EL differentiates 2 major categories of failure: medical (also including surgery-related failures) and non-medical. A medical failure would for example be an infection at the site of the implant housing or a misplacement of the active electrode array. A non-medical (=device-related) failure might be an electrode breakage or a loss of hermeticity at the implant housing.

In order to provide a complete reliability reporting to the public, MED-EL reports on all failures that have occurred with each cochlear implant (= 'extended' in the MED-EL terminology) containing medical failures, surgical failures, device-related and accident-related device failures. This is the category that is of highest concern to both, patients, and clinicians. MED-EL also reports separately on the device related failures that have occurred in 2 sub-groups: one only looking at device-related failures caused by manufacturing or design weaknesses, and the other additionally also including failures caused by mechanical impact to the device (= incl. accidents). The latter category may be more relevant to children, who have a higher risk of falls and head trauma than adults.

Cumulative Survival Rate / Cumulative Failure Rate

Based on the categorization described above, an actuarial calculation for the purpose of preparing a report on cumulative experience for each of the three reported failure categories, and for each individual cochlear implant is performed, in accordance with the principles in statistics developed by Kaplan and Meier. The calculation method is described in detail in Annex A of the international standard ISO 5841-2:2014. MED-EL is fully compliant to this calculation method.

The cumulative survival rate can be differentiated in 2 scenarios: the 'extended cumulative survival rate' gives the probability for successful treatment with one particular type of cochlear implant over time, whereas the 'device-related cumulative survival rate' is looking at the percentage of functioning implants over time (in one group excluding impact related failures, in the other group including these). As mentioned above, the 'extended cumulative survival rate' is most informative for patients and clinicians alike, as patients directly see their risk for failed treatment and clinicians may estimate the burden to their clinic due to these failed treatments.

The cumulative failure rate is defined as the complement to the cumulative survival rate and can be calculated for the same three failure categories 'extended', 'device-related including accidents', and 'device-related excluding accidents'.

Non-Implantable Components

Reliability information of non-implantable, external components is also of high interest, to the manufacturers, the clinicians and to the patients. Often, this information is not easy to

obtain and to calculate. To only get relevant results, MED-EL decided to calculate reliability rates only for serialized components, like audio processors. These are also traced in a separate database, at least to the point of sale and after they are returned to the manufacturer for service and repair. Other components, like cables, batteries, and battery compartments ... are considered being consumable items which are replaced relatively frequently, often times without notification to the manufacturer.

Failure Categorization

Upon receipt of a presumably faulty audio processor for service and repair, MED-EL analyzes the device and investigates the root cause of failure in a similar manner as with the implantable components. Each audio processor returned for a complaint undergoes failure analysis. There are 2 major categories that returned devices will fall into: those that have a technical defect, and those that are found to be still working according to the specifications, but which may show some cosmetic degradation. Faulty devices will be repaired – if the repair is worth wile.

Average Monthly Service Rate

The average monthly service rate is the metric chosen to display the reliability performance for each individual MED-EL audio processor. This calculates as the ratio of returned, faulty audio processors compared to the total audio processors sold worldwide. This number gives a good estimate of the overall reliability performance and can be useful in analyzing the trending behavior of audio processor reliability performance. To simplify the graphical representation in public reporting, this metric is not subdivided into different failure modes.

Data / Results

Implantable Components

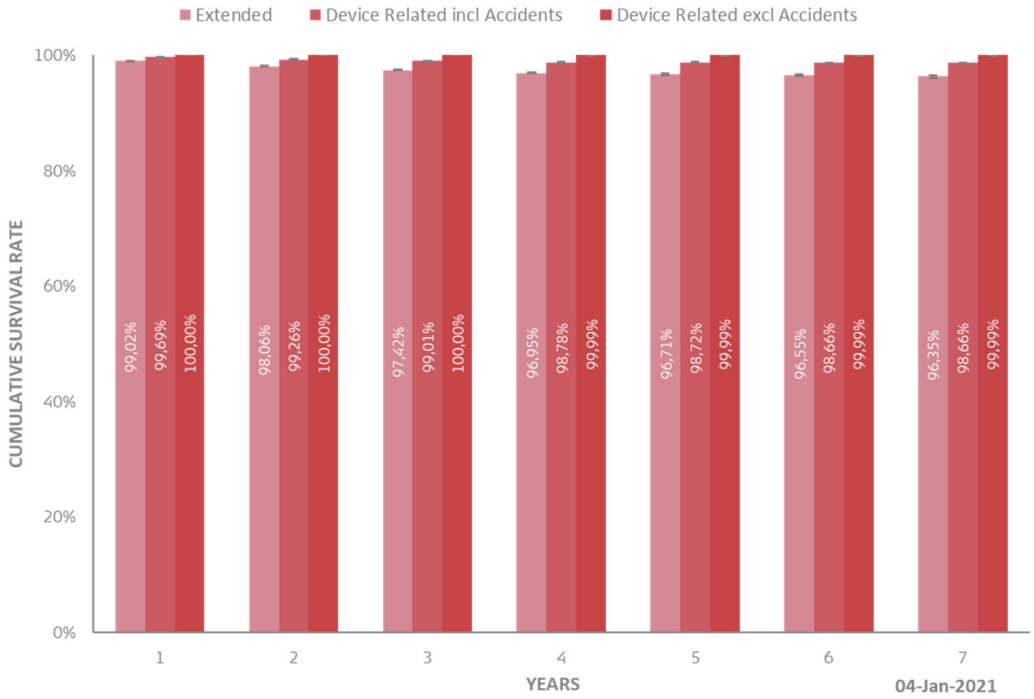
The bar charts on the following pages show the most recent reliability performance data for the MED-EL cochlear implant product range over time, including 95% confidence intervals. For each time interval, 3 bars a depicted: one showing the extended cumulative survival rate ('extended'), including medical, surgical, accident-related and device-related failure modes; the second showing device-related failure modes including accident-related failures; and the third showing device-related failure modes without accident-related failures.

Newest generation implants are shown first, with earlier generation implants following on the subsequent pages. It can clearly be seen from the charts that the newer generation implants have become more reliable, which is due to the continuous effort of MED-EL to improve the robustness and safety of our product designs.

SYNCHRONY 2 (all variants)

With 18 months of field data being available for the Synchrony 2 implant series (as of January 2021), MED-EL can claim excellent reliability performance, with a Cumulative Survival Rate of 99.44% after one year, counting all explantations (Extended CSR). The Device Related Cumulative Survival Rate is still at 100.00%, this means that no device-related failure has occurred.

SYNCHRONY (all variants)



Literature

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ISO 14708-7:2013, Implants for surgery – Active implantable medical devices – Part 7: Particular requirements for cochlear implant systems