

MED-EL Cochlear Implant Systems

Reliability Report | October 2025

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



hearLIFE

Contents

1	Introduction	
	A Complete 360° View on Safety and Reliability	2
2	Implant Reliability	
	Leading in Cochlear Implant Reliability	4
	Compliance With Implant Reliability Reporting Standards	5
	The Value of a Reliable Implant	6
	SYNCHRONY 2 Implant Reliability	7
	SONATA 2 Implant Reliability	8
	CONCERTO 2 Implant Reliability	9
	SYNCHRONY ST Implant Reliability	10
	SYNCHRONY Implant Reliability	11
	CONCERTO Implant Reliability	12
	SONATA Implant Reliability	13
	PULSAR Implant Reliability	14
	Number of Registered Implants	15
3	Electrode Safety	
	First, Do No Harm	17
	Reliable Scala Tympani Placement	18
	Reducing Tip Fold-Over for Reliable Hearing Performance	19
	Safe and Reliable Atraumatic Deep Insertion	20
4	Safe Stimulation	
	Precise, Controlled Stimulation	21
5	MRI Safety	
	Made for MRI	22
6	Audio Processor Reliability	
	Reliable Hearing for Everyday Activities	23
	The Value of a Reliable Audio Processor	24
	SONNET 3 Reliability	26
	RONDO 3 Reliability	27
	SONNET 2 Reliability	28
	RONDO 2 Reliability	29
7	A Reliable Partner	30
8	References	31

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

The World Leader 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 35 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 Statement 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.		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 and number of registered implants are clearly specified.
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

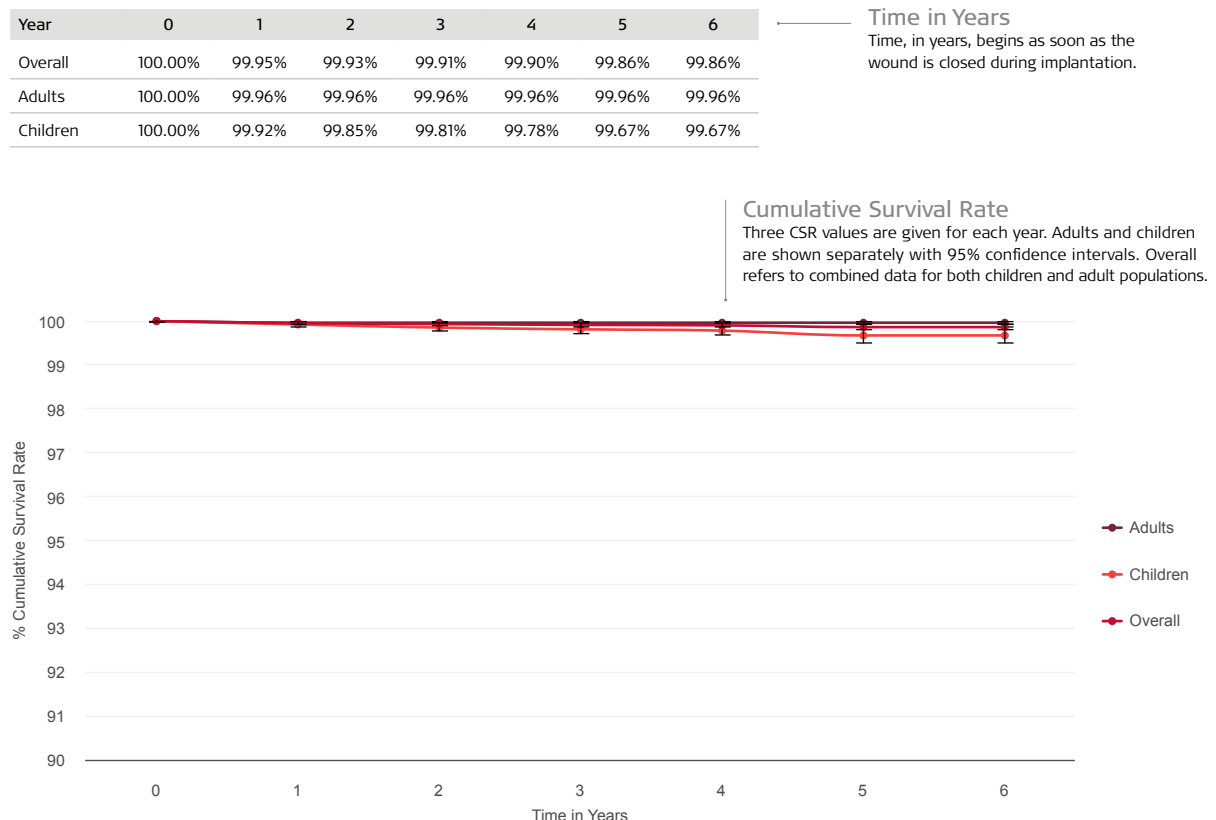
higher satisfaction for implant recipients. The Cumulative Survival Rate (CSR) is the measure of each implant model's reliability over time. For example, a CSR of 99% after seven years means that the probability of the cochlear implant providing continued benefits after seven years is 99%.

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



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.

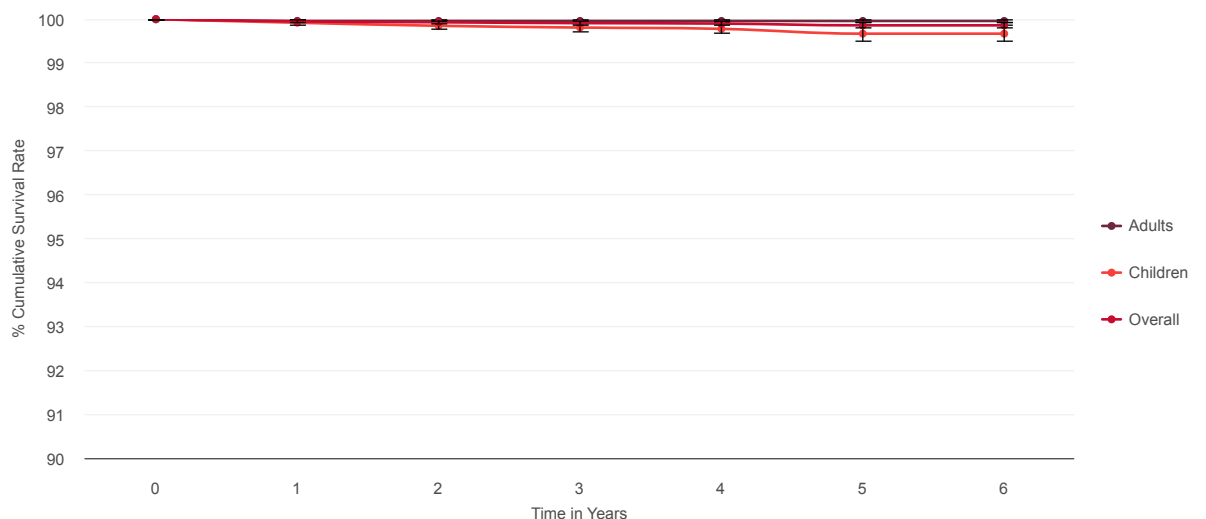
Not only is it packed full of the latest hearing technology. It's also designed with the safety and reliability to provide years of amazing hearing.

SYNCHRONY 2 has one of the best cochlear implant reliability performance records on the market, with an overall CSR of 99.86% within six years.



SYNCHRONY 2

Year	0	1	2	3	4	5	6
Overall	100.00%	99.95%	99.93%	99.91%	99.90%	99.86%	99.86%
Adults	100.00%	99.96%	99.96%	99.96%	99.96%	99.96%	99.96%
Children	100.00%	99.92%	99.85%	99.81%	99.78%	99.67%	99.67%



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

SONATA 2 Implant Reliability

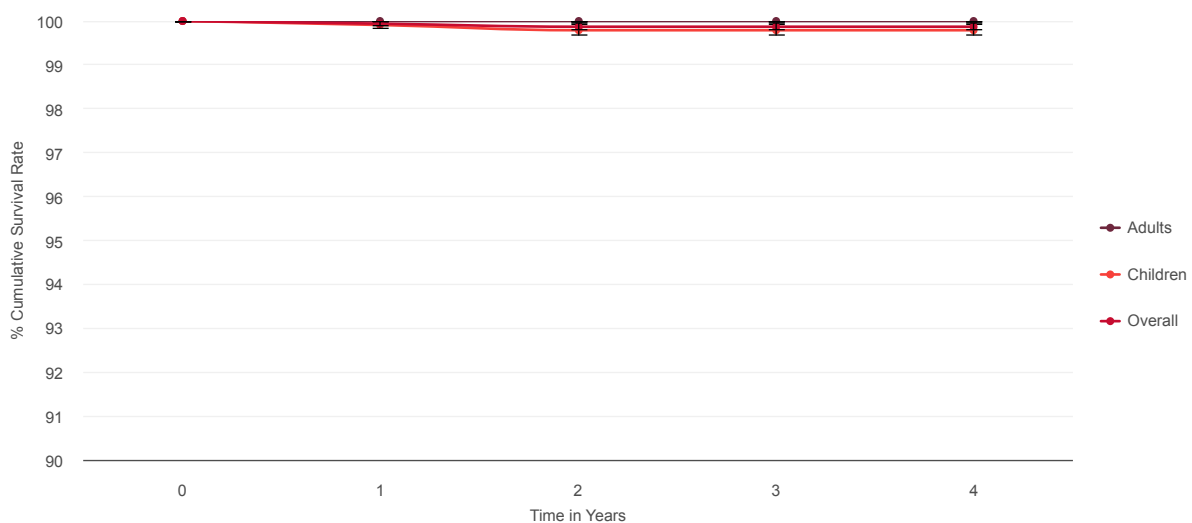
SONATA 2 has a symmetrical central electrode lead design for optimal surgical handling. It also features our second-generation diametric magnet, the S-Vector magnet, which is 25% stronger than its predecessor for optimized audio processor retention. In addition, the S-Vector magnet enables 3.0 Tesla 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 99.87% within four years.

SONATA 2

Year	0	1	2	3	4
Overall	100.00%	99.94%	99.87%	99.87%	99.87%
Adults	100.00%	100.00%	100.00%	100.00%	100.00%
Children	100.00%	99.91%	99.79%	99.79%	99.79%



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

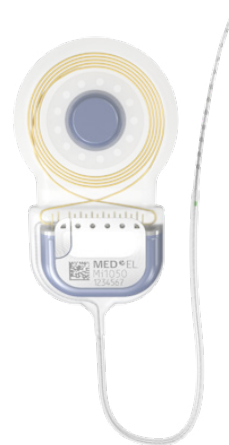
* The SONATA 2 cochlear implant is MR conditional. Recipients with a SONATA 2 cochlear implant may be safely MRI scanned at 1.5 and 3.0 Tesla following the conditions detailed in the instructions for use.

** Unless required for diagnostic reasons.

CONCERTO 2 Implant Reliability

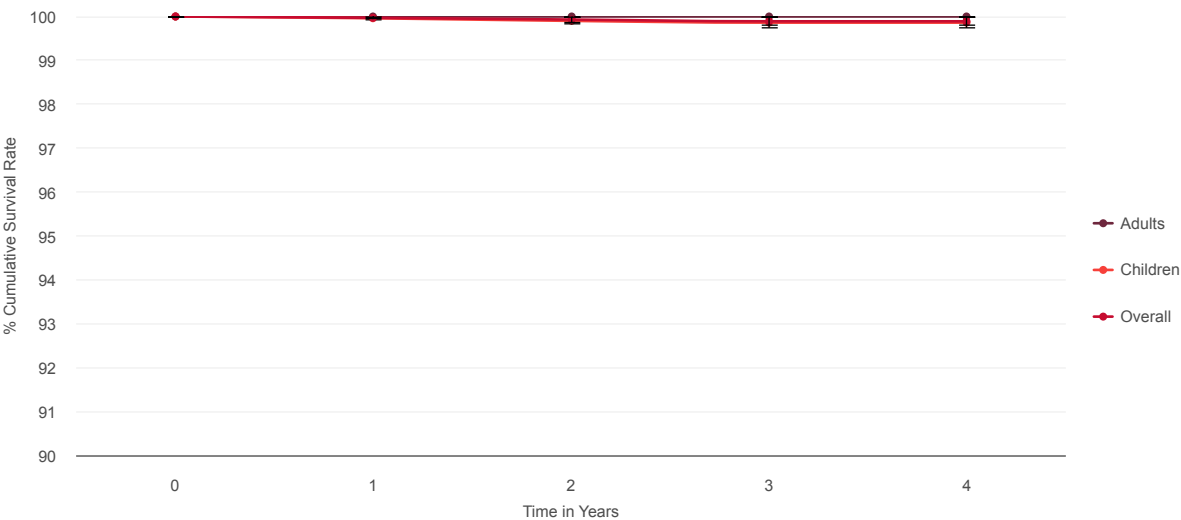
CONCERTO 2 provides superior hearing performance with long-term safety and peace of mind. It features a symmetrical central electrode lead and a thin housing design for simplified implant placement.

CONCERTO 2 was commercially released in January 2021 and has an overall CSR of 99.89% within four years.



CONCERTO 2

Year	0	1	2	3	4
Overall	100.00%	99.97%	99.93%	99.89%	99.89%
Adults	100.00%	100.00%	100.00%	100.00%	100.00%
Children	100.00%	99.96%	99.90%	99.86%	99.86%



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

SYNCHRONY ST Implant Reliability

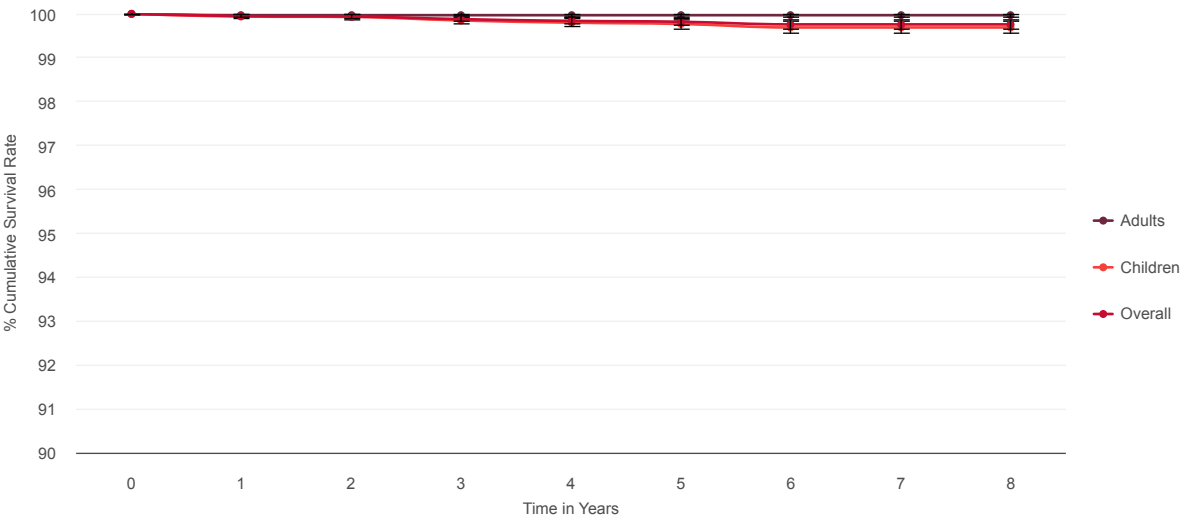
With SYNCHRONY ST, recipients get peace of mind knowing they have an implant that delivers outstanding MRI safety,* proven reliability, and exceptional hearing quality.

Commercially released in January 2017, SYNCHRONY ST has an overall CSR of 99.76% within eight years.



SYNCHRONY ST

Year	0	1	2	3	4	5	6	7	8
Overall	100.00%	99.95%	99.94%	99.88%	99.84%	99.82%	99.76%	99.76%	99.76%
Adults	100.00%	99.97%	99.97%	99.97%	99.97%	99.97%	99.97%	99.97%	99.97%
Children	100.00%	99.94%	99.93%	99.85%	99.80%	99.77%	99.69%	99.69%	99.69%



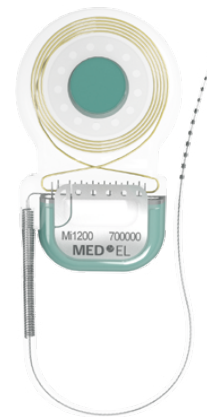
Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

* 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

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.*

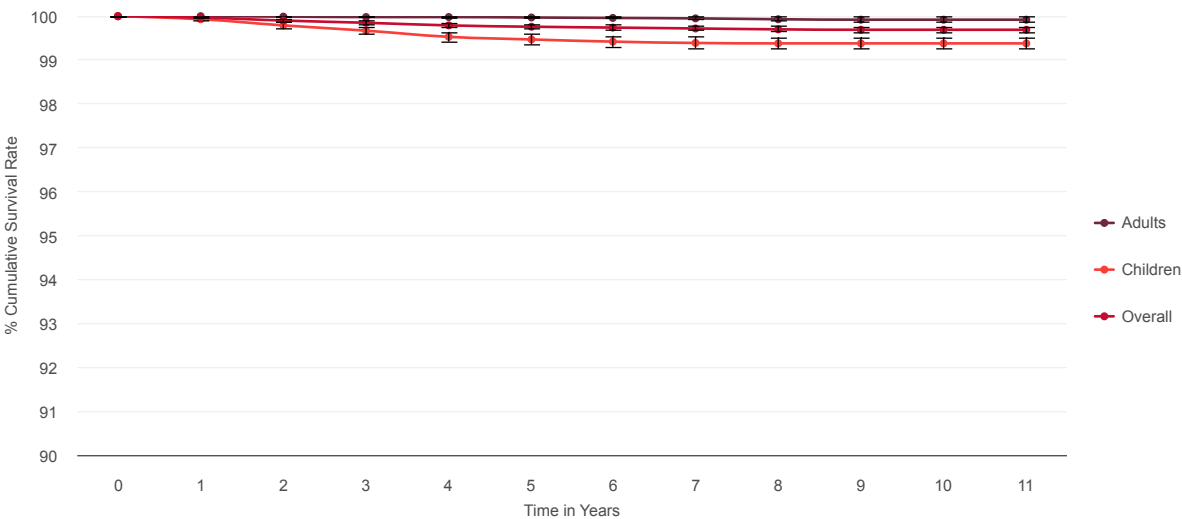
The SYNCHRONY implant has an overall CSR of 99.69% within 11 years.



SYNCHRONY

Year	0	1	2	3	4	5	6	7	8	9	10
Overall	100.00%	99.97%	99.90%	99.85%	99.79%	99.76%	99.74%	99.72%	99.70%	99.69%	99.69%
Adults	100.00%	100.00%	99.99%	99.98%	99.98%	99.97%	99.96%	99.95%	99.93%	99.92%	99.92%
Children	100.00%	99.93%	99.79%	99.67%	99.53%	99.47%	99.42%	99.39%	99.38%	99.38%	99.38%

Year	11
Overall	99.69%
Adults	99.92%
Children	99.38%



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.

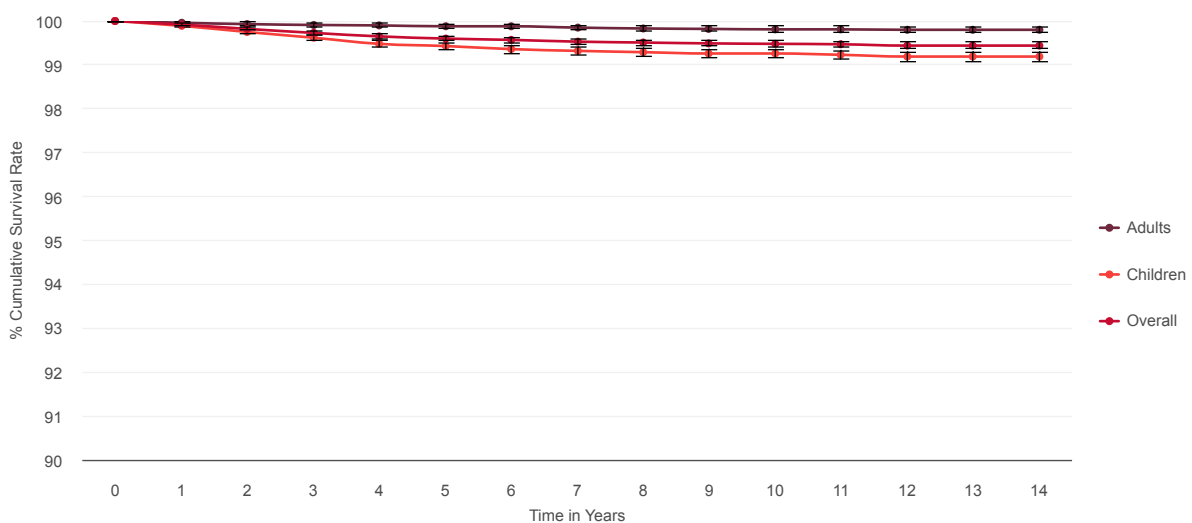
The CONCERTO implant has an overall CSR of 99.44% within 14 years.



CONCERTO

Year	0	1	2	3	4	5	6	7	8	9	10
Overall	100.00%	99.92%	99.82%	99.73%	99.65%	99.60%	99.57%	99.53%	99.51%	99.49%	99.48%
Adults	100.00%	99.96%	99.93%	99.91%	99.90%	99.88%	99.88%	99.85%	99.83%	99.82%	99.81%
Children	100.00%	99.89%	99.75%	99.62%	99.48%	99.43%	99.36%	99.32%	99.29%	99.26%	99.26%

Year	11	12	13	14
Overall	99.47%	99.44%	99.44%	99.44%
Adults	99.81%	99.80%	99.80%	99.80%
Children	99.23%	99.19%	99.19%	99.19%



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.

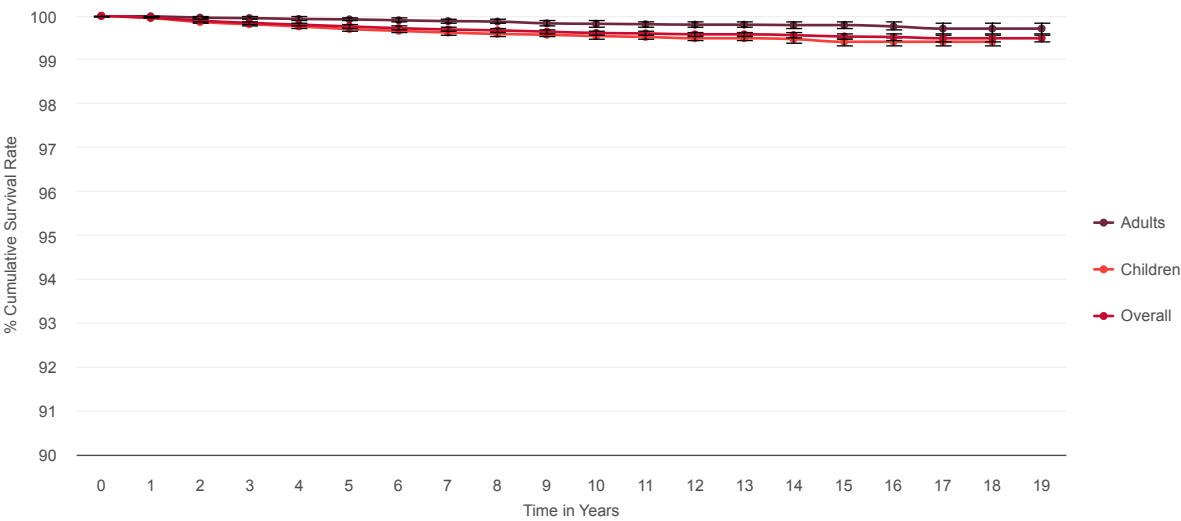
SONATA was commercially released in June 2006 and has an overall CSR of 99.49% within 19 years.



SONATA

Year	0	1	2	3	4	5	6	7	8	9	10
Overall	100.00%	99.96%	99.89%	99.84%	99.80%	99.76%	99.72%	99.69%	99.67%	99.64%	99.61%
Adults	100.00%	99.99%	99.96%	99.95%	99.93%	99.92%	99.90%	99.88%	99.87%	99.83%	99.82%
Children	100.00%	99.95%	99.86%	99.81%	99.76%	99.70%	99.66%	99.62%	99.59%	99.57%	99.54%

Year	11	12	13	14	15	16	17	18	19
Overall	99.60%	99.58%	99.58%	99.56%	99.53%	99.52%	99.49%	99.49%	99.49%
Adults	99.81%	99.80%	99.80%	99.79%	99.79%	99.76%	99.71%	99.71%	99.71%
Children	99.52%	99.49%	99.49%	99.47%	99.41%	99.41%	99.41%	99.41%	*



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 18 years instead of 19.

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.

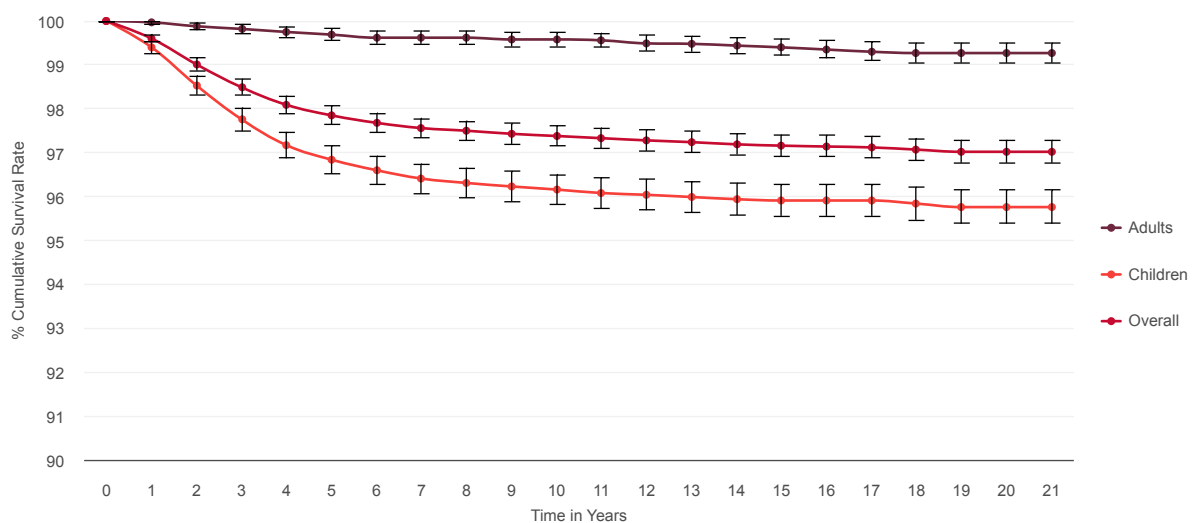
Within 21 years, the PULSAR has an overall CSR of 97.02%.



PULSAR

Year	0	1	2	3	4	5	6	7	8	9	10
Overall	100.00%	99.60%	99.01%	98.49%	98.09%	97.85%	97.68%	97.56%	97.50%	97.43%	97.38%
Adults	100.00%	99.97%	99.88%	99.82%	99.75%	99.69%	99.62%	99.62%	99.62%	99.58%	99.58%
Children	100.00%	99.40%	98.53%	97.76%	97.17%	96.84%	96.60%	96.41%	96.31%	96.23%	96.16%

Year	11	12	13	14	15	16	17	18	19	20	21
Overall	97.33%	97.28%	97.24%	97.19%	97.16%	97.14%	97.12%	97.07%	97.02%	97.02%	97.02%
Adults	99.56%	99.49%	99.48%	99.44%	99.40%	99.35%	99.30%	99.27%	99.27%	99.27%	99.27%
Children	96.08%	96.04%	95.99%	95.94%	95.91%	95.91%	95.91%	95.84%	95.76%	95.76%	95.76%



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



Number of Registered Cochlear Implants Worldwide

With more than 300,000 registered cochlear implants, MED-EL's life-changing technology has brought the joy of sound to people with hearing loss around the globe.

Over
300,000
registered MED-EL
cochlear implants
worldwide

	Overall	Adults	Children
SYNCHRONY 2	41,103	28,129	12,974
SONATA 2	12,288	4,666	7,622
CONCERTO 2	13,151	3,001	10,150
SYNCHRONY ST	13,120	3,428	9,692
SYNCHRONY	51,552	26,753	24,799
CONCERTO	57,125	21,487	35,638
SONATA	91,593	22,465	69,128
PULSAR	19,043	6,780	12,263
C40/C40+*	20,590	-	-

* Reliability reporting not required for C40/C40+ according to ISO 5841-2:2014; for information only



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 35 years, we've worked to create our ultra-flexible electrode arrays.

Uniquely engineered, our electrode arrays are the most atraumatic electrode arrays available.⁶ 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.^{7,8}



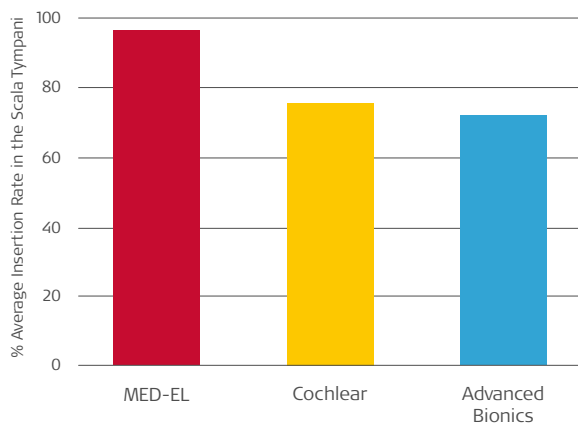
Reliable Scala Tympani Placement

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.^{9,10,11,12}

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.^{6,13,14,15,16,17,18,19}

Average Insertion Rate in the Scala Tympani

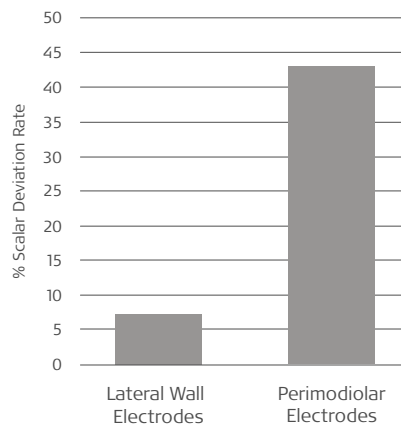
Average Insertion Rate in the Scala Tympani



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

Scalar Deviation Rate

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.^{20,21,22,23}

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 20,000.²⁴ In comparison, tip fold-over occurred 1 in 36 times with pre-curved electrodes used by a competitor.²⁴

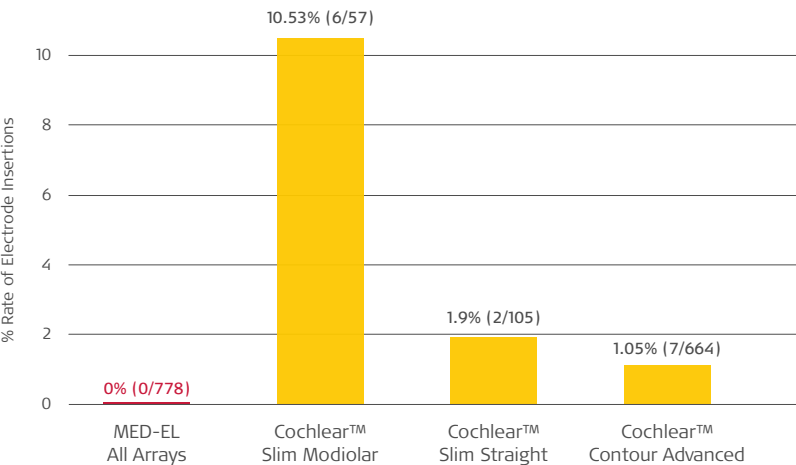
Likelihood of Tip Fold-Over

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

Rate of Electrode Insertion With Tip Fold-Over

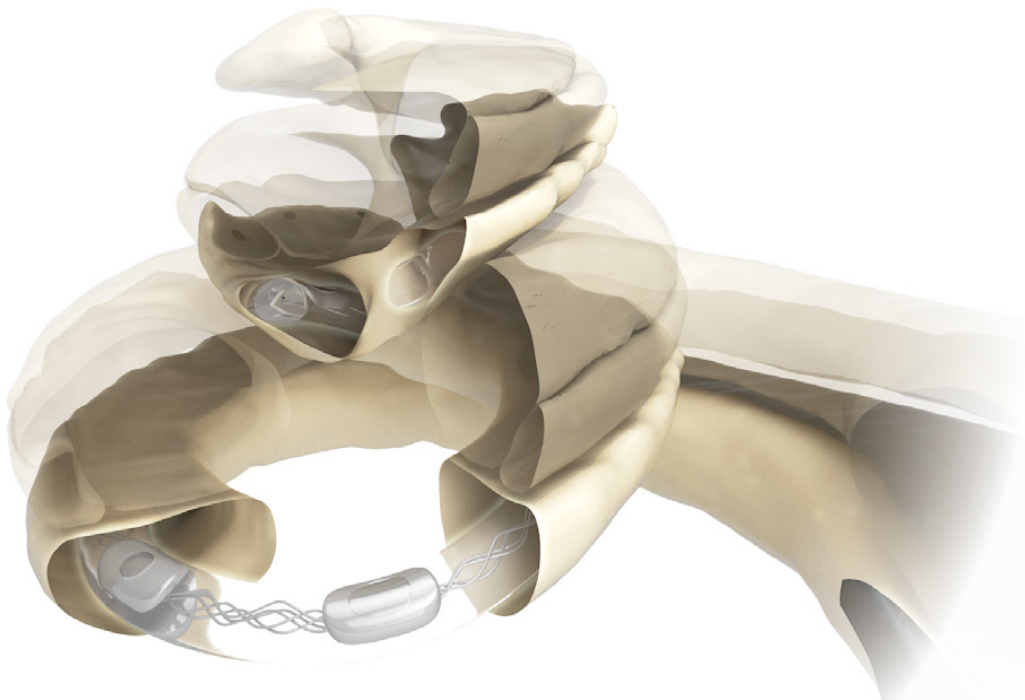


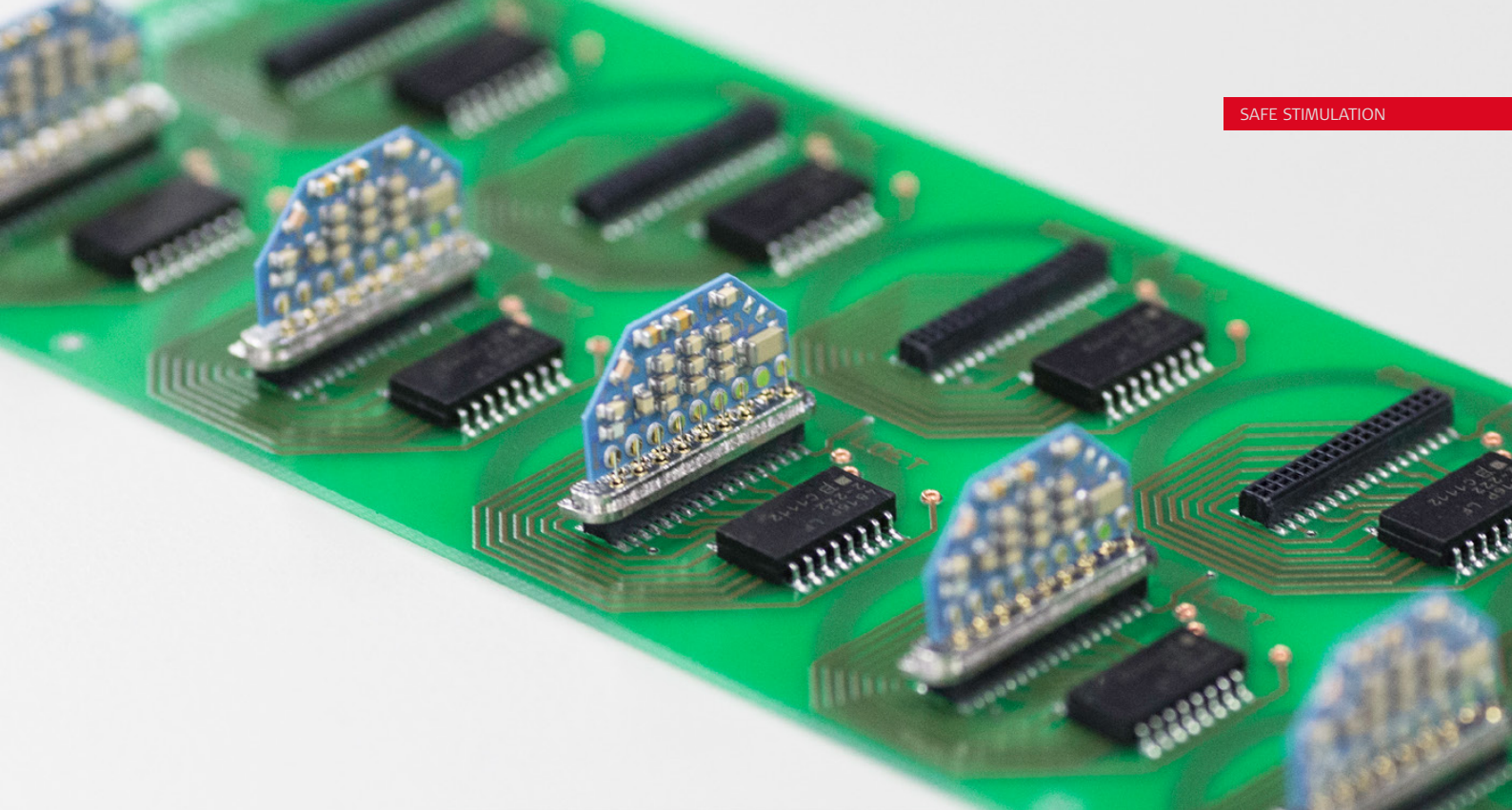
Gabrielpillai et al. 2018

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.^{26-28, 31-34} 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.^{29,30}

	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

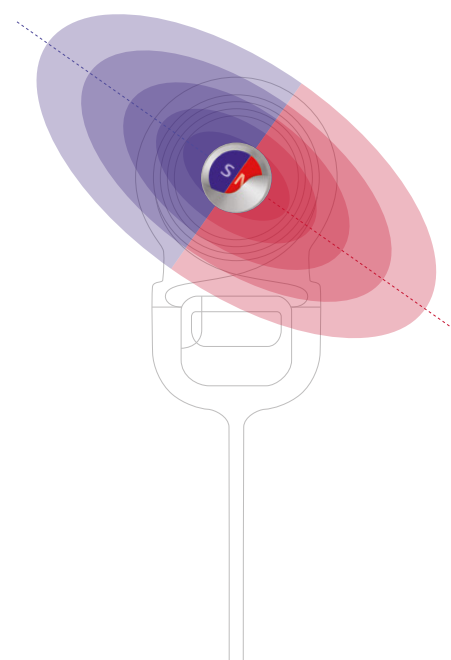
Reliable Hearing for Everyday Activities

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.

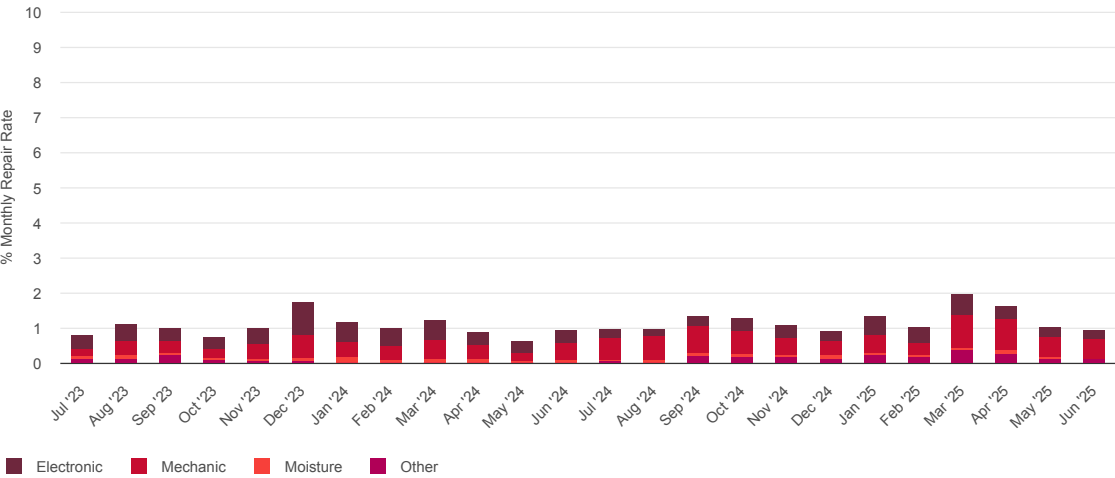
Understanding Audio Processor Reliability Reports

2025

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
Electronic	0.52%	0.43%	0.62%	0.37%	0.28%	0.24%
Mechanic	0.53%	0.33%	0.92%	0.90%	0.55%	0.56%
Moisture	0.07%	0.10%	0.08%	0.10%	0.07%	0.03%
Other	0.20%	0.13%	0.35%	0.25%	0.09%	0.09%

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.

SONNET 3 Reliability

Introduced in 2024, SONNET 3 features integrated direct streaming, a convenient touch key, and an optional flexible earhook—all while providing users the closest to natural hearing with our smallest and lightest behind-the-ear audio processor.

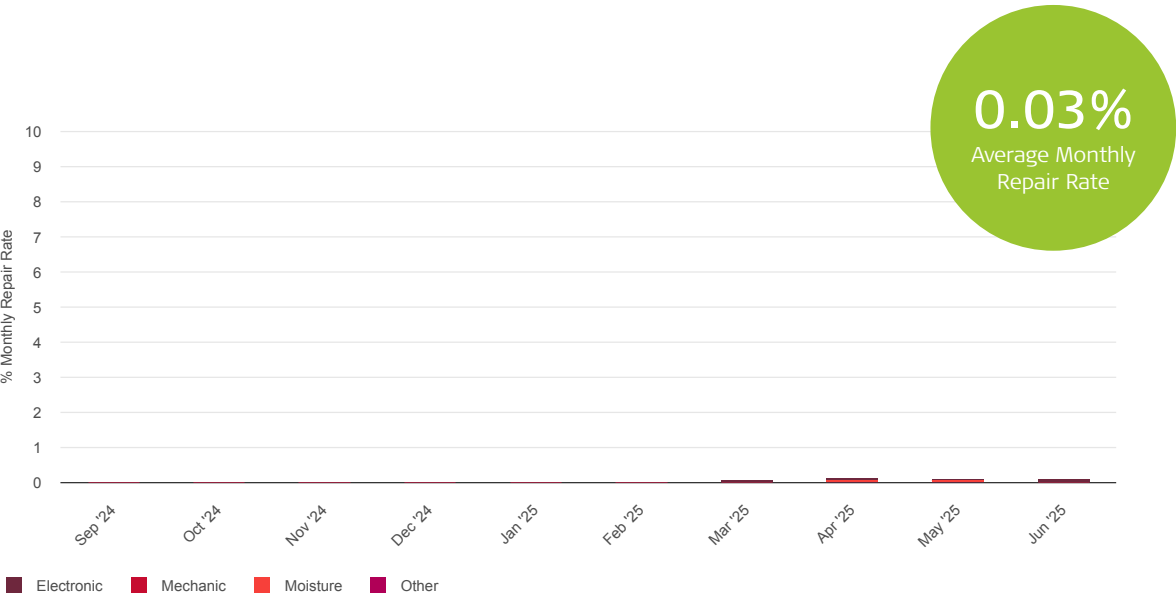


2024

Month	Sep	Oct	Nov	Dec
Electronic	0.00%	0.00%	0.00%	0.00%
Mechanic	0.00%	0.00%	0.00%	0.00%
Moisture	0.00%	0.00%	0.00%	0.00%
Other	0.00%	0.00%	0.00%	0.00%

2025

Month	Jan	Feb	Mar	Apr	May	Jun
Electronic	0.00%	0.00%	0.03%	0.04%	0.03%	0.05%
Mechanic	0.00%	0.00%	0.00%	0.03%	0.02%	0.01%
Moisture	0.00%	0.00%	0.00%	0.02%	0.02%	0.00%
Other	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%



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.



2023

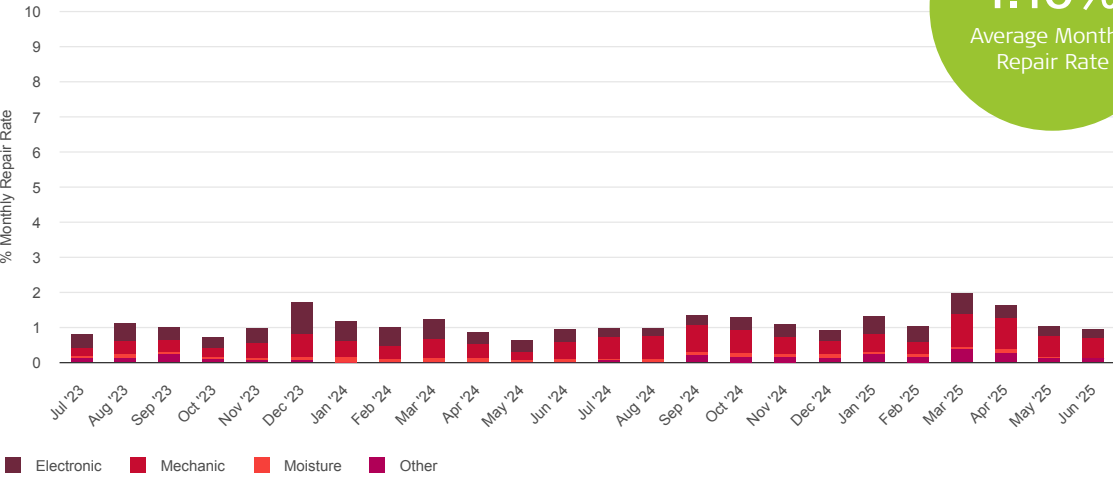
Month	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.40%	0.49%	0.40%	0.32%	0.45%	0.93%
Mechanic	0.22%	0.41%	0.30%	0.24%	0.42%	0.65%
Moisture	0.06%	0.10%	0.08%	0.08%	0.07%	0.11%
Other	0.12%	0.11%	0.22%	0.08%	0.03%	0.02%

2024

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.58%	0.52%	0.57%	0.38%	0.34%	0.34%	0.25%	0.20%	0.26%	0.37%	0.35%	0.31%
Mechanic	0.43%	0.40%	0.54%	0.39%	0.24%	0.51%	0.62%	0.68%	0.78%	0.65%	0.48%	0.39%
Moisture	0.12%	0.08%	0.10%	0.09%	0.03%	0.07%	0.04%	0.07%	0.10%	0.12%	0.10%	0.09%
Other	0.01%	0.00%	0.01%	0.01%	0.00%	0.00%	0.04%	0.01%	0.17%	0.14%	0.13%	0.12%

2025

Month	Jan	Feb	Mar	Apr	May	Jun
Electronic	0.52%	0.43%	0.62%	0.37%	0.28%	0.24%
Mechanic	0.53%	0.33%	0.92%	0.90%	0.55%	0.56%
Moisture	0.07%	0.10%	0.08%	0.10%	0.07%	0.03%
Other	0.20%	0.13%	0.35%	0.25%	0.09%	0.09%



SONNET 2 Reliability

SONNET 2 is our behind-the-ear audio processor that was released in 2019. Made for the most natural hearing in any listening environment, SONNET 2 offers all-day comfort and wireless connectivity in a durable design. SONNET 2 has an average monthly repair rate of 0.70%.



2023

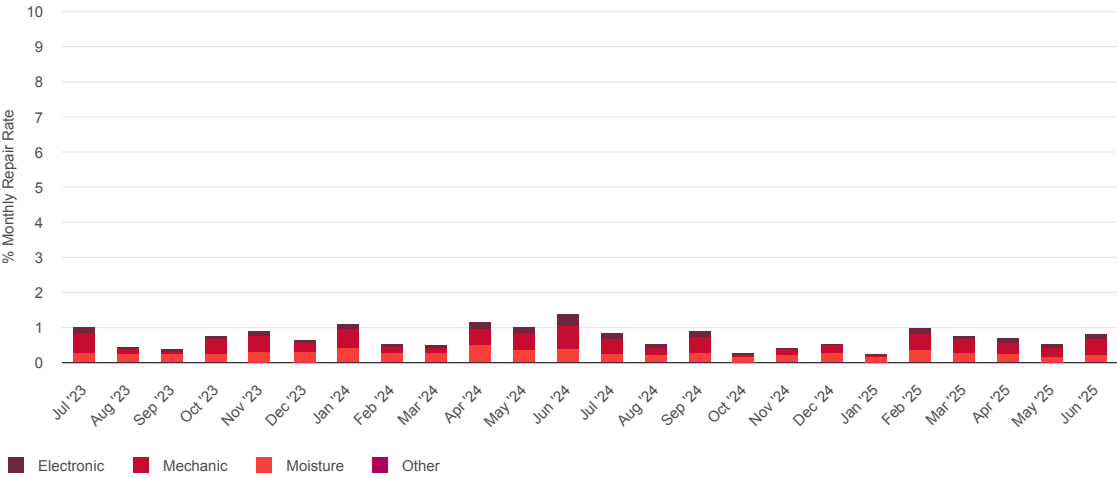
Month	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.18%	0.08%	0.04%	0.11%	0.12%	0.07%
Mechanic	0.56%	0.14%	0.09%	0.43%	0.45%	0.22%
Moisture	0.26%	0.21%	0.21%	0.22%	0.28%	0.30%
Other	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

2024

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.12%	0.07%	0.08%	0.21%	0.18%	0.32%	0.15%	0.10%	0.16%	0.05%	0.06%	0.06%
Mechanic	0.55%	0.18%	0.16%	0.45%	0.52%	0.66%	0.43%	0.20%	0.47%	0.06%	0.17%	0.20%
Moisture	0.39%	0.25%	0.24%	0.48%	0.31%	0.36%	0.23%	0.19%	0.24%	0.13%	0.18%	0.25%
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%

2025

Month	Jan	Feb	Mar	Apr	May	Jun
Electronic	0.05%	0.18%	0.11%	0.15%	0.12%	0.11%
Mechanic	0.04%	0.48%	0.38%	0.33%	0.24%	0.48%
Moisture	0.13%	0.31%	0.25%	0.21%	0.15%	0.18%
Other	0.00%	0.00%	0.01%	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 0.86%.



2023

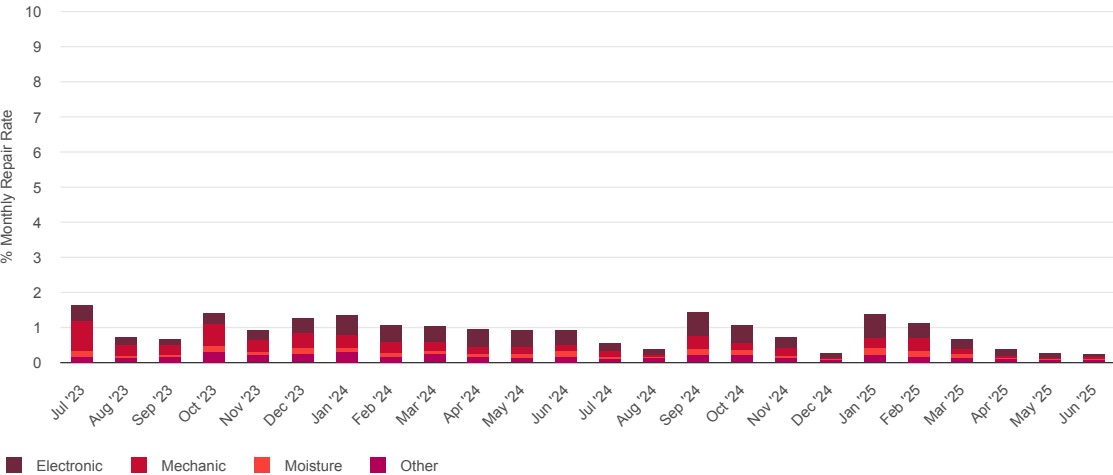
Month	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.47%	0.24%	0.18%	0.31%	0.30%	0.41%
Mechanic	0.85%	0.29%	0.28%	0.65%	0.32%	0.42%
Moisture	0.14%	0.05%	0.06%	0.13%	0.11%	0.18%
Other	0.14%	0.12%	0.13%	0.30%	0.17%	0.23%

2024

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Electronic	0.56%	0.46%	0.44%	0.49%	0.48%	0.41%	0.25%	0.17%	0.69%	0.49%	0.31%	0.12%
Mechanic	0.37%	0.31%	0.26%	0.22%	0.19%	0.20%	0.14%	0.05%	0.37%	0.22%	0.20%	0.04%
Moisture	0.11%	0.11%	0.11%	0.08%	0.11%	0.12%	0.05%	0.03%	0.19%	0.15%	0.08%	0.04%
Other	0.27%	0.15%	0.20%	0.14%	0.12%	0.15%	0.08%	0.11%	0.18%	0.17%	0.11%	0.04%

2025

Month	Jan	Feb	Mar	Apr	May	Jun
Electronic	0.67%	0.43%	0.29%	0.16%	0.12%	0.09%
Mechanic	0.28%	0.39%	0.13%	0.07%	0.06%	0.06%
Moisture	0.22%	0.16%	0.11%	0.05%	0.03%	0.02%
Other	0.18%	0.13%	0.10%	0.06%	0.03%	0.05%





MED-EL

A Reliable Partner

For more than 35 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 July 1, 2025. The average monthly repair rates for audio processors are from data on file as of July 1, 2025.

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.

MED-EL Offices Worldwide

AMERICAS

Argentina

medel@medel.com.ar

Brazil

office@br.medel.com

Canada

officecanada@medel.com

Mexico

office-mexico@medel.com

United States

implants@medelus.com

ASIA PACIFIC

Australia

office@medel.com.au

China

office@medel.net.cn

Hong Kong

office@hk.medel.com

India

implants@medel.in

Indonesia

office@id.medel.com

Japan

office-japan@medel.com

Malaysia

office@my.medel.com

Philippines

office@ph.medel.com

Singapore

office@sg.medel.com

South Korea

office@kr.medel.com

Thailand

office@th.medel.com

Vietnam

office@vn.medel.com

EMEA

Austria

office@at.medel.com

Belgium

office@be.medel.com

Denmark

nordic@medel.com

Finland

office@fi.medel.com

France

office@fr.medel.com

Germany

office@medel.de

Italy

ufficio.italia@medel.com

Netherlands

office@nl.medel.com

Norway

norge@medel.com

Portugal

office@pt.medel.com

South Africa

customerserviceZA@medel.com

Spain

office@es.medel.com

Sweden

nordic@medel.com

Switzerland

office-ch@medel.com

Turkey

medelturkey@medel.com

United Arab Emirates

office@ae.medel.com

United Kingdom

customerservice@medel.co.uk

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