

MED-EL Cochlear Implant Systems

Reliability Report | April 2023

Compliant With International Standard ISO 5841-2:2014 and European Consensus Statement



hearLIFE

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A Complete 360° View on Safety and Reliability

Hearing connects us to so many of life's cherished moments. That's why we're always here to help people with hearing loss experience these wonderful moments day after day.

Since the very beginning, the development of our life-changing devices has been guided by a complete 360-degree view of reliability and safety. It's not only about making our cochlear implants and audio processors as reliable as possible. Electrode design, safe stimulation, and MRI safety are also integral aspects of cochlear implant safety. Without taking these into account, creating a safe and reliable hearing experience just isn't possible.

Every MED-EL recipient is a person who trusts us. We know they count on us to connect them to everything they love every day, and we are committed to providing them with devices that meet the highest quality, safety, and reliability standards on the market.





Our complete 360° approach to cochlear implant safety and reliability focuses on five critical areas:

- ✓ **Implant Reliability**
 Implant reliability includes both manufacturer-reported data as well as data reported by clinics in peer-reviewed publications.
- ✓ **Electrode Safety**
 Electrodes should not harm the delicate structures in the cochlea while providing effective stimulation.
- ✓ **Safe Stimulation**
 Stimulation must be safe and exclude harmful direct currents.
- ✓ **MRI Safety***
 Modern cochlear implants should provide the possibility to undergo MRI scans without the need for surgery,** without discomfort, and without hearing downtime.
- ✓ **Audio Processor Reliability**
 Audio processor reliability includes both reports on repair rates as well as audio processor retention on the head.

* MED-EL cochlear implants since 1994 are MR conditional. Recipients with a MED-EL cochlear implant may be safely MRI scanned following the conditions detailed in the instructions for use at www.medel.com/isi
 ** Unless required for diagnostic reasons.

Implant Reliability

Leading in Cochlear Implant Reliability

All of our latest-generation titanium implants have an overall cumulative survival rate over 99%—reliability performance that no other cochlear implant manufacturer has achieved.^{1,2,3}

The outstanding reliability of our cochlear implants is not by chance. It is the result of the focused oversight and expert craftsmanship that takes place in our state-of-the-art manufacturing facilities. Unlike other cochlear implant producers who outsource manufacturing overseas, every single MED-EL implant is produced at our global headquarters in Austria—and it has been that way for over 30 years. This allows us to consistently maintain the highest standards of European quality and engineering.

We take every detail into consideration, from quality-oriented design and development to vigorous testing and clinical support. With our cutting-edge processes, superior components, and exceptional quality control, it is no coincidence that every MED-EL cochlear implant meets the highest standards for quality, safety, and reliability. But don't take our word for it—the data speaks for itself.

With all of our latest-generation titanium implants since 2006 having an overall cumulative survival rate over 99%, MED-EL leads in cochlear implant reliability.^{1,2,3}

Compliance With Implant Reliability Standards

MED-EL reliability reporting is done in accordance with the International Standard ISO 5841-2:2014⁴ and the principles set out in the European Consensus on Cochlear Implant Failures and Explantations.⁵

Consensus Statement Principles	MED-EL Compliance	MED-EL Reporting Practice
All device failures must be reported to the competent authority and must be included in the calculation of the cumulative survival rate (CSR). Reporting of the CSR should be in accordance with ISO Standard 5841-2:2000.		All device malfunctions and all medical/surgical complications with a causal relationship to the device are reported to the competent authority as is required by medical devices laws. For public reporting, MED-EL uses the applicable definitions, categorization scheme and calculation procedures of the ISO Standard 5841-2:2014 which has replaced the previous version 5841-2:2000.
Manufacturer's reports of device failure should indicate the sources of data and the sample size. There must be no exclusions. The time period over which the data was collected should be specified.	 Data is complete. Time period and sources are specified.*	The source of data is MED-EL's global complaint database/implant registration database. All devices that have been registered as implanted are included in the calculations. The time period is clearly specified. <i>* The overall population registered as implanted is not given explicitly for business confidentiality reasons.</i>
Reports of CSR should give complete historical data of given device, describing any technical modifications (which can be integrated into historical data by starting at time 0).		MED-EL reports publicly on all implants for at least 20 years following market release. In the reports, all electrode variants are accumulated by implant housing model (e.g., SONATA or CONCERTO). Complete historical data are included for all these devices as well as data on technical modifications.
The complete data set of the "mother" product should always be supplied when presenting data on subsequent device modifications.		MED-EL reports publicly on all implants for at least 20 years following market release. In the reports, all electrode variants are accumulated by implant housing model (e.g., SONATA or CONCERTO). Complete historical data are included for all these devices as well as data on technical modifications of the "mother" product (e.g., CONCERTO Pin data is included in the CONCERTO data).
A new device can be attributed when there has been a change in the case and/or the electrodes and/or the electronics and has been labeled by its own CE mark.		This is a legally binding practice, which MED-EL—like any other manufacturer of active implantable medical devices—must and does fully adhere to.
Cumulative survival rates should be split into data for adults and for children and 95% confidence intervals (80% or 90% if the population is below 1000 units) should be provided.		For each implant model, the cumulative survival rate data are stratified by age groups into adults and children (younger than 18 years), with 95% confidence intervals.
Device survival time starts to count with closure of the wound intraoperatively.		All devices are considered implanted as soon as the wound was closed.

The Value of a Reliable Implant

Choosing a cochlear implant can be a decision for life. That's why our implants are designed to give recipients superior sound quality, long-term reliability, and optimal MRI compatibility. With a MED-EL cochlear implant, recipients have hearing they can always count on. Higher implant reliability can lead to lower risk of additional surgery and

higher satisfaction for implant recipients. The Cumulative Survival Rate (CSR) is the measure of each implant model's reliability over time. For example, a CSR of 99% after seven years means that the probability of the cochlear implant providing continued benefits after seven years is 99%.

What Data Is Included?

The data shows the entire lifetime of the implant model and includes all registered implants globally. It also includes accident-related failures.

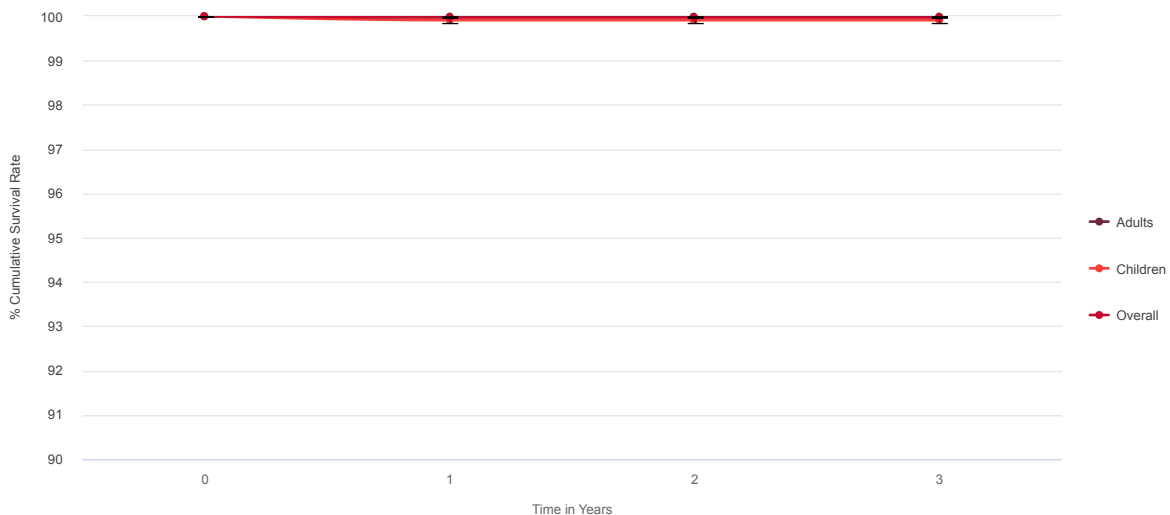
Understanding Implant Reliability Reports

Implant Name

Year	0	1	2	3
Overall	100.00%	99.97%	99.97%	99.97%
Adults	100.00%	99.99%	99.99%	99.99%
Children	100.00%	99.91%	99.91%	99.91%

Time in Years
Time, in years, begins as soon as the wound is closed during implantation.

Cumulative Survival Rate
Three CSR values are given for each year. Adults and children are shown separately with 95% confidence intervals. Overall refers to combined data for both children and adult populations.



Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

SYNCHRONY 2 Implant Reliability

Commercially released in June 2019, SYNCHRONY 2 is our latest cochlear implant and the smallest titanium cochlear implant in the world.

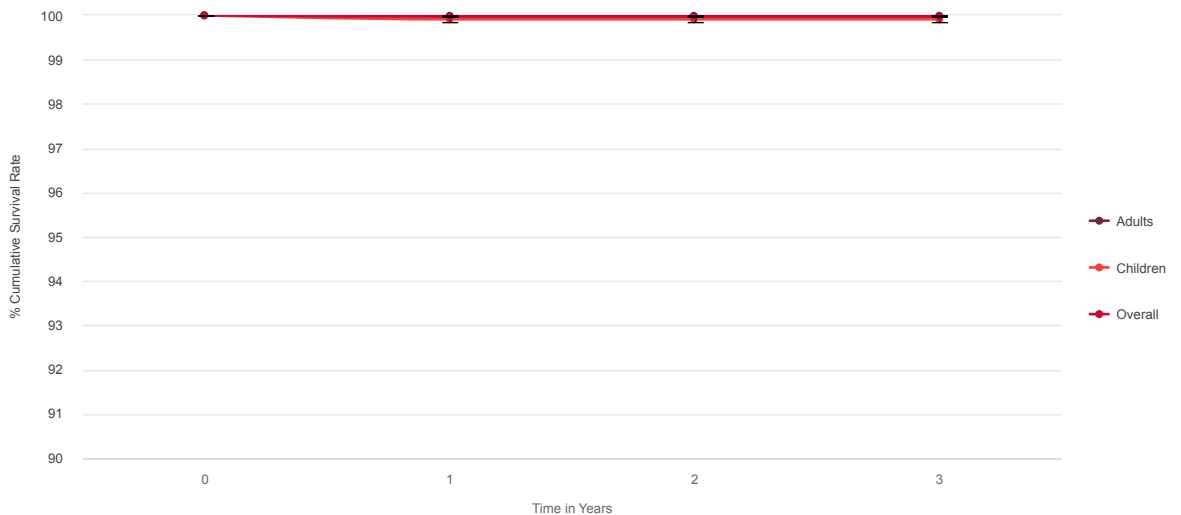
Not only is it packed full of the latest hearing technology. It's also designed with the safety and reliability to provide years of amazing hearing.

SYNCHRONY 2 has one of the best cochlear implant reliability performance records on the market, with an overall CSR of 99.97% within three years.



SYNCHRONY 2

Year	0	1	2	3
Overall	100.00%	99.97%	99.97%	99.97%
Adults	100.00%	99.99%	99.99%	99.99%
Children	100.00%	99.91%	99.91%	99.91%



Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

SONATA 2 Implant Reliability

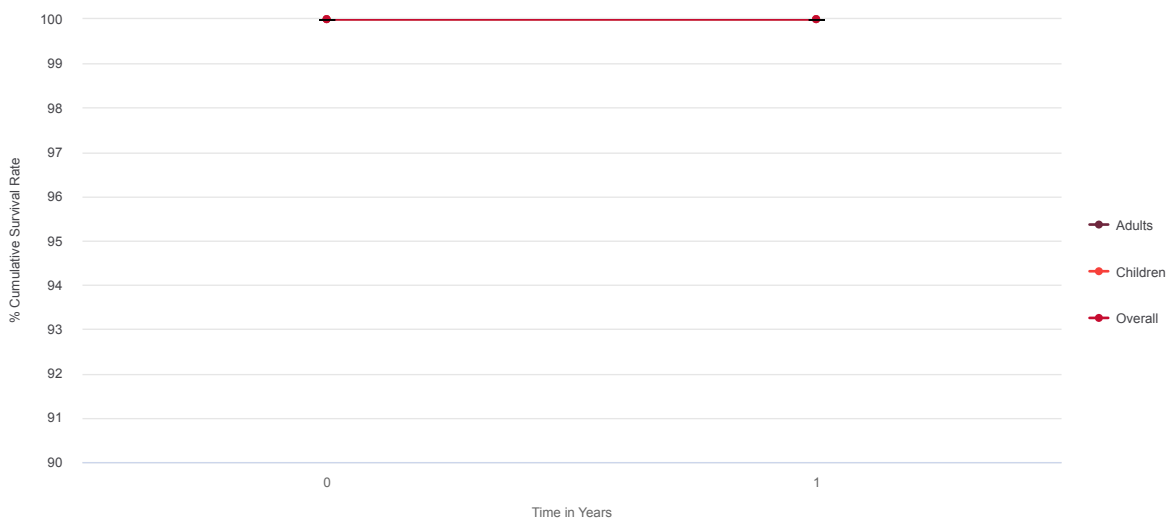
SONATA 2 has a symmetrical central electrode lead design for optimal surgical handling. It also features our second-generation diametric magnet, the S-Vector magnet, which is 25% stronger than its predecessor for optimized audio processor retention. In addition, the S-Vector magnet enables 3.0 Tesla MRI scans* with no surgery,** no hearing downtime, and has the same small MRI artifacts as our previous generation magnet.



SONATA 2 was commercially released in January 2021 and has an overall CSR of 100.00% within one year.

SONATA 2

Year	0	1
Overall	100.00%	100.00%
Adults	100.00%	100.00%
Children	100.00%	100.00%



Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

* The SONATA 2 cochlear implant is MR conditional. Recipients with a SONATA 2 cochlear implant may be safely MRI scanned at 1.5 and 3.0 Tesla following the conditions detailed in the instructions for use.

** Unless required for diagnostic reasons.

CONCERTO 2 Implant Reliability

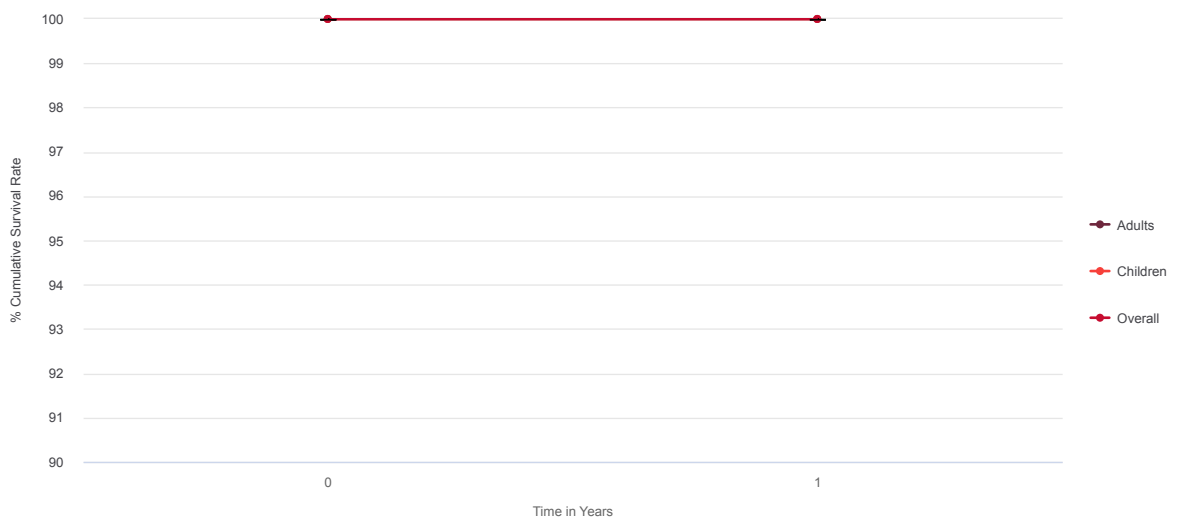
CONCERTO 2 provides superior hearing performance with long-term safety and peace of mind. It features a symmetrical central electrode lead and a thin housing design for simplified implant placement.

CONCERTO 2 was commercially released January 2021 and has an overall CSR of 100.0% within one year.



CONCERTO 2

Year	0	1
Overall	100.00%	100.00%
Adults	100.00%	100.00%
Children	100.00%	100.00%

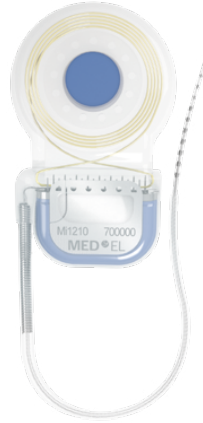


Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

SYNCHRONY ST Implant Reliability

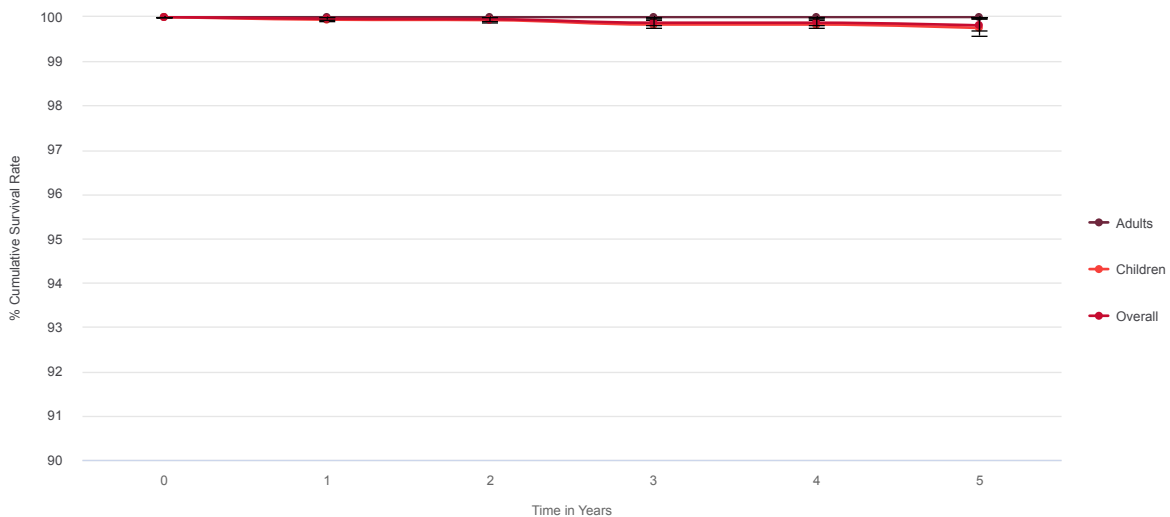
With SYNCHRONY ST, recipients get peace of mind knowing they have an implant that delivers outstanding MRI safety,* proven reliability, and exceptional hearing quality.

Commercially released in January 2017, SYNCHRONY ST has an overall CSR of 99.81% within five years.



SYNCHRONY ST

Year	0	1	2	3	4	5
Overall	100.00%	99.96%	99.95%	99.87%	99.87%	99.81%
Adults	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%
Children	100.00%	99.94%	99.93%	99.83%	99.83%	99.75%

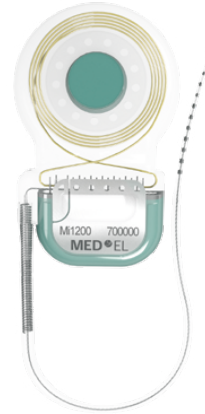


Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

SYNCHRONY Implant Reliability

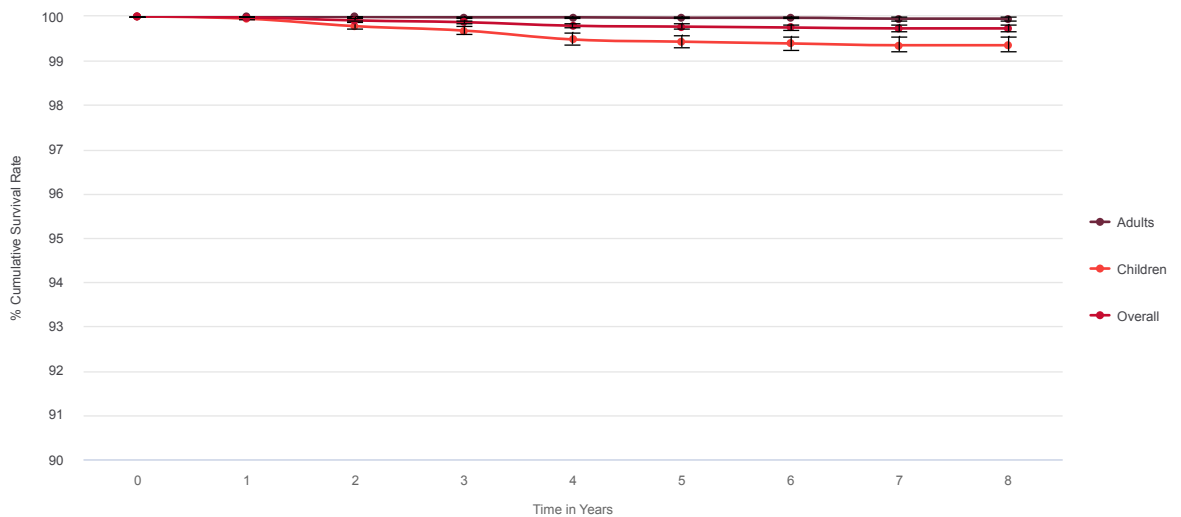
Commercially released in June 2014, SYNCHRONY revolutionized hearing implant design with the world's first rotatable, self-aligning diametric magnet enabling high-resolution 3.0 Tesla MRI scans without the need for magnet removal.*

The SYNCHRONY implant has an overall CSR of 99.73% within eight years.



SYNCHRONY

Year	0	1	2	3	4	5	6	7	8
Overall	100.00%	99.98%	99.91%	99.87%	99.79%	99.77%	99.75%	99.73%	99.73%
Adults	100.00%	100.00%	99.99%	99.98%	99.98%	99.97%	99.97%	99.95%	99.95%
Children	100.00%	99.95%	99.78%	99.68%	99.48%	99.43%	99.39%	99.35%	99.35%



Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

* Unless required for diagnostic reasons. MED-EL cochlear implants since 1994 are MR conditional. Recipients with a MED-EL cochlear implant may be safely MRI scanned following the conditions detailed in the instructions for use at www.medel.com/isi

CONCERTO Implant Reliability

When commercially released in July 2010, CONCERTO was the world's smallest and lightest titanium cochlear implant. It offers superior hearing performance with proven reliability for long-term safety and peace of mind.

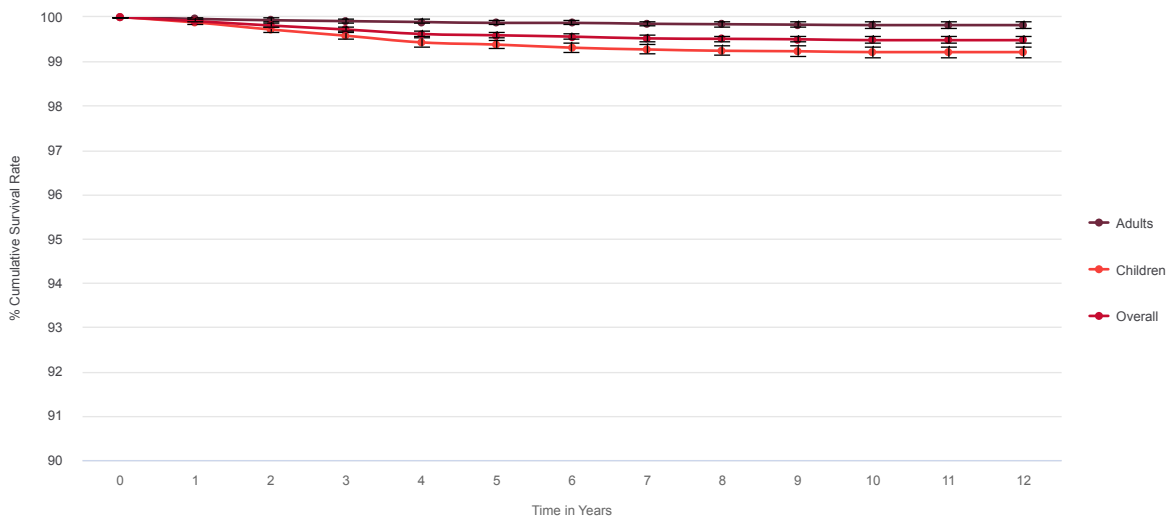


The CONCERTO implant has an overall CSR of 99.48% within 12 years.

CONCERTO

Year	0	1	2	3	4	5	6	7	8	9	10
Overall	100.00%	99.91%	99.81%	99.72%	99.62%	99.59%	99.56%	99.52%	99.51%	99.50%	99.48%
Adults	100.00%	99.96%	99.93%	99.91%	99.89%	99.87%	99.87%	99.85%	99.84%	99.83%	99.82%
Children	100.00%	99.88%	99.72%	99.58%	99.43%	99.38%	99.31%	99.27%	99.24%	99.23%	99.21%

Year	11	12
Overall	99.48%	99.48%
Adults	99.82%	99.82%
Children	99.21%	99.21%



Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

SONATA Implant Reliability

With a robust, impact-resistant and durable titanium body and secure step design, SONATA has a proven track record of exceptional long-term reliability and stability.

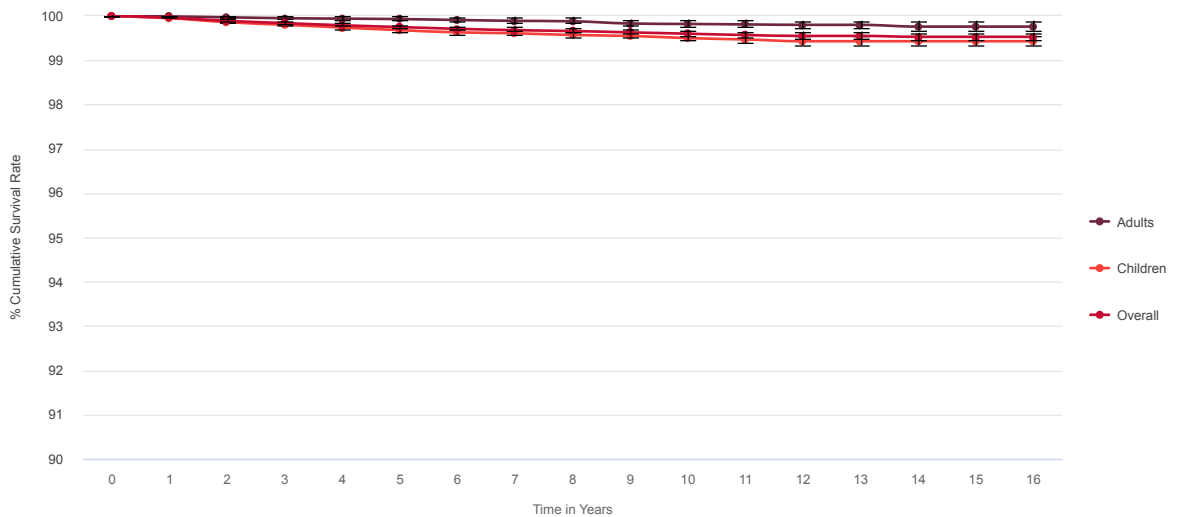
SONATA was commercially released in June 2006 and has an overall CSR of 99.53% within 16 years.



SONATA

Year	0	1	2	3	4	5	6	7	8	9	10
Overall	100.00%	99.96%	99.89%	99.84%	99.79%	99.75%	99.71%	99.68%	99.66%	99.63%	99.60%
Adults	100.00%	99.99%	99.97%	99.95%	99.94%	99.93%	99.91%	99.89%	99.88%	99.83%	99.82%
Children	100.00%	99.95%	99.86%	99.80%	99.74%	99.68%	99.63%	99.61%	99.57%	99.55%	99.50%

Year	11	12	13	14	15	16
Overall	99.57%	99.55%	99.55%	99.53%	99.53%	99.53%
Adults	99.81%	99.80%	99.80%	99.76%	99.76%	99.76%
Children	99.47%	99.43%	99.43%	99.43%	99.43%	99.43%



Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

* Within the first month(s) SONATA was on the market, all recipients were adults. Therefore, data for the children population is within 15 years instead of 16.

PULSAR Implant Reliability



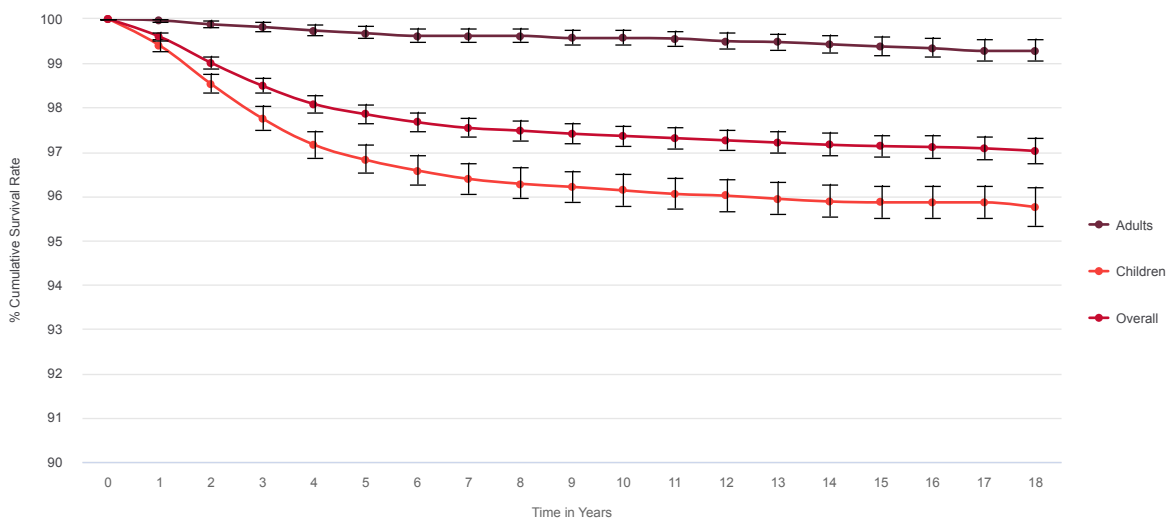
Commercially released in March 2004 with ceramic housing, the PULSAR cochlear implant was designed to be compatible with future technology. In fact, it is still compatible with our latest technology and accessories, including the RONDO 3 audio processor.

Within 18 years, the PULSAR has an overall CSR of 97.02%.

PULSAR

Year	0	1	2	3	4	5	6	7	8	9	10
Overall	100.00%	99.60%	99.01%	98.49%	98.08%	97.85%	97.67%	97.54%	97.48%	97.41%	97.36%
Adults	100.00%	99.97%	99.88%	99.82%	99.74%	99.68%	99.62%	99.62%	99.62%	99.57%	99.57%
Children	100.00%	99.40%	98.53%	97.75%	97.16%	96.82%	96.58%	96.39%	96.28%	96.21%	96.13%

Year	11	12	13	14	15	16	17	18
Overall	97.31%	97.26%	97.21%	97.16%	97.13%	97.11%	97.08%	97.02%
Adults	99.56%	99.50%	99.48%	99.43%	99.38%	99.34%	99.28%	99.28%
Children	96.05%	96.01%	95.94%	95.88%	95.86%	95.86%	95.86%	95.75%



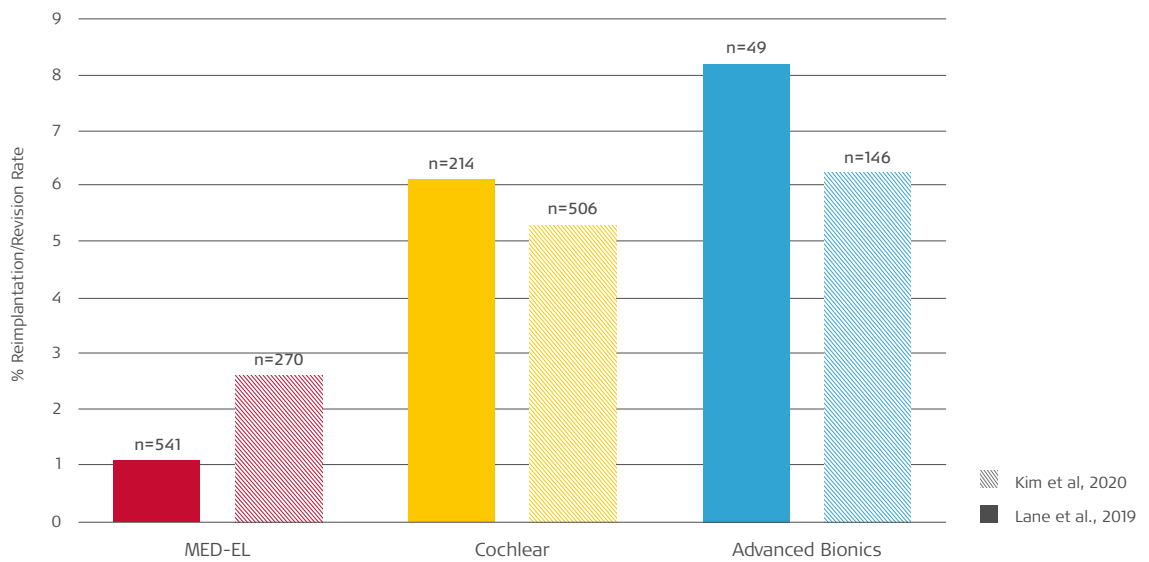
Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

Clinic-Reported Reliability

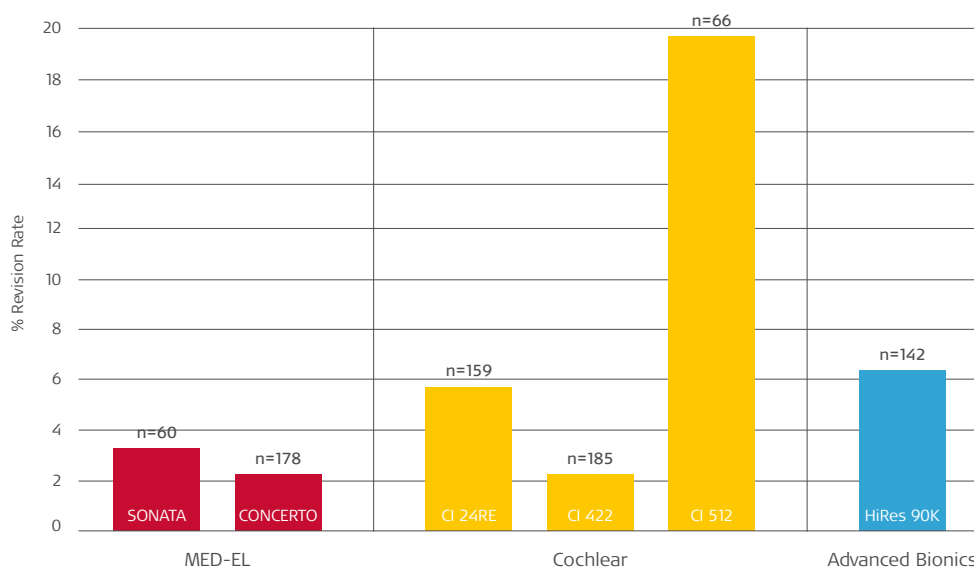
We know that manufacturer's reports alone don't always paint the whole picture. Two recent publications offer a comprehensive overview of reimplantation rates based on cochlear implant

manufacturer.^{6,7} Both independent studies found that reimplantation rates were the lowest with MED-EL cochlear implants.

Reimplantation and Revision Rate by Manufacturer



Reimplantation and Revision Rate by Implant Series





Electrode Safety

First, Do No Harm

A deaf ear is not a dead ear, and the cochlea is filled with intricate structures that we want to protect. That's why, for more than 30 years, we've worked to create our ultra-flexible electrode arrays.

Uniquely engineered, our electrode arrays are the most atraumatic electrode arrays available.⁸ They reduce the risk of tip fold-over, preserve the delicate structures of the inner ear, and gently adapt to each individual cochlea for deep, atraumatic, and reliable electrode insertion.

The Role of Lateral Wall Electrode Arrays

Flexible lateral wall arrays are a key factor in allowing deep, safe, and atraumatic insertion. Our slim lateral wall electrodes gently adapt to the shape of each cochlea, protecting those delicate natural structures. This results in both a lower scalar deviation rate and a lower frequency of tip-fold over compared to perimodiolar electrodes.^{9,10}

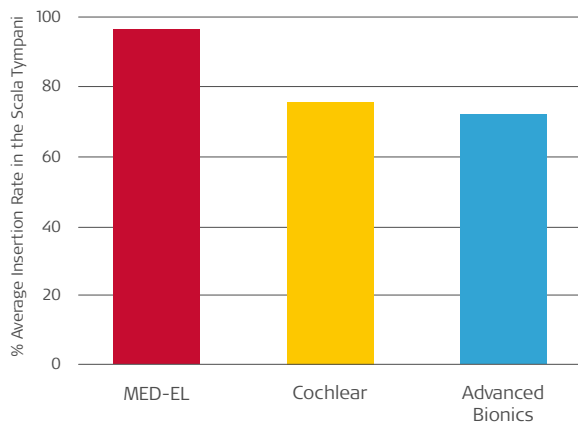


Reliable Scala Tympani Placement

To preserve the delicate structures of the cochlea, the electrode array must be placed fully in the scala tympani. If the electrode deviates into the scala vestibuli, it could allow the endolymph and perilymph fluids to mix. This would impair essential nerve function and destroy any residual hearing. This could permanently affect a recipient's hearing performance and leave them unable to benefit from new technologies such as improved coding strategies.^{11,12,13,14}

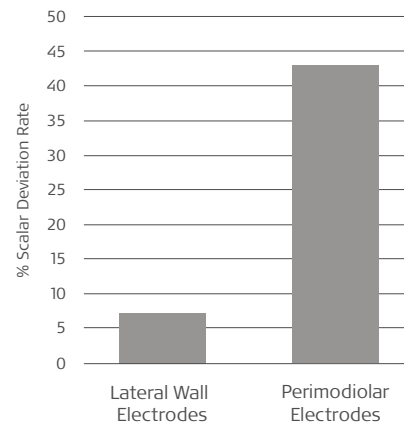
Stiff electrode arrays are far more likely to penetrate and damage the delicate membranes between the scala tympani and scala vestibuli. In contrast, MED-EL's ultra-flexible, free-fitting arrays are proven to consistently enable scala tympani placement, with an average insertion rate of nearly 100%. This way, we can safely preserve those delicate structures and deliver better hearing performance to recipients.^{8,15,16,17,18,19,20,21}

Average Insertion Rate in the Scala Tympani



Data on File, MED-EL, n=1,399, Literature Search Report, 2020.

Scalar Deviation Rate



Jwair et al., 2020

Reducing Tip Fold-Over for Reliable Hearing Performance

If the tip of the electrode array folds over on itself, the interface between the electrode contacts and the cochlea can be seriously impacted. Not only can this make fitting the implant more complicated, it also reduces the overall hearing performance for the recipient.^{22,23,24,25}

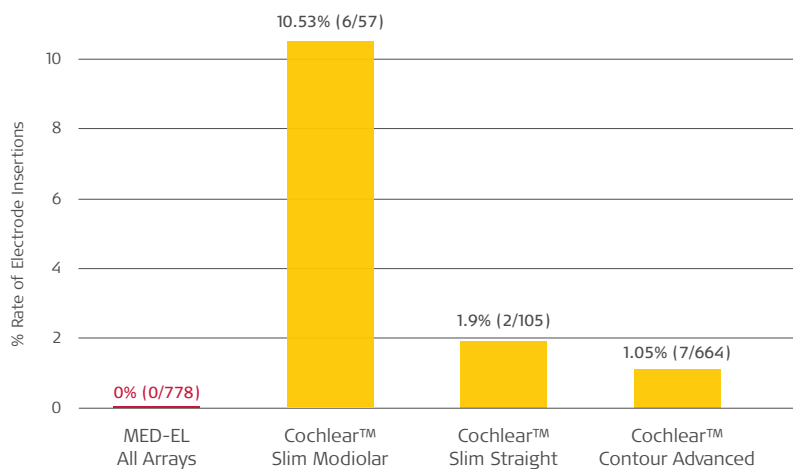
MED-EL electrode arrays are designed to gently adapt to the anatomy of each individual cochlea, minimizing the risk of the tip folding over or getting lodged. In fact, the likelihood of tip fold-over with our electrodes is as low as 1 in 20,000.²⁶ In comparison, tip fold-over occurred 1 in 36 times with pre-curved electrodes used by a competitor.²⁶

Likelihood of Tip Fold-Over

Cochlear	Advanced Bionics	MED-EL
1 in 36 cases	1 in 91 cases	1 in 20,000 cases

Results of a meta-analysis from 17 peer-reviewed publications (n=3001). MED-EL data includes additional sources. MED-EL, data on file.

Rate of Electrode Insertion With Tip Fold-Over

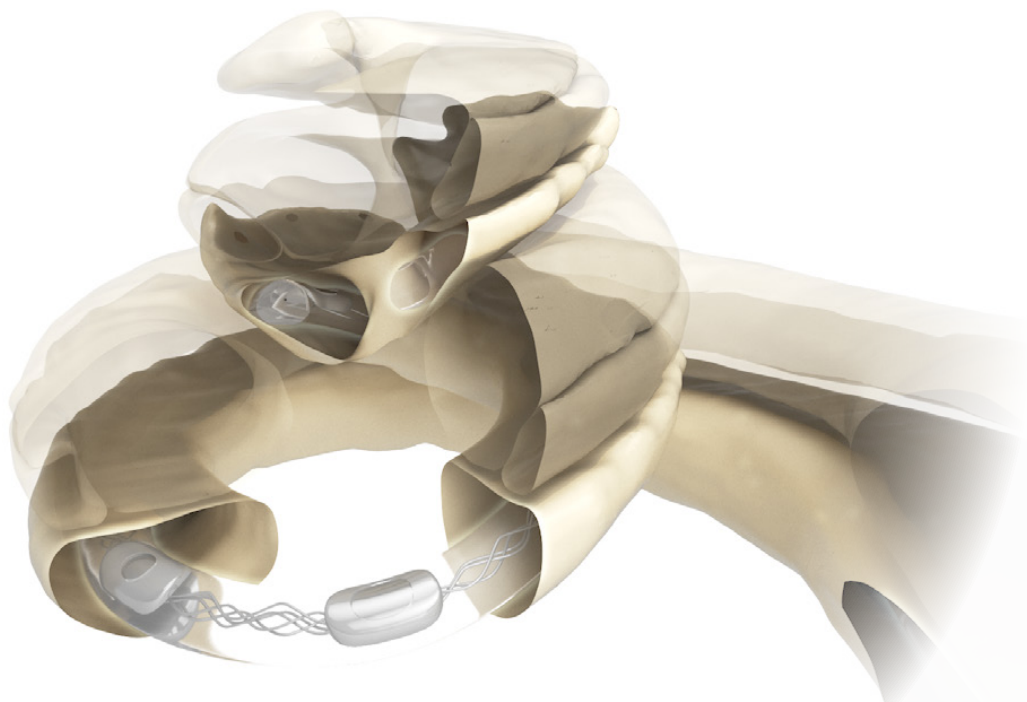


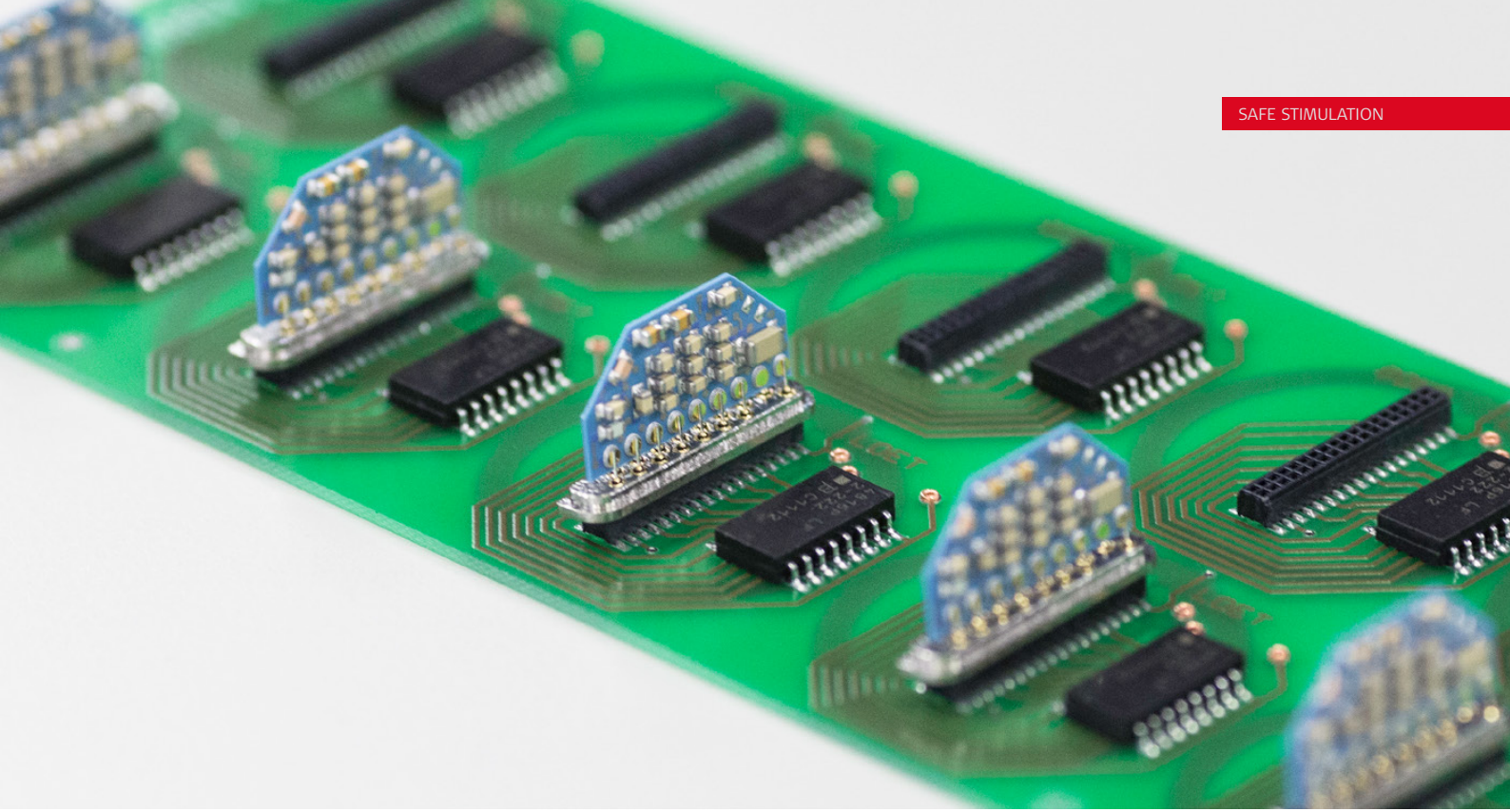
Gabrielpillai et al. 2018

Safe and Reliable Atraumatic Deep Insertion

As the cochlea nears the apex, the cross section of the scala tympani tapers in diameter to approximately 0.7 mm at 720°. This is why it is important to ensure the array can safely fit in the cochlear duct. However, with other thin arrays, the electrode array only covers the basal turn where a reduced diameter is not necessary.

Our lateral wall FLEX arrays use a tapered FLEXTip for the 5 apical electrode contacts, making FLEX series the thinnest full-length electrode arrays available. With a tip diameter of 0.4 x 0.5 mm or less, the FLEXTip can be safely and reliably placed in the second turn of the scala tympani without harming the basilar membrane.





Safe Stimulation

Precise, Controlled Stimulation

When it comes to the long-term safety of cochlear implants, safe stimulation is an absolute must. If direct current reaches the cochlea, it could result in the dissolution of electrode contacts or even damage to neural tissue.^{28-30, 33-36} That's where safety capacitors come in. They work as a gatekeeper, letting alternative current flow back and forth, while blocking harmful direct current and ensuring safe stimulation.

Independent Safety Capacitors

Unlike some cochlear implant manufacturers, MED-EL has an independent safety capacitor for every electrode channel. That way, we can ensure safe, precise, and fast stimulation in the long term.^{31,32}

	MED-EL	Advanced Bionics	Cochlear
Safety Capacitors on Every Channel	✓	✓	✗



MRI Safety

Made for MRI

Creating a reliable cochlear implant means creating one that's ready for the future. With most people needing an MRI in the next 10 years, we believe that every single hearing implant should be designed for outstanding MRI safety.* That's why we created the revolutionary SYNCHRONY implant magnet—a rotatable, self-aligning magnet that enables 3.0 Tesla MRI scans* with no surgery,** and no hearing downtime.

Great Protection. Guaranteed.

Because of our long and positive experience with MRIs and cochlear implants, we offer a life-long MRI guarantee. In the very unlikely event that it's damaged during an MRI scan we will replace the implant.***

Our MRI guarantee is:

- Valid for all MED-EL multichannel cochlear implants since 1994.
- Life-long and worldwide.
- The first and only offered by any hearing implant producer.

With no need to remove the magnet and a guarantee against damage during an MRI, we can offer a reliable cochlear implant experience whatever life brings.

* MED-EL cochlear implants since 1994 are MR conditional. Recipients with a MED-EL cochlear implant may be safely MRI scanned following the conditions detailed in the instructions for use found at <https://www.medel.com/isi>

** Unless required for diagnostic reasons.

*** The terms and conditions of the MRI Guarantee can be found at <https://www.medel.com/terms/mri-guarantee>



Audio Processor Reliability

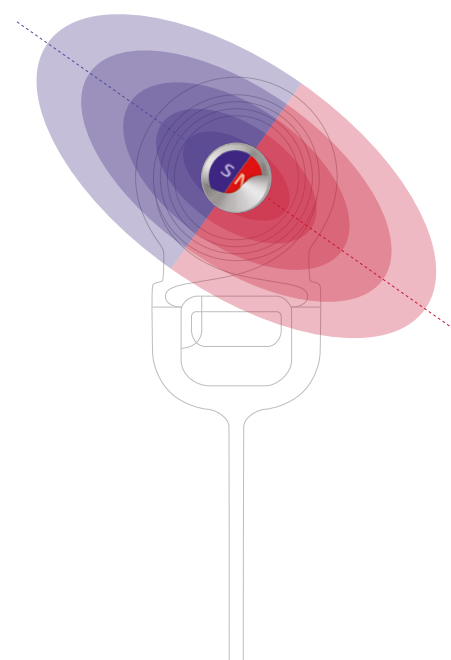
Reliable Hearing for Everyday Activities

It's not just our implants that are designed to deliver outstanding reliability, but our audio processors too. With a reliable audio processor, recipients not only have reliable hearing for everyday activities but also save time and money. And it's more convenient for hearing professionals as well. With fewer issues, time is saved on fitting replacements and administrating returns.

Optimized to Stay Securely in Place

Audio processor retention is an important and often overlooked reliability issue. MED-EL audio processors are optimized to stay securely in place thanks to our unique S-Vector magnet technology. With 25% greater magnet pull strength, recipients can trust that their audio processors won't fall off.

Thanks to the increased magnetic pull strength of the S-Vector magnet, MED-EL cochlear implant recipients who take part in sports like sprinting or swimming—or have professions in which they often move their heads—don't have to worry about their single-unit audio processor falling off. Optimizing audio processor retention means that recipients and their audiologists now have more freedom to choose between a behind-the-ear audio processor or a single-unit audio processor based on their own preferences, rather than their lifestyle or anatomical conditions such as skin flap thickness.





The Value of a Reliable Audio Processor

A working and reliable external audio processor is required to make use of each implant to hear. A reliable audio processor means reliable hearing for everyday activities. Recipients take their audio processors with them everywhere they go, so they

need audio processors they can rely on. Audio processors designed with durability in mind have lower repair rates because they can often withstand typical environmental threats, such as being dropped on the floor or exposed to moisture.

How Is Audio Processor Reliability Reported?

The Monthly Repair Rate, or Failed Component Return Rate (FCRR), is the measure of reliability for each audio processor model. It is a percentage that indicates the total number of audio processors returned within a month compared to the total number of that same audio processor sold by the end of that month. For example, if the monthly

repair rate for an audio processor is 0.15%, it means that 15 audio processors have been returned for repair out of all 10,000 audio processors sold in the world by the end of that month. The lower the monthly repair rate, the more reliable the audio processor is. A low repair rate indicates a low tendency for an audio processor to be returned for repair.

What Kind of Repairs Need to be Made?

The monthly repair rate data is divided into categories for each month for each audio processor model. MED-EL tests the audio

processors it receives for repairs. Those that do not work are classified based on why they failed.

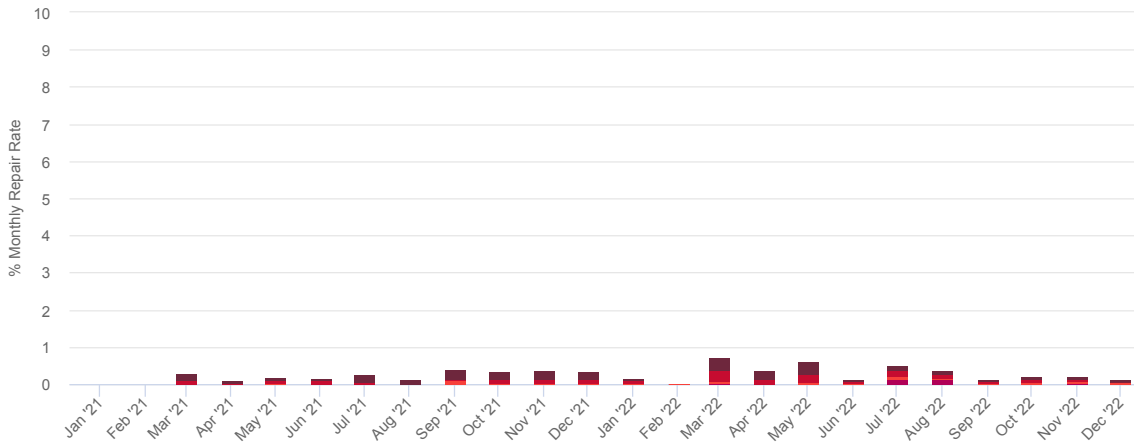
Understanding Audio Processor Reliability Reports

2022

Monthly Repair Rate
After release on the market, a monthly repair rate is shown for each month within the last two years.

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.09%	0.01%	0.33%	0.24%	0.33%	0.06%	0.11%	0.11%	0.06%	0.09%	0.05%	0.05%
Mechanic	0.07%	0.01%	0.32%	0.14%	0.21%	0.02%	0.19%	0.10%	0.02%	0.05%	0.07%	0.01%
Moisture	0.02%	0.03%	0.01%	0.01%	0.06%	0.05%	0.06%	0.05%	0.04%	0.06%	0.03%	0.06%
Other	0.00%	0.00%	0.05%	0.00%	0.00%	0.00%	0.14%	0.12%	0.01%	0.01%	0.05%	0.01%

Reasons for Repair
Returned audio processors are categorized based on why they stopped working.



- Other**
failures describe those which do not fit in any of the categories.
- Moisture**
failures result from water exposure or moisture ingress excluding corrosion unless it results in functional failure.
- Mechanic**
failures are caused by physical damage, mechanical stress, or UV or chemical exposure.
- Electronic**
failures result from functional failures of the electronics or the electronic assembly.



RONDO 3 Reliability

Released in 2020, RONDO 3 offers sleek simplicity, superior hearing performance, wireless charging, and seamless connectivity in a stylish design—making it an ideal choice for any recipient.

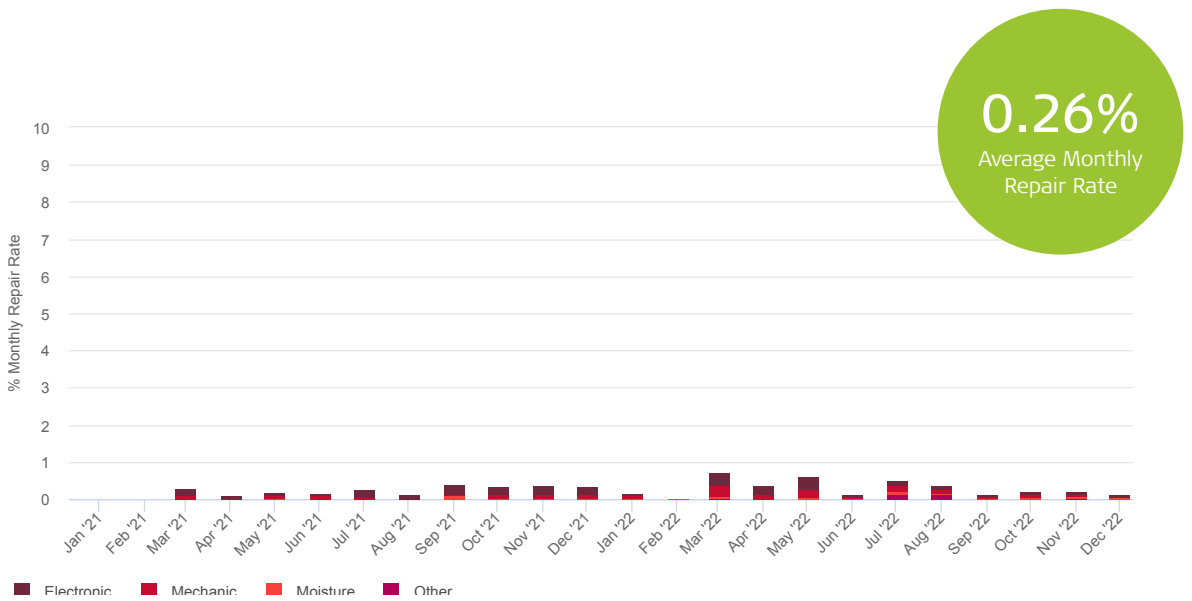


2021

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.00%	0.00%	0.22%	0.08%	0.11%	0.09%	0.18%	0.14%	0.26%	0.23%	0.25%	0.21%
Mechanic	0.00%	0.00%	0.10%	0.02%	0.07%	0.09%	0.07%	0.00%	0.04%	0.08%	0.09%	0.08%
Moisture	0.00%	0.00%	0.00%	0.00%	0.02%	0.00%	0.01%	0.01%	0.09%	0.04%	0.03%	0.05%
Other	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%

2022

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.09%	0.01%	0.33%	0.24%	0.33%	0.06%	0.11%	0.11%	0.06%	0.09%	0.05%	0.05%
Mechanic	0.07%	0.01%	0.32%	0.14%	0.21%	0.02%	0.19%	0.10%	0.02%	0.05%	0.07%	0.01%
Moisture	0.02%	0.03%	0.01%	0.01%	0.06%	0.05%	0.06%	0.05%	0.04%	0.06%	0.03%	0.06%
Other	0.00%	0.00%	0.05%	0.00%	0.00%	0.00%	0.14%	0.12%	0.01%	0.01%	0.05%	0.01%



SONNET 2 Reliability

Released in 2019, SONNET 2 is our latest behind-the-ear audio processor. Made for the most natural hearing in any listening environment, SONNET 2 offers all-day comfort and wireless connectivity in a durable design.

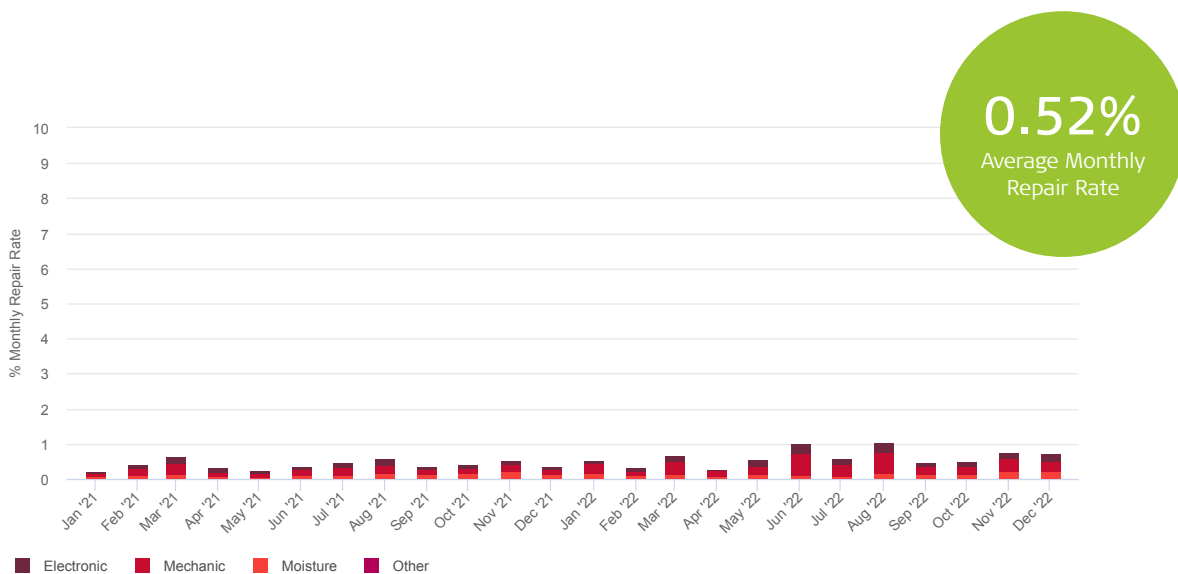


2021

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.03%	0.12%	0.22%	0.12%	0.07%	0.10%	0.13%	0.21%	0.12%	0.10%	0.13%	0.11%
Mechanic	0.09%	0.21%	0.31%	0.16%	0.12%	0.20%	0.26%	0.18%	0.12%	0.13%	0.22%	0.14%
Moisture	0.08%	0.09%	0.12%	0.06%	0.05%	0.09%	0.09%	0.18%	0.15%	0.17%	0.20%	0.12%
Other	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%

2022

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.12%	0.10%	0.15%	0.06%	0.18%	0.27%	0.16%	0.31%	0.11%	0.12%	0.16%	0.22%
Mechanic	0.28%	0.14%	0.37%	0.15%	0.25%	0.65%	0.33%	0.57%	0.22%	0.23%	0.40%	0.30%
Moisture	0.16%	0.09%	0.15%	0.08%	0.12%	0.11%	0.08%	0.18%	0.14%	0.15%	0.19%	0.20%
Other	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%



RONDO 2 Reliability

RONDO 2 was released in 2017 as the world's first audio processor with a built-in battery that can be recharged wirelessly. RONDO 2's reliable and cost-efficient design makes it one of the most affordable audio processors available. RONDO 2's average monthly repair rate is 0.57%.

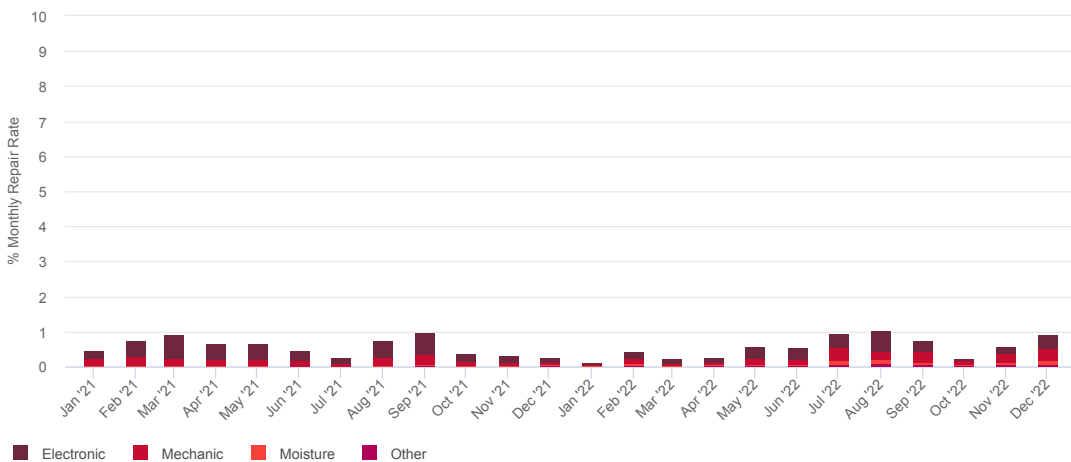


2021

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.23%	0.46%	0.70%	0.46%	0.48%	0.32%	0.18%	0.47%	0.65%	0.21%	0.20%	0.12%
Mechanic	0.23%	0.27%	0.21%	0.18%	0.18%	0.15%	0.10%	0.25%	0.25%	0.15%	0.10%	0.07%
Moisture	0.02%	0.04%	0.03%	0.03%	0.03%	0.01%	0.01%	0.02%	0.05%	0.03%	0.02%	0.05%
Other	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.03%	0.00%	0.00%	0.03%

2022

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.07%	0.18%	0.14%	0.16%	0.35%	0.34%	0.41%	0.57%	0.32%	0.06%	0.23%	0.38%
Mechanic	0.06%	0.16%	0.06%	0.06%	0.16%	0.15%	0.36%	0.26%	0.29%	0.10%	0.23%	0.36%
Moisture	0.01%	0.05%	0.02%	0.03%	0.05%	0.04%	0.12%	0.10%	0.07%	0.06%	0.07%	0.09%
Other	0.01%	0.04%	0.01%	0.03%	0.02%	0.02%	0.06%	0.10%	0.07%	0.02%	0.06%	0.08%





MED-EL Headquarters
in Innsbruck, Austria

MED-EL

A Reliable Partner

For more than 30 years, MED-EL has been a trusted partner and innovation leader in hearing implants. We create and manufacture our implants directly in our Austrian headquarters, ensuring they follow state-of-the-art European engineering, and meet the highest standards in quality and reliability. With this focused oversight and our dedication to quality, we can check and verify every single step of the design and process.

MED-EL has always been privately owned by our founders, so for us reliability is not a percentage or an earnings report for investors. With no share-

holders to answer to, we're in a unique position where we can put the safety and peace of mind of our recipients above all else. And because we believe that everyone should benefit from the latest hearing technology, our latest audio processors work for all our recipients since 1994.

Choosing MED-EL means putting your trust in us. We promise to always be there for you.

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All failures are classified and included in the calculation of the cumulative survival rate (CSR) in accordance with the ISO 5841-2:2014 standard. All registered and currently marketed implants are included in the reliability calculations, and every explanted and returned implant is subject to systematic failure analysis. All failures are classified, and Cumulative Survival Rates (CSR) are calculated in accordance with ISO 5841-2:2014. All confirmed device malfunctions including accident-related failures are considered for reporting. Device survival time starts to count with closure of the wound. Implant cumulative survival rates are from data on file as of January 2, 2023. The average monthly repair rates for audio processors are from data on file as of December 31, 2022.

The results of the calculations are reported following principles of the European Consensus on Cochlear Implant Failures and Explantations, with adults and children being shown separately and with 95% confidence intervals. Please note that confidence intervals smaller than 0.1% may not be clearly visible in the graphs. The sample size of each model and population are not provided. MED-EL publishes reliability data one year after the first implantation at the earliest.

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